

A guide to establishing a national haemovigilance system



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Preface

The World Health Organization Blood Transfusion Safety programme was established to develop strategies for blood safety and promote them on a global, regional and national basis through advocacy and the provision of technical support to WHO Member States.

WHO recognizes the importance of haemovigilance to identify and prevent occurrence or recurrence of transfusion-related unwanted events, and to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient. Whilst national haemovigilance systems are well established in many countries, there is a lack of effective haemovigilance in many resource-limited settings, and implementation in such settings remains an important and challenging problem.

The primary aim of this document is to support countries where haemovigilance is not already in place in establishing effective national systems for haemovigilance throughout the transfusion chain.

The specific objectives are to provide:

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

Other countries may find the document helpful in strengthening their existing systems.

The intended audience includes the following organizations and institutions:

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

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1. Introduction

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 system problems can drive the introduction of measures to enhance the quality, safety, efficacy and cost-effectiveness of blood and blood products as well as of the donation and transfusion processes.

What is haemovigilance?

Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking actions to prevent their occurrence or recurrence.

Haemovigilance was established in the mid-1990s in response to concerns regarding transfusion-transmitted viral infections. Since then, haemovigilance programmes have drawn attention to the importance of many previously unrecognized and potentially preventable adverse events, including incorrect blood component transfused, transfusion-related acute lung injury and bacterial contamination of platelets. The resulting modifications to transfusion policies, standards and guidelines, and improvements to processes in blood services and transfusion practices in hospitals, have led to improved patient safety.

More recently the scope of haemovigilance has been expanded to include adverse events in blood donors, thus helping to improve safety for the donor as well as the patient.

Haemovigilance should be fully integrated into the quality systems of all institutions involved with the blood and blood products supply chain, including donation, testing, processing, inventory management, storage and distribution, and clinical transfusion, to ensure donor and patient safety at all levels.

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