World Health Organization

National Haemovigilance System

AIDE-MÉMOIRE

for ministries of health

The transfusion of blood and blood products is a life-saving intervention. However, there are risks of adverse events associated with the donation of blood and its components, and with the transfusion of blood and blood products to patients. Adverse events include all reactions, incidents, near misses, errors, deviations from standard operating procedures and accidents associated with blood donation and transfusion. Learning from adverse events and identifying systems problems can drive the introduction of measures to enhance the quality, safety, efficacy, and cost-effectiveness of blood and blood products as well as the donation and transfusion processes.

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. Haemovigilance includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, as well as the development and implementation of recommendations to prevent their occurrence or recurrence. The ultimate goal of haemovigilance is continuous quality improvement of the transfusion chain through corrective and preventive actions to improve patient safety and outcomes, enhance donor safety and reduce wastage. Haemovigilance should be fully integrated into the quality systems of all institutions involved in the donation and provision of blood and blood products, including processing, inventory management, storage and distribution, and in clinical transfusion.

The organization of a haemovigilance system is largely determined by the structure of the national blood system and the health system. A system of haemovigilance is dependent on the traceability of blood and blood products from donors to recipients and vice versa, and on the monitoring, reporting, investigation and analysis of adverse events. The rigorous management of information generated through this system is key to introducing amendments in blood policies and guidelines that lead to changes in processes and practices in donation and transfusion.

The establishment of a haemovigilance system involves coordination and collaboration among all stakeholders, including the ministry of health, blood transfusion services, hospitals, professional bodies, public health institutions and regulatory agencies, as well as patient and donor groups.

Words of advice

- **Provide effective leadership, governance and adequate resources for establishing and maintaining an effective haemovigilance system**
- **Incorporate haemovigilance into national blood and health policies and systems**
- **Adopt a stepwise approach in establishing a haemovigilance system**
- **Engage all stakeholders in the blood transfusion chain**
- **Set up efficient organizational arrangements for the haemovigilance system and ensure integration with institutional quality management systems**
- **Develop a confidential and non-punitive system**

Checklist

Leadership and governance

- ❑ Haemovigilance as an element of the national blood policy and plan, and legislative and regulatory framework
- ❑ Haemovigilance advisory committee(s)
- ❑ Adequate human and financial resources
- ❑ Standards and definitions
- ❑ Confidential and non-punitive system
- ❑ Traceability of blood and blood products from donors to patients and vice versa
- ❑ Quality system throughout the transfusion chain
- ❑ Corrective and preventive action.

Organization and coordination

- ❑ Identification of stakeholders and responsible organizations and institutions
- ❑ Organizational arrangements for the haemovigilance system
- ❑ Coordinated links with organizations and institutions involved in the system
- ❑ Defined roles and responsibilities of all stakeholders
- ❑ Haemovigilance education and training for all health-care staff
- ❑ Monitoring, reporting, investigation and analysis of adverse events, with recommendations for safety and quality improvements.

Haemovigilance in the donation and provision of blood and blood products

- ❑ Donor haemovigilance: recognition, clinical management, monitoring, reporting, investigation and analysis of adverse events associated with donation
- ❑ Policies, guidelines, protocols and standard operating procedures for all processes
- ❑ Reporting of errors and deviations associated with these processes
- ❑ Post-donation information and look-back
- ❑ Liaison between blood transfusion services and hospital blood banks, transfusion committees and clinical services.

Haemovigilance in clinical transfusion

- ❑ Patient haemovigilance: recognition, clinical management, monitoring, reporting, investigation and analysis of adverse events associated with transfusion
- ❑ Clinical guidelines, hospital protocols, standard operating procedures, patient identification and sample labelling
- ❑ Hospital transfusion committees
- ❑ Response to recall and look-back notification
- ❑ Coordination between hospital departments and services, and liaison with blood transfusion services.

Key elements

Leadership and governance

The ministry of health (MoH) holds ultimate responsibility for its national blood system and for the quality, safety and sufficiency of the supply of blood and blood products. A haemovigilance system contributes to the safety of donation, blood products and transfusion. It improves risk management, increases trust and should be confidential and non-punitive in nature. The MoH should provide effective leadership and governance for a national haemovigilance system, including:

- systematic and comprehensive surveillance of the entire transfusion chain as an element of the national blood policy and plan, and legislative and regulatory framework;
- haemovigilance advisory committee(s) with medical, scientific and quality expertise;
- adequate human and financial resources for the establishment, development and sustainability of the haemovigilance system
- standards and definitions in line with international recommendations.

The MoH should define the scope and elements of the haemovigilance system for a stepwise development of the system. This should include:

- Reporting characteristics: whether it is mandatory, voluntary or mixed;
- Coverage: whether it concerns donors, processes, clinical practices or patients;
- Blood products: whether it covers only blood components for transfusion or also plasma-derived medicinal products;
- Types of events to be reported: whether it covers all types of adverse events or selected reactions, near misses and errors;
- Severity of adverse events to be reported: fatal, serious or all levels of severity;
- Imputability: the probability of attribution (definite, probable and possible, or also unlikely and excluded) in the context of blood donation, processing and clinical transfusion;
- Collection and use of denominators to calculate rates of adverse events.

An efficient haemovigilance system requires:

- Traceability of the blood product from donor to patient, and vice versa;
- Effective structure and clear channels for adverse events reporting, investigation, feedback and communication of findings, as well as monitoring and evaluation;
- Methods and mechanisms for data collection, validation and analysis;
- Guidelines, procedures and formats for notification and modalities of reports;
- A quality system throughout the transfusion chain, and implementation of corrective or preventive actions to quickly rectify weaknesses and deficiencies.

Organization and coordination of a haemovigilance system

A haemovigilance system requires coordination and collaboration between multiple stakeholders involved in the donation, provision, transfusion, surveillance and regulation of blood and blood products. Haemovigilance may operate at local and institutional levels, but national coordination and management are vital for effective surveillance. The MoH should:

- Establish organizational arrangements and mechanisms to engage and coordinate all key stakeholders;
- Define the roles, responsibilities and accountabilities of all stakeholders;
- Facilitate international cooperation with existing haemovigilance networks.

Core haemovigilance coordination and management functions include:

- Establishment of links and communication with participating organizations and institutions;
- Education and training of all personnel on haemovigilance;
- Collection, management and review of data on adverse events from all organizations involved in the blood transfusion chain;
- Identification of underlying systems and process failures, weaknesses, gaps and deficiencies that have led to adverse events;
- Recommendations for the improved safety of donors, blood products and patients through changes in policies, strategies, standards, guidelines and procedures;
- Production and dissemination of reports and recommendations;
- Development of a rapid alert and early warning platform to communicate and share information;
- Periodic review, monitoring and evaluation of the haemovigilance system.

Haemovigilance in the donation and provision of blood and blood products

In a national haemovigilance system, blood centres and transfusion services have the following roles and responsibilities:

- Donor haemovigilance, including recognition and clinical management of adverse events associated with donation, and their monitoring, reporting, investigation and analysis;
- Implementation of policies, guidelines, protocols and standard operating procedures for all processes in the donation and provision of blood and blood products;
- Epidemiological surveillance of donors, post-donation information and look-back;
- Identification, recording and reporting of:
  - Near misses, errors and deviations associated with these processes;
  - Abnormalities in intermediate and finished blood products.
- Traceability of each donation from the donor to blood processing, the blood product, its issue to a health-care facility and transfusion to the patient, and vice versa;
- Response to notification of a patient adverse event, by retrieval of all blood components associated with the index blood component(s);
- Implementation of haemovigilance as part of the quality system, and mechanisms for taking corrective and preventive actions and monitoring their outcomes;
- Training and assessment of staff involved in all steps of the donation and provision of blood and blood products;
- Liaison with hospitals: administration, blood banks, transfusion committees and clinical services.

Haemovigilance in clinical transfusion

In a national haemovigilance system, hospitals and other health-care facilities have the following roles and responsibilities:

- Patient haemovigilance, through recognition and clinical management of adverse events associated with transfusion, and their monitoring, reporting, investigation and analysis;
- Correct identification of patients, samples and blood products, and appropriate labelling;
- Implementation of hospital standards, clinical guidelines and protocols for safe blood transfusion, investigation of adverse events and reporting by clinical services;
- Traceability and documentation of transfused blood products in patient records;
- Response to product recall and look-back notification;
- Active participation in a hospital transfusion committee;
- Integration of haemovigilance in the hospital quality system, and mechanisms for taking corrective and preventive actions and monitoring outcomes;
- Training and assessment of staff involved in all steps of clinical transfusion, including clinical decision-making, pre-transfusion sampling, laboratory practice, handling of blood units in the clinical area, bedside administration of transfusion and patient monitoring;
- Regular audit of clinical transfusion practices;
- Mechanisms for coordination between hospital departments and clinical services, and liaison with blood transfusion services.

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