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User guide for navigating resources on stepwise implementation of haemovigilance systems

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WHO recognizes the importance of haemovigilance, systematic blood safety surveillance, to identify and prevent occurrence or recurrence of transfusion-related adverse events, and to increase the safety, efficacy and efficiency of blood transfusion. The WHO Action Framework to Advance Universal Access to Safe, Effective and Quality-Assured Blood Products 2020–2023 reaffirms the importance of haemovigilance as one of the strategic objectives of global efforts to improve capacity to monitor, investigate and assess adverse events in blood donors and transfusion recipients.

While national haemovigilance systems are well established in some countries, there is a lack of effective blood safety surveillance in many settings, as outlined in the WHO fact sheet on blood safety and availability. An effective haemovigilance system is an integral part of a comprehensive quality system in blood establishments and hospitals and should cover blood collection, testing, processing, storage, distribution and availability of blood and blood products, transfusion decision-making, administration, and monitoring of blood transfusions. It improves quality by enhancing the ability to objectively identify, learn from, and take appropriate actions to improve suboptimal practices at local and national levels.

In a 2015 WHO Global Database on Blood Safety survey of all WHO regions, only 49% of countries who responded reported having a national haemovigilance system. One of the challenges cited was lack of ability of blood establishments and hospitals to carry out end-to-end traceability from collection to use of blood and blood products, and to conduct surveillance. Even where haemovigilance systems are in place, opportunities exist to further raise the bar in safety and quality by expanding the scope of these systems – for example, by incorporating rapid alert or early warning channels; by including capture of poor transfusion decision-making, under- or unnecessary transfusion, and avoidable blood wastage; and in analysis of risks related to particular patient groups, procedural weaknesses, and alternatives to blood transfusion.

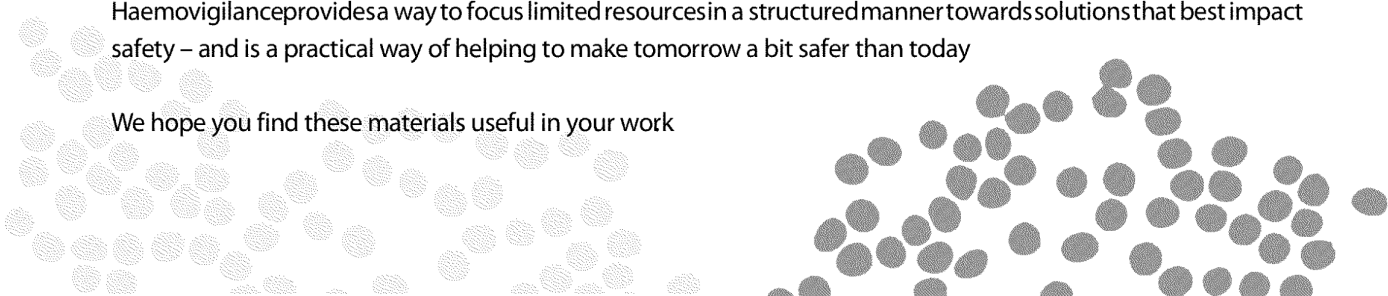
Recognizing that all countries can take steps, both small and large, to improve blood safety, and to assist countries as they develop and evolve their haemovigilance systems, WHO has developed this *User guide for navigating resources on stepwise implementation of haemovigilance systems*, working with experts from the International Haemovigilance Network (IHN), the International Society of Blood Transfusion (ISBT), WHO-related units, and others in haemovigilance systems worldwide.

The specific objectives are to:

- outline the necessary steps for implementation of haemovigilance systems in blood establishments and hospitals;
- support development of haemovigilance as part of the activities of a nationally coordinated blood system; and
- provide information and technical guidance resources on monitoring and investigating adverse events.

WHO and its partners have made these tools and resources available to Member States and to the public at the International Society of Blood Transfusion (ISBT) Working Party on Haemovigilance website (<https://www.isbtweb.org/working-parties/haemovigilance>) and the Notify Library (<https://www.notifylibrary.org/content/educational-material>). Haemovigilance provides a way to focus limited resources in a structured manner towards solutions that best impact safety – and is a practical way of helping to make tomorrow a bit safer than today.

We hope you find these materials useful in your work.



## S AUQI F( B ) ( D ( URK

The development and publication of this document were coordinated by **Yuyun Siti Maryuningsih**, Team Lead, Blood and Other Products of Human Origin, Health Products Policy and Standards Department, World Health Organization (WHO), Geneva, Switzerland

Acknowledgements are due to the working group members who contributed to drafting the chapters:

**Yetmgeta Abdella**, WHO Regional Office for the Eastern Mediterranean, Cairo, Egypt

**Paul Ashford\***, Roper Management Consultants, Minster on Sea, United Kingdom of Great Britain and Northern Ireland

**Mauricio Beltran Duran**, WHO Regional Office for the Americas/Pan American Health Organization, Washington, DC, United States of America (USA)

**Jean-Claude Faber**, LuxConsulTrans, Luxembourg, Luxembourg

**Nadia Khaldi**, Établissement Français du Sang, France

**Kevin Land Vitalant**, University of Texas at San Antonio, Texas, USA

**André Loua**, WHO Regional Office for Africa, Brazzaville, Congo

**Yuyun Siti Maryuningsih**, WHO, Geneva, Switzerland

**Shruthi Narayan\***, Serious Hazards of Transfusion (SHOT) and Consultant Donor Medicine, NHS Blood and Transplant, the United Kingdom

**Olexandr Polischuk**, WHO Regional Office for Europe, Copenhagen, Denmark

**Washington Samukange**, Paul-Ehrlich-Institut, Langen, Germany

**Wided Sghaier**, Établissement Français du Sang, France

**Jinho Shin**, WHO Regional Office for the Western Pacific, Manila, Philippines

**Wilbert Sibanda**, Nelson Mandela University, Port Elizabeth, South Africa

**Aparna Singh Shah**, WHO Regional Office for South-East Asia, New Delhi, India

**Surinder Singh**, JSS Academy of Higher Education and Research, Mysuru, Karnataka, India

**Jacintha Toohey**, University of KwaZulu-Natal, Durban, South Africa

**Mary Townsend\***, International Society of Blood Transfusion Working Party on Haemovigilance, Vitalant, Scottsdale, Arizona, USA

**Teguh Triyono**, National Committee of Blood Transfusion, Yogyakarta, Indonesia, and member of WHO Advisory Group for Blood Regulation, Availability and Safety

**Barbee Whitaker\***, United States Food and Drug Administration, Center for Biologics Evaluation and Research, Silver Spring, Maryland, USA

**Johanna C. Wiersum-Osselton**, TRIP (Transfusion and Transplantation Reactions in Patients) Hemovigilance and Biovigilance Office, Sanquin Blood Bank, and International Haemovigilance Network, Leiden, Netherlands

**Erica Wood\***, International Society of Blood Transfusion, Amsterdam, Netherlands; and Monash University, Melbourne, Australia

**Junping Yu**, WHO, Geneva, Switzerland

\* Core editing group members.



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**Arwa Al Riyami**, Sultan Qaboos University Hospital Oman, Muscat, Oman and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Ai Leen Ang** Health Sciences Authority, Singapore;

**Justina Kordai Ansah**, National Blood Service, Accra, Ghana and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Kamel Boukef**, University of Monastir, Monastir, Tunisia and member of WHO Expert Committee on Biological Standardization;

**Ubonwon Charoonruangrit**, Mae Fah Luang University, Bangkok, Thailand and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Ana Emilia del Pozo**, Hospital de Pediatria Garrahan, Buenos Aires, Argentina and member of WHO Expert Committee on Biological Standardization;

**Dragoslav Domanović**, European Centre for Disease Prevention and Control, Stockholm, Sweden;

**Androulla Eleftheriou**, Thalassemia International Federation, Nicosia, Cyprus;

**Peter Flanagan**, New Zealand Blood Service, Wellington, New Zealand;

**Mahrukh Getshen**, National Blood Bank, JDW, National Referral Hospital, Thimphu, Bhutan;

**Mindy Goldman**, Canadian Blood Services, Ottawa, Canada;

**Mary Gustafson**, Plasma Protein Therapeutics Association, Annapolis, Maryland, USA;

**Anneliese Hilger**, Paul-Ehrlich-Institut, Langen, Germany, and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Alan Kitchen**, Expert on Transfusion Medicine, Billericay, Essex, the United Kingdom, and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Pawinee Kupatawintu**, National Blood Centre, Thai Red Cross Society, Bangkok, Thailand;

**Kumudu K.S. Kuruppu**, National Blood Transfusion Service, Colombo, Sri Lanka, and member of the WHO Advisory Panel for Transfusion Medicine;

**Cheuk Kwong Lee**, Hong Kong Red Cross Blood Transfusion Service, Hong Kong Special Administrative Region, China, and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Dora Mbanya**, Centre Hospitalier et Universitaire de Yaoundé, Cameroon;

**Paul McKinney**, National Blood Centre, Dublin, Ireland, and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Eric Parent**, Héma-Québec, Québec, Canada, and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Sangeeta Pathak**, Max Super-specialty Hospital, New Delhi, India;

**Ratti Ram Sharma**, Department of Transfusion Medicine, PGIMER, Chandigarh, India, and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Betina Sørensen**, Aalborg University Hospital and Danish Society for Clinical Immunology, Aalborg, Denmark;

**Chanthala Souksakhone**, Lao Red Cross Blood Services, Vientiane, Lao People's Democratic Republic;

**Sitalakshmi Subramanian**, Department of Transfusion Medicine and Immunohematology, Bangalore, India;

**Jean Baptiste Tapko**, Expert on Transfusion Medicine, Yaoundé, Cameroon, and member of WHO Advisory Group for Blood Regulation, Availability and Safety;





**Diana Teo**, Expert on Transfusion Medicine, Singapore, and member of WHO Expert Committee on Biological Standardization;

**Nicole Verdun**, Centre for Biologics Evaluation and Research, Food and Drug Administration, Silver Spring, Maryland, USA and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Silvano Wendel**, Hospital Sírio Libanês, Sao Paulo, Brazil, and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

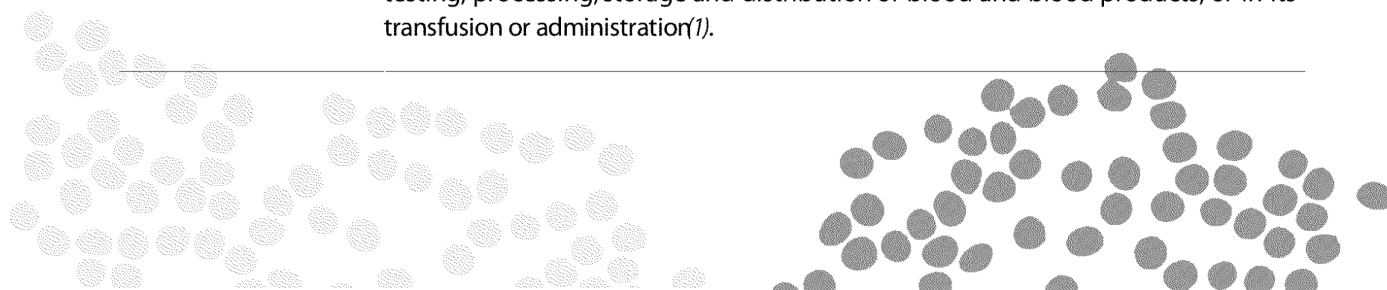
**Yong Ming Zhu**, Shanghai Blood Centre, Shanghai, China, and member of WHO Advisory Group for Blood Regulation, Availability and Safety;

**Shimian Zou**, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland, USA.



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TERM	DESCRIPTION (reference)
<b>Adverse event</b>	Any undesirable or unintended occurrence associated with transfusion or donation. It includes all adverse reactions, incidents, near misses, errors, unplanned deviations from standard operating procedures and accidents(1).
<b>Adverse event reporting</b>	Sending information on adverse events to the haemovigilance system for further investigation, analysis and feedback(1).
<b>Adverse reaction</b>	Any unintended response in donor or patient associated with the collection or transfusion of blood or blood products(1).
<b>Blood establishment</b>	Any structure, facility or body that is responsible for any aspect of the collection, testing, processing, storage, release or distribution of human blood or blood components (including source plasma) when intended for transfusion or further industrial manufacturing. It encompasses the terms blood bank, blood centre, plasma collection centre, blood service and blood transfusion service(2).
<b>Blood product</b>	Any therapeutic substance derived from human blood, including blood for transfusion (that is, whole blood and blood components), plasma for fractionation (either separated from whole blood or prepared by apheresis), and plasma-derived medicinal products(3).
<b>Corrective action</b>	Action taken to remedy the nonconformance and/or care for the donor or patient(1).
<b>Donor haemovigilance</b>	The systematic monitoring of adverse reactions and incidents in the whole chain of blood donor care, with a view to improving quality and safety for blood donors(4).
<b>Haemovigilance</b>	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, as well as the development and implementation of recommendations to prevent their occurrence or recurrence(5).
<b>Haemovigilance feedback report</b>	Report of aggregated analysed data from the haemovigilance system(1).
<b>Imputability</b>	The probability that an identified probable cause was the actual cause of an adverse event after the investigation is completed(4).
<b>Incident</b>	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 its transfusion or administration(1).



TERM	DESCRIPTION (reference)
<b>Incorrect blood component transfused</b>	A patient was transfused with a blood component that did not meet the appropriate requirements or that was intended for another patient (4).
<b>Low- and middle-income countries</b>	Resource-constrained countries with a gross national income per capita that is below a value determined each year by the World Bank (2).
<b>National haemovigilance system</b>	A haemovigilance system that is implemented throughout a country and with a national level of coordination, data analysis and reporting (1).
<b>Near miss</b>	An error or unplanned deviation from procedure that was detected and corrected prior to undesirable or unintended impact (4).
<b>Notification</b>	Mandatory information on a notifiable event to the regulatory authority (1).
<b>Preventive action</b>	Action taken to eliminate the cause of a potential nonconformity or other potential undesirable situation (1).
<b>Recipient<sup>a</sup> haemovigilance</b>	The systematic monitoring of adverse reactions and incidents in the provision and transfusion of blood and blood products to patients (4).
<b>Serious adverse reaction or event (SARE)</b>	Adverse event or reaction that results in serious harm to a person. A more specific definition is often provided by regulatory authorities as the basis for mandatory reporting (4).

<sup>a</sup>The terms “patient” and “recipient” are used interchangeably in this document.

The above definitions are based on the documents listed below:

1. A guide to establishing a national haemovigilance system. Geneva: World Health Organization; 2016 (<https://apps.who.int/iris/handle/10665/250233> accessed 22 July 2021).
2. Guidance on increasing supply of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma. Geneva: World Health Organization; 2021 (<https://apps.who.int/iris/bitstream/handle/10665/340171/9789240021815-eng.pdf>, accessed 22 July 2021).
3. Guidance on centralization of blood donor testing and processing. Geneva: World Health Organization; 2021 (<https://apps.who.int/iris/bitstream/handle/10665/340182/9789240020825-eng.pdf>, accessed 22 July 2021).
4. de Vries RRP, Faber JC, editors. Hemovigilance: an effective tool for improving transfusion safety. Chichester, United Kingdom: Wiley-Blackwell; 2012.
5. Aide-mémoire for ministries of health: national haemovigilance system. Geneva: World Health Organization; 2015 (<https://apps.who.int/iris/handle/10665/340564> accessed 22 July 2021).









## 1.1 Purpose of this resource

Haemovigilance is a system of blood safety surveillance that includes the detection, monitoring, reporting, investigation, and analysis of adverse events related to the donation, processing, and transfusion of blood and blood products, as well as the development and implementation of recommendations to prevent their occurrence or recurrence and thus improve safety for blood donors and recipients.

Blood transfusion professionals and policy-makers in many countries recognize the need for haemovigilance systems but are sometimes unable to develop or implement these systems due to various barriers, including lack of knowledge, lack of resources, lack of standardized practices, fragmented blood services, and lack of support from all stakeholders needed for successful implementation.

Implementing effective surveillance for blood collection and transfusion safety is a major endeavour, and this document is designed to support a stepwise approach. It recognizes that all countries can take steps, both small and large, to improve blood safety, and is designed to assist countries as they develop and evolve their haemovigilance systems. Whilst national haemovigilance systems are well established in some countries, there is a lack of effective haemovigilance in many settings, and implementation remains an important challenge.

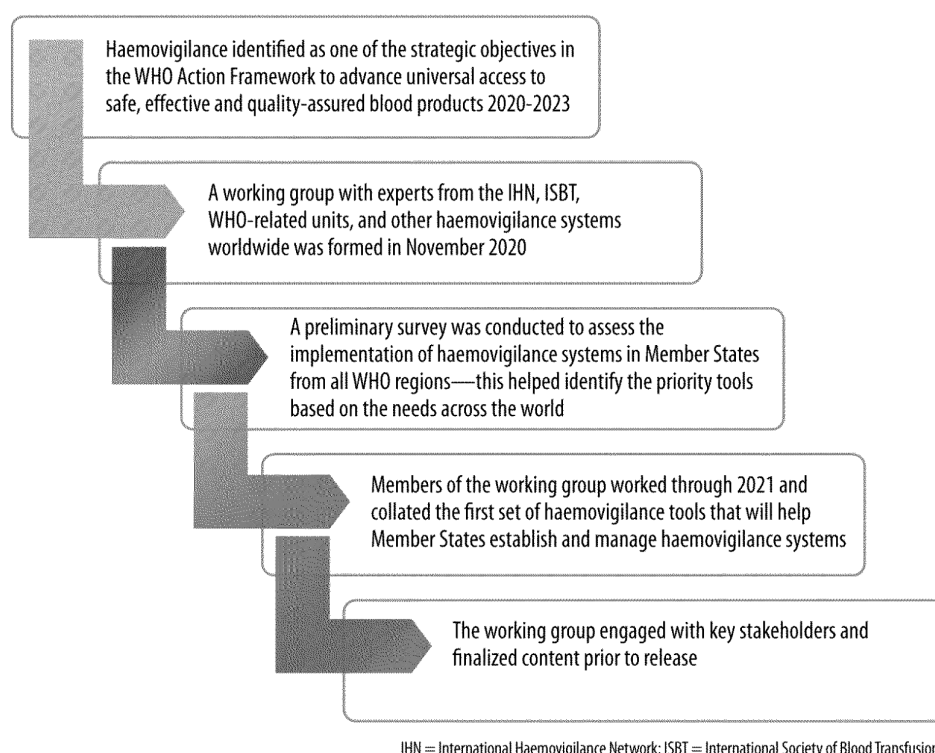
Realizing this challenge and acknowledging the importance of haemovigilance to increase the safety, efficacy and efficiency of blood transfusion, “effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems,” has been set as one strategic objective of the World Health Organization (WHO) Action Framework to Advance Universal Access to Safe, Effective and Quality-Assured Blood Products 2020–2023<sup>(1)</sup>.

In the latter part of 2020, WHO issued a survey to identify specific needs of countries seeking to implement or improve their haemovigilance programmes (see Chapter 2). The survey results identified that priority areas for additional support included the need for educational and training modules, guidelines and guidance documents, and data capture systems. This document provides references to tools and resources (including educational materials and data collection and

reporting templates) and definitions to assist countries to develop and improve local and national haemovigilance systems in line with the WHO aide-mémoire on national haemovigilance systems and the WHO guide to establishing a national haemovigilance system (2, 3).

Compilation of these tools and resources is one activity for implementation of the Action Framework. These are expected to assist Member States in establishing and managing haemovigilance systems in a stepwise manner. Haemovigilance challenges exist in both low- and middle-income countries and in well-resourced settings; therefore, the tools and resources referenced herein may be useful to any organization interested in enhancing blood safety, whether on a local, regional or national level. Figure 1.1 presents the process and timeline by which the user guide was developed.

**Fig. 1.1 User guide compilation process and timeline**



## 1.2 Relationship to WHO aide-mémoire and guide on national haemovigilance systems

The WHO aide-mémoire for ministries of health on national haemovigilance systems (2), published in 2015, aims to guide ministries of health in the organization and coordination of a national haemovigilance system. It emphasizes that the ministry of health has ultimate responsibility for its national blood system and for the quality, safety and sufficiency of supply of blood and blood products; recognizes the important role of haemovigilance in contributing to safety; and calls on the ministry of health to provide effective leadership and governance for a national haemovigilance system.

In addition to the aide-mémoire, to support countries where haemovigilance is not already in place and to support countries in strengthening their existing haemovigilance systems, the WHO guide to establishing a national haemovigilance system

was published in 2016 (3). This guide provides policy recommendations on establishing a haemovigilance system as part of national blood and health systems, and guides information and technical aspects on the specific measures and actions needed to implement a haemovigilance system. This user guide builds on the foundation provided by the aide-mémoire and the guide by identifying and enumerating tools and reference materials for this implementation.

## 1.3 Target audience

This document is intended to provide information and links to resources and tools that are applicable to all key stakeholders who may be involved in haemovigilance, including:

- ministries of health;
- bodies responsible for policy-making on blood safety, such as national blood commissions or councils;
- regulatory agencies;
- scientific and professional bodies;
- blood establishments;
- hospitals, including hospital blood banks and transfusion committees or health care facilities where transfusion takes place;
- blood donor organizations and other nongovernmental organizations involved in blood system strengthening and blood donor education and recruitment;
- public health institutions;
- patient groups;
- development partners

## 1.4 Overview of haemovigilance

Transfusion of blood or blood products is a life-saving therapeutic option for many patients. Blood products go through a series of steps from blood collection, through processing, testing, distribution and issue, and ultimately transfusion to a patient. Adverse events can occur along the way, affecting donors, patients and the products themselves. Successful mitigation of these negative events requires end-to-end, or vein-to-vein, traceability.

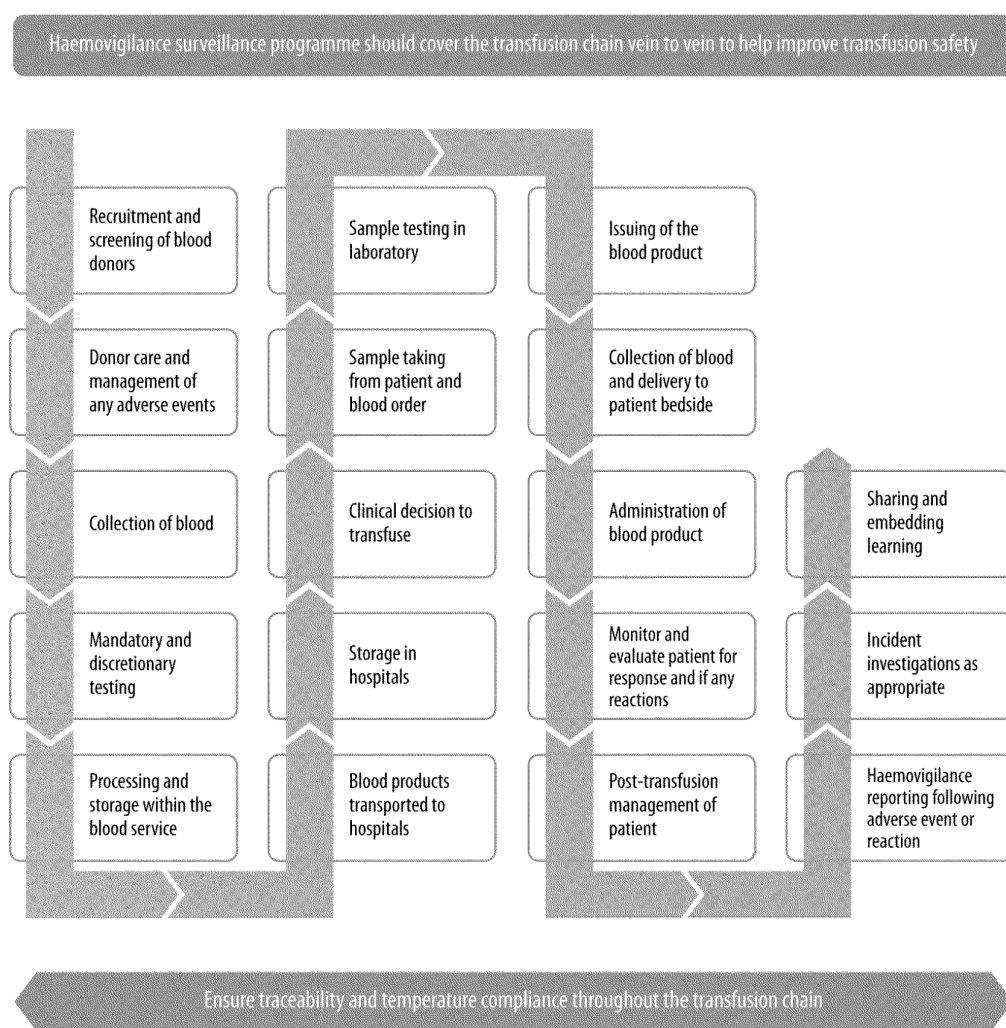
The process of collecting, aggregating, analysing and acting on adverse event data is the general definition of vigilance. Haemovigilance is similar to pharmacovigilance, but relating specifically to blood safety surveillance. WHO defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. Haemovigilance goes further in that the product source, the

<sup>1</sup> <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance>.

collection of blood, and manufacture of the blood product are also included. Adverse events associated with processing and clinical use of plasma-derived medical products are generally covered under pharmacovigilance, though practice varies internationally.

A haemovigilance system should be an integral part of the overall quality system covering all aspects of the transfusion chain from donor to recipient (Figure 1.2).

**Fig. 1.2 Vein-to-vein haemovigilance**



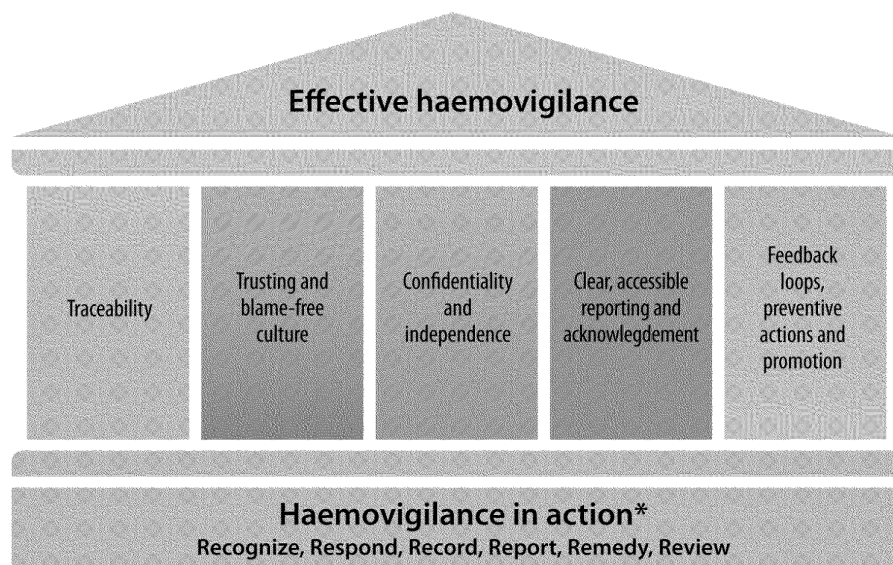


The basic premise of a national haemovigilance system is the development of a coordinated approach to the continuous improvement of the safety, availability and appropriate use of blood and blood products and related activities across all organizations involved in the transfusion chain. It is important to recognize that haemovigilance is not just about collecting data; it also helps to:

- identify trends in reported incidents
- identify common risk factors
- recognize areas for improvement
- develop interventions to address recognized concerns

Haemovigilance must contribute to improving and enhancing transfusion safety, for donors, donations, recipients and staff. It should be part of the patient safety continuum in every organization. Ongoing surveillance will evaluate the success of interventions in improving transfusion safety and must be reviewed regularly. Figure 1.3 depicts the five pillars for effective haemovigilance.

**Fig. 1.3 Five pillars for effective haemovigilance**



\*These are discussed further below

For any haemovigilance system to be effective and efficient, the following are essential

**Traceability.** This involves being able to reliably follow the information trail from donor to recipient and vice versa in a timely manner

**Trusting and blame-free culture.** Staff should be comfortable and empowered to report incidents and reassured that they will not be blamed for their occurrence. Leadership commitment, policies and practical steps should be in place to foster a supportive environment and ensure a positive reporting culture.

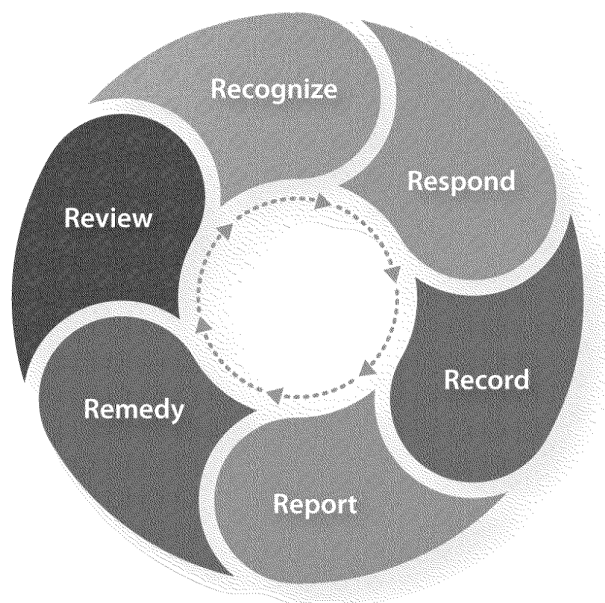
**Confidentiality and independence.** It is essential that donor, patient and staff confidentiality is maintained. Haemovigilance activities should be independent, driven by data and not unduly influenced by any health care organization or outside party.

**Clear, accessible reporting and acknowledgement.** Submitting a report should be as easy as possible for the reporter. The reporting forms (paper-based or digital) should be readily available to anyone wishing to file a report. They should be easy to compile, provide adequate opportunity for narrative and make maximum use of the “tick off” or “checkbox” format. The forms should ideally encourage safety improvement suggestions, such as how to prevent reoccurrence of an event or how to deal with it. To encourage further submission of reports, the haemovigilance system should clearly communicate to its reporters that the submitted reports are a valuable safety asset and acknowledge the efforts made by reporting persons.

**Feedback loops, preventive actions and promotion.** Whenever possible, feedback on the actions taken in response to a report shall be provided as a direct report to the reporting person and in the form of collective feedback to the reporting community. The de-identified information received from the reporting systems should be available to health care staff in a timely manner, which will help motivate people to further improve the reporting of adverse events. Failure to achieve this goal will reduce the effectiveness and value of the system.

Figure 1.4 summarizes the “six Rs” of the haemovigilance cycle, as referred to in Figure 1.3 above.

**Fig. 1.4 Haemovigilance cycle: the six Rs**



The six Rs of the haemovigilance cycle can be defined as follows:

**Recognize.** Staff should be able to promptly recognize adverse events, and haemovigilance activities should pick up trends in reported transfusion events and reactions.

**Respond.** Staff should be able to respond appropriately to recognized adverse events and initiate optimal management.

**Record.** Accurate, timely documentation is vital for haemovigilance. Appropriate documentation will ensure that all relevant details are available as part of the report submitted to the haemovigilance system.

**Report.** A positive reporting culture is crucial for haemovigilance. Reporting to local quality management systems and external reporting to the haemovigilance system will help ensure learning from errors and reactions.

**Remedy.** Reporting facilitates recognition of trends through root cause analysis, identification of risk factors and appropriate mitigating actions.

**Review.** With ongoing surveillance, haemovigilance activities will help evaluate the success of interventions in improving transfusion safety and identify other measures that need to be instituted.

As haemovigilance systems develop, they should adopt systematic ways of capturing the appropriate data necessary to monitor each key step of the process. For those countries without a fully implemented vein-to-vein surveillance programme, it can be helpful to focus on the steps that can be taken to incrementally work towards a more complete programme. Knowledge sharing – in the form of standard definitions, guidelines, tools or workshop activities – is an important way that countries and health professionals can learn from each other and share best practices, thereby assisting countries in setting up and further developing their haemovigilance systems.

Haemovigilance can be subdivided into donor haemovigilance, process haemovigilance, and haemovigilance in clinical transfusion.

*Donor haemovigilance* is the systematic monitoring of adverse reactions and incidents throughout the donation process, with a view to improving quality of care and safety for blood donors (4). Good donor care requires that adverse reactions such as dizziness and fainting, local symptoms such as haematoma, and long-term implications such as iron depletion are detected. Staff should be trained to identify signs and symptoms of reactions, provide treatment to donors with reactions, and give advice to reduce the likelihood of recurrence. Reactions should be accurately recorded according to standardized definitions. Serious reactions should be reported to the national authorities in accordance with regulatory requirements. Individual haemovigilance systems should define what should and should not be reported.

*Process haemovigilance* applies the principles of detection, assessment, understanding and prevention to the testing, processing, storage, distribution, unit selection, and issue steps that take place between collection and clinical use, and is part of a comprehensive quality system.

*Haemovigilance in clinical transfusion* applies these same techniques and principles to the care and safety of patients who need or receive blood and blood product transfusions. Good patient care requires monitoring of recipients by trained staff during and after the transfusion episode and the accurate documentation of any adverse events according to standardized definitions. Serious events, including lack of availability of blood or blood components where needed, should be reported to the national authorities in accordance with regulatory requirements.

The implementation of national haemovigilance systems still varies widely. Some countries have an established national system, some have a patchwork of variably effective systems, and some still face obstacles and challenges. The decision of the national authority is important in determining the form of the national haemovigilance system to be applied, the organizational system used, the reporting methods, the institutions responsible, and the preparation of regular reports.







To help collate these tools, a digital survey questionnaire was designed to assess the challenges and resource needs of haemovigilance systems in countries across the six WHO regions. The survey was divided into five sections:

- A. details of the person or organization submitting the response to the questionnaire;
- B. organization and management of the haemovigilance system;
- C. coverage and scope of the existing haemovigilance system;
- D. major challenges and constraints faced and strategies for the implementation of an effective national haemovigilance system;
- E. expectations of WHO for improving the haemovigilance system.

The digital questionnaire was circulated online in English and French to collect feedback for the working group for global haemovigilance. The questionnaire was promoted internationally through the WHO regional offices and relevant organizations, including the International Haemovigilance Network and the International Society of Blood Transfusion (see Annex 1 for survey questions).

Participation was voluntary, and was open to all professionals involved in the transfusion chain. A total of 151 responses were received, 141 of which were considered after removal of duplicates. Responses came from 87 countries representing all of the six WHO regions.

As expected, the results showed a wide range of development of haemovigilance systems, from nationally coordinated systems with government involvement and national aggregation of data, through to institution-level systems with no nationally coordinated reporting. Interestingly, the perception of individuals in the same country sometimes differed markedly, and this suggests variation in the understanding of terms such as “national haemovigilance system”.



Despite this wide range of respondent settings and backgrounds, the responses to challenges and barriers to implementation were remarkably consistent. The main barriers to implementation were identified as:

- lack of dedicated financial provision, leading to financial constraints and limited financial resources;

- lack of trained personnel;

- the failure to identify all stakeholders and service providers and bring them into a common comprehensive system.

Priority areas for technical support and capacity-building were identified as:

- education support to strengthen the workforce (technical as well as skills development);

- infrastructure support and technology upgrades;

- financial support

In responding to questions on the ways in which WHO can support haemovigilance implementation, respondents identified education and training modules as the highest priority





There is no universal solution for implementing haemovigilance. Several important elements contribute to building a haemovigilance system; the order and manner in which these elements are introduced depends on the local priorities, circumstances and available resources.

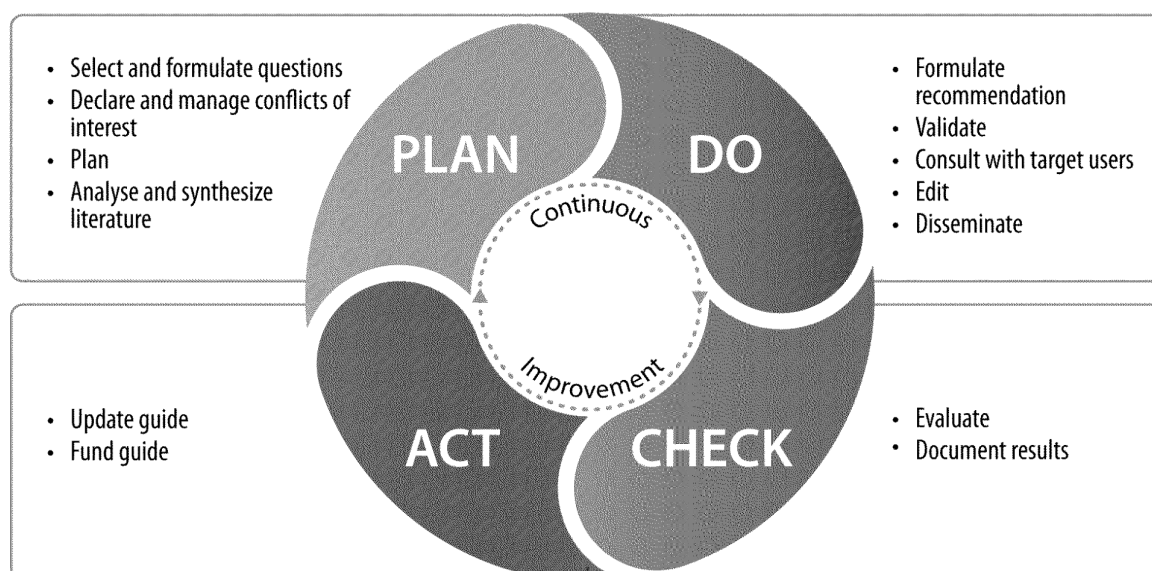
Financial support to establish a haemovigilance system was identified in the survey as a major challenge for many countries. While this is intended to be the responsibility of the national government or ministry of health, there are many approaches to supporting the development of such a system. For example, professional societies, standard-setting organizations, and local or regional authorities can be the catalysts for initial steps.

A systematic approach will help identify key steps in the process and potential barriers, and will allow smoother implementation with good engagement of all key stakeholders. This is a dynamic process with many interconnected parts, all of which should be reviewed and updated regularly to deliver an effective solution.

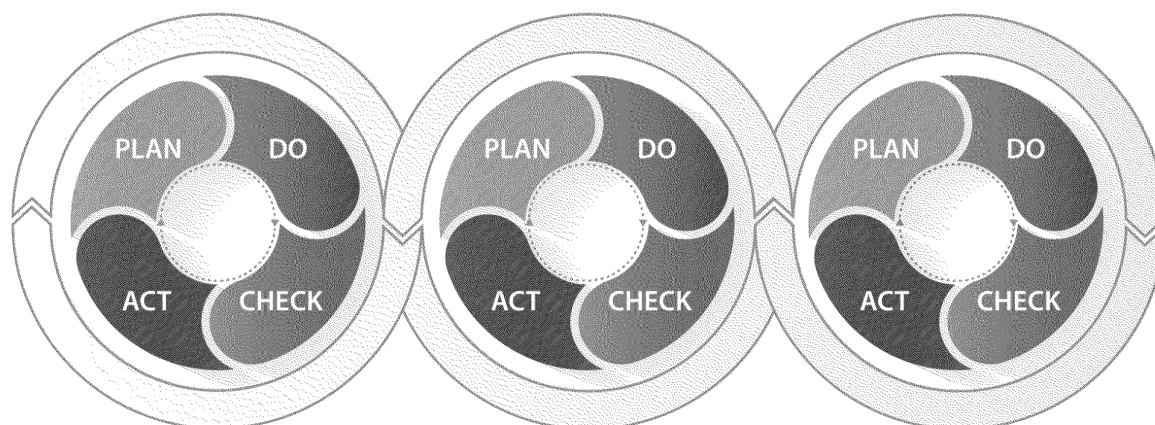
The Deming cycle – “Plan, Do, Check, Act” (PDCA) – is a central concept in quality management (Figure 3.4). It is an iterative, four-stage approach for continually improving processes, products or services, and for resolving any identified issues. It involves systematically developing and testing possible solutions to a problem or issue, assessing their results, and implementing the ones that have been shown to work, followed by ongoing monitoring for continuous improvement of the system.

This practical PDCA framework and structure for identifying improvement opportunities and evaluating them objectively can be applied to all haemovigilance activities, both in implementation of a new system and in ongoing quality improvement activities, so that reporting results in tangible improvements in transfusion and donor safety.

Besides the PDCA approach, alternative continuous improvement approaches can be used to implement and refine haemovigilance systems.

**Fig. 3.1 The Deming cycle: Plan, Do, Check, Act**

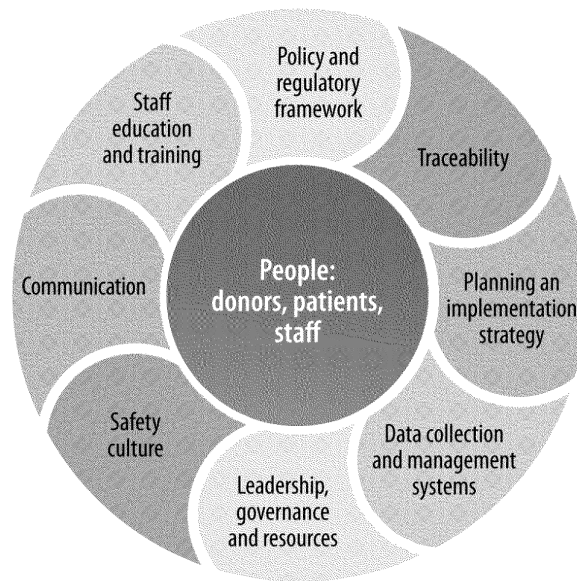
Continuous improvement can be achieved through repeated application of this quality cycle, as shown in Figure 3.2.

**Fig. 3.2 Applying the Deming cycle to achieve continuous improvement**



The building blocks for a haemovigilance system are shown in Figure 3.3, while the various components are described in the following paragraphs

**Fig. 3.3 Building blocks for a haemovigilance system**



### **Policy and regulatory framework**

National policy support and an associated regulatory framework for haemovigilance are important, and these should be documented in the national blood policy (Box 3.1). If such a commitment is not immediately available, it is still possible for haemovigilance to be initiated by any committed party (for example, a hospital or blood establishment, or a scientific or professional society) with a view to obtaining broader policy and regulatory support in the future

#### **Box 3.1 Policy and regulatory framework**

A national haemovigilance policy should define the principles, aims, and objectives; the responsibilities and responsible entities; and the resources, tasks, and tools.

The responsible national authority or equivalent should consider the following steps:

- define a framework for the haemovigilance system and its stakeholders, based on the national blood system and national blood policy (if available);

- include haemovigilance as a requirement of accreditation, licensing and inspection of blood establishments and hospitals.



## Traceability

Bidirectional traceability – the link from donor to recipient and vice versa – is fundamental for establishment of a haemovigilance system (Box 3.2).

### Box 3.2 Traceability

Traceability must be ensured “from vein to vein”.

Blood establishments must:

- assign unique identifiers to each donation event and each component;
- maintain processing and testing records;
- retain data linking a particular component to the donor and collection (date);
- for each donation or component, record details of the transfusing facility to which it was distributed, or its disposition (for example, damaged, discarded, outdated).

Hospitals must:

- record and retain the details of components issued and transfused, including patient information;
- retain records of components taken out of stock (for example, on expiry) and discarded.

Traceability enables investigations to be conducted for routine audit and when things go wrong – for example, rechecking the donor’s testing results after a report of suspected transfusion-transmissible infectious disease, or investigating a suspected recipient transfusion reaction.

## Planning an implementation strategy

In planning or designing a haemovigilance system (Box 3.3), the plan should include logical and realistic short-, medium- and long-term strategies, based on a stepwise approach. In order to develop these strategies, a detailed assessment of the existing haemovigilance situation in the country is helpful

Ideally, such an assessment should:

- have national coverage;
- include all segments of the blood chain (vein to vein);
- identify any existing elements useful for haemovigilance;
- detect important gaps and obstacles for implementation of a haemovigilance system (gap analysis);
- consider likely future developments in the country



### Box 3.3 Planning a haemovigilance implementation strategy

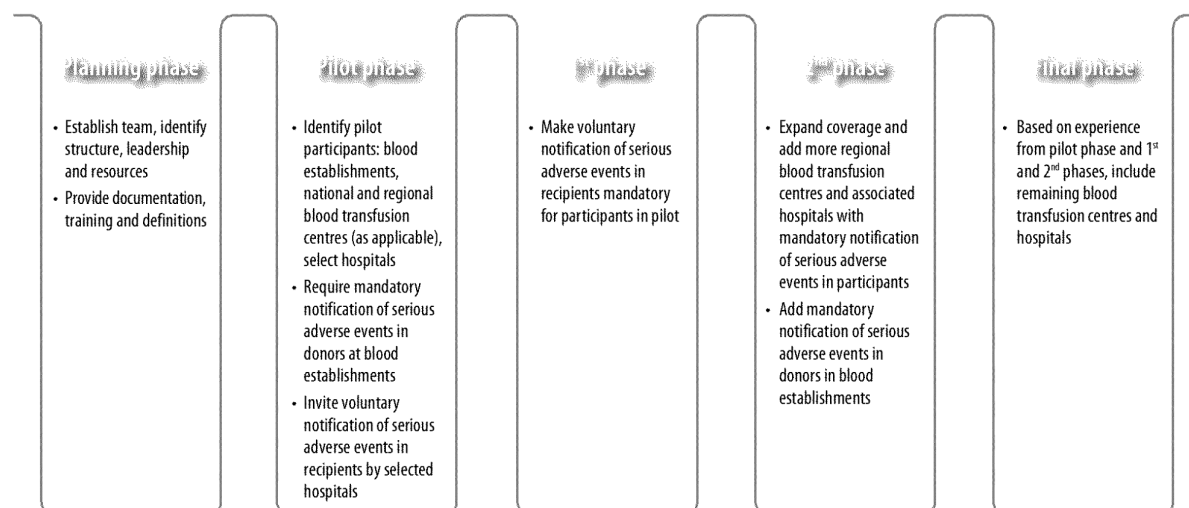
When planning a haemovigilance system, consider the following aspects:

- the architecture of the blood transfusion chain in the country and any existing haemovigilance activities, including national, regional, local and institutional participants and arrangements;
- initial and ultimate scope (covering transfusion recipients, blood donors, blood components, processes in the blood chain);
- oversight and governance responsibilities;
- existing and potential resources, including staffing and funding;
- education and training needs and resources;
- planned initial and ultimate scope (covering transfusion recipients, blood donors, blood components, processes in the blood chain);
- whether the system will include voluntary or mandatory participation;
- mechanisms for reporting and notification of adverse events;
- use of standard adverse event definitions, severity grading, and imputability scaling, as well as type and frequency of reporting;
- data resources and management (including data capture and data confidentiality);
- communications needs and strategy;
- other relevant local considerations.

The organizational implementation plan and timeline with milestones should be established. It should reflect a sequential and stepwise approach and may include, for example, a pilot phase and subsequent phases, as appropriate. An example plan with a possible roadmap is outlined in Figure 3.4.

Box 3.4 summarizes the key initial steps for implementing haemovigilance in hospitals and blood establishments, while Box 3.5 highlights a few suggestions that may assist smooth implementation of a haemovigilance system.

**Fig. 3.4 Example of a high-level organizational and implementation plan**



*Note:* The figure above is an example of the multiphasic approach and that, irrespective of scale, the steps are similar.



### Box 3.4 Implementation: initial steps

Within the context of a national policy (if one is in place, or as a stand-alone activity where necessary), hospitals and blood establishments can start by implementing the following measures (for example as a pilot project) with the objective of progressively establishing a national haemovigilance system.

#### At the hospital:

establish a hospital transfusion committee or equivalent as a forum to:

- provide governance oversight of transfusion in the hospital;
- review policies and procedures, audit data, and education and training related to haemovigilance in the hospital;
- review severe and other significant transfusion reactions and adverse events;
- facilitate communication between the hospital and the blood establishment (for example, for any transfusion-related adverse reaction when the root cause is related to the blood component or to activities in the blood supply system);

assign responsibilities and resources for haemovigilance in the hospital;

identify a responsible person for haemovigilance reporting to senior management, as part of the quality system;

educate all relevant staff on the importance of good bedside transfusion practice, including positive identification of blood components and intended recipients, correct labelling procedures for blood samples, and early recognition of adverse events;

identify necessary resources for haemovigilance operations at the hospital level, such as:

- staff (for example, quality manager, haemovigilance officer or transfusion nurse with dedicated responsibility and allocated time for these activities);
- equipment and tools, including documented procedures;

incorporate haemovigilance into quality systems, including risk management and reporting systems;

establish a reporting system for transfusion-related adverse events (including reporting forms, use of standardized definitions, reporting hierarchy and follow-up) or adapt or integrate with existing systems, followed by effective investigation activity;

integrate reporting of transfusion-related adverse events (transfusion vigilance system) into the patient's medical record;

use the complete quality cycle (plan, do, check, act) in haemovigilance activities;

monitor follow-up on corrective and preventive actions triggered by the haemovigilance system;

arrange for performance assessment and subsequent improvement of haemovigilance through regular management review.

#### At the blood establishment:

assign responsibility for haemovigilance in the blood establishment (for example, to a quality manager);

educate all relevant staff on the importance of good donor care, including pre-donation health screening, and identification, early recognition and reporting of adverse events and follow-up of post-donation information;

ensure that there is a blood donor counselling programme and follow-up system for donation reactions;

ensure effective communication channels between blood establishments, hospitals, and other consignees to deal rapidly with risks arising from donation or transfusion (adverse events when the root problem is related to the blood component or to activities in the blood supply system);

integrate reports of donation reactions (donor vigilance system) into the applicable blood establishment report (for example, annual activity report), so that haemovigilance becomes integrated into the quality system;

ensure that the complete quality cycle is embedded in haemovigilance (plan, do, check, act);

ensure that proper follow-up on corrective and preventive actions triggered by the haemovigilance system is in place;

arrange for performance assessment and subsequent improvement of haemovigilance through regular top management reviews.





**Box 3.5 Tips for smooth and effective implementation**

The following may be helpful:

- Before piloting a haemovigilance activity, consider what documents, staff training and communication will be required.
- Start with small-scale planning and testing of each new activity – for example, consider trying it out in one department or one hospital before expanding in scale or scope.
- Implement iterative changes to test a range of variables.
- Document every step, including seeking feedback from staff and other stakeholders on what went well and what did not.
- Check that the actions have been carried out as planned and whether they have achieved the desired goals and expected results, and assess the differences (compare “plan” and “do”).
- When problems occur, identify their causes, adapt the plan and check again before final implementation.
- Consider culture and environmental concerns: staff, patients and management may have anxieties or fears about reporting unsafe practices, errors or adverse events, so consider how to positively frame and communicate important messages for all stakeholders and engage them in all aspects of developing, implementing and improving the system.

**Data collection and management systems**

Haemovigilance requires collection, analysis and interpretation of key data (or core information). The data elements should be collected in conformity with standardized internationally harmonized definitions. Care should be taken in the design of the data collection system to ensure that it is readily accessible, simple to use, and captures data in a consistent and accurate manner. These data should be collated into a structured and secure database. Analysis and evaluation of data leads to improvement of quality and safety through corrective and preventive actions based on recommendations and instructions, investigation and research, and reports and feedback.

**Leadership, governance and resources**

Within the context of a national policy (if one is in place or as a stand-alone activity), hospitals and blood establishments should identify a haemovigilance lead person to be responsible for implementation of the haemovigilance system locally, establish lines of governance and communication, and allocate financial and human resources (staff with allocated time and responsibility, information technology resources). Local teams should be established to record, report, investigate and analyse adverse event data related to blood donation and transfusion. Leaders should facilitate and work collaboratively with all key stakeholders to bring about sustainable and tangible improvements in patient safety.

**Safety culture**

Reporting patient safety incidents, augmented by an open learning culture that supports incident reporting, is a key element in upholding health and safety in the workplace. The aim of any haemovigilance scheme is to help reduce incidents that result in patient harm by sharing the learning from reported incidents. This needs a workplace culture that supports reporting, deals with people in a just way, and acknowledges that learning from reported incidents can contribute to implementation of system changes to improve patient safety. Leaders should move away from a culture that deals with errors punitively. Within a just culture, staff encourage each other to see errors as events and those events as opportunities to learn, which in turn will improve understanding while encouraging one another to be honest in disclosure without fear of retribution.



## Communication

Clear channels of communication between reporters, haemovigilance experts and all key stakeholders must be established for an effective haemovigilance system. This will promote timely communication, encourage appropriate responses, and facilitate urgent actions that may need to be taken based on the reports received. All communication should be documented and made accessible to authorized staff. Learning from haemovigilance reports and safety messages can be disseminated to all staff involved in transfusion in several ways, as indicated in Box 3.6. Consideration should be given to what information needs to be communicated, with whom, when and how. Some haemovigilance services provide printed copies of these materials, but electronic (online) materials are usually fast and relatively inexpensive to develop and can reach a wide audience quickly.

### Box 3.6 Dissemination of findings and recommendations

Successful and effective methods to disseminate findings and recommendations include:

- newsletters
- annual or targeted reports (for example, the Serious Hazards of Transfusion annual reports (5))
- interactive meetings
- webinars
- video clips and podcasts
- case studies
- posters and presentations
- peer review publications

## Staff education and training

All staff involved in the transfusion chain must be trained for their tasks and responsibilities and have access to educational programmes on haemovigilance. Initial and refresher training should be provided and recorded in staff training records.

Educational resources on haemovigilance, such as workshops and training materials, may be developed and delivered locally by regulatory authorities, hospitals and blood establishments. Many others are freely available through websites of established national haemovigilance systems and professional societies. A compilation of available resources is available as part of this guide on the ISBT website and Chapter 4 describes how to access these resources.





Experts in blood safety and surveillance assembled existing resources from around the world to assist WHO Member States and those concerned with blood safety in the development and improvement of haemovigilance processes and systems. These are described below and include educational materials in written, visual presentation, or video format, as well as templates that can serve as examples of resources specific to low- and middle-income countries. An effort has been made to acquire source document resources in English, French and Spanish. These materials are hosted on the website of the International Society of Blood Transfusion (ISBT), in partnership with WHO, and will be maintained by the ISBT Working Party on Haemovigilance. These materials are owned by their creators and may change over time; they are presented as a resource for your use.

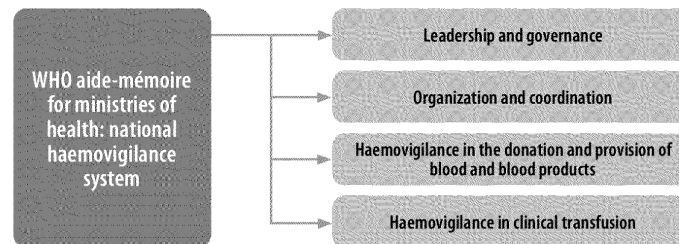
Materials in other WHO languages will be made available as they are identified. Additional materials can be submitted to the ISBT Working Party on Haemovigilance for consideration as a resource.

## 4.1 Educational materials and resources

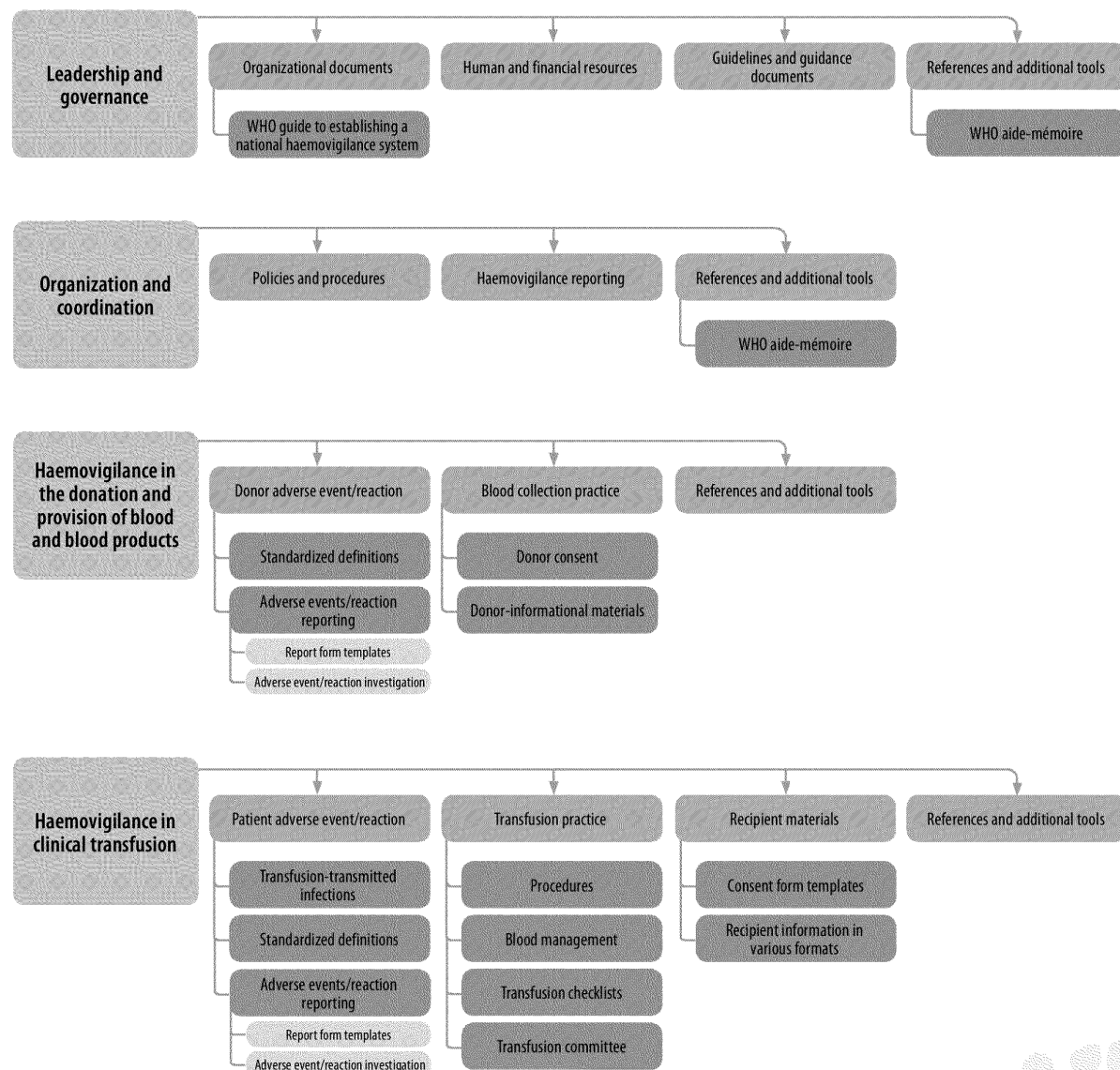
The materials are classified into categories and subcategories that align with the WHO aide-mémoire on national haemovigilance systems and are available publicly through the websites of the International Society of Blood Transfusion Working Party on Haemovigilance (<https://www.isbtweb.org/working-parties/haemovigilance>) and the WHO Notify Library (<https://www.notifylibrary.org/content/educational-materials>).

The structure of the WHO aide-mémoire is illustrated in Figures 4.1 and 4.2. The ISBT resource directory structure follows this organization, and the tools and resources described in this document can be found within directories with these names. Brief introductory information is found in short Word files in each section, along with materials and references to videos and podcasts available elsewhere.

**Fig. 4.1 High-level structure of haemovigilance tools and documents using the internal document structure of the WHO aide-mémoire**



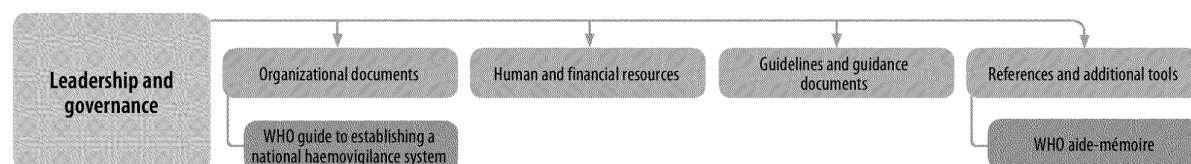
**Fig. 4.2 Full directory structure of the compendium of haemovigilance tools and documents using the internal document structure of the WHO aide-mémoire**





Selected categories of tools and resources are briefly described following the figures where they are introduced (Figures 4.3 to 4.6). The tools and resources themselves are to be found in the directories bearing the category name.

**Fig. 4.3 Category 1: Leadership and governance**



### Organizational documents

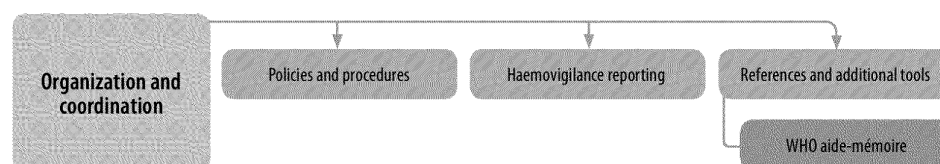
High-level organizational documents define haemovigilance for each country and describe the mission, vision, goals and responsibilities for each part of the national haemovigilance structure

### Human and financial resources

Appropriate and sufficient human and financial resources are essential to the implementation and operation of a national haemovigilance system. Tools and resources are provided that can assist in the identification and justification of these resources. Some of these include:

- writing an effective business case to support funding for haemovigilance efforts;
- conducting a strengths, weaknesses, opportunities and threats (SWOT) analysis, which can be used to appraise options and to assist in decision-making;
- using driver diagrams to identify areas to improve quality and provision of services

**Fig. 4.4 Category 2: Organization and coordination**



### Policies and procedures

**Policies.** Haemovigilance systems must establish a blood safety surveillance policy to be followed by blood establishments and transfusion services. Example resources for these are available from WHO in the information sheet for national health authorities on blood transfusions safety. Other resources are available in the WHO guide to establishing a national haemovigilance system, and can be found in this directory

**Procedures.** Each haemovigilance system must develop procedures that include information for blood establishments and transfusion services on what information to report to the national system. Procedures should be established for how to report, the reporting forms required, where to report, and how often and when to report adverse events or summaries thereof



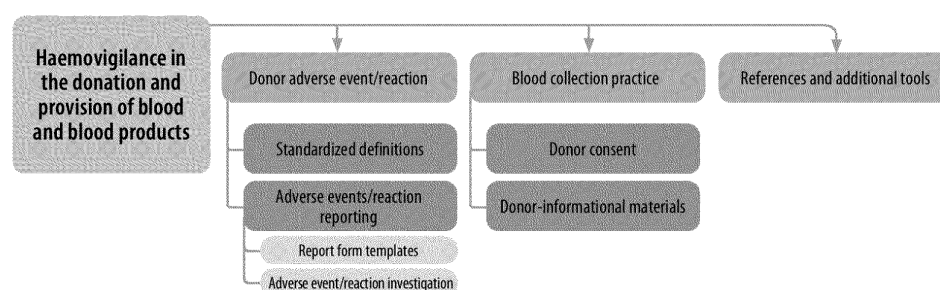
### Haemovigilance reporting: examples

Haemovigilance systems should endeavour to prepare an annual haemovigilance report. These reports can be quite simple in the early stages of system development and, over the years, grow to be complex, with recommendations for practice improvements. Included in the resources are publicly available sample reports from haemovigilance systems, both national and regional, in English, French and Spanish.

### References

WHO aide-mémoire

**Fig. 4.5 Category 3: Haemovigilance in the donation and provision of blood and blood products**



### Donor adverse events

The essence of donor haemovigilance is the recognition, management and prevention of donor adverse events. It is essential that blood collection staff are trained to promptly recognize donor reactions and to take immediate action to prevent progression of symptoms and to treat the donor.

**Standardized definitions.** Consistent application of adverse event definitions is essential to the practice of vigilance in any domain. The International Society for Blood Transfusion (ISBT), the International Haemovigilance Network (IHN), the Association for the Advancement of Blood and Biotherapies (AABB), and other groups have collaborated to develop and validate consensus definitions for blood donor reactions, adverse transfusion reactions, donor and patient reaction severity and imputability. Haemovigilance systems should begin by using these defined and tested definitions.

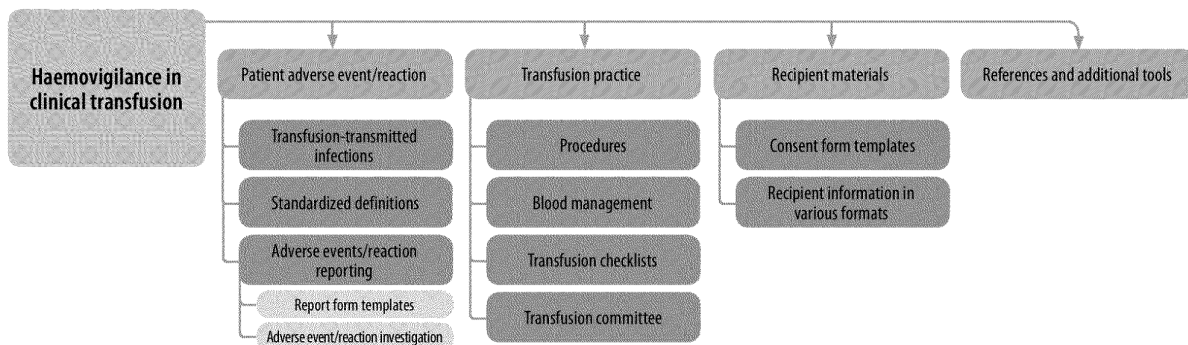
### Blood collection practice

Good blood collection practices minimize reactions to donation based on eligibility criteria (to prevent donors with underlying conditions from donating) and phlebotomy practices. At the same time, the recipient is protected from receiving blood from potentially infected donors or blood that is collected in such a way that it can be contaminated during collection and subsequent processing.

**Donor consent.** Informed consent is a pillar of best practice for any medical intervention, including for blood donation. Informed consent is a dynamic event involving more than a signature on a form, and includes ensuring that the subject (in this case, the blood donor) understands the purpose, risks, and benefits of, and alternatives to, a given procedure. Information related to a procedure can be provided in any number of ways, including through printed materials, discussions and audio-visual media. Documents provided include consent forms that can serve as templates and model informational materials.

**Donor information materials.** After blood donation, blood donors should contact the blood establishment if they develop symptoms of concern (for example, a fever, sore throat or other features that may suggest an infection) or experience a post-donation reaction. Included here are example materials for blood establishments to inform donors of when and how to contact them, should one of these events occur

**Fig. 4.6 Category 4: haemovigilance in clinical transfusion**



#### **Patient adverse events and transfusion reactions**

The essence of patient haemovigilance is the recognition, management and prevention of adverse transfusion reactions. It is essential that staff performing transfusions are trained to promptly recognize transfusion reactions and to take immediate action to prevent progression of symptoms and to treat the patient. The ultimate challenge of haemovigilance is to identify risks in order to prevent reactions.

**Adverse events/reaction reporting.** Reporting requirements may vary depending on the national haemovigilance system. Some systems require reporting of all adverse transfusion reactions, some require reporting only of serious reactions, some only of fatalities. Each system must decide the appropriate reporting threshold and their capacity to receive reports. If the central reporting office does not have the capacity to process and analyse all reports, then appropriate adjustments should be made – for example, only reporting serious adverse events.

– **Report form templates.** Properly designed adverse event and reaction report forms can assist in the recognition and classification of events and may be the first step in providing data to the haemovigilance surveillance programme. Transfusion reaction forms should include sufficient information to classify transfusion reactions, including recipient demographics (age, gender, underlying medical conditions, relevant medications) and implicated components (volumes infused, signs and symptoms, pertinent laboratory results, fluid balance, vital signs, radiographic examination reports and treatment). Forms relating to adverse events should capture the nature of the error or event, systemic factors that contributed to the event and the results of local incident investigations. Many templates and forms are available as part of the WHO guide to establishing a national haemovigilance system.

**Adverse event investigation.** The investigation of adverse events is critical to ensuring patient safety, preventing further harm, and maintaining a high-quality transfusion environment. The results of these investigations should

be turned into educational opportunities (without blame) to inform staff of potential risks, to improve practice, and to lead to the development of safer systems. Prevention of future adverse events should be the goal of all investigations. There are many resources available for investigation, including root cause analysis and the “five whys” (6).

### Transfusion practice

**Procedures.** Establishing good-quality transfusion practice is essential to effective blood transfusion. Clinicians and other staff involved in the provision of blood to a patient should be well trained. In this section, materials are noted for educating all professionals who are involved in clinical transfusion in important safety areas. Staff should be familiar with identification and management of transfusion reactions as well as adverse transfusion events, including transfusion errors and near misses. Staff should be able to lead or participate in investigating incidents, applying human factor principles, identifying systemic factors that result in errors, and taking appropriate, effective preventive actions. These include ensuring that the correct blood unit is being transfused to the correct patient, as well as monitoring for systemic factors that lead to errors and incidents. These must be remedied through changes to practice, policies, or procedures in order to prevent future errors and adverse events of the same nature.

**Patient blood management.** Patient blood management is based on the premise of providing the right component to the right patient in the right dose at the right time for the right reason. Included in blood management is the concept that sometimes the best transfusion is the one *not* given. Principles of patient blood management guide transfusing physicians in selecting the best component to treat the patient. This protects the patient as well as the blood supply, since it reduces wastage of precious resources.

**Hospital transfusion committee.** A peer review committee that addresses hospital transfusion policies and practices and that reviews reported reactions is a key component of recipient haemovigilance. The composition and functioning of the committee should be defined and should have the support of the hospital executive team.

### Recipient materials

**Consent form templates.** Informed consent is a pillar of ethical practice for any medical intervention, including for blood transfusion to a patient. Informed consent is a dynamic event involving more than a signature on a form, and includes ensuring that the patient understands the purpose, risks and benefits of, and alternatives to, a given procedure. Information related to a procedure can be provided in any number of ways, including through printed materials, discussions and audio-visual media.

**Recipient information in various formats.** Recipient education is an essential component of recipient informed consent. Patient educational materials can be provided in print documents, verbally, or via various media (for example, videos). Providing information to patients prior to a transfusion can enlist them as agents in recognizing their own reactions. Provision of post-transfusion information, especially for outpatient transfusion, is important to enable patients to recognize symptoms that should prompt them to alert their health care provider and take steps to protect themselves.

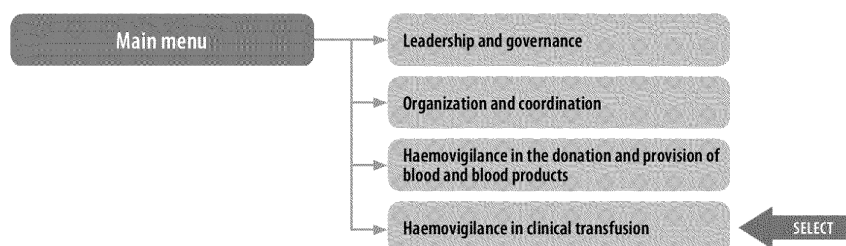




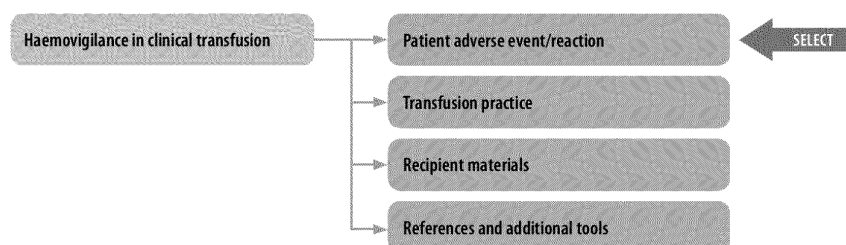
## 4.2 How to locate tools and resources described in this document

As an example for how to locate resources, the following series of steps may be taken. If you need to develop a transfusion reaction form, examples and templates can be found by selecting the appropriatedirectories within the ISBT resource (<https://www.isbtweb.org/resources/resource-library-search/who-hv-tool.html>).

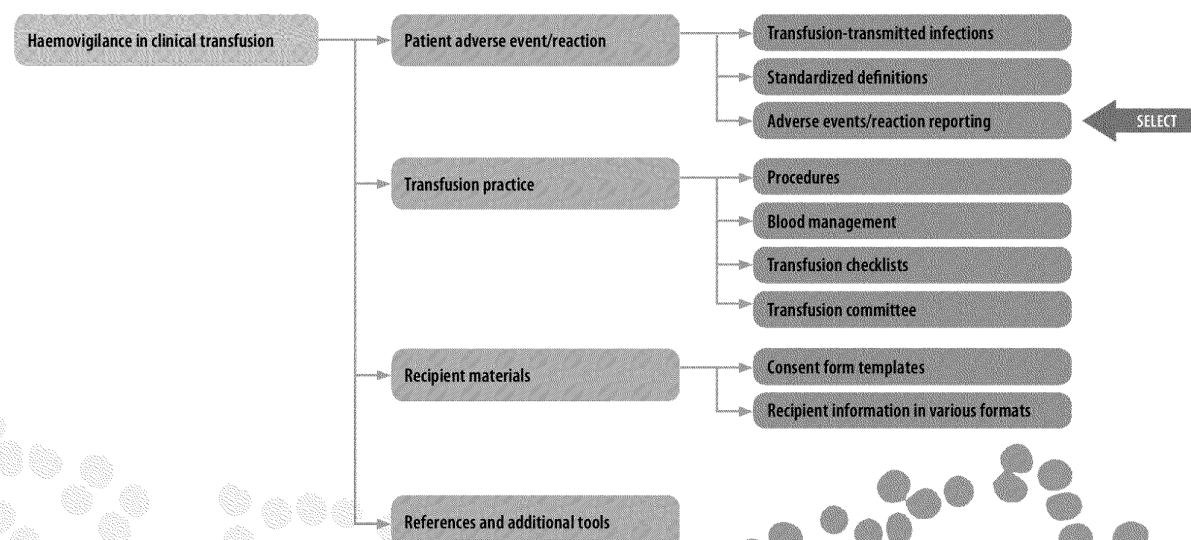
1. From the main directory, select “Haemovigilance in clinical transfusion”



2. The “Haemovigilance in clinical transfusion” directory will appear; from there, select “Patient adverse event/reaction.”

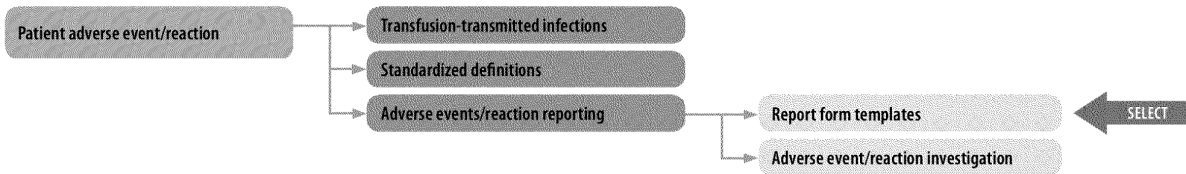


3. The “Patient adverse event/reaction” directory will appear; from there, select “Adverse events/reaction reporting”

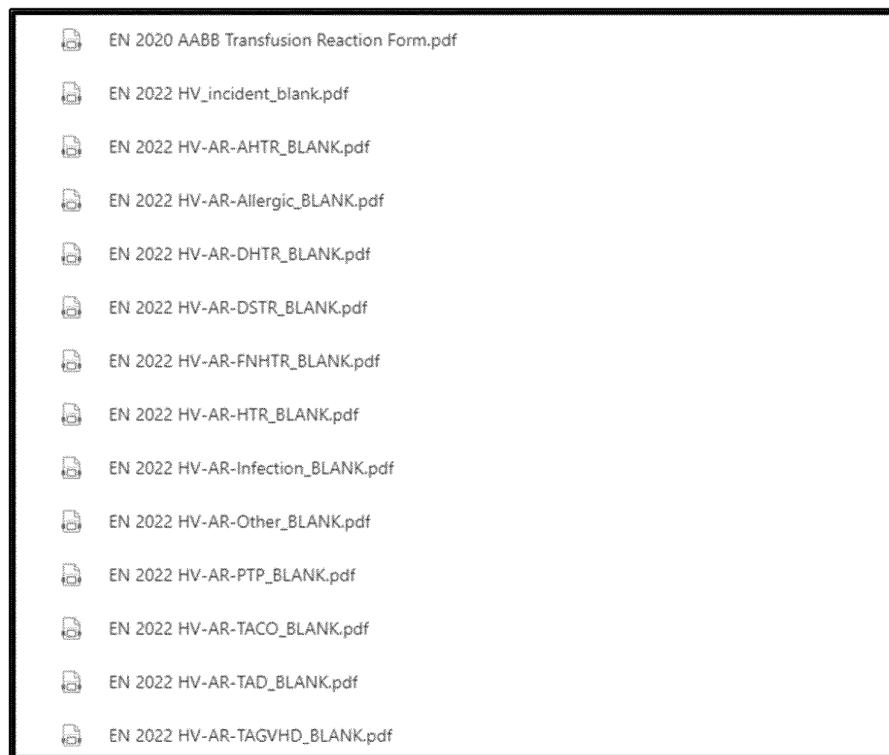




4. The “Adverse events/reactionreporting” directory will appear; from there, select “Report form templates.” A list of the example forms and templates will be in the final directory. Select as many as are needed to find a template that can be modified to meet the current need



5. The following publicly available report form templates are among those available for download



### 4.3 Example haemovigilance tool and its use: Plan, Do, Check, Act (PDCA)

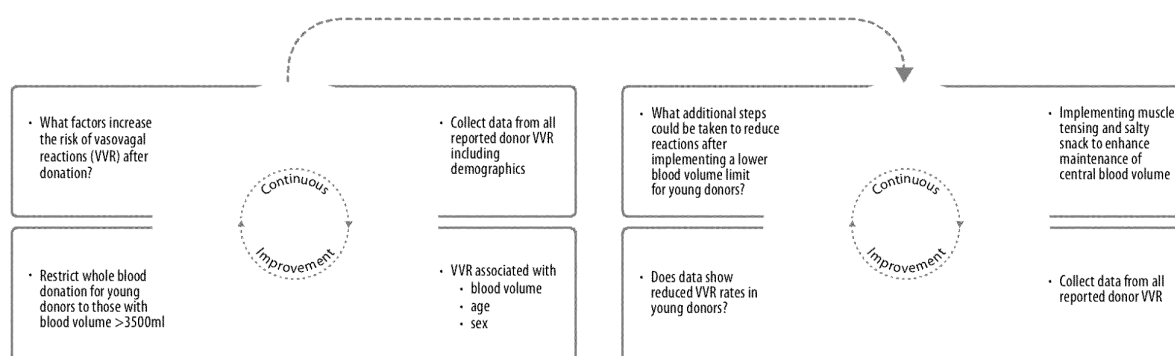
There are many tools that can be used to address the adverse findings from a haemovigilance system. One of these has been described above: the PDCA (Plan, Do, Check, Act), or Deming cycle of continuous quality improvement

#### 4.3.1 PDCA cycle of continuous improvement

An illustrative example of such a quality improvement cycle in donor haemovigilance is the mitigation of donor vasovagal reactions (Figure 4.7). With the exception of small bruises, vasovagal reactions (VVRs) are the most common

type of donor adverse reaction. Collection and analysis of donor reaction data suggested that, especially in young donors, VVR rates increased dramatically as the blood volume of the donor decreased. Some centres in the United States of America implemented restrictions on collection of blood from such low-blood-volume donors and demonstrated improvement in VVR rates (7). Subsequent cycles of data collection demonstrated that VVRs could be further reduced by encouraging muscle tensing and oral salt and fluid intake during and after blood donation. Thus, successive cycles of donor haemovigilance sequentially reduced donor VVRs. A useful checklist for conducting PDCA is presented in Box 4.1.

**Fig. 4.7 Sequential cycles of PDCA to mitigate donor VVRs**



#### Box 4.1 Example PDCA checklist

	YES	NO
<b>PLAN</b>		
Has any issue or opportunity related to the haemovigilance pathway been identified?		
Has this issue been validated by data or confirmed by consensus of all key stakeholders?		
Have all key stakeholders been invited to participate?		
Have all declarations of interest been captured and plans to manage potential conflicts put in place?		
Has an appropriate time been established so that all the team members can participate in the meetings?		
Has the team created a goal statement of what is aimed to be achieved?		
Does the goal pass the SMART test (specific, measurable, actionable, realistic, timely)?		
Has a baseline measurement of the problem or issue been clearly defined?		
Has a process for baseline measurement been defined: what is to be measured, by whom, and how often?		
Do those collecting the measurements know exactly how and when they are to undertake the task?		
Have all potential challenges been considered and identified (for example, staff development, patients, procedures, resources)?		
Are the challenges written in the form of problem statements (for example, "The equipment needed is not always where it should be")?		
Have the current steps in the process or pathway been identified to determine which, if any, are contributing to the problem?		
Have the key causes been selected, validated with data, and then confirmed with the staff that are knowledgeable of the process or impacted by the problem?		
Has an optimal solution (step-by-step system of changes) been identified that would remove or minimize the challenges preventing achievement of the goal?		
Has the proposed process been evaluated for all possible weaknesses? Have the supportive changes to the new process been identified (for example, staffing, equipment, resources, training)?		
Is the benefit of the solution worth the cost or effort of implementing the new process? How has this been determined?		

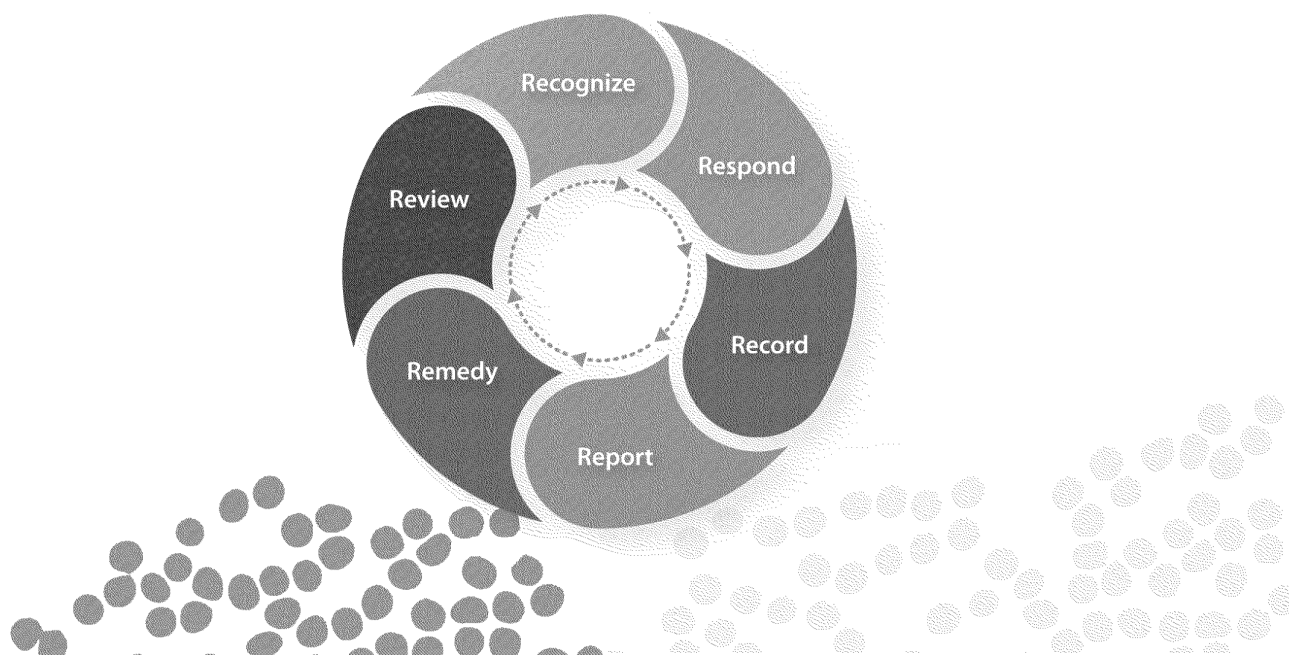
Has the proposed solution been validated with those knowledgeable of the process and those who are impacted by the problem (including leaders) who are not on the team?		
Is there a plan and schedule to make the implementation of the solution or change run smoothly (including staffing, equipment resources and training)?		
Have the changes, as necessary, been made to forms, procedures, facility and training?		
Has the period for testing the proposed solution been identified and communicated?		
Has the plan for measuring been created, including what is to be measured, by whom, how often, and how progress is to be communicated?		
Has the implementation plan been shared with the rest of the staff to gain their input and reservations?		
<b>DO</b>		
Are you testing the potential solution or change, if feasible?		
Are you following your measurement plan?		
Are you making refinements to the solution as needed?		
Has the final solution or change been documented and implemented?		
Have all the key stakeholders and all those who are likely to be impacted by this plan been informed and feedback sought?		
<b>CHECK</b>		
Have you analysed and compared your data to your prediction?		
Have all results been documented accurately and disseminated to all key stakeholders?		
<b>ACT</b>		
Have the learnings from this improvement cycle been summarized?		
Have all the changes needed been incorporated into all relevant policies and procedures?		
Is monitoring in place to ensure that changes implemented are sustained and continue to have the impact as planned?		

*Note:* Users are encouraged to review the list and draft a checklist that is applicable to their unique local situation.

### 4.3.2 Application of the six Rs for continuous improvement

Figure 4.8 summarizes the “six Rs” of the haemovigilance cycle (see also section 1.4 above)

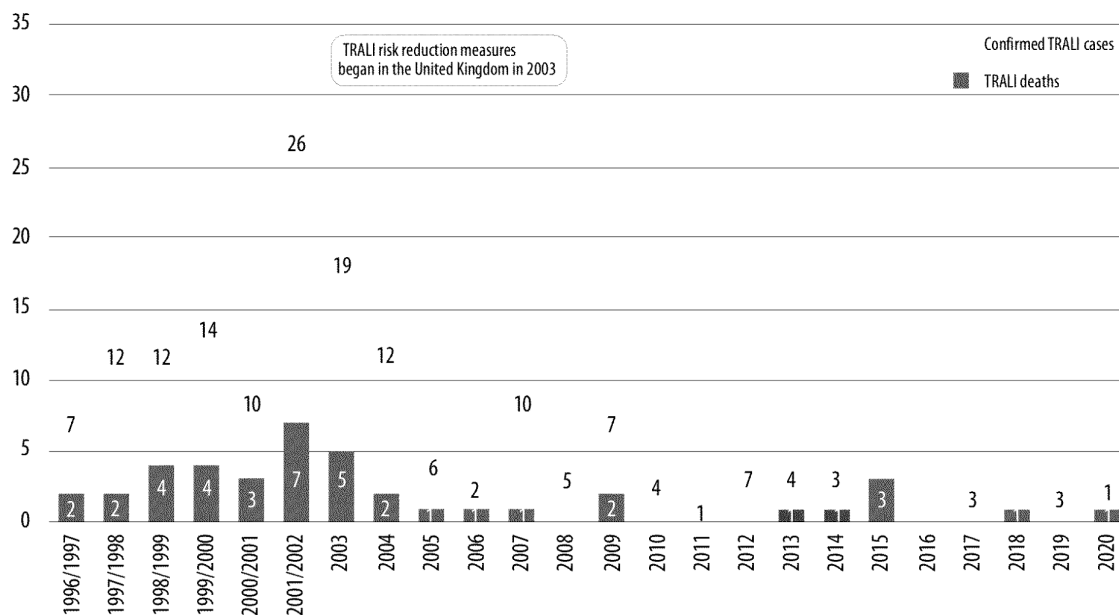
**Fig. 4.8 Haemovigilance cycle: the six Rs**





An illustrative example of a clinical haemovigilance cycle is the story of transfusion-related acute lung injury (TRALI) (Figure 4.9). The Serious Hazards of Transfusion (SHOT) haemovigilance programme helped identify that TRALI was most common after transfusion of plasma-rich blood components such as fresh frozen plasma or platelets (8,9) (**Recognize**). Data were analysed, common themes were recorded, and potential mitigating actions identified, introduced and reported. Upon tracing these blood products back to specific blood donors, it was found that the implicated donors were usually females who had been HLA/HNA<sup>2</sup> sensitized during pregnancy (**Respond, Record, Report**). This led the United Kingdom blood services (and many blood services worldwide) to switch to using male donors for producing fresh frozen plasma, resuspending pooled platelets in male plasma or in platelet additive solution and screening female apheresis platelet donors for leucocyte antibodies (**Remedy**). SHOT has subsequently documented a significant reduction in both reported cases of and mortality from TRALI (**Review**). It is only through ongoing haemovigilance that this risk mitigation measure was identified and implemented, and the effectiveness of this has been demonstrated.

**Fig. 4.9 TRALI cases reported to SHOT 1996–2020**



## 4.4 Documentation and data capture

Hemovigilance data capture begins with clear and timely documentation of adverse events, including completion of required data elements. The completed documentation should be reported, as required, to haemovigilance systems for data analysis at the appropriate level (local, institutional, national, and international haemovigilance activities). The process and mechanism of data collection may vary between countries and institutions, and frequently reflect the organization and maturity of the haemovigilance system.

Historically, reports of adverse events were entered onto paper forms. Over time, paper forms have given way to electronic data capture. Both mechanisms have advantages and disadvantages. Paper forms are generally simple to complete but require physical copies of the form to be easily accessed; furthermore, as the number of data elements

<sup>2</sup> HLA = human leukocyte antigen; HNA = human neutrophil antigen.



increases, completion becomes time consuming. In addition, to perform data analysis, data elements from paper forms must be entered into an electronic database, a process that is also time consuming and potentially subject to error.

There are several advantages to implementing electronic data capture in haemovigilance systems including data accuracy, streamlining operational processes, bypassing double entry (once onto the paper form and then again into an electronic database) and minimizing the need for physical storage space. Such a system saves on paperwork management time, whilst reducing paper usage and producing less waste. While the initial costs of developing new electronic data capture systems can be high, there are several inexpensive data collection systems available currently. Haemovigilance systems in early stages of development can potentially explore such inexpensive electronic data collecting systems and implement it right from the start.

Box 4.2 provides helpful hints

#### **Box 4.2 Helpful hints**

Start with a minimal data set: when data collection first begins in a new haemovigilance system, there is a tendency to ask for too much information; this can result in low reporting rates, reporting fatigue, and errors or delays in data entry.

Check boxes and predefined options are preferred over “free text” options, to help with the subsequent data analyses.

Choose the system that works for you – there is no single system that suits all situations.

#### **A. Use of mobile apps in haemovigilance**

Smartphones and other mobile devices present an opportunity for national regulatory authorities and haemovigilance centres to collect safety reports directly from health care professionals, donors, patients and the public as a form of electronic data capture. Web-based forms and mobile devices offer a platform for developing real-time haemovigilance systems that can enable near-instantaneous transmission of patient safety information at the point of need, and potentially improve health outcomes.

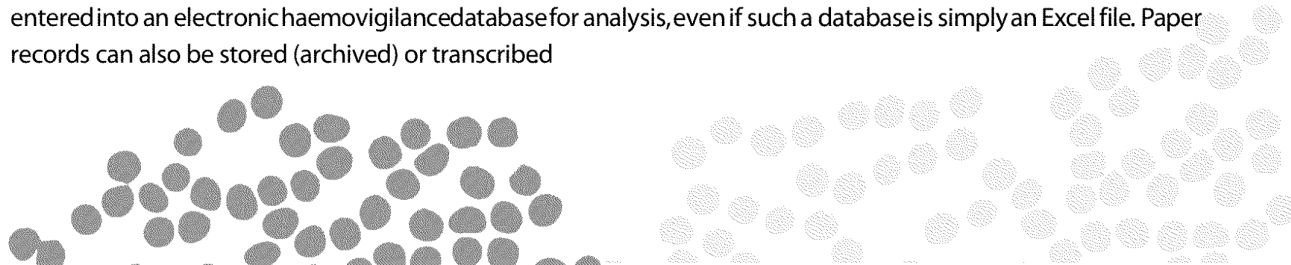
#### **B. Electronic data entry**

Data can be entered directly onto an online form that is emailed centrally or completed on a surveillance website. Typically, more data are requested at this stage of data gathering. Electronic data transfer from one system to another, use of barcodes, and other features help offset the burden of data capture. Advanced databases can be added to the back end, allowing for more robust analysis.

One example of such a system for reporting and managing haemovigilance data is the e-Fit tool used in France. Since the introduction of haemovigilance in 1994, the reporting tools available to the French haemovigilance network have continued to evolve. Initially in paper format and then in a rudimentary electronic application, the reporting of adverse events in recipients has been done since 2004 in a secure electronic application (e-Fit).

#### **C. Paper forms**

While electronic submission is the preferred method, the use of paper records, including those submitted by facsimile/fax or mail, is often the initial method for data capture. Paper-based data collection can be an important step in validating the critical data elements that need to be collected and can provide a record of the data that can later be entered into an electronic haemovigilance database for analysis, even if such a database is simply an Excel file. Paper records can also be stored (archived) or transcribed.



Since paper forms are completed manually, it is important to limit how many data elements are requested. Data capture should focus on demographic data (gender, age or date of birth), while avoiding personalized information as much as possible for confidentiality. Data elements should be well defined and harmonized to international standard definitions and structures, to the extent possible.





A successful haemovigilance system is complex and takes time to develop. Many large successful systems started small, based on the dedication of a few practitioners to improving blood donor and transfused patient safety. Building a business plan that includes results from a preliminary data collection exercise from a pilot programme often helps to engage key stakeholders and champions. The important thing is to get started with a well-defined project that can be reasonably achieved and, in the end, will have a clear set of deliverables that can be measured to demonstrate improved overall blood safety.

The resources identified in this document are located at <https://www.isbtweb.org/resources/resource-library-search/who-hv-tools.html> and are not exhaustive.

WHO, the International Haemovigilance Network ([www.ihn-org.com](http://www.ihn-org.com)), the Notify Library ([www.notifylibrary.org](http://www.notifylibrary.org)), the International Society of Blood Transfusion ([www.isbtweb.org](http://www.isbtweb.org)) and many existing national haemovigilance systems have haemovigilance resources that are regularly updated. Many are freely available for use and adaptation and are available in the peer-reviewed literature. We encourage you to review them and the resources referenced in this document, as they can provide valuable formal guidance for ministries of health, blood establishments, hospitals, and individuals in preparing to establish or improve a national, regional, or local (institutional) haemovigilance system.

The haemovigilance community is full of people and groups willing to share ideas, materials and lessons learned. Please do consider joining professional or scientific groups to become an active member of a committee or working party focused on haemovigilance; this will help connect you to the wider community and provide opportunities for sharing ideas, experiences and resources.



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### Other key resources

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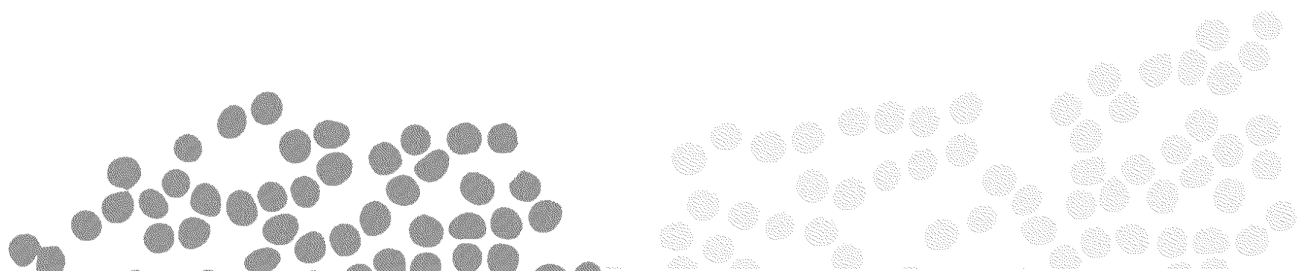
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### *Survey in English*

#### **Haemovigilance survey questionnaire**

The World Health Organization (WHO) has established a working group on “Haemovigilance Tools” as an activity under the Action Framework to Advance Universal Access to Safe, Effective and Quality-Assured Blood Products 2020–2023 (Action Framework).

Under the Action Framework, WHO has prioritized effective blood safety surveillance/haemovigilance supported by comprehensive and accurate data collection systems within one of the six strategic objectives

Towards this objective WHO seeks to develop a guidance document on stepwise development of a national haemovigilance system for use in Member States. The document is intended to build upon the 2016 WHO guidance entitled “A Guide to Establishing a National Haemovigilance System” moving from “what to do” to “how to do it

The WHO working group requests responses to the attached survey to help focus the work of this group. In order to capture a broad range of perspectives, the survey is being distributed concurrently through the WHO Regional Focal Points and the International Society of Blood Transfusion (ISBT) to policy makers, professionals working in the field, and other stakeholders

This survey is distinct from GDBS. The results will remain confidential and will be used solely for development of haemovigilance tools

Kindly provide your responses to this digital survey by 10th January 2021.

#### *Note:*

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 (A guide to establishing a national haemovigilance system, WHO 2016).





## Details of the person/organization submitting the response to the questionnaire

### Country

.....

### Name of the responding/corresponding person

.....

### Organization and designation/position within organization of the responding person

.....

### Contact email

.....

### Contact (telephone) along with the country code

.....

## Organization and management

### 1. Is there an organized haemovigilance system in your country?

☐ YES    ☐ NO

If your answer is **YES** to the Question 1:

#### ***At what level is the data aggregated?***

- ☐ National  
☐ Regional

#### ***Is the government involved?***

- ☐ Yes  
☐ No

#### ***Is reporting...***

- ☐ Voluntary  
☐ Professionally mandated  
☐ Governmentally mandated  
☐ Mixed (e.g. mandated for serious events and voluntary for others)



If your answer is **NO** to the Question 1:

***Is there a national scientific/professional society for blood transfusion in the country?***

☐ Yes

☐ No

***Is there a central point for the co-ordination of blood transfusion policy and activity in the country?***

☐ Yes

☐ No

## Major challenges, constraints and strategies

### ***2. What are the primary challenges and barriers to implementing a Haemovigilance system in your country?***

- ☐ A. Need for dedicated financial provision/financial constraints/limited financial resources
- ☐ B. Need for organizational structure/governing body/central reporting authority
- ☐ C. Need for government oversight
- ☐ D. Need to identify all stakeholders/service providers and bring them common comprehensive system
- ☐ E. Lack of trained personnel
- ☐ F. Unavailability of technical/subject expertise for setting up of haemovigilance system
- ☐ G. Lack of country specific reporting formats and guidance document
- ☐ H. Lack of centralized comprehensive digital data capture system
- ☐ I. Unwillingness to participate /report in Haemovigilance
- ☐ J. Lack of statistical and analytical tool
- ☐ K. Other (please mention)

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### ***3. Please identify the top 3 priority areas for haemovigilance technical support and/or capacity building in your country (tick the box for any (3) of the following):***

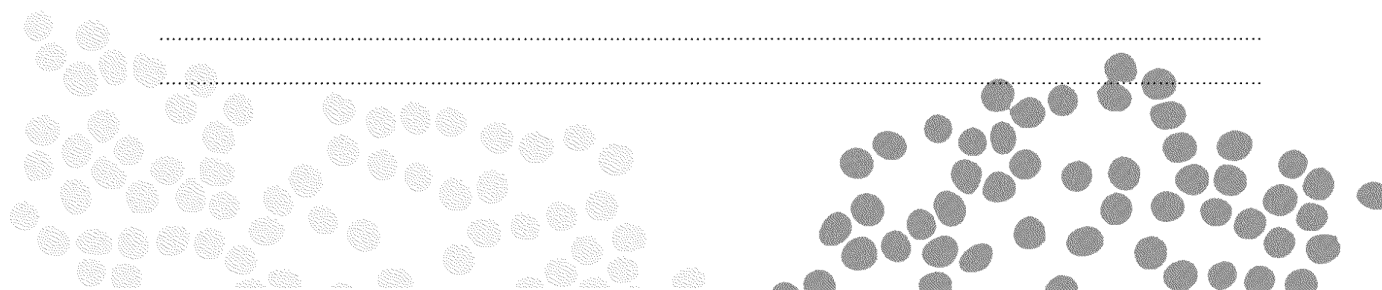
- ☐ A. Financial
- ☐ B. Organizational/administrative
- ☐ C. Legal framework
- ☐ D. Country specific guideline and guidance document creation
- ☐ E. Educational: technical/manpower skill development
- ☐ F. Infrastructural support/technology upgradation
- ☐ G. Networking
- ☐ H. Statistical and analytical tools
- ☐ I. Other (please mention)

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**4. Please identify the top 3 priority tools that would help implement a haemovigilance program in your country (tick the box for any (3) of the following):**

- ☐ A. Standard and validated definitions
- ☐ B. Guidelines/guidance documents
- ☐ C. Educational and training modules
- ☐ D. Certified technical expertise
- ☐ E. Standardized reporting formats
- ☐ F. Data capture system
- ☐ G. Statistical and analytical tool
- ☐ H. Organizational structure for networking
- ☐ I. Other (please mention)

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**5. For your country's three top priority tools, what format would be preferred (respondent can select multiple formats for the 3 selected top priority tools; place tick mark in the table):**

	TOOL		
	Poster	Document	Video
A. Standard and validated definitions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. Guidelines/guidance documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C. Educational and training modules	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D. Certified technical expertise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E. Standardized reporting formats	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F. Data capture system	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G. Statistical and analytical tool	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H. Organizational structure for networking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

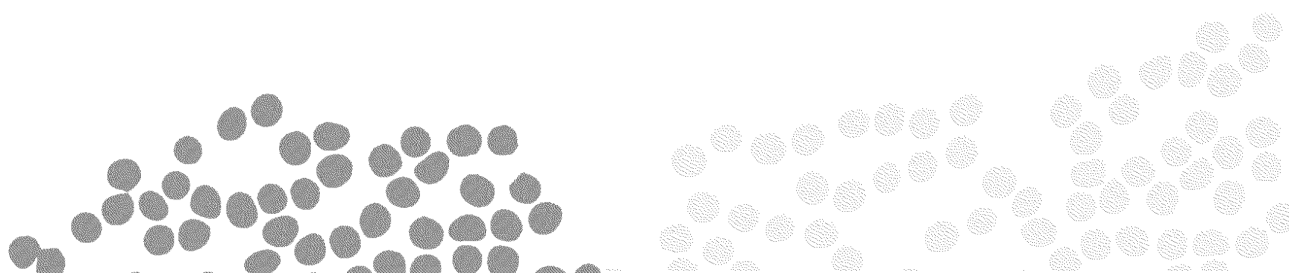
If any other tool and format of the tool is anticipated, please specify

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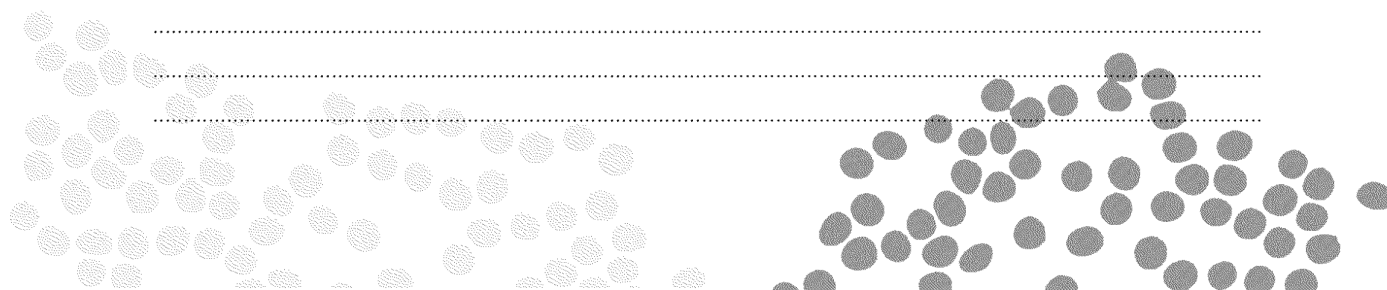
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**7. Please provide the scope of Haemovigilance (if any) in your country:**

☐ YES      ☐ NO (go to 7B)

*a. Do all blood collection centers participate?*

*b. What percentage participate, if any?*



**7B. Does the system include collection of data on recipient-related adverse events/adverse reactions?**

- ☐ YES (go to 7B.a)      ☐ NO (end of the Questionnaire)

If your answer is YES to 7B Optional follow-up questions if data are available:

**a. Do all hospitals participate?**

- ☐ YES (go to 7B.b)      ☐ NO (go to 7B.c)

**b. Has the data of adverse reactions of transfusion been integrated into the hospital information system?**

.....

**c. What percentage participate, if any?**

.....

**d. Please describe/comment on 7A.b:**

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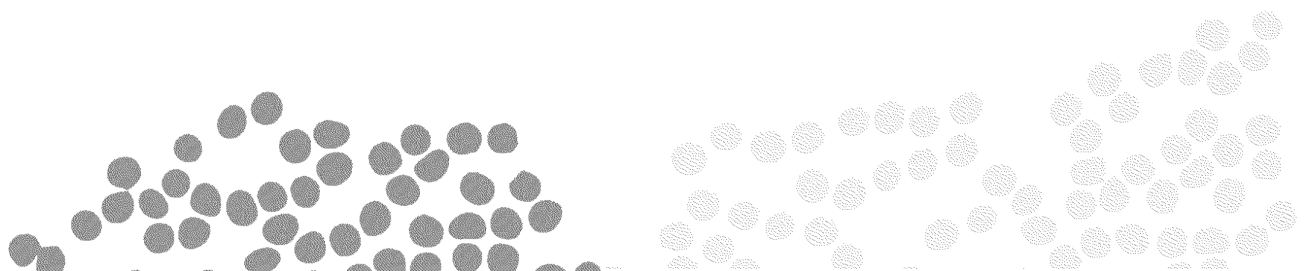
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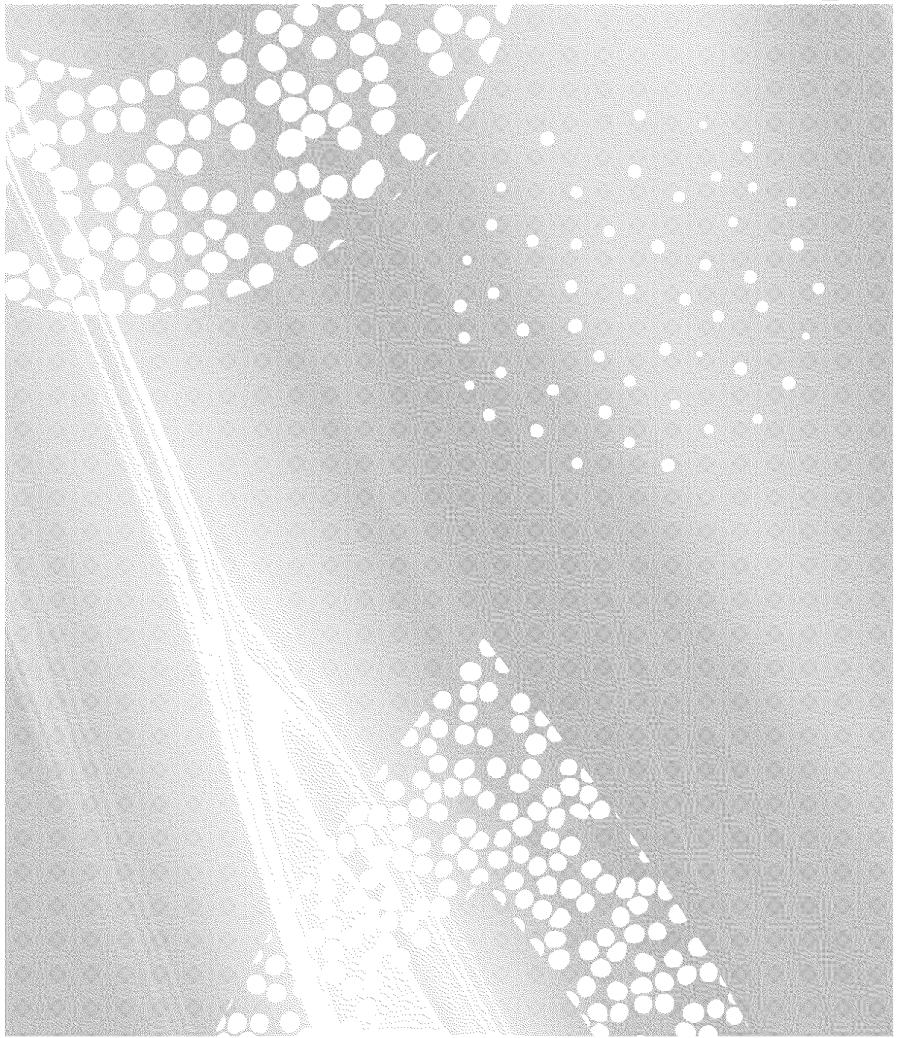
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*Thank you for your contribution!*





## CONTACT

World Health Organization  
 Department of Health Products Policy and Standards  
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