

WHO events addressing public health priorities

Regional consultation on haemovigilance¹

Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse events and reactions in order to investigate their causes and outcomes, and prevent their occurrence or recurrence. A haemovigilance system is an integral part of quality management in a blood system and is required for the continual improvement of the quality and safety of blood products and the transfusion process. The establishment of a haemovigilance system involves all relevant stakeholders and should be coordinated between the national blood programme under the ministry of health, blood services, hospital clinical units and transfusion laboratories, hospital transfusion committees, professional bodies, public health institutions, regulatory agencies and other stakeholders.

In the World Health Organization (WHO) Eastern Mediterranean Region (EMR), only 10 countries report having protocols for reporting adverse transfusion events and for post-transfusion management of patients (1). WHO and its partners, including the Arab Hemovigilance Network (AHN), International Society of Blood Transfusion (ISBT), International Haemovigilance Network (IHN) and American Association of Blood Banks (AABB) promote the establishment and strengthening of haemovigilance systems in the Region.

In order to strengthen haemovigilance in the Region, the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) convened a regional consultation on haemovigilance from 4 to 5 December,

2016 in Amman, Jordan. The objectives of the consultation were to:

- highlight the importance of national haemovigilance systems for the continual improvement of the quality and safety of blood products and the transfusion process;
- review the status, successes and challenges of establishing and/or strengthening national haemovigilance systems;
- introduce the WHO guide to establishing a national haemovigilance system; and
- develop recommendations and priorities for action for establishing and/or strengthening national haemovigilance systems.

Representatives from Afghanistan, Bahrain, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco,

Pakistan, Palestine, Qatar, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia and United Arab Emirates attended the consultation. Participants also included experts from Islamic Republic of Iran, Luxembourg, Pakistan, Saudi Arabia, Tunisia and United Arab Emirates, and representatives of international and regional organizations including AHN, ISBT, IHN and AABB, as well as staff from WHO headquarters and WHO/EMRO.

Since 1975, WHO has passed a number of resolutions and decisions pertaining to blood safety and haemovigilance. WHO global strategy for the safety and availability of blood transfusion identifies haemovigilance as a cornerstone; however, until recently, haemovigilance has not received adequate attention. Only 79 (out of 175) countries report existence of a national haemovigilance system (2). WHO convened a global consultation on haemovigilance in 2012, which came up with recommendations and priorities for action to establish and strengthen haemovigilance systems as part of overall quality systems in blood transfusion. This led to the development of an aide-memoire and a guidance document on establishing national haemovigilance systems (3).

Country presentations reflected on status haemovigilance at different levels, as follows:

- In Egypt, haemovigilance is not organized at the national level. The quality management system, which is implemented at a narrow scale, includes traceability of blood products.
- In the Islamic Republic of Iran, a national haemovigilance system was established in 2009 and has been expanded to 701 hospitals. Provincial and national offices have been established for donor haemovigilance.
- In Morocco, haemovigilance work was initiated in 1995 and reporting became mandatory in 2005. Currently, the country has a national haemovigilance system under the Ministry of Public Health; however, reporting of reactions has decreased over the years.
- In Pakistan, haemovigilance is a relatively new concept. Regulatory authorities are being strengthened and haemovigilance data (generated from individual large centres) have been presented at regional and international forums.
- In Qatar, haemovigilance work was initiated in early 2016, but not at the national level.

¹ This report is extracted from the Summary report on the Regional Consultation on Haemovigilance, Amman, Jordan, 5–4 December 2016 (http://apps.who.int/iris/bitstream/1/254703/10665/1C_Meet_Rep_2017_EN_19555.pdf, accessed 1 August 2017).

- In Saudi Arabia, haemovigilance work started after the WHO Global Consultation in Dubai 2012 (3). An electronic haemovigilance website was established since 2014, covering all blood centres and hospitals under the Ministry of Health. Reporting is mandatory for all blood centres under the Ministry of Health, but is not anonymous.
- In Tunisia, the regulatory aspects of haemovigilance is well established; however, the notification rate is still low, i.e. below 0.7 adverse events for 1000 units of blood components transfused. The blood programme requires sensitization and awareness of clinicians at a larger scale.
- In the United Arab Emirates, all hospital-based blood banks have reported donor haemovigilance data on a monthly basis since 2011. However, the recipient haemovigilance system is in its infancy and needs a well-structured system for reporting and analysing data.

Participants identified, discussed and agreed on recommendations and priorities for action for the implementation of haemovigilance systems across national blood transfusion services in the Region. These recommendations and priorities for action are directed to blood centres, hospitals, national blood services, ministries of health, international partners and WHO, as well as participants of the regional consultation.

Recommendations

At blood centre and blood service level

1. In the absence of a national haemovigilance programme, implementing a donor vigilance system to ensure adequate donor care.
2. Establishing mechanisms for liaison with hospitals, hospital blood banks, hospital transfusion laboratories and hospital transfusion committees.
3. Integrating haemovigilance into quality management systems.

At hospital level

1. Establishing a system for implementing and monitoring the use of guidelines on appropriate clinical use of blood and blood products.
2. Establishing and maintaining a hospital transfusion committee to develop a system to collect, analyse, use and disseminate data on recipient adverse events.
3. Setting up a mechanism for providing awareness, training and education on haemovigilance and transfusion safety to all appropriate staff.
4. Designating / appointing a haemovigilance officer in hospitals where blood transfusion is performed, with clearly defined responsibilities for safe transfusion practice including haemovigilance.

5. Establishing mechanisms for external liaison with supplying blood centres and blood services, and for internal cooperation with hospital blood banks, transfusion laboratories and transfusion committee(s), with clear channels of communication.

At national level

1. Recognizing that haemovigilance is essential for quality and safety of blood donation and transfusion practice.
2. Including both donor and recipient haemovigilance in the national blood policy.
3. Maintaining a national haemovigilance system covering the entire blood chain including donors, recipients, processes and products.
4. Advocating, guaranteeing and assuring a non-punitive environment during the development and maintenance of a haemovigilance system.
5. Providing necessary and sustainable financial and human resources for effective implementation of a haemovigilance system.
6. Defining the roles and responsibilities for haemovigilance between blood centres/blood services and hospitals, and maintaining clear channels of communication.
7. Using IHN/ISBT/AABB standard definitions, and using reporting forms that are in line with these consensus definitions.

At regional level

1. Advocating for establishment of national haemovigilance systems based on mandatory reporting of donor and recipient adverse events.
2. Supporting countries planning to establish a national haemovigilance system.
3. Organizing regional and national training events on haemovigilance as part of quality management training.
4. Promoting and facilitating regional collaboration and networking.
5. Promoting recognition of blood transfusion services as an identifiable unit separate from laboratory services.
6. Promoting the benefits of sharing and analysis of data across countries.

At global level

1. Urging countries to plan and implement a national haemovigilance system as per WHO guidance published in 2016 (4).
2. Adopting an addendum to the WHO guidance document listing internationally agreed definitions (IHN/ISBT/AABB).

3. Requesting IHN, ISBT and AABB to establish a joint working group to determine whether current consensus definitions are suitable for developing countries and, if necessary, develop a compatible simplified set of definitions.
4. Updating the quality management training modules for blood transfusion services with respect to haemovigilance, with particular emphasis on traceability and look-back activity.

References

1. World Health Organization. Blood safety and availability. Geneva: World Health Organization; 2017 (<http://www.who.int/mediacentre/factsheets/fs279/en/>, accessed 1 August 2017).
2. World Health Organization. Global status report on blood safety and availability 2016. Geneva: World Health Organization; 2017 (<http://apps.who.int/iris/bitstream/10665/254987/1/9789241565431-eng.pdf>, accessed 1 August 2017).
3. World Health Organization. WGO global consultation on haemovigilance, Dubai, 20–22 November 2012 (http://www.who.int/bloodsafety/haemovigilance/global_consultation/en/, accessed 1 August 2017).
4. World Health Organization. A guide to establishing a national haemovigilance system. Geneva: World Health Organization; 2016 (<http://www.who.int/bloodsafety/haemovigilance/haemovigilance-guide/en/>, accessed 1 August 2017).