REPUBLIC OF GHANA
MINISTRY OF HEALTH

FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority.

NATIONAL BLOOD SERVICE GHANA

National Haemovigilance Framework for Ghana

REPUBLIC OF GHANA
MINISTRY OF HEALTH

FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority.

NATIONAL BLOOD SERVICE GHANA
NATIONAL BLOOD
SERVICE GHANA

National Haemovigilance Framework for Ghana

October 2022

TABLE OF CONTENTS

ACRONYMS

ABRF	-	African Blood Regulatory Forum
AE	-	Adverse Events
AR	-	Adverse Reaction
BB	-	Blood Banks
BE	-	Blood Establishment
CHAG	-	Christian Health Association of Ghana
DTC	-	Drugs and Therapeutic Committees
DV	-	Donor Vigilance
FDA	-	Food and Drugs Authority
GHPP	-	Global Health Protection Programme
GHS	-	Ghana Health Service
GMP/GPP	-	Good Manufacturing Practices / Good Production Practices
HBB	-	Hospital Blood Bank
HCP	-	Health Care Professionals
HFP	-	Haemovigilance Focal Person
HTC	-	Hospital Transfusion Committees
HV	-	Haemovigilance
ICP	-	Institutional Contact Person
ISBT	-	International Society of Blood Transfusion
NBS	-	National Blood Service
NHO	-	National Haemovigilance Office
PEI	-	Paul Ehrlich Institute
SAE	-	Serious Adverse Event
TTI	-	Transfusion Transmissible Infections
TAC-VBP	-	Technical Advisory Committee on Safety of Vaccines and Biological Products

INTRODUCTION

Haemovigilance comprises a set of organised surveillance procedures relating to adverse events (i.e. serious, non-serious or unexpected) in blood donors or recipients. It is a system of surveillance and alarm, from blood collection to the follow-up of transfusion recipients, gathering and analysing adverse events along the blood transfusion chain in order to correct their cause and prevent recurrence. Haemovigilance therefore means an organised system for observing, recording, analysing and reporting when something goes wrong with blood donation and blood transfusion and using lessons learnt to prevent future occurrence. Haemovigilance is an important part of the quality systems in blood transfusion management to ensure blood safety.

The National Blood Service (NBS) and the Food and Drugs Authority (FDA) are the two agencies under the Ministry of Health responsible for establishing and maintaining the haemovigilance system in Ghana. It is important to define clearly the haemovigilance system and the roles and responsibilities of all stakeholders in order to ensure efficient national haemovigilance system in Ghana for stakeholders including Zonal Blood Centres, transfusing facilities and healthcare professionals.

The objective of the framework is therefore to record all steps involved in the haemovigilance process, reporting of adverse events and the roles and responsibilities of all stakeholders.
The Ghana national haemovigilance governance structure with the organisations at the various levels is shown in Figure 1.
.

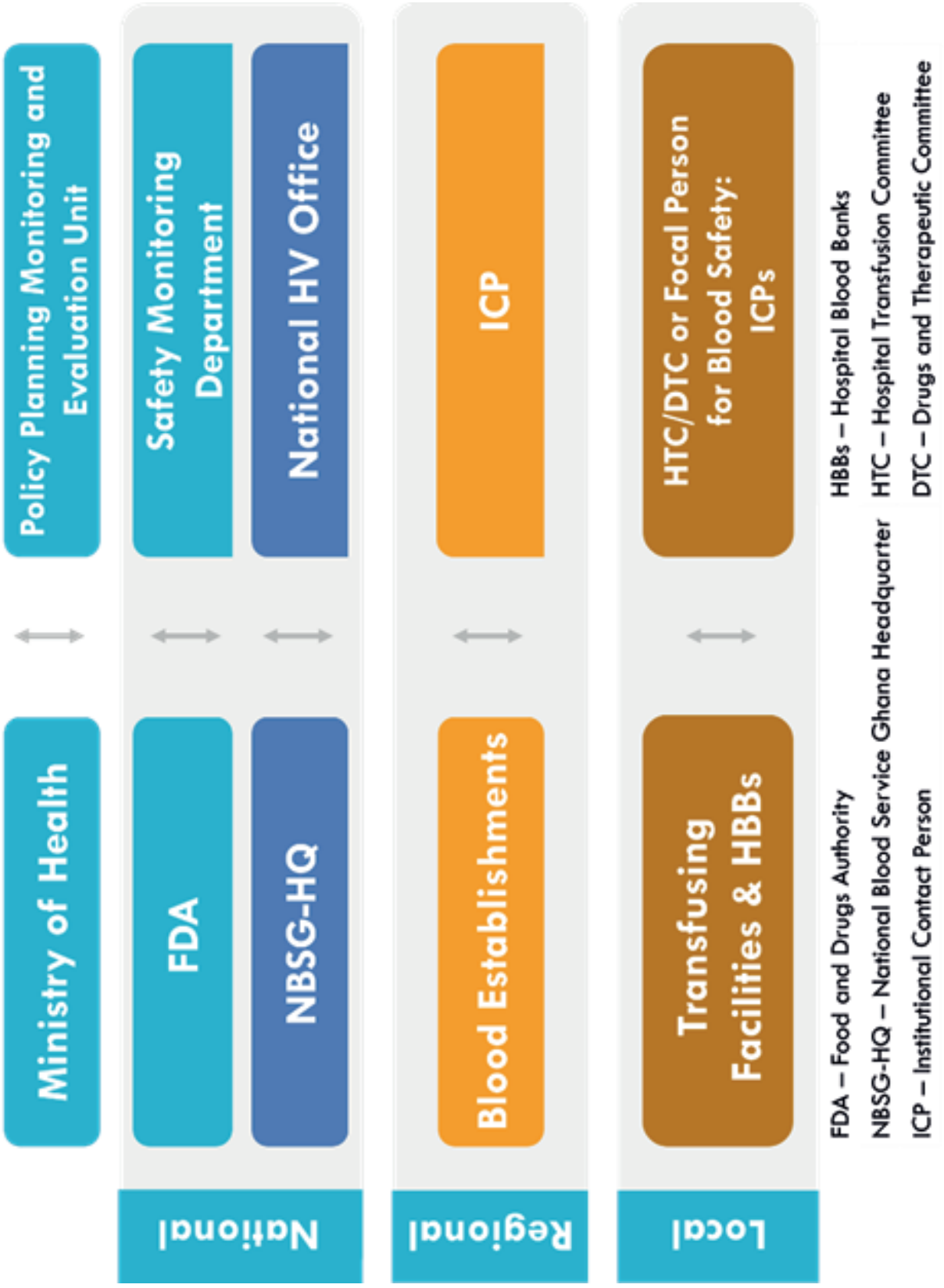

Figure 1 Haemovigilance in Ghana - Governance Structure

WHY CONDUCT HAEMOVIGILANCE?

Haemovigilance is an integral part of quality management in the blood value chain and is required for the continual improvement of the quality and safety of blood products and the blood transfusion process. Haemovigilance systems provide valuable data on a range of adverse events related to blood donation and clinical blood transfusion, from donor syncopal events to Transfusion-Transmissible Infections (TTIs), immunological and non-immunological transfusion reactions, near-misses and errors.

The primary aims of haemovigilance are to assure monitoring of blood transfusion, to collect data on sequelae of blood transfusions, to inform health policy, to improve blood transfusion standards, to assist in the formulation of guidelines in the field of blood transfusion and to increase the safety and quality of the entire blood transfusion process. One key aim is to develop an 'open' culture within donor centres and hospitals, where reporting of blood donation and blood transfusion hazards, near-misses and actual adverse consequences can occur without blame or punishment (or fear of blame or punishment). The intention is to encourage participation and reporting rather than achieving a seemingly 'perfect' zero score.

In practice the different steps of this quality process are:

i. recognition/assessment of an occurrence (deviating from the "norm/unexpected outcome");
ii. reporting (according to established criteria and definitions, and using standard reporting tools);
iii. collection of data (following written procedures);
iv. compilation (using a predefined matrix);
v. evaluation (according to agreed techniques);
vi. conclusions (feedback to those concerned and all stakeholders);
vii. actions (corrective and/or preventive) and follow-up.

HAEMOVIGILANCE IN GHANA

Transfusion of blood and blood products is an essential therapy that saves lives in acute emergencies, improves quality of life in numerous medical conditions and enables many complex medical and surgical procedures.

The objectives of the national haemovigilance programme in Ghana is to:

a. collect data on adverse reactions and adverse events of blood transfusions and blood donations
b. improve blood transfusion and blood donation standards and
c. practice
d. inform health policy in Ghana
   assist in the formulation of guidelines in the field of blood
e. transfusion and blood donations
   increase the safety and quality of the entire blood transfusion and blood donation process in Ghana

Section 125 (subsection 2) of the Public Health Act, 2012, Act 851 requires marketing authorisation holders and local representatives to monitor the safety of products granted marketing approval and report adverse effect or event to the Authority during the period under which the product is registered.

Subsection 3 of Section 125 also mandates the Food and Drugs Authority to continually monitor the safety of the products regulated under the Public Health Act, 2012, Act 851 (which includes blood and blood products) by analysis of adverse effect or event reports and take appropriate regulatory action when necessary.
Reporting of adverse events by healthcare professionals and patients is voluntary and non-punitive.

The roles and responsibilities of different stakeholders within the haemovigilance system i Ghana is depicted in Figure 2, together with the data collection and reporting obligations at each level.

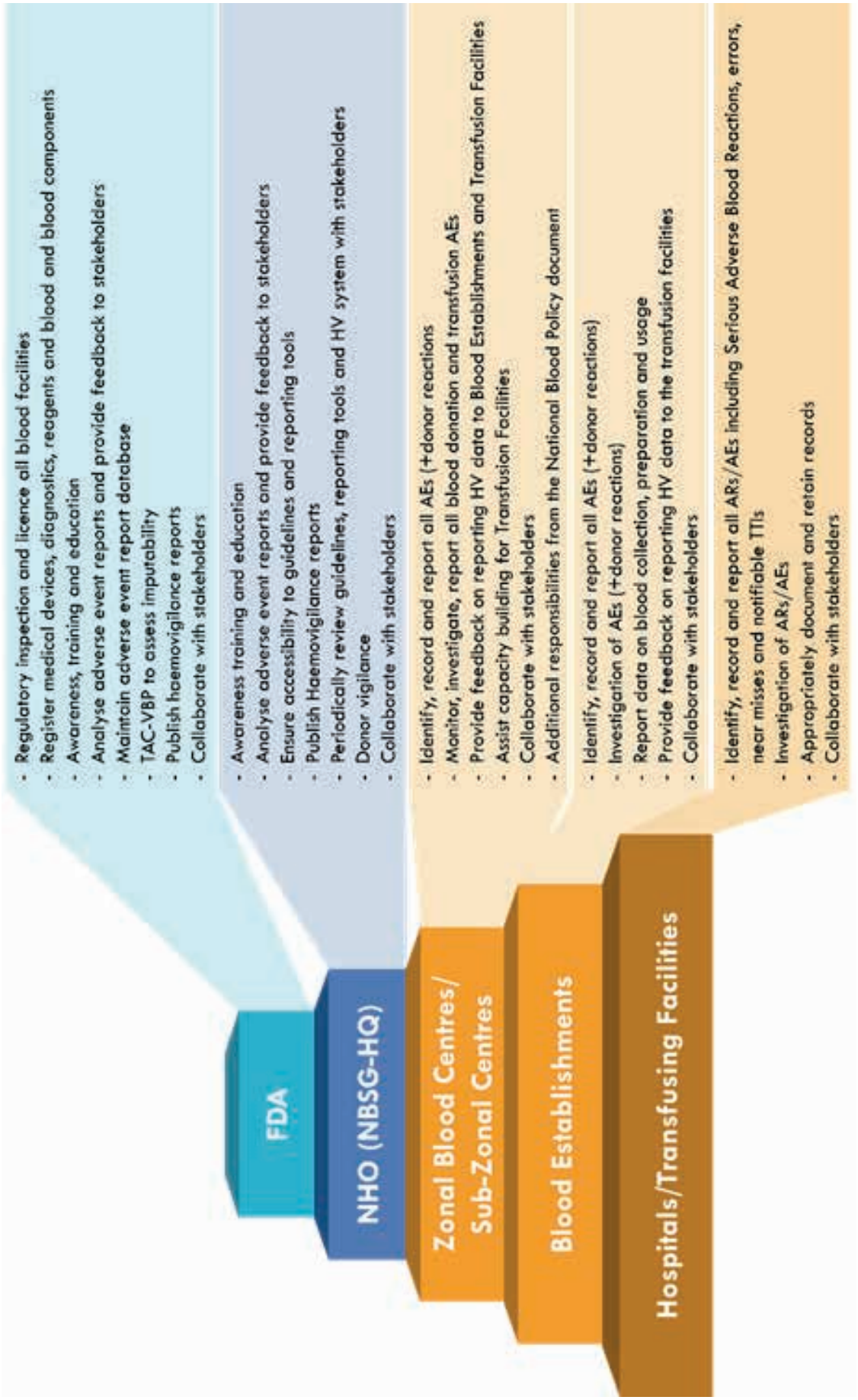

Figure 2 Roles and Responsibilities

The roles and responsibilities of different stakeholders are outlined below.

Food and Drugs Authority

1. Carry out regulatory inspections of all blood facilities towards licensure and listing of blood and blood products prepared in the facility, license those facilities which are in compliance with GPP/GMP and list blood products prepared and/or stored in the facility.
2. Register medical devices, diagnostics, reagents and blood products in line with applicable guidelines.
3. Collaborate with the National Blood Service and Service Delivery Agencies (GHS, CHAG, Private and Teaching Hospitals) to establish, maintain and review the national haemovigilance system in Ghana.
4. Assist the National Blood Service to provide awareness, training and education to healthcare professionals on the need for transfusion safety and the importance of reporting adverse events.
5. Collate and jointly analyse adverse event reports from blood establishments and transfusing facilities (hospitals), provide feedback to all stakeholders and the National Blood Service and take the necessary regulatory action to protect donor and patient safety.
6. Maintain a database on adverse event reports received
7. Constitute an independent expert Advisory Committee (The Technical Advisory Committee on Safety of Vaccines and Biological Products) to carry out imputability of adverse event reports received and make recommendations on improvements in blood transfusion safety in Ghana.

National Blood Service Ghana

1. Design, maintain and periodically review the national haemovigilance system in collaboration with the FDA and Service Delivery Agencies (GHS, CHAG, Private and Teaching Hospitals).
2. Periodically revise haemovigilance guidelines and reporting tools in collaboration with the FDA and Service Delivery Agencies (GHS, CHAG, Private and Teaching Hospitals)

3. Ensure accessibility of haemovigilance guidelines and reporting tools.
4. Provide awareness, training and education to healthcare professionals on the need for transfusion safety and the importance of reporting adverse events in collaboration with the FDA and Service Delivery Agencies (GHS, CHAG, Private and Teaching Hospitals).
5. Jointly carry out analysis of adverse event reports from blood establishments and provide feedback to stakeholders.
6. Submit adverse event reports received from blood establishments for review by the Technical Advisory Committee on Safety of Vaccines and Biological Products.
7. Maintain a database on adverse event reports received.

Zonal Blood Centres

1. Monitor, investigate, report all blood donation and transfusion AEs.
2. Assist in capacity building for the transfusing facilities (including training, supportive supervision, etc.).
3. Provide feedback to reporting facilities and Sub-Zonal Centres.
4. Additional ones from the National Blood Policy.

Sub-Zonal Centres

1. Identify, record and report all adverse events.
2. Investigate adverse events and take corrective and preventive action.
3. Report data on blood collections and usage.
4. Assist in capacity building for the transfusing facilities (including training, supportive supervision, etc.).
5. Provide feedback on reporting HV data to the transfusing facilities.

Hospitals/Blood transfusing facilities

1. Identify, record and report all adverse events
2. Investigate adverse events and take corrective and preventive action.
3. Appropriately document and retain transfusion records.

The adverse event reports received from the haemovigilance system are strictly confidential and will not be disclosed with third parties.

The Process

In Ghana, haemovigilance is undertaken at transfusing facilities (public and private), blood establishments and national level, supported by a national data collection and reporting process.

All adverse events (serious and non-serious) should all be reported by HCPs, Existing FDA Institutional Contact Persons (ICPs) serving a supervisory role similar to Haemovigilance Focal Persons (HFP) and taking responsibility for reporting adverse events to blood products in their facilities.

Data should be collected at the hospital and blood establishment levels. Transfusing facilities should report all Adverse Reactions to the Hospital Blood Banks (HBBs)/ Transfusion Medicine Department. The HBB should have an internal system in place to notify the ICPs/HFP immediately an adverse reaction report is received.

HFP/ICP in the transfusing facilities should be notified of reports and they should conduct review in real-time of all initial reports. The HFP will conduct an initial review and assessment (1st imputability) and forward reports to the NBS-HQ.

The HFP/ICP will also compile and submit reports to their local hospital transfusion committees (or the Drugs and Therapeutic Committees where the local Hospital Transfusion Committees are not available) who would be responsible for the review of reported adverse events to assess the validity, severity and imputability of the adverse reaction with respect to whether it was reported correctly, the seriousness, and assessment of the cause of the adverse reaction. The HFP will initiate, investigate and report adverse events in accordance with the national dataset. In addition, the HFP should give regular feedback to the transfusing facilities/ wards.

The NBS-HQ will notify the FDA of all adverse event reports received (imputability 2 and 3) in real-time.

1. The NBS-HQ will collate all other adverse reactions and analyse data on monthly basis and submit to the FDA.
2. The NBS-HQ will provide ongoing support to the HFP and as appropriate to the medical, nursing and technical staff.
3. The NBS-HQ will advise on improvements to the safety of transfusion practice based on available data.
4. Support training of medical, nursing and technical staff in haemovigilance.
5. Support the audit function of hospitals in relation to transfusion practice.

Food and Drugs Authority

1. Collaborate with the NBS-HQ to review and evaluate adverse events related to the collection and transfusion of blood and blood products.
2. Formulate safety regulatory decisions and communication with stakeholders.
3. Ensure the quality and safety of blood and blood products used in hospitals, blood banks and other facilities in Ghana.
4. Inspect and authorize all blood facilities in Ghana to ensure compliance with regulations for blood safety.
5. Share data with Service delivery agencies (CHAG, GHS, District Hospitals)

The FDA in collaboration with the NBS-HQ will collect and publish the national haemovigilance report annually. However, other stakeholders can make academic publications based on information from the Haemovigilance system.

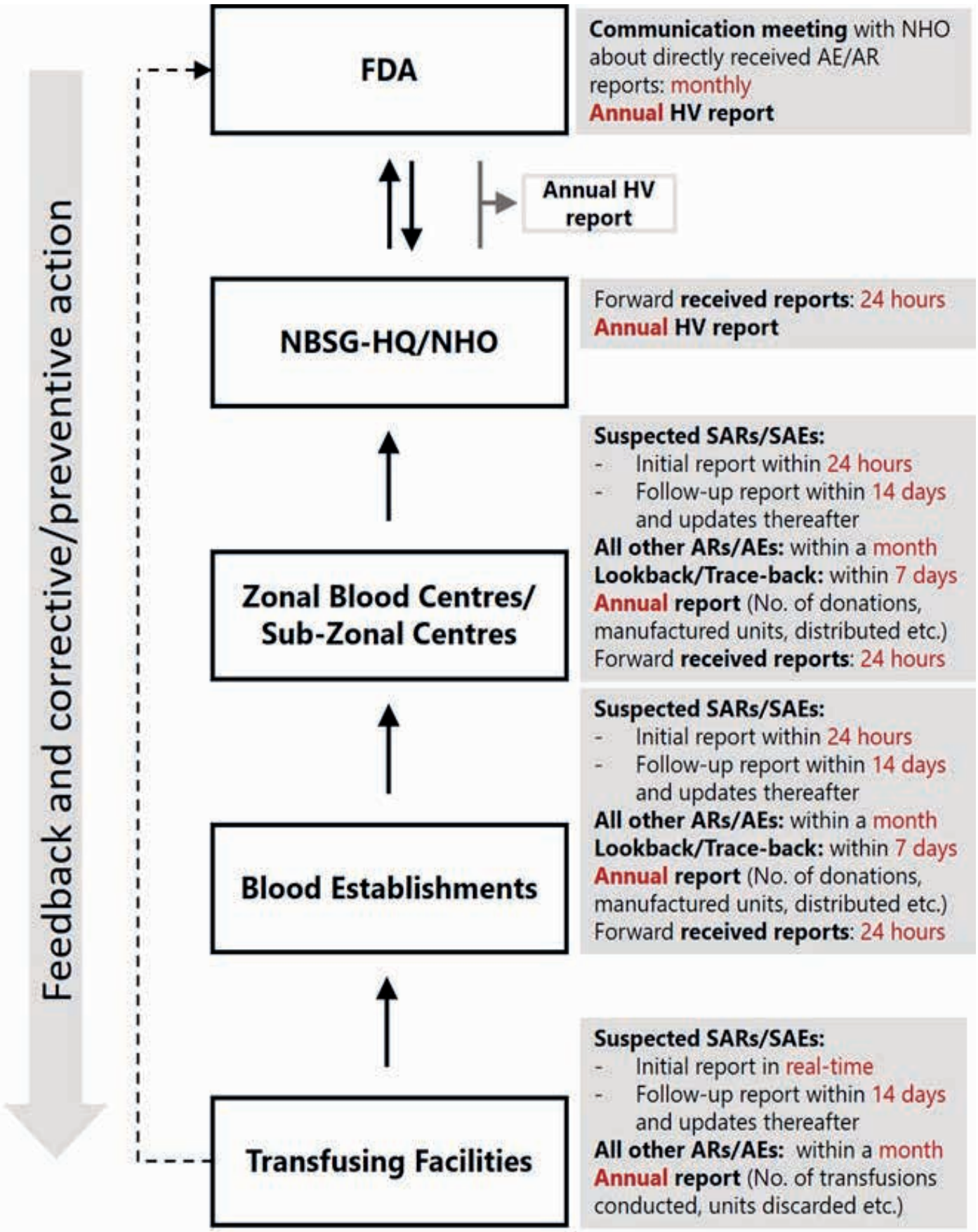

Figure 3 Haemovigilance reporting and data flow

Collection and submission of haemovigilance data

A standard HV reporting tool with the agreed minimum dataset requirements to contribute to a comprehensive national dataset will be made available to all transfusing facilities and blood establishments. This requires all transfusing facilities and blood establishments to enter data from the HV reporting tool into the HV database in real-time.

The NBS-HQ will transfer collated and analysed data to the FDA on a monthly basis.

The FDA requests data from hospitals and blood establishments through the NBS-HQ, however, in cases where the FDA receives adverse reaction reports directly from hospitals and blood establishments, there will be data reconciliation to ensure that all information received by the FDA is submitted to the NBS-HQ and vice-versa.

To support a national approach to haemovigilance, all transfusing hospitals and blood establishments at all levels should progressively align their reporting systems with the agreed minimum dataset requirements to contribute to a comprehensive national dataset.

National Haemovigilance Report

Haemovigilance data, supplied through blood establishments/centres, will be analysed for national trends and other indicators. Reports will also refer to the national data in the context of previous national haemovigilance data. National haemovigilance reports are compiled collaboratively by FDA and the NBS-HQ with support from the TAC-VBP. The national HV report will be published annually.

National Haemovigilance Reporting Process

All national haemovigilance data is held and managed by the NBS-HQ and the FDA in a secure manner to ensure confidentiality of these reports. All HCPs are to meet relevant privacy requirements to promote confidentiality of these reports at all times.

Haemovigilance data will be presented to the TAC-VBP for discussion and possible recommendations to ensure transfusion safety. It is the role of the TAC-VBP to advise on further data analysis and revision and to develop conclusions and national recommendations based on the resulting evidence.

Publication Process

The NBS-HQ and FDA are responsible for publishing national haemovigilance reports and other reports, presentations, case studies, commentaries or research articles in relevant academic or professional body forums.

The NBS-HQ and FDA will actively engage with the health, education and quality and safety sectors to disseminate national recommendations widely, effectively and efficiently and will seek written feedback from primary stakeholders on published national haemovigilance reports.

ACTION PLAN

The Action Plan for the FDA and NBS over the next three years includes training on the haemovigilance systems for all stakeholders and the development of online reporting to complement data collection at all levels to improve the current national haemovigilance system and ensure timely reporting.

A number of activities will be undertaken to improve the consistency of data provided for national reporting, as outlined below:

1. **Develop HV policy**

2. **Develop training manuals** on HV for different stakeholder groups (policy makers, healthcare workers, BE staff).

3. **Education and Training tools** for HV policy makers, healthcare workers and Blood Establishment (BE) staff.
   Training and education on best practice management, with regard to the use of blood and blood products, to optimize patient outcomes, minimize adverse events and ensure judicious use of blood and blood products training for the three groups (policy makers, healthcare workers, BE staff).

4. **Upgrade of Med Safety App and SafetyWatch system to include haemovigilance reporting**
   The existing data reporting tools will be upgraded to include haemovigilance reporting and training will be conducted nationwide to promote the use of electronic reporting.

5. **Audits**
   Development of audit tools for use by organizations to conduct clinical audits to improve the quality of incident and haemovigilance reporting by systematically reviewing the care provided against set criteria
   Quality improvement strategies such as audits record reviews, peer review, standard reviews (to see if standards are being met, guidelines followed and or evidence-based practice used) and patient surveys.