NATIONAL BLOOD SERVICE GHANA

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Guidelines for Haemovigilance in Ghana

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Abbreviations

AABB	Association for the Advancement of Blood and Biotherapies
AE	Adverse Event
AR	Adverse Reaction
BE	Blood Establishment
CHAG	Christian Health Association of Ghana
DTC	Drugs and Therapeutic Committees
DV	Donor Vigilance
EBA	European Blood Alliance
FDA Ghana	Food and Drugs Authority Ghana
FFP	Fresh Frozen Plasma
GHS	Ghana Health Service
HBB	Hospital Blood Bank
HCP	Health Care Professionals
HFP	Haemovigilance Focal Person
HTC	Hospital Transfusion Committee
HV	Haemovigilance
IBCT	Incorrect Blood Component Transfused
ICP	Institutional Contact Person
INH	International Haemovigilance Network
ISBT	International Society for Blood Transfusion
MoH	Ministry of Health
NBSG	National Blood Service Ghana
NHO	National Haemovigilance Office
NRA	National Regulatory Authority
PDMPs	Plasma-Derived Medicinal Products
RBC	Red Blood Cells
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SZC	Sub-Zonal Centre
TAC-VBP	Technical Advisory Committee on Safety of Vaccines and Biological Products
TTI	Transfusion Transmissible Infection
TWG	Technical Working Group
WB	Whole Blood
WBC	White Blood Cells
WHO	World Health Organisation
ZBC	Zonal Blood Centre

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Preface

Haemovigilance is the systematic surveillance of transfusion-related adverse events (AE) and reactions (AR), encompassing all activities of the blood transfusion chain, vein-to-vein, from blood donor to transfused patient which is aimed at improving the safety of the transfusion process.

Having a haemovigilance system is an integral part of quality management in a blood system and is essential for the continual improvement of the quality and safety of blood products and helps increase the safety, efficacy and efficiency of blood transfusion, which in turn improves patient safety.

The overall aim of this guideline, is to create a working document for Ghanaian health workers involved at different stages of the transfusion chain to follow in order to guide their activities and bring about standardization of the activities within the blood transfusion chain, taking into consideration the country's systems for managing blood as a medicinal product, including but not limited to its quality, safety and efficacy.

The specific objectives are to provide:

- Policy guidance on establishing a haemovigilance system as part of the national blood and health systems;
- Information and technical guidance on the specific measures and actions needed to implement a haemovigilance system.

The intended audience includes the following organizations and institutions:

- Ministry of Health;
- National Blood Service Board;
- FDA, Medical and Dental Council, Nurses and Midwifery Council, Allied Health Professional Council, Pharmacy Council;
- Public health institutions, healthcare training institutions;
- National Blood Service (NBSG), Zonal Blood Centres, Sub-Zonal Centres, and blood establishments;
- Hospitals, including hospital blood banks or health care facilities where transfusion takes place;
- Blood donor organizations such as National Association of Blood Donors in Ghana;
- Patient groups such as the Sickle Cell Foundation of Ghana and Ghana Haemophilia Society;
- Scientific and professional bodies such as the Technical Advisory Committee on Safety of Vaccines and Biological Products (TAC-VBP), Ghana Medical Association, Ghana Registered Nurses and Midwives Association, Pharmaceutical Society of Ghana, and Ghana Association of Medical Laboratory Scientists;
- Development partners and international organizations.

Glossary

The following definitions apply to the haemovigilance system in Ghana and are largely based on the WHO definitions concerning blood and blood products and definitions from the EU Blood Guide.

(AE) reporting	Sending information on adverse events to the haemovigilance system for further investigation, analysis and feedback.
Adverse event (AE)	Any undesirable or unintended occurrence associated with transfusion or donation. It includes all adverse reactions, incidents, near misses, errors, deviations from standard operating procedures and accidents.
Adverse reaction (AR)	Any unintended response in donor or patient associated with the collection or transfusion of blood or blood products.
Blood collection	The procedure whereby a single donation of blood is collected in an anticoagulant and/or stabilizing solution, under conditions designed to minimize microbial contamination, cellular damage and/or coagulation activation of the resulting blood donation.
Blood component	A constituent of blood (erythrocytes, leukocytes, platelets, cryoprecipitate and plasma) that can be prepared by various separation methods and under such conditions that it can be used either directly for therapeutic purposes or for further processing/manufacturing.
Blood establishment (BE)	Any structure, facility or body that is responsible for any aspect of the collection, testing, processing, storage, release and/or distribution of human blood or blood products when intended for transfusion or further industrial manufacturing.
Blood products	Any therapeutic substances derived from human blood, including whole blood, blood components and plasma-derived medicinal products (PDMPs). However, in this Guideline, the term “Blood Products” excludes PDMPs.
Blood Related Adverse Event	A blood related adverse event is an incident and/or reaction in which harm resulted, or potentially could have resulted, from the transfusion/administration of a blood product.
Corrective action	Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.
Donor	A person in defined good health conditions who voluntarily donates blood or blood components, including plasma for fractionation.
Haemovigilance	Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking actions to prevent their occurrence or recurrence.
Haemovigilance feedback report	Report of aggregated analysed data from the haemovigilance system.
Imputability	The likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process.

Incident	Any untoward occurrence associated with an activity or process, such as the collection, testing, processing, storage and distribution of blood and blood products, or in the transfusion or administration.
Incorrect blood component transfused (IBCT)	All events related to IBCT must be included in haemovigilance reporting, even if the event did not result in injury or damage.
Look-back	The process of investigation on the fate of recipients of previously donated blood or blood products resulting from a report that the donation may have presented a risk of transmission of infection (donor to receiver).
Manufacture	All operational processes or steps — including purchase or selection of materials and products, production, quality control, release, storage and distribution of products and the related controls — used to produce a blood product. This includes also the donation process.
Near miss	An error or deviation from standard procedures or policies which, if undetected, could result in the determination of a wrong blood group or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but which was recognized before the transfusion took place.
Notification	Mandatory information on a notifiable event to the regulatory authority.
Preventive action	Action taken to eliminate the cause of a potential nonconformity or other potential undesirable situation.
Quality management system	A management system that directs and controls an organisation with respect to quality and that ensures that steps, processes, procedures and policies related to quality activities are being followed
Serious Adverse Event	Serious adverse events are those that might have led to death or life-threatening, disabling or incapacitating conditions for recipients or donors, or which might have resulted in prolonged hospitalization or morbidity.
Serious Adverse Reaction	Unintended response in donor or in recipient associated with the collection or transfusion of blood or blood products that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs hospitalization or morbidity.
Traceability	The ability to reliably follow the information trail from donor to recipient and vice versa in a timely manner. Traceability is essential to ensure the ability to recall at-risk products, to identify recipients of non-conforming products that may require additional follow-up, and to fully investigate adverse events.
Trace-back	The process of investigating a report of a suspected transfusion-associated adverse reaction in a recipient to identify a potentially implicated donor (receiver to donor).
Transfusing facility	Healthcare facilities where blood and blood products are transfused to patients.
Transfusion reaction	A transfusion reaction refers to an undesirable response to a transfusion, which may or may not be a result of a clinical incident depending on the nature of the event.

1. Background

Blood is an essential medicine and there is no substitute for human blood. The transfusion of blood products can be life-saving. Thus, the availability, safety and efficacy of blood and blood products is an important aspect in national health systems. However, the processes within the transfusion chain bear risks – to transfusion recipients, blood donors and even health care personnel involved in handling and manufacture of blood products.

Haemovigilance (HV) is the shared responsibility of healthcare professionals, the National Blood Service and the Food and Drugs Authority. It involves operational linkages between clinical departments, hospital blood banks, blood establishments and national authorities. Reporting and analysis of adverse events (AE) and adverse reactions (AR) associated with transfusion requires close co-operation between the clinical department where transfusion took place, the hospital blood bank that issued the transfused blood component and the blood establishment that collected and distributed the blood unit (if different from the hospital blood bank).

A haemovigilance system shall ensure efficient, detailed, and timely reporting of incidents in the transfusion chain to allow review, analysis, feedback and possible action by the Area-Sub Centres, Zonal Blood Centres, National Blood Service Ghana and the Food and Drugs Authority to increase the safety of blood and blood products. Haemovigilance, in summary, is a set of surveillance, feedback and action in response to adverse events and adverse reactions, both in donor and recipient. The system further covers the manufacturing process from donation to issue of a blood component unit. The system relies on well-organized reporting structures and defined roles and responsibilities to enable efficient involvement of all stakeholders. Haemovigilance therefore is an integral part of quality management system to further improve product quality and patient safety.

Haemovigilance in Ghana covers adverse events related to blood donation and transfusion, from donor syncopal events to transfusion-transmitted infections, immunological complications and non-immunological transfusion reactions, near-misses, and incidents. The goal of a well-established HV system in Ghana is to have a functioning surveillance of all processes involved in the blood transfusion chain; collecting and analysing data and using the achieved knowledge for regulatory feedback to increase the overall safety of the process of transfusion.

Essential to this process is extensive reporting which can be achieved best in a ‘no blame’ or a ‘no punishment’ concept involving all transfusing facilities which can greatly facilitate the reporting and investigation.

In Ghana, blood establishments within the NBSG are orchestrated on a local, zonal (Zonal Blood Centres and Sub-Zonal Centres), and on a national level (NBSG-HQ) to ensure the supply of blood and blood products to all transfusing facilities.

2. Legislation and Policies

In Ghana, blood services are structured through the **National Blood Service Act, 2020 (Act 1042).** Further, it describes functions of different stakeholders involved and diverse requirements for blood donation and transfusion. Taken together, this document organises the structure of the National Blood Service Ghana (NBSG).

The framework for the regulation of medicinal products is defined by the **Public Health Act, 2012 (Act No. 851 of 2012)**. Part Seven of the Act establishes the Food and Drugs Authority Ghana (FDA Ghana) and mandates the FDA to regulate the manufacture, importation, exportation, supply, possession or offering for sale 'food, herbal medicinal products, cosmetics, drugs, medical devices and household chemical substances and also defines FDA's responsibilities.

The **Regulatory Framework for Blood, Blood Components and Blood Products** [8] regulates licensing of blood facilities, listing of blood and blood products as well as registration of Plasma-Derived Medicinal Products (PDMPs) and requires blood facilities to report all SAEs and SARs.

Vigilance activities in Ghana are covered in two separate documents: The **National Pharmacovigilance Policy for Ghana** provides a framework for pharmacovigilance activities and describes requirements for safety monitoring of products under the FDA's mandate. The **National Haemovigilance Framework for Ghana** establishes the structure and organisation of Haemovigilance activities: Vigilance concerning Blood and Blood Products.

3. Scope of Haemovigilance in Ghana

The requirements to report apply to all blood establishments and transfusing facilities. Haemovigilance covers all AEs and ARs that occur throughout the transfusion chain for blood and blood products.

Adverse reactions to PDMPs (e.g., Human Immunoglobulin (non-specific), Human Immunoglobulin (specific), Albumin) are outside the scope of haemovigilance reporting. Adverse events relating to these products should be captured in standard FDA adverse reaction reporting forms.

Table 1 Scope of Haemovigilance

Recipient	Product	Processes	Donors
Transfusion: - Adverse Reactions (all severities) - Incidents (e.g., IBCT) - Near misses	Blood Products: - RBC - Platelets - FFP - Whole Blood - Cryoprecipitate	Incidents: - Manufacturing • Collection • Handling • Processing - Storage - Distribution - Transport	Blood Donation: - Adverse Donor Reactions - Lookback - Trace-back

4. Haemovigilance Governance Structure in Ghana

The haemovigilance system is organized and implemented under the responsibility of the NBSG-HQ and FDA, in a network (see Fig. 1) integrating different levels: national (FDA and National Haemovigilance Office – NBSG-HQ), regional (Zonal Blood Centres and Sub-Zonal Centres of the NBSG) and local levels (Transfusing facilities and HBB, HTC/DTC or focal person for blood safety).

Haemovigilance is undertaken at the local and regional levels, supported by a centralized national data collection and reporting process via the National Haemovigilance Office located at the NBSG Headquarters. The Technical Advisory Committee on Safety of Vaccines and Biological Products (TAC-VBP), an independent committee of the FDA, carries out imputability of selected adverse events and reaction reports received and recommends appropriate regulatory action to promote patient safety.

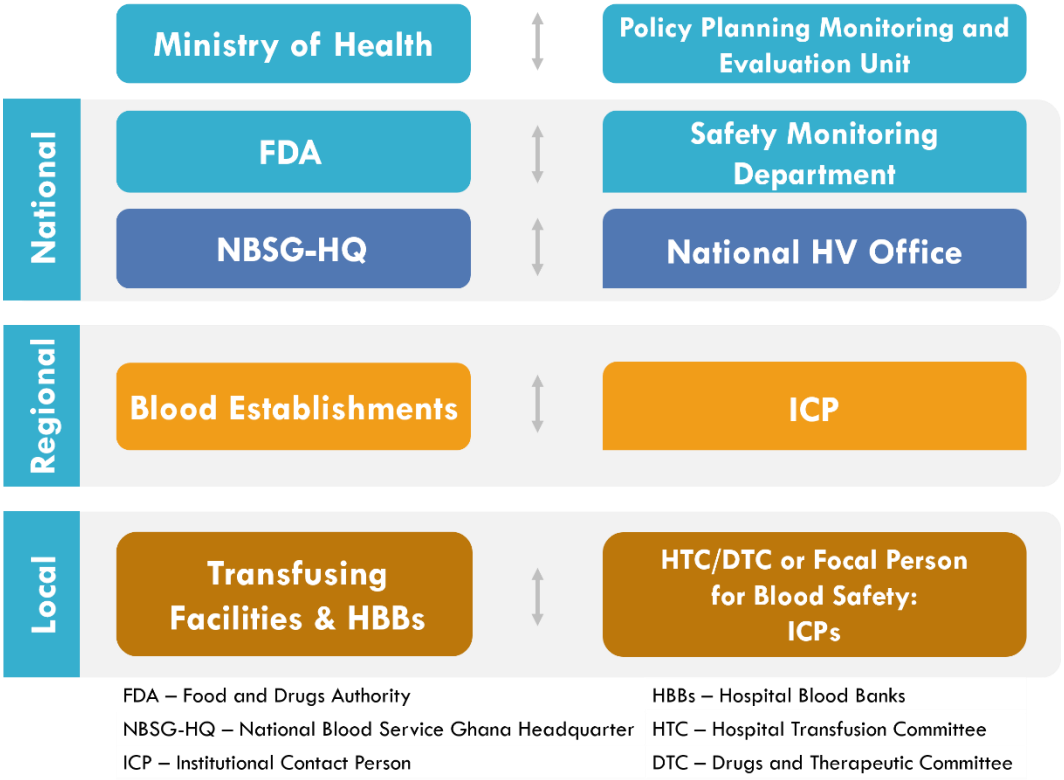


Figure 1 Haemovigilance Governance Structure in Ghana

(Source: National Haemovigilance Framework for Ghana)

5. Reporting and Investigation of ARs and AEs

5.1. Reporting Process

The main method used in Ghana for blood safety monitoring is spontaneous reporting. However, the FDA or the NHO (NBSG-HQ) may implement active reporting for specified products or AEs and/or ARs.

5.1.1. What to report?

All AEs/ARs must be reported to the FDA and to the National Haemovigilance Office at the NBSG-HQ. An overview of adverse reactions and adverse events to be reported are specified in table 2 and are defined in Annex I – Adverse Event Definitions of these guidelines.

Reportable data

The following minimum data must be reported in order to understand the adverse event or adverse reaction: Patient/Donor, Blood Products/Procedure, Adverse event, Reporter/Facility as applicable:

Table 2 Overview of reportable data

Patient/Donor	Blood Products/Procedure	Adverse Event	Reporter/Facility
Patient/Donor initials	Product type and modification	Type of adverse event	Reporting jurisdiction
Date of birth	Product ID and donation date	Date and time of transfusion	Contact details reporter/reporting facility
Age	Manufacturer/origin blood establishment	Symptoms and suspected diagnosis	
Gender	Concomitant blood products/medication	Contributing factors	
Blood group	WB/Apheresis donation	Outcome	

5.1.2. Who should report?

Transfusing Facilities

All transfusing facilities/hospitals as defined in the National Haemovigilance Framework for Ghana.

Blood Establishments

All blood establishments as defined in the Framework for Blood, Blood Components and Blood Products.

Health Professionals

Any health professional in a transfusing facility or blood establishment who identifies a suspected AE or AR should report.

5.1.3. When to report?

Reporting Timelines

- Transfusing facilities should report all suspected SAEs and SARs to the Blood Establishment the transfused unit/units originated from in real-time (initial report). Follow-up reports should be submitted within 14 days and after that whenever updates are available. Further, transfusing facilities should report all other AEs and ARs to the NBSG-HQ via their Zonal Blood Centres within a month.

- Blood establishments are required to report all SAEs and SARs to their Zonal Blood Centres within 24 hours, including reports for suspected SAEs and SARs received from Transfusing facilities. Follow-up reports should be submitted within 14 days and after that whenever updates are available. Further, BEs should report all other AEs and ARs to the NBSG-HQ via their Zonal Blood Centres within a month, including received reports. Reports about Look-back or Trace-back procedures are to be submitted within 7 days.
- Zonal Blood Centres as well as Sub-Zonal Centres are required to report all suspected SAEs and SARs to the NBSG-HQ within 24 hours. Follow-up reports should be submitted within 14 days and after that whenever updates are available. All other reports on AEs and ARs are to be reported within a month. Reports about Look-back or Trace-back procedures are to be submitted within 7 days. Reports received from other BEs and/or Transfusing facilities are forwarded to NBSG-HQ in real-time.
- The NBSG-HQ reports all received reports of AEs and ARs to the FDA within 24 hours.
- The FDA communicates with the NBSG-HQ about all directly received reports on AEs and ARs via a monthly Meeting.

If the reporting hospital or blood establishment becomes aware of relevant additional information about a SAE or SAR they have previously submitted to the FDA or NBSG-HQ they can submit a follow-up report whenever the information becomes available or include the information in the final report.

5.1.4. How and where to report?

Reporting forms

Haemovigilance reporting forms should be used for reporting transfusion reactions (initial and follow-up report: forms 1a and 1b, respectively), suspected TTIs (Trace-back: form 2), donor lookback procedures (initial and final report: forms 3a and 3b, respectively), donor reactions (form 4), and incidents (such as adverse events during manufacture, transport, storage, handling and near misses: form 5). These capture the minimum information considered important in order to fully understand the AE or AR. Form 6 is the rapid alert reporting form, see also chapter 12 - Rapid Alert Systems. Additionally, forms 7 and 8 have been developed to capture annual statistics on number of donations, number of units produced, and number of units distributed and on blood usage at blood establishments and hospitals respectively. These forms are summarised in Annex II – Haemovigilance Reporting Forms and are available at the end of this guideline and can be downloaded from the FDA website via (https://fdaghana.gov.gh/application-form.php).

How and where to report?

The chart in figure 2 depicts the haemovigilance reporting flow in Ghana. The reports can be submitted either via email or post, via online reporting or through the MedSafety App.

Transfusing Facilities should report to the respective blood establishment from where the transfused blood products were received by using the official reporting forms.

- Transfusing facilities should inquire about the contact details for reporting from all blood establishments that are providing blood to the facility.

Blood Establishments should report to their Zonal Blood Centres or Sub-Zonal Centres by using the official reporting forms and also forward reports received from transfusing facilities.

Blood Establishments should inquire about the contact details of their respective Zonal Blood Centre or Sub-Zonal Centre or use the following email addresses:

- Southern Zonal Blood Centre (SZBC) - southern.haemovigilance@nbs.gov.gh
- Central Zonal Blood Centre (CZBC) - central.haemovigilance@nbs.gov.gh
- Northern Zonal Blood Centre (NZBC) - a central email address will be published shortly

Zonal Blood Centres and Sub-Zonal Centres should report directly to the NHO at the NBSG-HQ by using the official reporting forms and also forwarding reports received from blood establishments and transfusing facilities.

- NBSG National Haemovigilance Office contact details:

  Email address: haemovigilance@nbs.gov.gh

  Messaging: 0277 688 588

  Phone: 0800 688 588 (toll-free)

The **NBSG-HQ/NHO** forwards received reports to the FDA.

The **FDA** communicates with NHO about directly received reports.

5.1.5. Haemovigilance process flow

The process flow of reporting AEs and ARs in Ghana is depicted in figure 2.

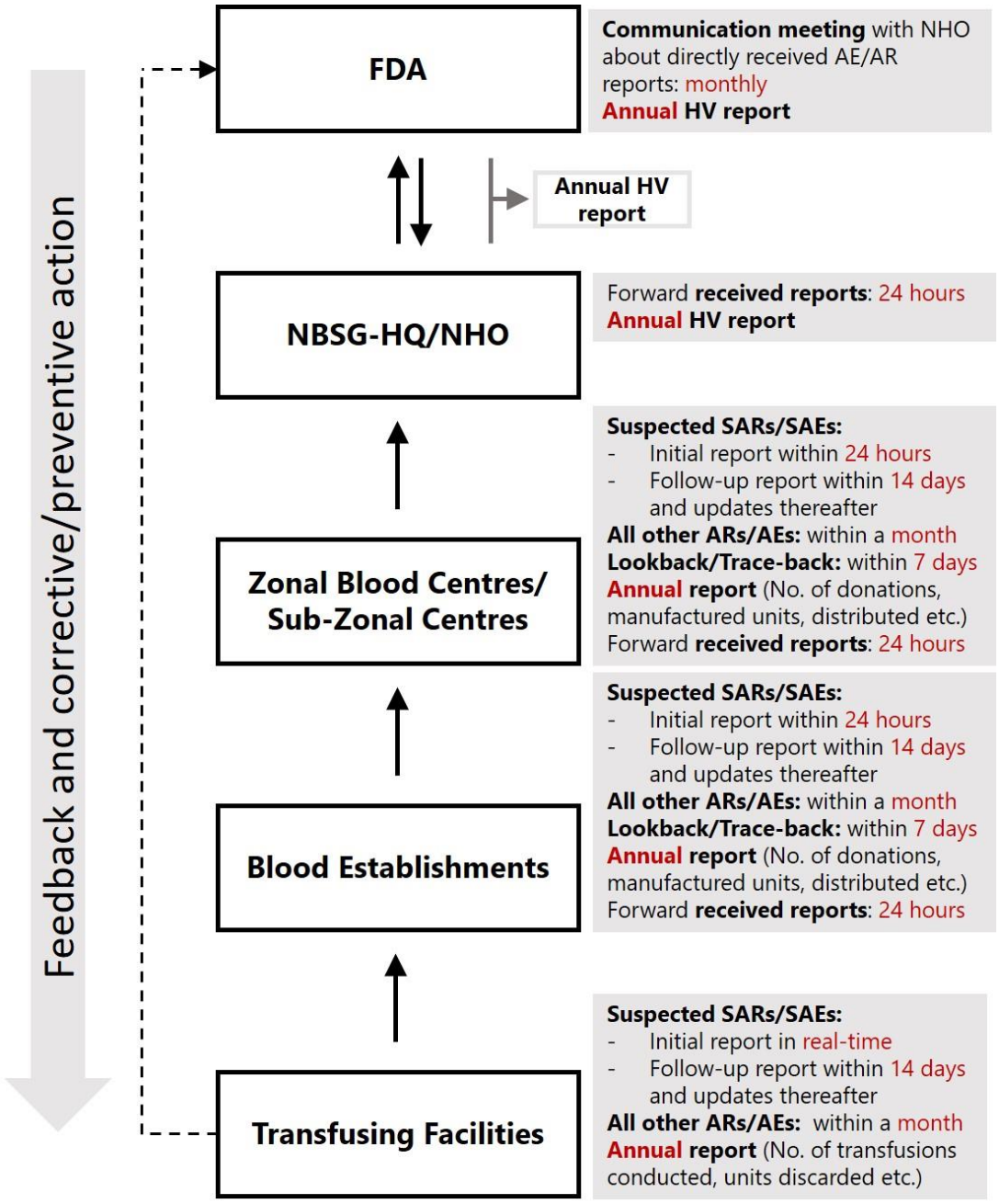


Figure 2 Flow of Haemovigilance Reporting in Ghana

FDA and NBSG-HQ are responsible for amending and updating the imputability, outcome severity scoring system and list of reportable additional data to align with changes at the national level.

5.2. Investigation of ARs and AEs

All ARs and AEs must be investigated to further characterise them as well as determine the root causes to facilitate implementation of appropriate corrective actions.

5.2.1. Who should investigate?

- Transfusing facilities and Blood Establishments should investigate all ARs and AEs that occur in their facilities in accordance with national procedures.

In addition, blood establishments should investigate all cases reported to them by the transfusing facilities where a blood unit they supplied is implicated for example in cases of suspected TRALI, bacterial contamination or suspected TTIs.

5.2.2. Follow-up on reports submitted to the FDA and NHO (NBSG-HQ)

Transfusing facilities and Blood Establishments should be aware that they may be contacted when necessary, for additional information with regards to the (serious) AE or AR reports submitted to the FDA and to NBSG-HQ. When a follow-up is required, the FDA or NBSG-HQ will contact the institutional contact person (ICP) indicated on the report via email or telephone.

Reasons for follow-up by the FDA/NBSG-HQ may include but is not limited to the following:

- Missing important information
- Contradicting information provided
- Legibility issues requiring clarification

5.2.3. Flow Chart for Reporting and Investigation of Transfusion Related Adverse Reactions

Transfusing ward: Suspected AR/AE identified by nurse/physician/physician assistant.



Transfusing ward: Immediate management of patient and notification of physician.



Transfusing ward: Fills out Transfusion Record Form A/B and sends along with the following to the Blood Bank: (i) Blood bag with transfusion set attached (ii) post-transfusion blood sample (iii) Sample of first urine after identification of reaction. Perform ward AR investigations.



Transfusing ward (As necessary):

i. Sends blood samples to the laboratory for FBC, Coagulation screen, renal function tests, liver function tests.
ii. Sends post transfusion blood sample to Microbiology laboratory for blood culture.
iii. Sends patient for chest x-ray.

Attending physician consolidates reports from other departments/labs and reports results and inferences to the HBB.



Hospital Blood Bank: Investigates transfusion reaction as per established procedures and notifies the ICP immediately.



Institutional contact person (ICP):

i. Assesses imputability level in coordination with patient physician.
ii. Fills out and sends initial report/follow-up AR report (**form 1a/form 1b)** to the respective blood establishment (origin of transfused blood product).



Blood Establishment:

i. Where applicable, immediately forwards received AR reports to ZBC/SZC.
ii. Where applicable, fills out and sends initial report/follow-up AR report (**form 1a/form 1b)** to NHO
iii. Investigates events and received reports about reactions.



Zonal Blood Centre/Sub-Zonal Center:

iv. Where applicable, immediately sends AR reports (either **forms 1a or 1b**) to NBSG-HQ.
v. Investigates reactions which could possibly be caused by product such as suspected TRALI; bacterial contamination, improper labelling etc.



NBSG-HQ (NHO):

i. Forwards AR reports to FDA.
ii. Performs imputability assessment.
iii. Reviews, records and analyses all reports and compile monthly/annual reports.



FDA:

i. Receives, reviews and analyses all reports of serious ARs.
ii. Performs imputability assessment.
iii. Publishes HV annual report in collaboration with NBSG-HQ.

6. Roles and Responsibilities

Information flow is an essential element in a well-functioning haemovigilance system. To achieve the unhindered collaboration of all parties involved, the roles and responsibilities within the haemovigilance system must be clearly defined and officially assigned.

The provision of haemovigilance data to the National Haemovigilance Office (NHO) (NBSG-HQ) and the FDA is voluntary for transfusing facilities and HBBs. All blood establishments (e.g. Zonal Blood Centres and Sub-Zonal Centres) are required by the Regulatory Framework for Blood, Blood Components and Blood Products [8] to report all SAEs and SARs to FDA. However, all transfusing facilities, HBBs, blood establishments, ZBCs and SZCs in Ghana are encouraged to participate in haemovigilance activities by reporting all AEs/ARs to demonstrate compliance with the National Haemovigilance Framework for Ghana and contribute to patient safety in relation to the use of blood and blood products.

Data is collected at the local and regional levels and they are responsible for the review of all the reported AEs/ARs within their institutions to assess the validity and imputability through agreed national form(s) and guidance. Following the review and speculation on the complications and reactions, the data is aggregated and provided to the NBSG-HQ within the agreed timelines via email/post/online. All ARs/AEs are additionally sent directly to the Safety Monitoring Team of the FDA within the agreed reporting timelines. The NBSG-HQ is responsible for the national analysis by collecting all the data on blood transfusion chain complications in its central database, reporting to the Safety Monitoring Team of the FDA and development of the annual haemovigilance report. The Safety Monitoring Team at the FDA in turn communicate to organizations involved in the blood transfusion processes in the form of policies, rules, and trainings.

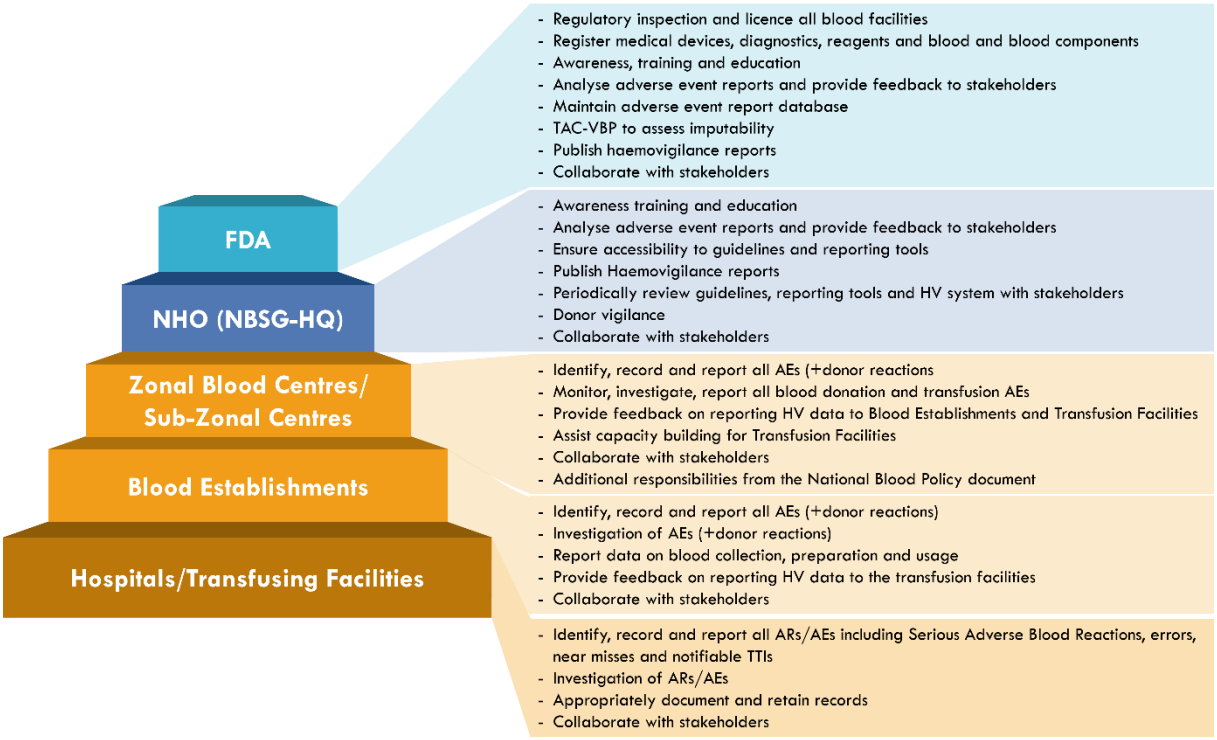


Figure 3 Roles and responsibilities in Haemovigilance in Ghana

(Source: National Haemovigilance Framework for Ghana)

6.1. Local level – Clinical Staff in Transfusing Facilities, HBBs and Laboratories

In case of a suspected adverse transfusion reaction, the attending HCP should stop the transfusion immediately and manage the recipient appropriately. All necessary measures should be taken and the event reported.

Adverse events related to blood donation and clinical blood transfusion, from donor syncopal events to transfusion-transmitted infections (TTIs), immunological and non-immunological transfusion reactions, near misses, incidents and errors should be identified, managed and reported within the institution. Prevention is key and hospital policies and procedures, including staff training and competency assessment, should be developed and monitored with this in mind. Various clinical governance review and reporting structures exist, including oversight by the hospital transfusion or blood management committee.

6.1.1. Healthcare Professionals

Specific roles include:

- Any healthcare professional, who observes, detects or is aware of any incidents, events, side effects, reactions, accidents, errors, near misses etc. occurring in a recipient of labile blood products or around the transfusion process is responsible for reporting it immediately to the Institutional Contact Person (ICP) of their facility via the respective AR/AE reporting form (Annex II – Haemovigilance Reporting Forms).
- Document the details of the patient as well as the implicated units/products in the patient's file.
- Assess the imputability levels of the ARs in coordination with the designated Institutional Contact Person (ICP) within the facility.
- Maintain records of the complications in the patient's medical record, including the report from the investigation completed by the designated Institutional Contact Person (ICP).

6.1.2. Designated Institutional Contact Person (ICP)

Specific roles include:

- Responsible for the review of reported incidents to assess the validity and imputability of the incident with respect to whether it was reported correctly, the seriousness of the incident, and assessment of the cause of the incident being related to the transfusion.
- Investigate blood related adverse events as per local policies and reporting guidelines.
- Report details of the clinical and laboratory investigations to the HTC.
- Enter necessary details as per documentation required in the respective reporting form (Annex II – Haemovigilance Reporting Forms).
- Responsible for sending validated data (email/post/online) within requested timeframes to the Zonal Blood Centre/Sub-Zonal Centre from which the labile blood product was received and to the FDA.
- Report reliable denominator information annually for adequate data analysis to NBSG-HQ and the FDA: number of blood units issued, number of recipients transfused.
- Responsible for drafting internal haemovigilance-related SOPs, administering training, ensuring peer review, auditing, supervising, reporting and initiating corrective/preventive actions.
- Review the reports for improving hospital transfusion practices.
- Local analysis of incidents and implementation of actions to decrease risks associated with transfusions.

6.2. Zonal Level – Zonal Blood Centres and Sub-Zonal Centres

Blood centres are the producers of labile blood products of all types as well as the providers of transfusion related services. At the same time, they are also the users of the consumables, disposables, reagents, equipment, etc. They therefore play a key role in haemovigilance.

Blood centres are responsible for protecting donor health and ensuring product safety and quality. Adverse events, incidents and near misses are identified, managed and reported as part of the institutional quality management system. Blood establishments are required to report defined categories of donor and product safety events to the FDA and the NBSG-HQ at the national level.

Specific roles include:

- Identify, record and report all AEs (incl. donor reactions) received (from own institution, Sub-Zonal Centres and hospitals/transfusing facilities/HBBs) to the NBSG-HQ as well as to the FDA within the agreed timelines.
- Responsible for reporting AEs/ARs occurring in a blood donor or post-donation information without delay to the designated Institutional Contact Person (ICP).
- Coordination with hospital personnel where labile blood products are issued.
- Investigation of AEs/Imputability.
- Preparation and submission of reports.
- Report reliable denominator information for adequate data analysis to the NBSG-HQ and the FDA, i.e.: number of blood donors, number of donations, number and type of blood products manufactured, and number of units issued.
- Provide feedback on reporting HV data to Sub-Zonal Centres, hospitals/HBBs/transfusing facilities.
- Assist capacity building for transfusing facilities.

6.3. National Level

6.3.1. National Haemovigilance Office – NBSG-HQ

Specific roles include:

- Responsible for supervising haemovigilance activities relating to collection, testing, storage distribution and clinical use of labile blood products.
- Review completeness, quality check and imputability of AE reports.
- Review, analyse, compare and compute received data.
- Communicate recommendations for quality improvement to the ZBCs, SZCs, transfusing facilities and FDA.
- Annual National Haemovigilance reporting and analysis:
    - Collect and collate data from ZBCs / SZCs and transfusing facilities
    - De-identified patient and health provider data reported
    - Comparative and cumulative data
    - Publish national HV report
- Identify possible items for active surveillance such as clinical audits.
- Preparation of SOPs, guidance documents and training manuals.
- Provide training to transfusing facilities, local blood establishments and ZBCs / SZCs.
- Identify opportunities for improvement.
- Provide feedback on reporting HV data to ZBCs, SZCs, hospitals/HBBs/transfusing facilities.

6.3.2. Safety Monitoring Department – FDA

Action must be taken on haemovigilance findings, so the development, recommendation, and implementation of interventions, as well as their monitoring through a quality systems approach, are fundamental. Published annual reports are helpful, not just for the data they contain, but also for sharing ideas and experience relating to practice change.

The ultimate outputs from haemovigilance systems are the ‘learnings’ and recommendations thus reports for clinicians, policymakers and the community are vital.

Specific roles include:

- Responsible for effective leadership and governance via monitoring and controlling blood transfusion activities; legislating, budgeting and inspecting.
- Review completeness, quality check and imputability of AE reports.
- Collection of all data on blood transfusion chain complications in a central database.
- Use HV data for improving blood safety through policy changes and quality management.
- Provide feedback on HV data to NBSG-HQ, ZBCs, SZCs, hospitals/HBBs/transfusing facilities.
- Awareness creation, training and education.
- Publish national HV report.

- Maintain national HV database
- Ensure confidentiality and anonymity for donors, patients and reporters

6.3.3. TAC on Safety of Vaccines and Biological Products (TAC-VBP) – FDA

Expert reference groups/technical advisory committees, with clinical, laboratory, patient safety and other specialist knowledge, are part of some haemovigilance systems. They can make major contributions to case reviews and development of recommendations. Because many individual hospitals do not have the required expertise for detailed case reviews, especially for rare scenarios, a central committee with relevant clinical expertise can contribute to ensuring data quality, enabling valid aggregation and analysis of submitted reports.

Specific roles include:

- Case review, validation, imputability, analysis and recommendations.
- Review regularly the standards of blood transfusion, donor selection, donor deferral, and TTI testing among other responsibilities.

6.3.4. Ministry of Health

The Ministry of Health is ultimately responsible for blood services in Ghana and thus responsible for the quality, safety and sufficiency of the supply of blood and blood products. Therefore, the government plays key policy and operational roles for the provision of governance, reporting structures and ensuring adequate human and financial resources for haemovigilance programme. If the system is not operated by the ministry of health directly, robust mechanisms should be in place for policy-makers to receive and act on haemovigilance reports, including communication of the results to health services and other stakeholders.

Specific roles include:

- Formulation of overall policy and implementation via agencies
- Financing for HV activities and policy implementation

7. Haemovigilance Data Collection

7.1. Reportable blood-related adverse events

Definitions of blood-related adverse events to be reported for haemovigilance reporting are provided in Annex I – Adverse Event Definitions. FDA and NBSG-HQ is responsible for amending and updating the agreed dataset and associated definitions to align with changes at the national level.

7.2. Imputability Scoring System

Reported adverse reactions should be accompanied by an imputability score such as described by the Commission Directive 2005/61/EC of the European Union [5] and the "Proposed Standard Definitions for Surveillance of Non-Infectious Adverse Transfusion Reactions" from ISBT [9]. The imputability is the assessment of the strength of relation between transfusion/blood donation and observed adverse reaction in recipient/donor respectively. The imputability is scored once the investigation is completed. In table 3 the imputability scoring system, amended after the ISBT proposal (incl. 2005/61/EC values), is described:

Table 3 Imputability Criteria

(Adapted from EU Directive 2005/61/EC [5] and ISBT [9, 10].)

Value	Assessment	Criteria
3	**Definite (certain)**	When there is conclusive evidence beyond reasonable doubt that the AR can be attributed to the transfusion/blood donation.
2	**Probable (likely)**	When the evidence is clearly in favour of attributing the AR to the transfusion/blood donation.
1	**Possible**	When the evidence is indeterminate for attributing the AR to the transfusion/blood donation or an alternate cause.
0	**Unlikely (doubtful)**	When the evidence is clearly in favour of attributing the AR to causes other than the transfusion/blood donation.
	Excluded	When there is conclusive evidence beyond reasonable doubt that the AR can be attributed to causes other than the transfusion/blood donation.
NA	**Not assessable**	Insufficient data available.

7.3. Outcome Severity Scoring System

Reported AEs and ARs should be accompanied by an outcome severity score. The International Society for Blood Transfusion (ISBT) Working Party on Haemovigilance has published a grading system for transfusion reactions [9]. A Table for severity grading of adverse transfusion reactions amended from the ISBT Working Party on Haemovigilance is provided below (see table 4):

Table 4 Severity Grading System for Adverse Transfusion Reactions

(Adapted from the ISBT [9].)

Value	Criteria
Grade 1 (Non-Severe)	The recipient may have required medical intervention (e.g. symptomatic treatment) but lack of such would not result in permanent damage or impairment of a body function.

Value	Criteria
Grade 2 (Severe)	The recipient required in-patient hospitalization or prolongation of hospitalization directly attributable to the event; and/or The AR resulted in persistent or significant disability or incapacity; or The AR necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function.
Grade 3 (Life threatening)	The recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death.
Grade 4* (Death)	The recipient died following an adverse transfusion reaction.
Outcome not available	The clinical outcome might be pending or is not final yet.

**Grade 4 severity should only be attributed to AR when the imputability score is 2, 3 or 4.*

Kindly refer to Annex III – Example of Imputability and Severity Scoring of Adverse Reactionsfor an example of how imputability and severity scoring of transfusion adverse reactions is performed.

Further, the ISBT has published together with the Association for the Advancement of Blood and Biotherapies (AABB), the International Haemovigilance Network (IHN) and the European Blood Alliance (EBA) a severity grading system for adverse donor reactions (see table 5) [11].

Table 5 Grading system for adverse donor reactions

Value	Criteria
Grade 1	No Outside Medical Care *AND* Short duration ≤ 2 weeks *AND* No limitation on Activities of Daily Living *AND* resolved with no or minimal intervention
Grade 2	Outside Medical Care, no hospitalization *OR* Duration >2 weeks- ≤ 6 months *OR* Limitations on Activities of Daily Living for ≤2 weeks
Grade 3	Not life-threatening *AND any of the following* Hospitalization *OR* Duration >6 months *OR* Limitations on Activities of Daily Living >2 weeks *OR* Require surgery *OR* Other serious complications
Grade 4	Immediate medical intervention required to prevent death.
Grade 5	Death.

7.4. Potential Severity of Transfusion Errors

The potential severity is a measure of the harm that the error may cause to the patient if the error is not detected. High severity level is assigned to errors that have potential to cause serious injury (including fatal outcome), whereas low and medium severity levels are assigned to errors with potential to cause no or minor/transient injury, respectively. Table 6 displays a set of errors with the potential of high severity.

Table 6 Potential Severity of Transfusion Errors

(Adapted from Transfusion Error Surveillance System (TESS) Report [12].)

Type of Error	Description
Product Request	– Order for wrong patient
Sample Collection	– Sample labelled with wrong patient identification – Not labelled – Wrong patient collected (not from intended patient) – Label incomplete/illegible for key patient identifiers (e.g., name, identification, birthdate) – Armband incorrect/not available
Sample Handling	– Paperwork and sample ID do not match
Sample Receipt	– Sample accepted in error
Sample Testing	– Sample labelled with incorrect lab number – Sample/test tubes mixed up/mislabelled
Request For Pick-Up	– Request for pick-up on wrong patient
Unit Issue	– Product issued to wrong patient – Laboratory Information System (LIS) warning overridden (in error or outside SOP) – Wrong type/dose of product issued to right patient
Unit Transfusion	– Administered product to wrong patient – Administered wrong type/dose of product to patient
Miscellaneous	– Patient registration incomplete/incorrect

8. Data Management and use of HV Data

The primary data source for haemovigilance data are reports of adverse events and adverse reactions that are made by the transfusing facilities and blood establishments to the National Haemovigilance Office and to the FDA. A standardised evaluation procedure is employed by the FDA to assess all reports received.

Table 7 Overview of Data Source, Type of Data and Output

Data Source	Type of Data	Output
Transfusing Facilities	All AE/AR reports	Notification forms, Imputability assessment
Blood Establishments	All AE reports, All Donor AR reports	Notification forms, Imputability assessment
National Haemovigilance Office	Blood Usage Statistics, HV Reports, All AE/AR reports	Annual Reports, Imputability assessment
FDA	BE and transfusing facility annual activity reports, All AE/AR reports, National Database	Annual Reports, Imputability assessment

8.1. Privacy and Security of Data

Adverse event reports to the national system should not include information that could identify the patient or donor, but should include a unique identifier enabling the national haemovigilance officers to request further details if necessary. Any database of haemovigilance reports must operate in compliance with applicable regulations on confidentiality of individual recipient and donor data.

No patient or donor will be identified in the data sent by hospitals or blood establishments to the FDA and/or NBSG-HQ. The identities of the reporters and institutions should not be shared with third parties unless in situations consistent with law.

8.2. Data Storage

A reliable system for information storage with an appropriate backup system should be in place to retain reports for traceability purposes. The system should be qualified to store data safely over long periods. The length of time certain reports and data should be stored is regulated though the Standards for Practice of Blood Transfusion in Ghana guideline. See also Chapter 9 on Traceability. The system must be in compliance with the Data Protection Act, 2012 (Act 843) [13].

8.3. Data analysis

Haemovigilance data received from all over the country shall be analysed by the FDA in collaboration with the NBSG-HQ. Data on adverse events including transfusion reactions reported through the reporting system shall be analysed with regard to, but not limited to, the following parameters:

For transfusion reactions:

- Type of blood product transfused
- Type of transfusion reaction
- Clinical diagnosis of the patient, age, and gender
- Seroprevalence of transfusion-transmitted infections
- First time or repeat transfusion
- Clinical outcome
- Imputability

For donor reactions:

- Type of donation
- Type of reaction
- First time or repeat donation
- Outcome
- Imputability

For other AEs

- Collection (whole blood, apheresis)
- Testing (donations)
- Processing
- Storage
- Distribution
- Materials
- Near-misses

Specifications for the above-mentioned topics:

  - Product defect
  - Equipment failure
  - Human error

The TAC-VBP with support from experts in fields such as transfusion medicine, haematology, microbiology, virology, and statistics will be entrusted with the following defined responsibilities regarding analyses of data:

- Review quality and completeness of data
- Collation and analysis of information from the adverse events data submitted
- Define bio-statistical methods to be used for the analysis
- Create standardized post analytical reports that will help understand the information that is derived from adverse reaction data
- Make evidence-based recommendations and devise formats and guidance documents for follow-up actions after implementation of recommendations

8.3.1. Examples of practical considerations for haemovigilance data analysis

Assessing the probability that an adverse event will occur

It is necessary to know both the number of occasions on which the adverse event has occurred (numerator data) and the number of times the associated procedure or process has occurred in total (denominator data). For example, if a blood centre sends three reports of virus transmission in a year and the total volume of blood provided by that centre is 120,000 units, then the risk of transmission is 1 in 40,000. However, if the total volume of blood provided is 6000 units, the risk of transmission is 1 in 2000.

Vigilance for patients (recipients)

The ideal denominator here is the number of units of the relevant blood product transfused and the number of patients receiving the blood product. However, accurate data on products transfused may not be available and in such cases, a surrogate, such as the number of units of blood products distributed from the blood transfusion service to the hospital or issued from the hospital blood bank to the clinical area, can be used. Demographic and clinical data (e.g. sex, age, disease or indication for transfusion) for transfused patients can help identify patients at higher risk of an adverse event.

Vigilance for donors

The denominator data may be the number of donations collected or the number of times potential donors present. Adverse events may thus be expressed as, for example, number per 100,000 whole blood donations. Where possible, both adverse reactions or complications and collections should be broken

down into the main collection types - whole blood donation versus apheresis, first-time donors versus repeat donors.

9. Traceability

A traceability system should enable complete Look-back and Trace-back procedures, if possible, through a computer database. Collected blood and blood products and issued units should be traceable from donor to recipient and *vice versa.* It is important to be able to identify previous donations or related blood products or recipients of units from donors that for example have been tested positive for TTI. Further, it is necessary to trace issued units that for example caused an AR back to the original donation/ associated donor to identify other recipients of those blood products.

9.1. Identification of Donor, Donation, and Recipient

There should be a system in place to uniquely identify each donor, donation, testing samples, resulting blood products, and the recipient of such products.

9.1.1. Donor identification

Identification of a donor should take place before the donation via a nationally recognized official identification document. The requirements for identification processes should be laid out in SOPs at every donation site. Entering donor data into a database should be covered by a SOP for copying critical data, including descriptions of practical execution following Good Manufacturing Practice (GMP) standards (e.g., four-eye-principle). Before donation, donor data on the questionnaire and donation form has to be cross-checked with the ID card and/or the donor database.

9.1.2. Identifying donation and blood products

The system must allow for unique identification of a donation and any resulting products. The labelling system should follow the national standards and coding system.

9.1.3. Recipient identification

All hospitals and transfusing facilities must have SOPs and guidance documents in place that have requirements for recipient and product identification. Recipient data should be available for health care workers to cross-check patient's identity with recipient data on product label directly before transfusion.

9.2. Record Keeping

A system of record keeping should be in place that covers the complete transfusion chain from donor to recipient. Linkages between the different information should be clear and traceable: donor, donation, and questionnaire; donation number, test results, and product unit ID; product unit ID and recipient. These linkages may be maintained in databases and reporting forms (e.g. donation form, manufacture report, transfusion report).

9.2.1. What needs to be captured and by whom?

Data must be recorded by appropriate stakeholders at different stages throughout the transfusion chain. All acquired data should be handled according to national requirements for data protection and access to the information should be restricted to authorized personnel.

Blood Establishments

Blood Establishments that collect donations are required to store identification data of donors, reports of donations that contain the donor ID and the donation number and the completed questionnaires.

Testing establishments have to store reports of testing results that are unmistakably linked to the donation number and test tubes.

Establishments that process blood and blood products are required to keep records about the origin of the blood donation (if the donation is located elsewhere), about the quality of the manufactured products (compliance) including storage conditions, and about the destination of the products. The final unit/product ID must be linked to the original donation ID.

Facilities that store and transport blood and blood products

Facilities that store and/or transport blood and blood products units must keep records about storage and transport conditions, following the respective guidance documents.

Transfusing Facilities and HBBs

All transfusing facilities and HBBs that conduct transfusion of blood and blood products must have a system recording the origin of the units and final destination which is either 'issue for a patient' or 'disposal'. Further, the facilities are required to keep transfusion records that contain the product unit ID as well as the patient identification information.

9.2.2. Minimum Retention period

It should be clear for all stakeholders involved in the transfusion chain how long to store records about the different activities and processes. The respective retention periods of the documentation as stated in the Standards for Practice of Blood Transfusion in Ghana (available shortly at [14]) are as follows:

Table 8 Minimum retention time of records

Records	Time	Responsible
Transfusion records	10 years	Transfusing facilities, hospitals
Donation records	10 years	Blood Establishments (BEs)
Laboratory testing records	10 years	Testing facilities, BEs
Manufactured products/units	10 years	BEs
Issued units	10 years	Transfusing facilities, HBBs (for recipients); and BEs (for delivered units to transfusing facilities)
HV reports	10 years	All involved parties

9.2.3. Critical Data

Data that must under all circumstances be transcribed correctly, such as laboratory test results, are 'critical data'. Manual entry of critical data should be verified by a second authorised person. There should be secure methods for transcription in place.

9.3. Look-back and Trace-Back

9.3.1. Look-back

A "Look-back" is an investigation on the fate of recipients of previously donated blood or blood products resulting from recognition that the donation may have presented a risk of transmission of infection.

A blood establishment must initiate Look-back investigations on recognition that there may have been risk of transmitting an infection from a donor to a recipient.

Look-back is required under the following circumstances:

- When a donor has undergone seroconversion during their blood donation career
- Donors identified to be infected and reported to the Blood Service from an outside source
- Donors identified as infected by a TTI through the introduction of a new, more sensitive screening test applied to all donations.

General principles for Look-back investigations

Look-back investigations, should be managed through a generic system which incorporates the following steps at the BE and Transfusing Facility:

At the BE:

- Identification of potentially infectious donations
- Identification of all blood products prepared from those donations and their immediate quarantine and/or recall of unused products
- Documentation of the fate of the blood products
- Retest of retained samples from the potentially infectious donation
- Notification of hospital blood bank in receipt of involved blood products
- Notification of NBSG-HQ and FDA through completion of the designated forms

At the Transfusing Facility:

- Identification of the fate of the product, including details of any identified recipient
- For recipients not known to be dead, a procedure for notification, generally following notification of the treating physician
- A protocol for management of recipient notification and testing (if required)
- Notification of case details to BE, NBSG-HQ and FDA through completion of the designated forms

9.3.2. Trace-back

A Trace-back is an investigation carried out by the Blood Establishment when they receive a report that a patient has been identified with a transfusion transmissible infection following the transfusion of blood or blood products.

Trace-back is required when a recipient of blood or blood products has been identified to be infected with a transfusion transmissible infection for which another more likely cause is not apparent.

General principles for Trace-back investigations

Trace-back investigations, should be managed through a generic system which incorporates the following steps at the Transfusing Facility and BE:

At the Transfusing facility:

- Identification of recipients potentially infected through transfusion via patient reports or routine patient management and testing
- Identification of unit IDs of all blood products transfused to the recipient
- Notification respective blood establishments who supplied the transfused products.
- Notification of recipient of outcome of investigations
- Notification of NBSG-HQ and FDA through completion of the designated forms

At the BE:

- Identification of products from implicated donations and quarantine and/or recall them if not used
- Retest of retained samples from the respective donations
- Identification of respective donors of implicated blood and blood products
- Follow-up on donors and obtain samples for testing as appropriate
- Where an infection similar to that identified in recipient is detected in any donor of the transfused products, perform phylogenetic testing to verify/confirm TTI transmission where possible
- Notification of transfusing facility of the outcome of investigations
- Notification of NBSG-HQ and FDA through completion of the designated forms

10. Haemovigilance Methods

10.1. Spontaneous Reporting System (Passive)

Spontaneous reporting system is a haemovigilance method that solely relies on the health care professionals in transfusing facilities and blood establishments to detect and take the initiative to report adverse reactions and adverse events. There are no active measures taken to look for adverse effects other than encouraging health care professionals to report to the NBSG-HQ or FDA. This is the most commonly used method in haemovigilance and reporting in Ghana is voluntary.

Advantages of Spontaneous Reporting System

- Administratively easiest to establish and least labour intensive
- Relatively inexpensive
- Covers the whole population and includes all blood products
- There is continual monitoring throughout life-cycle of product
- Detects signals of new, rare or serious adverse reactions/events

Disadvantages of Spontaneous Reporting System

- Usually associated with gross under-reporting
- Captures only suspected ARs/AEs
- Denominator unknown
- There is strong bias in reporting
- Risk factors cannot be identified with certainty due to absence of rates

10.2. Active Methods

10.2.1. Intensified Spontaneous Reporting

This is an extension of the Spontaneous Reporting System used to enhance the reporting of ARs/AEs of specific blood products and blood products in early post-approval phase.

Generally, the advantages and disadvantages of spontaneous reporting apply.

10.2.2. Targeted Spontaneous reporting

This is intensified ARs/AEs reporting within a defined cohort. Specific targets are defined such as specific population, specific clinics, specific blood products, all ARs or specific ARs.

Advantages of Targeted Spontaneous Reporting

- Can utilize existing ARs/AEs reporting infrastructure
- Possible to implement monitoring programme that targets specific issue of concern (AR/AE, product, patient group)
- Captures useful information; less “background noise”

Disadvantages of Targeted Spontaneous Reporting

- Under-reporting remains a problem
- Captures only suspected ARs/AEs
- May limit reporting only to specific ARs/AEs
- Relies on competency of the reporter

10.2.3. Cohort Event Monitoring

Cohort event monitoring (CEM) is a prospective observational cohort study of adverse events associated with one or more blood product. It is useful for gathering more information on the safety profile of a new blood product in the post-approval phase thereby acting as an early warning system.

Enrolled patients are actively followed up during treatment to record all adverse events.

Advantages of Cohort Event Monitoring

- Identify risk factors for adverse reactions

- Able to produce rates
- Produce a near complete profile of the adverse events and/or adverse reactions for the blood product of interest
- Very effective in identifying signals at an early stage

Disadvantages of Cohort Event Monitoring

- More labour intensive and more costly than spontaneous reporting
- Requires more training of the health workers who will implement

10.2.4. Retrospective Studies

These involve review and analysis of historical information on ARs and AEs.

11. Rapid Alert Systems

The haemovigilance system in Ghana includes a Rapid Alert System (RAS) or an early warning mechanism for the rapid dissemination of information on important events, emerging hazards or trends. This system is not a replacement for urgent notifications to the blood centres, but it is an information channel enabling rapid diffusion of important information concerning emerging threats of whatever kind. It typically works via phone calls or alternatively by SMS, email or instant chat messages. Quick transmission of information on important hazards or trends is needed to inform stakeholders in the transfusion chain.

The main objective of a RAS is to enable the taking of corrective actions in the shortest period of time. RAS in haemovigilance is used to signal the appearance of clusters of clinical signals after transfusion. A good RAS permits quick and safe transmission of correct and precise data to quality assurance responsible persons in blood transfusion centres and to competent authorities. This allows for decisions to be made on possible action(s) to be taken in order to maintain or improve safety in blood transfusion.

In principle, three types of rapid alert systems can be defined as follows:

1. **Quality and Safety Defects:** Alerts requiring field corrective actions (e.g. recall, quarantine, discard, etc.) for the blood or blood products that might impact patient safety after collection, preparation, and during usage of these products.
2. **Information Notices:** Alerts related to field corrective actions performed in the medical device sector, medicinal products sector or other sector(s), which are of relevance to the blood and blood products sector.
3. **Epidemiological Notices:** Alerts related to important epidemiological developments (e.g. disease outbreaks) which may have cross-border implications in the field of blood donation and transfusion.

Because of the importance of the message and the preciseness of the information to prevent unnecessary and unjustified actions, a number of practical aspects should be taken into account.

Less urgent information should not be transmitted to ensure its effectiveness.

11.1. Before using the Rapid Alert System:

- The pertinent information has to be brought to the attention of the Institutional Contact person.
- The information has to be checked to be correct and as far as possible complete.
- In case a manufacturer of a device is implicated, written information and/or confirmation should be requested from the manufacturer.

11.2. Using the Rapid Alert System:

- Communication via phone call, SMS, e-mail or instant chat messages including essential information on the type of alert, products affected, if applicable recipient details (unique identifiers),
- A validated Rapid Alert Report Form (form 6) should be filled within 24 hours and send to the NBSG-HQ,
- The requested information should be filled in with special attention to lot and batch numbers (including medical devices), and other reference numbers needed for traceability, actions considered, suggested, or requested should be described,
- Additional information should be attached such as written information and/or confirmation from the manufacturer,
- The NBSG-HQ will forward the RAS report forms to the FDA in real-time.

11.3. After using the Rapid Alert System:

- Investigations on the adverse event should continue, additional information should be dispatched concerning outcome, impact, consequences, etc.,
- Where applicable, reports or actions from other countries or international organisations should be considered.

11.4. When to use the RAS

Each case needs to be newly assessed for if it is necessary to use the RAS.

Examples when to use the rapid alert system

- Transmission of emerging infections through transfusion
- Microbial contamination of blood or blood products
- Wrong product (label and contents are different products)
- Microbial contamination of sterile injectable or non-injectable products or components of blood bag and apheresis systems.
- Chemical contamination with potential serious medical consequence.
- Wrong active ingredient in a multi-component product with serious medical consequences.
- Missing or incorrect product information on leaflets or package inserts
- Non-compliance with specification e.g. assay stability, fill/weight
- Insecure closure with serious medical consequences
- Any other event as determined by the FDA

Examples when NOT to use the rapid alert system

- Non-serious adverse events and adverse reactions.

12. Feedback on reported AEs and ARs

Haemovigilance data should be analysed by FDA and the NBSG-HQ and an aggregate feedback report should be compiled and distributed to all organizations involved in the blood transfusion chain, other stakeholders and made available to the public. The feedback report should include recommendations for implementation of preventive action (this could be by transfusing facilities, blood establishments or ministry of health, or other relevant stakeholders) and it should be issued in a timely manner, to ensure effective use of the data to improve practice and to encourage submission of data.

Benchmarking and comparison of haemovigilance data between hospitals, blood transfusion centres and even countries requires reliable and correct denominator data [1]. These aid in sharing of experiences and best practices to improve the overall quality and safety of blood transfusion services.

The inclusion of illustrative anonymized case studies is also useful for educational and training purposes. Generic template reporting forms can be found in (Annex II – Haemovigilance Reporting Forms) and these provide a resource to assist in designing the national feedback report.

12.1. Annual Haemovigilance Reports

The annual Haemovigilance Report should be published annually by FDA in collaboration with the NBSG-HQ. The report contains information including but not limited to:

- Blood and blood product production and usage statistics
- Analysis of reported adverse reactions (donor + recipient) and events
    - Reporting denominator for AEs - total units (blood and blood products) processed
    - Reporting denominators for ARs
        - recipient: units issued, units transfused, recipients transfused;
        - donor: total donations
- Bacterial monitoring of platelet concentrates
- Donor infectious disease testing
- Adverse events associated with blood donation
- Trends in blood and blood product transfusion
- Recipients of blood and blood product transfusions (gender, age, etc.)

12.2. Communication Strategies

Feedback reporting can be done via phone call in emergencies, mailing to an email, SMS or recognized messaging applications and via postal services or via any agreed national shared haemovigilance platform.

Scientific meetings at different levels can support comprehensive feedback to relevant stakeholders.

General feedback can also be given through public means such as newsletters, publications, announcements, and use of audio-visual materials.

13. Training and Capacity Building

Successful national haemovigilance systems demonstrate some common characteristics including education and training. Appropriate education, training and competency assessment of all health care personnel involved in blood transfusion activities are essential. All personnel involved in the blood transfusion chain, from the blood transfusion service, the hospital blood bank through to the clinical areas in Ghana, should be trained in safe handling and administration of blood products and in haemovigilance. Training and standardisation of forms, procedures, reports and educational materials should be standardised across Ghana through the NBSG-HQ and FDA. All relevant stakeholders involved in the transfusion chain should be trained and documentation of training should be kept. Training should include the general principles of haemovigilance, its objectives and benefits, and individual roles and responsibilities. In addition, the reporting procedures, and national guidelines should also be included in the training on a regular basis. At all levels, trainings shall be regularly updated in response to haemovigilance reports and practice guidelines to ensure improvements to the practice.

Briefly, training and capacity building is a continuous process that should include:

- Role-specific training for all staff involved in the transfusion chain and for management of donor and patient complications
- Availability of current standard operating procedures and practice guidelines
- Documentation of training
- Competency assessment

Typically, education and training activities shall include:

- Pre-service training of doctors, nurses, laboratory scientists, pharmacists
- and other health care workers in:
    - appropriate prescribing
    - safe bedside procedures, correct patient identification and pre-transfusion sampling and labelling
    - safe administration of blood and blood products
    - recognizing, investigating and managing adverse reactions and events in patients or donors
    - quality data collection and processing
    - the practice of haemovigilance in general
- In-service training in good working practices, including an understanding of quality systems and the need to follow standard operating procedures.
- Haemovigilance-specific training that ensures a good understanding of:
    - the rationale and concept of haemovigilance
    - the national haemovigilance programme
    - detecting, recognizing, investigating and reporting adverse events
    - conducting root cause analysis
    - applying corrective and preventive actions to improve practice
- Addressing common concerns arising from the practice of haemovigilance e.g. barriers to reporting adverse events and communication-related issues.
- Specific trainings for staff with lead or coordination roles in haemovigilance since they require more, such individuals will require a broad knowledge of evidence-based transfusion practices and technical skills related to transfusion safety, together with leadership qualities, effective communication and teaching skills, and ability to influence practice and effect change. Further skills needed by staff with lead will include:
    - establishing and managing a central coordinating office
    - developing tools for data collection
    - characterizing adverse events
    - verifying reports
    - advising on investigation and root cause analysis of events
    - analysing and managing data
    - producing annual feedback reports and educational material

    - liaising with professional groups and stakeholder organizations
- Regular competence assessments carried out and documented to ensure that staff retain the necessary skills and knowledge for their specific roles in the transfusion chain.

All Training manuals developed by FDA and NBSG-HQ will be made available to all stakeholders.

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Annex I – Adverse Event Definitions

The following information is based on the 'Proposed Standard Definitions for Surveillance of Non-Infectious Adverse Transfusion Reactions' from ISBT [9]. Additional events were adopted from the Western Australia Haemovigilance Reporting Guideline [15] and the "Standard for Surveillance of Complications Related to Blood Donation" from the ISBT, AABB IHN [10]. The dataset of reportable adverse events for haemovigilance reporting is as follows:

Table 9 Haemolytic Transfusion Reactions (ISBT)

AE TYPE	DEFINITION
Acute haemolytic transfusion reaction (AHTR)	An AHTR has its onset within 24 hours of a transfusion. Clinical or laboratory features of haemolysis are present. Common signs of AHTR are: – Fever – Chills/rigors – Facial flushing – Chest pain – Abdominal pain – Back/flank pain – Nausea/vomiting – Diarrhea – Hypotension – Pallor – Jaundice – Oligoanuria – Diffuse bleeding – Dark urine Common laboratory features are: – Hemoglobinemia – Hemoglobinuria – Decreased serum haptoglobin – Unconjugated hyperbilirubinemia – Increased LDH and AST levels – Decreased haemoglobin levels Not all clinical or laboratory features are present in cases of AHTR. Blood group serology usually shows abnormal results, but absence of immunological findings does not exclude AHTR. AHTR may also be due to erythrocyte auto-antibodies in the recipient or to non-immunological factors like mechanical factors inducing haemolysis (malfunction of a pump, of a blood warmer, use of hypotonic solutions, etc.).
Delayed haemolytic transfusion reaction (DHTR)	A DHTR usually manifests between 24 hours and 28 days after a transfusion and clinical or laboratory features of haemolysis are present. Signs and symptoms are similar to AHTR but are usually less severe. DHTR may sometimes manifests as an inadequate rise of post-transfusion haemoglobin level or unexplained fall in haemoglobin after a transfusion. Blood group serology usually shows abnormal results.
Delayed serologic reaction (DSTR)	There is a DSTR when, after a transfusion, there is demonstration of clinically significant antibodies against red blood cells which were previously absent (as far as is known) and when there are no clinical or laboratory features of haemolysis. This term is synonymous with alloimmunization.

Table 10 Non-Haemolytic Transfusion Reactions (ISBT)

AE TYPE	DEFINITION
Febrile non haemolytic transfusion reaction (FNHTR)	There is a FNHTR in the presence of one or more of: – fever (≥38 °C oral or equivalent and a change of ≥1 °C from pre-transfusion value), – chills/rigors This may be accompanied by headache and nausea. occurring during or within four hours following transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition. FNHTR could be present in absence of fever (if chills or rigors without fever). **For the purpose of international comparison only the most serious cases of FNHTR should be accounted for:** – fever (≥39 °C oral or equivalent and a change of ≥2 °C from pre-transfusion value) and chills/rigors
Allergic reaction	An allergic reaction may present only with mucocutaneous signs and symptoms: – Morbilliform rash with pruritus – Urticaria (hives) – Localized angioedema – Edema of lips, tongue and uvula – Periorbital pruritus, erythema and edema – Conjunctival edema occurring during or within 4 hours of transfusion. In this form it usually presents no immediate risk to life of patient and responds quickly to symptomatic treatment like antihistamine or steroid medications. This type of allergic reaction is called 'minor allergic reaction' in many haemovigilance systems. **For the purpose of classification this type of allergic reaction would be graded as 1, i.e., non-severe.** An allergic reaction can also involve respiratory and/or cardiovascular systems and present like an anaphylactic reaction. There is anaphylaxis when, in addition to mucocutaneous systems there is airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs occurring during or very shortly after transfusion. **For the purpose of classification this type of allergic reaction would be graded as 2 (severe), 3 (life-threatening) or 4 (death) depending on the course and outcome of the reaction.** An allergic reaction classically results from the interaction of an allergen and preformed antibodies. A rise of Mast Cell Tryptase can support the diagnosis of an allergic reaction. IgA deficiency and/or anti-IgA in the recipient has been associated with severe allergic reactions but is only one infrequent cause out of many others.
Transfusion-associated graft-versus-	TA-GVHD is a clinical syndrome characterised by symptoms of fever, rash, liver dysfunction, diarrhoea, pancytopenia and findings of characteristic histological

AE TYPE	DEFINITION
host disease (TA-GVHD)	appearances on biopsy occurring 1-6 weeks following transfusion with no other apparent cause. The diagnosis of TA-GVHD is further supported by the presence of chimerism.
Post transfusion purpura (PTP)	PTP is characterized by thrombocytopenia arising 5-12 days following transfusion of cellular blood products with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system.
Transfusion-related acute lung injury (TRALI)	In patients with no evidence of acute lung injury (ALI) prior to transfusion, TRALI is diagnosed if a new ALI is present (all five criteria should be met): – Acute onset – Hypoxemia o PaO_2 / FiO_2 < 300 mmHg or o Oxygen saturation is < 90% on room air or o Other clinical evidence – Bilateral infiltrates on frontal chest radiograph – No evidence of left atrial hypertension (i.e. circulatory overload) – No temporal relationship to an alternative risk factor for ALI, during or within 6 hours of completion of transfusion. Alternate risk factors for ALI are: – Direct Lung Injury o Aspiration o Pneumonia o Toxic inhalation o Lung contusion o Near drowning – Indirect Lung Injury o Severe sepsis o Shock o Multiple trauma o Burn injury o Acute pancreatitis o Cardiopulmonary bypass o Drug overdose It has been suggested by the Toronto TRALI Consensus Panel to add a category of possible TRALI that would have the same definition as TRALI except for the presence of a temporal relationship to an alternative risk factor for ALI (as described above). In such a circumstance TRALI should be indicated with a possible imputability to transfusion. TRALI is therefore a clinical syndrome and neither presence of anti-HLA or anti-HNA antibodies in donor(s) nor confirmation of cognate antigens in recipient is required for diagnosis
Transfusion-associated circulatory overload (TACO)	TACO is characterized by any 4 of the following: – Acute respiratory distress – Tachycardia – Increased blood pressure – Acute or worsening pulmonary edema on frontal chest radiograph – Evidence of positive fluid balance occurring within 6 hours of completion of transfusion. An elevated BNP is supportive of TACO.

AE TYPE	DEFINITION
Transfusion-associated dyspnea (TAD)	TAD is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should be the most prominent clinical feature and should not be explained by the patient's underlying condition or any other known cause.
Hypotensive transfusion reaction	This reaction is characterized by hypotension defined as a drop in systolic blood pressure of ≥ 30 mmHg occurring during or within one hour of completing transfusion and a systolic blood pressure ≤ 80 mmHg. Most reactions do occur very rapidly after the start of the transfusion (within minutes). This reaction responds rapidly to cessation of transfusion and supportive treatment. This type of reaction appears to occur more frequently in patients on ACE inhibitors. Hypotension is usually the sole manifestation, but facial flushing and gastrointestinal symptoms may occur. All other categories of adverse reactions presenting with hypotension, especially allergic reactions, must have been excluded. The underlying condition of the patient must also have been excluded as a possible explanation for the hypotension.
Other transfusion reactions	**a) Haemosiderosis** Transfusion-associated haemosiderosis is being defined as a blood ferritin level of ≥ 1000 micrograms/l, with or without organ dysfunction in the setting of repeated RBC transfusions. **b) Hyperkalemia** Any abnormally high potassium level (> 5 mml/l, or ≥1.5 mml/l net increase) within an hour of transfusion can be classified as a transfusion- associated hyperkalemia. **c) Unclassifiable Complication of Transfusion (UCT)** Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined ATE and with no risk factor other than transfusion and no other explaining cause.

Table 11 Other Adverse Events and Transfusion Reactions

(From WA Haemovigilance Reporting Guideline and Swissmedic Haemovigilance Annual Report 2020 [15, 16].)

AE TYPE	DEFINITION (FROM ISBT)
Incorrect blood component transfused (IBCT)	All reported episodes where a patient was transfused with a blood component that did not meet the appropriate requirements or that was intended for another patient. **Include even if any of the following apply:** – the component was ABO compatible (e.g., an immune compromised patient requires irradiated cellular products but receives non- irradiated blood instead) – only a small quantity of blood was transfused and/or – there was no adverse reaction

AE TYPE	DEFINITION (FROM ISBT)
	Further examples: – **WBCT (Wrong Blood Component Transfused** e.g., non-allo-antibody-compatible blood product, HLA-incompatible, wrong product, transfusion of avoidable untested O negative blood products etc.), – **SRNM (Specific requirements not met** e.g., non-irradiated/non-washed blood products, phenotype not observed, SOP not followed etc.), – **HSE (Handling and storage errors**) e.g., wrong equipment used, transfusion after expiry of type and screen validity, incorrect storage of blood product etc., – **ADU (Avoidable, delayed or under-/over-transfusion**) e.g., transfusion volume not adapted, delayed transfusion, transfusion rate not adapted etc., – **RBRP (Right Blood Right Patient** e.g., incorrect blood product ID
Anaphylactoid or anaphylactic reaction	An allergic reaction can also involve respiratory and/or cardiovascular systems and present like an anaphylactic reaction. There is anaphylactic reaction when, in addition to mucocutaneous symptoms, there is airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/ bronchospasm, hypoxemia). Such a reaction usually occurs occurring during or very shortly after transfusion.
ABO incompatibility	All cases where a blood component was transfused which was ABO incompatible. Include all such events even if: – only a small quantity of blood was transfused, and/or – no adverse reaction occurred All cases are to be included, whether the first error occurred in the hospital transfusion laboratory or in clinical areas. **Note that these events are a subgroup of the IBCT category.**
Near Misses	Deviation discovered before the transfusion has taken place Discrepancies relating to patient identification, sample tubes or the prescribing of blood products Examples of Near Misses: – Blood transfusion request form not signed – Sample tubes not labelled correctly or blood transfusion request form incomplete – Minor discrepancy between tubes and order form – Wrong patient's date of birth – Missing labels from sample tubes – Issuing of products intended for discard – Wrong sample tubes retrieved – Different patient identification on sample tubes/form – Blood taken from wrong patient and only discovered because of discrepancy in blood group / wrong blood in tube (WBIT) – Blood product requested for the wrong patient – Wrong blood product requested – Blood products requested on the basis of haemoglobin, platelet or coagulation values that are wrong due to pre-analytical factors

AE TYPE	DEFINITION (FROM ISBT)
Transfusion transmitted infection (TTI)	The recipient had evidence of infection following transfusion of blood products and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection. **Transfusion transmitted bacterial infection** Transfusion transmitted bacterial infection should be clinically suspected if: – fever >39 °C or a change of >2 °C from pre-transfusion value and – rigors and – tachycardia >120 beats/min or a change of >40 beats/min from pre-transfusion value or a rise or drop of 30mmHg in systolic blood pressure within 4 hours of transfusion are present Possible transfusion transmitted bacterial infection: – detection of bacteria by approved techniques in the transfused blood component but not in the recipient's blood or – detection of bacteria in the recipient's blood following transfusion but not in the transfused blood component and no other reasons are ascertainable for the positive blood culture. Confirmed transfusion transmitted bacterial infection: – detection of the same bacterial strain in the recipient's blood and in the transfused blood product by approved techniques. **Transfusion transmitted viral infection** Following investigation, the recipient has evidence of infection post transfusion and no clinical or laboratory evidence of infection prior to transfusion and either, – at least one component received by the infected recipient was donated by a donor who had evidence of the same infection, **or,** – at least one component received by the infected recipient was shown to have been contaminated with the virus. Reports should at least consider HIV, Hepatitis B, Hepatitis C and Cytomegalovirus. **Transfusion transmitted parasitic infection** Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood, e.g. *Plasmodium* species.

Table 12 Classification of Other Adverse Events as per Activity Steps or Specification – Blood Establishment
(Source: European Commission SARE report 2019 [17])

ACTIVITY STEPS	SPECIFICATIONS OF AEs
– Donor Selection – Whole Blood Collection – Apheresis Collection – Testing Of Donations – Processing – Issue	– Detection of blood borne infection in a blood donor – Safety risks for blood donors (incidents that pose a threat to the health of blood donors) – Component Defect – Equipment Failure – Human Error: e.g., donor and donation mix-ups, incorrect release, incorrect labels, release of out-of-

ACTIVITY STEPS	SPECIFICATIONS OF AEs
– Compatibility Testing/ Cross-Matching – Storage – Distribution/Transport – Other Activity Step (Please Specify)	specification blood products, incorrect testing, incorrect packaging of product for transport, transport delayed / sent to wrong location, recall process not / incorrectly followed, order incompletely / incorrectly filled, Lookback / trace-back issues etc. – Materials: e.g. suspected quality defects, defective materials, reagents) – Other

Table 13 Donor Adverse Events

The ISBT Working Group on Donor Vigilance has published together with the AABB Donor Haemovigilance Working Group and the International Haemovigilance Network, a Standard for Surveillance of Complications Related to Blood Donation [10]. Below is a list of possible complications related to blood donations.

AE CATEGORY	AE SUB-CATEGORY	AE TYPE AND DEFINITION
A. Complications mainly with local symptoms These complications are directly caused by the insertion of the needle. Some of these are mainly characterized by occurrence of blood outside vessels, whereas others are mainly characterized by pain.	**A1.** Complications mainly characterized by the occurrence of blood outside the vessels.	**Haematoma (bruise)** Definition: a haematoma is an accumulation of blood in the tissues outside the vessels. Mechanism: the symptoms are caused by blood flowing out of damaged vessels and accumulating in the soft tissues. For apheresis procedures, haematomas may also be caused by infiltration of the soft tissues by red cells during the return phase of the procedure. Large haematomas, particularly those in deeper layers of the forearm, put pressure on surrounding tissues and may contribute to other complications such as nerve irritation and injury and more rarely compartment syndrome. Signs and symptoms: bruising, discolouration, swelling and local pain. Accumulation of blood in deeper tissues may result in more serious pain and pressure syndromes listed below. **Arterial puncture** Definition: arterial puncture is a puncture of the brachial artery or of one of its branches by the needle used for bleeding the donor. Mechanism: because of the rapid blood flow, the risk of a large haematoma is increased and thereby risks of more serious pain and pressure syndromes listed below. Signs and symptoms: a lighter red colour than usual of the collected blood can be seen. The needle and tubing may appear to pulsate; the blood bag fills very quickly. There may be weak pain localized to the elbow region. **Delayed bleeding (re-bleeding)** - optional category Definition: leakage of blood from the venipuncture site after the initial bleeding has stopped. Mechanism: re-bleeding may be related to pressure not being applied to the correct location or for an adequate duration, or premature removal of the bandage. After the donor has left the clinic, re-bleeding may be related to heavy lifting or strain to the donor's arm. Donors on certain medications, such as autologous donors on anticoagulants, may be at higher risk to re-bleed.

AE CATEGORY	AE SUB-CATEGORY	AE TYPE AND DEFINITION
		Signs and symptoms: spontaneous recommencement of bleeding from the venipuncture site, after pressure has been applied and the initial dressing has been removed, or leaking through the dressing.
	A2. Complications mainly characterized by pain	**Nerve injury/irritation** Definition: injury or irritation of a nerve Mechanism: a nerve may be hit directly by the needle at insertion or withdrawal, or there may be pressure on a nerve due to a haematoma or inflammation of the soft tissues. Include medically diagnosed cases, as well as cases reported on the basis of documented 'nerve' type symptoms. Signs and symptoms: radiating, often 'electrical' sharp pain moving away from the venepuncture site, and/or paraesthesias such as tingling, burning sensations in the hand, wrist or shoulder area but away from the venepuncture site. Symptoms may arise immediately when the needle is inserted or withdrawn. In cases associated with a haematoma, pain may not be apparent at the time and may start when the haematoma has reached a sufficient size, some time after insertion of the needle. Symptoms may be worse in certain positions or with certain arm motions. Rarely, weakness of the arm may develop. *Optional split by duration of symptoms:* *Symptoms resolving within 12 months: symptoms usually resolve within days, but rarely may persist for months or become permanent.* *Symptoms lasting more than 12 months.* **Other painful arm – optional category** Definition: pain in the arm is the primary symptom, without the characteristics of nerve irritation outlined above, or the presence of a large hematoma or other defined complications that may be painful. Mechanism: pain may be related to tissue injury, possibly due to hematoma in the deeper tissues. Signs and symptoms: pain in the arm, without characteristics of nerve irritation. May be described as an ache or heaviness in the arm, similar to that experienced after vaccination. Include all cases where arm pain is the main symptom, unless a diagnosis of nerve injury/irritation is suspected in the presence of nerve type symptoms recognised by trained staff.
	A 3. Localised infection/ inflammation	**Localised infection/inflammation** Definition: inflammation along the course of a vein, which may progress to localised infection several days after phlebotomy. There may be clotting in the vein. Mechanism: tissue damage and introduction of surface bacteria into the deeper tissues with venepuncture. The superficial vein itself (thrombophlebitis) or the surrounding subcutaneous tissue (cellulitis) may be predominantly affected. Signs and symptoms: warmth, tenderness, local pain, redness and swelling at the site of phlebotomy. The site and the vein may feel tender, firm, and warm to the touch. Fever may be present. *Optional split into 2 categories:*

AE CATEGORY	AE SUB-CATEGORY	AE TYPE AND DEFINITION
		Thrombophlebitis: the redness, swelling, and tenderness extend along the course of the vein. *Cellulitis: the redness, swelling and tenderness affect the soft tissues, and are not localised to the course of the vein*.
	A4. Other major blood vessel injury. These rare, serious conditions must always be medically diagnosed.	**Deep venous thrombosis (DVT)** Definition: thrombosis of a deep vein in the donor's phlebotomy arm. Mechanism: superficial venous thrombosis may progress into the deeper veins of the donor's arm. DVT may also rarely occur without previous signs and symptoms of superficial thrombosis. An additional risk factor for thrombosis, in particular, the use of oral contraceptives, may be present in these donors. Symptoms and signs: swelling and pain in the upper arm. May be accompanied by symptoms of superficial inflammation and thrombosis (see above). **Arteriovenous fistula** Definition: acquired connection between the vein and artery due to venepuncture lacerations. Mechanism: a channel forms between the lacerated vein and artery immediately post-venepuncture, or in the healing process. May be related to arterial puncture. Signs and symptoms: pulsating mass with a palpable thrill and associated bruit. The affected area may be warm, and the distal part of the arm may be cool if significant shunting of blood is present. The distal veins may be dilated and may pulsate **Compartment syndrome** Definition: increased intracompartment pressure leading to muscle and soft tissue necrosis. Mechanism: blood may accumulate in the frontal deep areas of the forearm, closing small blood vessels and resulting in muscle and nerve tissue necrosis. May be related to arterial puncture. Signs and symptoms: painful arm, particularly on movement; swelling, paresthesias and partial paralysis. **Brachial artery pseudoaneurysm** Definition: collection of blood outside an artery, contained by adventitia or the surrounding tissues alone. Mechanism: after a traumatic arterial puncture, blood may leak out of the artery and accumulate in the surrounding space. Signs and symptoms: pulsating mass in the arm. May be accompanied by pain and paraesthesias. May be preceded by a large hematoma following arterial puncture
B. Complications mainly with generalized symptoms: vasovagal reactions	/	**Vasovagal reaction** Definition: a vasovagal reaction (VVR) is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint). It is the most common acute complication related to blood donation. Mechanisms: both physiologic and psychological factors may be important. The reaction is generated by the autonomic nervous system and further stimulated by

AE CATEGORY	AE SUB-CATEGORY	AE TYPE AND DEFINITION
		psychological factors and the volume of blood removed, relative to the donor's total blood volume. Signs and symptoms: usually several of the following: discomfort, weakness, anxiety, light-headedness/dizziness, nausea, chills, sweating, vomiting, pallor, hyperventilation, rapid or a slow pulse. Hypotension and loss of consciousness (LOC) may occur and can be accompanied by loss of bladder or bowel control or convulsive movements. Reactions may occur before phlebotomy (rare), during phlebotomy or immediately after phlebotomy, when the donor stands up, in the refreshment area, or after the donor has left the collection site. Most reactions occur within 12 hours of phlebotomy. Reactions accompanied by LOC carry a risk of injury, particularly if they occur once the donor has left the collection site (delayed vasovagal reactions). Vasovagal reactions are divided in two main subgroups: – Without loss of consciousness (LOC) - the donor does not faint – With loss of consciousness (LOC) - the donor faints for a period of time Optional subdivision for donors with LOC: LOC < 60 seconds - without other signs and symptoms LOC ≥ 60 seconds - or with complications of convulsive movements, urinary or faecal incontinence Optional subdivision: With injury - injury caused by falls or accidents in donors with a vasovagal reaction without injury Optional subdivision: Location of reaction: – On collection facility*- symptoms occurred before donor has left the donation site – Outside collection facility - symptoms occurred after donor has left the donation site *in area within which staff can observe the donor and be responsible for the care of donors with complications
C. Complications related to apheresis	/	**Citrate reaction** Definition: neuromuscular hyperactivity related to reduced ionized calcium levels. Mechanism: infusion of citrate anticoagulant during apheresis causes a fall in ionised calcium levels, leading to neuromuscular hyperactivity. If untreated, symptoms may progress to tetany and severe cardiac arrhythmias, including cardiac arrest. Operator error with mix up of saline and citrate bags may occur with some apheresis equipment, and lead to rapid citrate infusion. Symptoms and signs: numbness or tingling of lips, feelings of vibrations, numbness or tingling in the fingers, metallic taste, chills, shivering, light-headedness, feeling of tightness, muscle twitching, rapid or slow pulse, shortness of breath. Symptoms may progress to carpopedal spasms and vomiting, and in severe reactions, to generalised muscle

AE CATEGORY	AE SUB-CATEGORY	AE TYPE AND DEFINITION
		contractions (tetany), shock, irregular pulse and cardiac arrest. **Haemolysis** Definition: donor red cells may be damaged, releasing haemoglobin. Mechanism: there may be malfunctioning valves, kinks or obstruction of the tubing, incorrect installation of equipment, or other equipment failures affecting the extracorporeal circuit. Incompatible replacement fluids, such as 5% dextrose in water, may be used in error. Signs and symptoms: pink or red plasma, blood in lines or filter may appear dark. The donor may notice pink or red urine after collection. **Air embolism** Definition: air bubble introduced into the donor's circulation. Mechanism: air may enter into the lines due to incomplete priming of lines, as a result of a machine malfunction or defective collection kits or through incorrect manipulation by staff. Air in the donor's pulmonary circulation may occlude the pulmonary arteries in the lung and cause cardiopulmonary symptoms. Air may pass to the arterial circulation through an atrial septal defect, and reduce blood flow to the brain. Signs and symptoms: bubbling sound or feeling at the venipuncture site. Cough, dyspnea, apprehension, sweating, chest pain, confusion, tachycardia, hypotension, nausea and vomiting. **Optional category: infiltration** Definition: intravenous solute (saline solution) enters the extravascular tissues during volume replacement (generally only applicable to double red cell procedures). Mechanism: the needle is no longer positioned in the intravascular space, so fluids enter the surrounding tissues. Signs and symptoms: swelling of the tissues at the venipuncture site.
D. Allergic reactions	/	**Allergy (local)** Definition: red or irritated skin at the venipuncture site. Mechanism: reaction caused by allergens or irritants in solutions used for disinfection of the arm (such as iodine or chlorhexidine) or in manufacture of the collection set. Irritation may also occur due to application of the adhesive bandage (bandage adhesive dermatitis). An allergic reaction to latex that may be in supplies such as gloves may also occur. Signs and symptoms: itching and redness at the venepuncture site, the bandage site, or the entire skin disinfection area. In a true allergic reaction, there may be a raised rash or hives in these areas that may expand to cover a larger area of the arm. The reaction may occur soon after donation or in the hours to days post-donation. **Generalised allergic reaction (anaphylactic reaction)** Definition: anaphylactic type reactions usually starting soon after the procedure is begun and may progress rapidly to cardiac arrest.

AE CATEGORY	AE SUB-CATEGORY	AE TYPE AND DEFINITION
		Mechanism: extremely rare reactions, attributed to donor sensitivity to ethylene oxide gas used to sterilize some collection kits. Signs and symptoms: apprehension, anxiousness, flushing, swelling of eyes, lips or tongue, cyanosis, cough, wheezing, dyspnea, chest tightness, cramps, nausea, vomiting, diarrhoea, tachycardia, hypotension, and altered mentation
E. Other serious complications related to blood donation	/	**Major cardiovascular event (MCE)** Acute cardiac symptoms (other than myocardial infarction or cardiac arrest). Myocardial infarction Cardiac arrest Transient ischemic attack Cerebrovascular accident Death Reporting is encouraged of MCE or death from any cause up to 24 hours after donation, with an assessment of imputability. Only cases with definite, probable or possible imputability should be included in international reporting. Major cardiovascular events, including death, may occur in the hours after attending the collection centre for blood donation. This can occur without any relation to the donation (for deaths, this is described by the term actuarial deaths).
F. Other complications	/	Other systemic reactions or complications that do not fit into the above, such as chest pain that may have been investigated as angina, but was actually musculoskeletal, or transmission of infection to a donor through erroneous re-use of equipment.

Annex II – Haemovigilance Reporting Forms

Reporting should not excessively affect the work of health care professionals, thus, reporting forms should be as brief as possible and as comprehensive as necessary for adequate assessment of cases. Providing different reporting forms that fit to the event or reaction to be reported allows the form to focus on only the specific information required. This keeps forms short and reduces the risk of reporting errors such as insufficient data transmission.

Reporting forms are attached at the end of this guideline.

Overview of the reporting forms:

1	**Form A**	Ward transfusion record, initial AR record
2	**Form B**	Ward transfusion reaction investigation record
3	**Form 1a**	Transfusion reaction – initial report
4	**Form 1b**	Transfusion reaction – follow-up report
5	**Form 2**	Suspected TTI/Trace-back
6	**Form 3a**	Donor Look-back – initial report
7	**Form 3b**	Donor Look-back – final report
8	**Form 4**	Donor reaction
9	**Form 5**	Incidents
10	**Form 6**	Rapid Alert Report
11	**Form 7**	Annual blood usage statistics – Transfusing Facilities
12	**Form 8**	Annual Activity Summary Report - Blood Establishments

Annex III – Example of Imputability and Severity Scoring of Adverse Reactions

Allergic Reaction (CDC - 2021 HV Module Protocol [18])

Case Definition	Severity	Imputability
Definitive: 2 or more of the following occurring during or within 4 hours of cessation of transfusion: – Conjunctival edema – Edema of lips, tongue and uvula – Erythema and edema of the periorbital area – Generalized flushing – Hypotension – Localized angioedema – Maculopapular rash – Pruritus (itching) – Respiratory distress; bronchospasm – Urticaria (hives) Probable: ANY 1 of the following occurring during or within 4 hours of cessation of transfusion: – Conjunctival edema – Edema of lips, tongue and uvula – Erythema and edema of the periorbital area – Localized angioedema – Maculopapular rash – Pruritus (itching) – Urticaria (hives)	Severe, Life-threatening, Death: Involves respiratory and/or cardiovascular systems and presents like an anaphylactic reaction. There is anaphylaxis when, in addition to mucocutaneous symptoms, there are airway symptoms, hypotension or associated symptoms like hypotonia and syncope. The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnea, cough, wheezing, bronchospasm, hypoxemia). Such a reaction usually occurs during or shortly after cessation of transfusion. Death should be used if death is possibly, probably or definitely related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction. Not Determined: The severity of the adverse reaction is unknown or not stated.	Definite: Occurs during or within 2 hours of cessation of transfusion AND No other evidence of environmental, drug or dietary risks. Probable: Occurs during or within 2 hours of cessation of transfusion AND There are other potential causes present that could explain symptoms, but transfusion is the most likely cause. Possible: Occurs 2 - 4 hours after cessation of transfusion OR Other present causes are most likely, but transfusion cannot be ruled out
OPTIONAL	OPTIONAL	OPTIONAL
Possible: N/A	Non-severe: There is no immediate risk to the life of the patient, and the patient responds quickly to symptomatic treatment.	

Form A – Ward transfusion record, initial AR record

NBSG/DS/DC/F-0223
Ver 1
July, 2020

Transfusion Record Form A (ver. 2)

Please complete **ALL** sections of this form fully. If *Not Applicable*, write N/A in the relevant section.

SECTION I – PATIENT INFORMATION

Surname:			First Name:	
Patient ID/NHIS:			Date:	
Hospital:			Department:	
			Ward:	
Gender: ☐ Male ☐ Female	AGE OF PATIENT: ☐ not stated	Pre-Transfusion: Hb:_____ Plat:_____	Patient's ABO/RhD Group : ☐ O ☐ A ☐ B ☐ AB ☐ Unknown	RhD: ☐ + RhD ☐ - RhD ☐ Unknown
Diagnosis:			Indication for Transfusion:	

Component Type: ☐ Whole Blood ☐ CRC ☐ Plat – Random ☐ Plat - Apheresis. ☐ FFP ☐ CRYO ☐ Other_____

Attribute of Component: ☐ Mirasol PRT

SECTION II - RECORD OF TRANSFUSION

Donation No (Batch No):	Expiry date of unit:	Transfused Unit ABO/RhD Group: ☐ Unknown ABO: ☐ O ☐ A ☐ B ☐ AB
Any previous Transfusions? ☐ Yes ☐ No		Rh: ☐ + RhD ☐ - RhD ☐ Unknown
Numbers of units/episodes transfused within Current admission/treatment cycle		NAME cross-checked pre-transfusion? ☐ Yes ABO/Rh cross-checked pre-transfusion? ☐ Yes Donation # cross-checked pre-transfusion? ☐ Yes

Record of Vital Signs: Please tick against fever, palpitation, hypo/hypertension under signs and symptoms when abnormal values are recorded

	Time	Pulse	Resp. Rate	Blood Pressure Systolic	Blood Pressure Diastolic	Temp	Oxygen Saturation Levels (SpO2)
Pre-Transfusion							
10-15 minutes							
30-60 minutes							
At Finish or Stop							

Were there any challenges completing this transfusion? ☐ NO ☐ YES, what was the Volume Transfused :_____mL Stop Date: _____ Stop Time:_____	If YES: What were the challenges? ☐ Challenges with venous access ☐ Clots/Poor blood flow/Hyper viscous unit ☐ Other Reason (Please State) _____

Was there a transfusion reaction: ☐ YES ☐ NO

SECTION III – TRANSFUSION REACTION REPORTING

During Transfusion: ☐ 0-15 mins ☐ 15-30 mins ☐ 30 mins-1 hrs ☐ 1-2 hrs ☐ 2-4 hrs ☐ >4 hrs

Post Transfusion: ☐ <30 mins ☐ 30 mins-1 hrs ☐ 1-2 hrs ☐ 2-6 hrs ☐ 6-24 hrs ☐ >24 hrs

Specimens accompanying this form: (Kindly indicate)

☐ No sample
☐ 2ml patient's blood sample (opposite arm) in EDTA tube
☐ 5ml patient's blood sample (opposite arm) in plain tube
☐ 20ml urine (if applicable)
☐ All blood bags and unused units with attached giving set

Signs/Symptoms (tick as many apply)

☐ Itching/Pruritus	☐ Dyspnoea	☐ Back pain/flank pain/Loin pain
☐ Chills/Rigors	☐ Chest pain / Tight chest	☐ Oliguria
☐ Fever	☐ Anxiety	☐ Dark urine
☐ Nausea	☐ Restlessness	☐ Unexplained bleeding
☐ Rash/Urticaria	☐ Palpitations (pulse = _____ bpm)	☐ Respiratory distress (wheezing/stridor)
☐ Flushing and sweating	☐ Hypotension (BP = _____ mmHg)	☐ Other _____
	☐ Hypertension (BP = _____ mmHg)	☐ Other _____

Please tick a Suspected Adverse Reaction:		**Suspected Severity*:**
☐ Incorrect blood component transfused (IBCT)	☐ Transfusion associated Graft versus Host disease (GvHD)	☐ Grade 1 (non-severe)
☐ Acute Haemolytic transfusion reaction (Immediate)	☐ Post- Transfusion Purpura (PTP)	☐ Grade 2 (severe)
☐ Delayed Haemolysis	☐ Transfusion associated dyspnea (TAD)	☐ Grade 3 (life-threatening)
☐ Delayed serologic reaction (DSTR)	☐ Hypotensive transfusion reaction	☐ Grade 4 (death)
☐ Febrile non-haemolytic transfusion reactions (FNHTR)	☐ Haemosiderosis	*Grade 4 should be used only if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity of the reaction should be as grade 1,2 or 3
☐ Allergic reactions	☐ Hyperkalemia	
☐ Septic Shock	☐ Unclassifiable Complication of Transfusions (UCT)	
☐ Transfusion related acute lung injury (TRALI)		
☐ Transfusion –Associated Circulatory Overload (TACO)		

Reporting Nurse: _____ **Contact Number:** _____ **Date:**_____

Reporting Physician: _____ **Contact Number:** _____ **Date:**_____

Form B – Ward transfusion reaction investigation record

Please return this form with samples and blood bags to Hospital Blood Bank as soon as possible

NBSG/DS/DC/F-023
Ver 1
July, 2020

Transfusion Record Form B (ver. 2)

Please complete **ALL** sections of this form fully. If *Not Applicable*, write N/A in the relevant section.

SECTION IV – TRANSFUSION REACTION INVESTIGATION FORM	
Patient information	
Surname:	First Name:
Patient ID/NHIS:	Date:
Hospital:	Ward:
Gender: ☐ Male ☐ Female	Time Issued:
Patients ABO/RhD Group : ABO: ☐ A ☐ O ☐ B ☐ AB ☐ Unknown	RhD: ☐ + RhD ☐ - RhD ☐ Unknown

Investigation of Transfusion Reaction		
Name of Person Performing Test _____Date _____		
Donation No:		Transfusion No.:
Donor's ABO/RhD Group : ABO: ☐ A ☐ O ☐ B ☐ AB ☐ Unknown	RhD: ☐ + RhD ☐ - RhD ☐ Unknown	Expiry date of unit/Age of blood:
Clerical Checks		Visual checks ☐ Haemoglobinaemia ☐ Haemoglobinuria

	Haemolysis	ABO	RhD	DAT	Antibody Screen	Antibody Identified	Anti-A, anti-B titre
Pre-Transfusion Sample							
Post-Transfusion Sample							

Donation/Batch No:	ABO/RhD and Haemolysis Testing				Cross-match PRE-Transfusion Sample				Cross-match POST-Transfusion Sample			
	Haemolysis	ABO	RhD	DAT	IS	37	IAT	Result	IS	37	IAT	Result

Verified Adverse Reaction: To be completed by Haemovigilance Officer	
☐ Incorrect blood component transfused (IBCT)	☐ Transfusion –Associated Circulatory Overload (TACO)
☐ Acute Haemolytic transfusion reaction (Immediate)	☐ Transfusion associated Graft versus Host disease (GvHD)
☐ Delayed Haemolysis	☐ Post- Transfusion Purpura (PTP)
☐ Delayed serologic reaction (DSTR)	☐ Transfusion associated dyspnea (TAD)
☐ Febrile non-haemolytic transfusion reactions (FNHTR)	☐ Hypotensive transfusion reaction
☐ Allergic reactions	☐ Haemosiderosis
☐ Septic Shock	☐ Hyperkalemia
☐ Transfusion related acute lung injury (TRALI)	☐ Unclassifiable Complication of Transfusions (UCT)
Verified Severity*:	**Imputability†:**
☐ Grade 1 (non-severe) ☐ Grade 2 (severe) ☐ Grade 3 (life-threatening) ☐ Grade 4 (death) *Grade 4 should be used only if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity of the reaction should be as grade 1,2 or 3	☐ Definite ☐ Probable ☐ Possible ☐ Unlikely ☐ Excluded †Only possible, probable and definite cases should be used for international comparisons
Transfusion Reaction Outcome: ☐ Complete Recovery ☐ Recovered with Complication ☐ Death	
Comments: _____	_____ Haemovigilance Officer Signature _____ Date:

Transfusion Reaction Initial Report – Form 1a

SECTION I – PATIENT INFORMATION

Patient Initials:			Date:	
Hospital:			Department: Ward:	
Gender: ☐ Male ☐ Female	Date of Birth/ Age: ☐ not stated	Pre-Transfusion: Hb: Plat:	Patient's ABO/RhD Group: ☐ O ☐ A ☐ B ☐ AB ☐ unknown	RhD: ☐+RhD ☐-RhD ☐ unknown
Diagnosis:			Indication for Transfusion:	

Component Type(s): ☐ Whole Blood ☐ CRC ☐ Plat – Random ☐ Plat Apheresis ☐ FFP ☐ CRYO ☐ Other:

Attribute of Component: ☐ Mirasol PRT

SECTION II – RECORD OF TRANSFUSION

Donation No(s):	Expiry date of unit(s):	Transfused Unit ABO/RhD Group:
		☐ O ☐ A ☐ B ☐ AB ☐+RhD ☐-RhD ☐ unknown
		☐ O ☐ A ☐ B ☐ AB ☐+RhD ☐-RhD ☐ unknown
		☐ O ☐ A ☐ B ☐ AB ☐+RhD ☐-RhD ☐ unknown

Any previous transfusions? ☐ Yes ☐ No	NAME cross-checked pre-transfusion? ☐ Yes
Numbers of units transfused within Current admission/treatment cycle:	ABO/RhD cross-checked pre-transfusion? ☐ Yes Donation # cross-checked pre-transfusion? ☐ Yes

Record of Vital Signs: Please tick against: fever palpitation, hypo/hypertension under signs and symptoms when abnormal values are recorded.

	Time	Pulse	Resp.Rate	Blood Pressure Systolic	Blood Pressure Diastolic	Temp.	Oxygen Saturation Levels (SpO_2)
Pre-transfusion							
10-15 min							
30-60 min							
At finish or stop							

Where there any challenges completing this transfusion? ☐ NO ☐ YES, what was the Volume Transfused: mL Stop Date: Stop Time:	If YES: What were the challenges? ☐ Challenges with the venous access ☐ Clots/Poor blood flow/ Hyper viscous unit ☐ Other reason (pleas state):

Was there a transfusion reaction? ☐ YES ☐ NO

SECTION III – TRANSFUSION REACTION REPORTING

During transfusion: ☐ 0-15 min ☐ 15-30 min ☐ 30 min-1 h ☐ 1-2 h ☐ 2-4 h ☐ >4 h

Post transfusion: ☐ <30 min ☐ 30 min-1 h ☐ 1-2 h ☐ 2-6 h ☐ 6-24 h ☐ >24 h

Specimens accompanying this form: (Kindly indicate)
☐ No sample
☐ 2 ml patient's blood sample (opposite arm) in EDTA tube ☐ 20 ml urine (if applicable)
☐ 5 ml patient's blood sample (opposite arm) in plain tube ☐ All blood bags and unused units with attached giving set

Signs/Symptoms (tick as many apply)

☐ Itching/Pruritus	☐ Dyspnoea	☐ Back/flank pain/Loin pain
☐ Chills/Rigors	☐ Chest pain/Tight chest	☐ Oliguria
☐ Fever: _____ °C	☐ Anxiety	☐ Dark urine
☐ Nausea	☐ Restlessness	☐ Unexplained bleeding
☐ Rash/Urticaria	☐ Palpitations (pulse: _____ bpm)	☐ Respiratory distress (wheezing/stridor)
☐ Flushing and sweating	☐ Hypotension (BP: _____ mmHg)	☐ Other:_____
	☐ Hypertension (BP: _____ mmHg)	☐ Other:_____

Please tick a Suspected Adverse Reaction:

☐ Incorrect blood component transfused (IBCT)	☐ Transfusion associated Graft versus Host disease (GvHD)	☐ Grade 1 (non-severe)
☐ Acute Haemolytic transfusion reaction (immediate)	☐ Post-transfusion purpura (PTP)	☐ Grade 2 (severe)
☐ Delayed Haemolysis	☐ Transfusion associated dyspnoea (TAD)	☐ Grade 3 (life-threatening)
☐ Delayed serologic reaction (DSTR)	☐ Hypotensive transfusion reaction	☐ Grade 4 (death)
☐ Febrile non-haemolytic transfusion reaction (FNHTR)	☐ Haemosiderosis	*Grade 4 should be used only if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity of the reaction should be as grade 1,2 or 3.
☐ Allergic reaction	☐ Hyperkalemia	
☐ Septic Shock	☐ Unclassified Complication of Transfusion (UCT)	
☐ Transfusion-related acute lung injury (TRALI)		
☐ Transfusion-associated circulatory overload (TACO)		

Reporting ICP:	Contact number:	Date:

Transfusion Reaction Follow-Up Report – Form 1b

SECTION IV – TRANSFUSION REACTION INVESTIGATION (REACTION FOLLOW-UP)

Patient information

Patient Initials:	Date:
Hospital:	Department:
Gender: ☐ Male ☐ Female	Ward:
Date of Birth/Age: ☐ not stated	Time issued:
Patient's ABO/RhD Group: ABO: ☐ O ☐ A ☐ B ☐ AB ☐ unknown	RhD: ☐+RhD ☐-RhD ☐ unknown

Investigation of Transfusion Reaction

Donation No:	Transfusion No:	
Donor's ABO/RhD Group: ☐ O ☐ A ☐ B ☐ AB ☐ unknown	RhD: ☐+RhD ☐-RhD ☐ unknown	Expiry date of unit/Age of blood:
Clerical checks	Visual checks ☐ Haemoglobinaemia ☐ Haemoglobinuria	

	Haemolysis	ABO	RhD	DAT	Antibody Screen	Antibody Identified	Anti-A, anti-B titre
Pre-transfusion sample							
Post-transfusion sample							

Donation No.:	ABO/RhD and Haemolysis testing				Cross-match PRE-transfusion sample				Cross-match POST-transfusion sample			
	Haemolysis	ABO	RhD	DAT	IS	37	IAT	Result	IS	37	IAT	Result

Signs/Symptoms (tick as many apply)

☐ Itching/Pruritus	☐ Dyspnoea	☐ Back/flank pain/Loin pain
☐ Chills/Rigors	☐ Chest pain/Tight chest	☐ Oliguria
☐ Fever: _____ °C	☐ Anxiety	☐ Dark urine
☐ Nausea	☐ Restlessness	☐ Unexplained bleeding
☐ Rash/Urticaria	☐ Palpitations (pulse: _____ bpm)	☐ Respiratory distress (wheezing/stridor)
☐ Flushing and sweating	☐ Hypotension (BP: _____ mmHg)	☐ Other:_____
	☐ Hypertension (BP: _____ mmHg)	☐ Other:_____

Verified Adverse Reaction:

☐ Incorrect blood component transfused (IBCT)	☐ Transfusion-associated circulatory overload (TACO)
☐ Acute Haemolytic transfusion reaction (immediate)	☐ Transfusion associated Graft versus Host disease (GvHD)
☐ Delayed Haemolysis	☐ Post-transfusion purpura (PTP)
☐ Delayed serologic reaction (DSTR)	☐ Transfusion associated dyspnoea (TAD)
☐ Febrile non-haemolytic transfusion reaction (FNHTR)	☐ Hypotensive transfusion reaction
☐ Allergic reaction	☐ Haemosiderosis
☐ Septic Shock	☐ Hyperkalemia
☐ Transfusion-related acute lung injury (TRALI)	☐ Unclassified Complication of Transfusion (UCT)

Verified Severity*:	**Imputability†:**
☐ Grade 1 (non-severe) ☐ Grade 2 (severe) ☐ Grade 3 (life-threatening) ☐ Grade 4 (death) *Grade 4 should be used only if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity of the reaction should be as grade 1,2 or 3.	☐ Definite ☐ Probable ☐ Possible ☐ Unlikely ☐ Excluded †Only possible, probable and definite cases should be used for international comparisons

Transfusion Reaction Outcome: ☐ Complete Recovery ☐ Recovery with Complications ☐ Death

Comments:	ICP Signature: Date: