Summary report on the

Regional consultation on haemovigilance

WHO-EM/LAB/391/E

Amman, Jordan
4–5 December 2016

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1. Introduction

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, haemovigilance systems are not well developed and only 10 countries report having protocols for reporting adverse transfusion events and for post-transfusion management of patients. 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.

The WHO Regional Office for the Eastern Mediterranean 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;
- develop recommendations and priorities for action for establishing and/or strengthening national haemovigilance systems.

Representatives from Afghanistan, Bahrain, Iran (Islamic Republic of), 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 Iran (Islamic Republic of), 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 the Regional Office for the Eastern Mediterranean.

In his welcoming message, delivered by Dr Maria-Cristina Profili, WHO Representative for Jordan, Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean, highlighted the need for a haemovigilance system for ensuring the safety of blood donors and patients. He reminded the participants that the Sixty-third Session of the WHO Regional Committee for the Eastern Mediterranean, in October 2016, endorsed the regional strategic framework for blood safety and availability. The strategic framework aims to establish national haemovigilance systems in 20 countries by 2025. Dr Alwan reiterated WHO's commitment to support all Member States in improving haemovigilance in the Region.

2. Summary of discussions

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 (WHO Global Database on Blood Safety, 2013). WHO convened a global consultation on haemovigilance in 2012, which agreed on 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.

There are a number of organizations with experience in haemovigilance. The foremost dedicated organization is IHN, formed in 2009 from the European Haemovigilance Network. Members of the network comprise national haemovigilance systems. In addition, individuals working in haemovigilance from member countries are free to participate in all aspects of the network. Currently, the membership structure is being reviewed to increase participation and contribution. Data reporting is voluntary and results are kept anonymous. IHN collaborates with multiple international organizations including WHO, AABB, ISBT and NOTIFY Library.

ISBT has a working party on haemovigilance, which focuses on both recipients and donors, and regularly publishes updates on international activities and works on definitions and tools. The Standard for Surveillance of Complications Related to Blood Donation has been developed by IHN, ISBT and AABB and provides uniform definitions. These are available on the ISBT website and could be used in the Region.

The national haemovigilance programme in the United States of America (AABB Center for Patient Safety) is a voluntary system with less than 10% participation. A pilot in the state of Massachusetts showed expedited implementation due to regulatory obligations. The current haemovigilance system, under the Centers for Disease Control’s National Healthcare Safety Network, relies upon unmonitored adherence to detailed case-definitions of adverse transfusion reactions, a written protocol and self-paced training for those reporting.

AHN is a voluntary, confidential and anonymous region-wide reporting system developed to increase transfusion safety in North Africa and the Middle East. Currently, development of software to generate online data is under process. Hosting of the system cannot be carried out by a commercial organisation and must be under an independent organization acceptable to all participants. The system will help the Arab League in its aim to improve health services in countries in the region. Support from the Arab League is sought to host the system. The participants suggested expanding the AHN as a regional haemovigilance network through WHO support.

Country presentations showed the presence of haemovigilance at different levels, and gave an overview of common issues, lessons learned and success stories.

- 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. The national haemovigilance structure has been submitted to the Ministry of Public Health and is being reviewed for endorsement and subsequent implementation.

- In Saudi Arabia, haemovigilance work started after the Dubai global consultation in 2012. An electronic haemovigilance website has been available 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 aspect 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. Recently, the Supreme National Blood Transfusion Committee agreed on a policy draft for recipient haemovigilance.

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.

3. Recommendations

At blood centre and blood service level

1. In the absence of a national haemovigilance programme, as an essential first step, implement a donor vigilance system to ensure adequate donor care.
2. Establish mechanisms for liaison with hospitals, hospital blood banks, hospital transfusion laboratories and hospital transfusion committees.
3. Integrate haemovigilance into quality management systems.

At hospital level

4. Establish a system for implementing and monitoring the use of guidelines on appropriate clinical use of blood and blood products.
5. Establish and maintain a hospital transfusion committee to develop a system to collect, analyse, use and disseminate data on recipient adverse events.
6. Put in place a mechanism for providing awareness, training and education on haemovigilance and transfusion safety to all appropriate staff involved in the transfusion process.
7. Designate/appoint a haemovigilance officer in hospitals where blood transfusion is performed, with clearly defined roles and responsibilities for safe transfusion practice including haemovigilance.
8. Establish mechanisms for external liaison with supplying blood centres and blood services, and for internal cooperation with hospital blood bank, transfusion laboratory and transfusion committee, with clear channels of communication.

At national level

9. Recognize that haemovigilance is essential for quality and safety of blood donation and transfusion practice, and that all elements of quality management systems should be implemented and maintained to ensure adherence to the requirements of haemovigilance.
10. Include both donor and recipient haemovigilance in the national blood policy, supported by the necessary legislative and regulatory framework.
11. Set up in a stepwise manner, and maintain, a national haemovigilance system covering the entire blood chain including donors, recipients, processes and products, taking into account the infrastructure of the national health system and capacity of the national blood service.
12. Advocate, guarantee and assure a non-punitive environment during the development and maintenance of a haemovigilance system; and

implement system improvements to continuously increase the safety of blood donation and transfusion.

13. Provide necessary and sustainable financial and human resources for effective implementation of a haemovigilance system.
14. Define the roles and responsibilities for haemovigilance between blood centres/blood services and hospitals, and maintain clear channels of communication.
15. Use IHN/ISBT/AABB standard definitions, and use reporting forms that are in line with these consensus definitions.

At regional level

16. Advocate for the establishment of national haemovigilance systems based on mandatory reporting of donor and recipient adverse events, which are to be evaluated for system implications (and not in a punitive fashion that adversely affects employees).
17. Support countries planning to establish a national haemovigilance system, and provide opportunities for monitoring and follow up of progress.
18. Organize regional and national training events on haemovigilance as part of quality management training.
19. Promote and facilitate regional collaboration and networking.
20. Promote the recognition of blood transfusion services as an identifiable unit separate from laboratory services.
21. Promote the benefits of sharing and analysis of data across countries.

At global level

22. Urge countries to plan and implement a national haemovigilance system as per WHO guidance published in 2016.
23. Adopt an addendum to the WHO guidance document listing internationally agreed definitions (IHN/ISBT/AABB).
24. Request 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; and to update the template forms (annexes to the guidance document) as required and illustrate them with examples (to include as an addendum to the guidance document).

25. Update the quality management training modules for blood transfusion services with respect to haemovigilance, with particular emphasis on traceability and look-back activity.

4. Priorities for action

1. Ministries of health to encourage blood centres/blood services and hospitals to set up haemovigilance systems in a stepwise manner.
2. Ministries of health to facilitate setting up and maintaining functional hospital transfusion committees and strengthen communication across the clinical interface.
3. WHO to provide high-level advocacy for ministries of health for establishing national haemovigilance systems.
4. WHO to facilitate dissemination and use of the ISBT/IHN/AABB definitions and data recording and reporting templates in line with the definitions.
5. WHO to support training of all stakeholders to ensure best practices are followed in donor care, blood collection, clinical transfusion and haemovigilance.

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