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CONGRESS REVIEW

Haemovigilance in China: experiences, challenges and strategies

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Haemovigilance (HV) plays an essential role in ensuring the safety of donors and recipients with regard to blood transfusions. China now has annually survey on blood collection and supply, but no national reporting system of AR/AE related to blood transfusion. By 2013, the first guideline on HV in China was released by the Blood Quality Management Committee of Chinese Society of Blood Transfusion (CSBT) and revised in 2015. For blood establishments and hospitals looking for help with setting up new plans or further improving blood transfusion safety, the guideline provides ample information on definitions, methodology and documentation protocols. Based on the guideline, a series of education and promoting programmes was developed in Shanghai and other regions. With the integration of HV into the existing expert symposiums and education courses in the past few years, hundreds and thousands of clinicians and blood bank practitioners got training and the importance of HV were recognized widely, and the principles of nonpunitive principle and learning from errors. In 2017, the working party on haemovigilance of CSBT was set up, which is a milestone for the progress of HV in China. Through the working party, we can study the practices of antecedence countries and learning their experiences, by formulating policies, evaluating modes and mechanisms, compiling standards and guidelines, improving information management and standardization from one region to the other, to establish a national HV systems step by step in China.

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Introduction

Haemovigilance (HV) is a continuous process of data collection and analysis of transfusion-related adverse reactions (AR) and adverse events (AE) to investigate their causes and outcomes and prevent their occurrence or recurrence [1]. As an important component of a blood quality system, HV has been established in several countries. According to World Health Organization (WHO) Global Database on Blood Safety (GDBS), there are 70 countries having a national HV system [2].

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As the most notable one of these systems, The Serious Hazards of Transfusion (SHOT) in the UK has prompted changes in transfusion practice from the selection and management of donors to changes in hospital practice. HV is also considered to be used for other important objectives, such as the training of transfusion practitioner, the implementation of patient blood management (PBM) and the development of clinical guidelines. China now has national data of blood collection and supply, but no national reporting system of AR/AE related to blood transfusion and blood donation. However, there are various forms reporting procedures at the level of hospital, blood services or regional pilot programmes. By 2013, the first guideline on HV in China was released by the Blood Quality Management Committee of Chinese Society of Blood Transfusion (CSBT) and revised in 2015. For blood

establishments and hospitals looking for help with setting up new plans or further improving blood transfusion safety, the guideline provides ample information on definitions, methodology and documentation protocols. Based on the guideline, a series of education and promoting programmes was developed in Shanghai and other regions. Here, we highlight the key facts and achievements that related to HV in China and discuss the challenges and strategies in the future.

The Experiences of HV in China

National Blood Collection and Supply Survey

In 1998, the Blood Donation Law started to be implemented in China, which is the highest law in the blood administration system. According to the law, the blood services are administrated by local government and health authorities, meanwhile the National Health and Family Planning Commission (NHFPC), previously the Ministry of Health (MOH) sets national standards and policies. From a decade ago, NHFPC continued to carry out national blood collection and supply survey annually. The data come from a total of 452 blood services (which are called blood station in China) across the country, including the number, volume and types of blood donations, donation rate, donor profile, general condition of blood services, blood testing, blood supply, blood discard and transfusion-transmitted infection (TTI) [3, 4, 5].

The report of National Blood Collection and Supply Survey is not in public, but is an internal reference material for relevant departments. Even so, its data were also cited by a few published papers. By which, we can get an overview about blood services in China. In some ways, the survey can be said to be one form of HV and is somewhat similar to the American Association of Blood Bank (AABB) Blood Survey. However, from the perspective of HV, there are some disadvantages in the survey: first, the data of TTI are incomplete and cannot fully reflect the actual situation of blood transfusion safety. Second, due to the lack of effective reporting procedure between hospitals and blood services, it is difficult for blood services to collect the data of clinical transfusion reactions and adverse events, which are not included in the survey. Third, to be carried out by competent authority, may lead to concerns of the reporting institutes regarding the punishment.

Developing the HV guideline

Besides the blood collection and supply survey made by government department, there were some HV-related practices such as reporting adverse reactions at the level of hospital, most of which were academic research project [6, 7, 8]. There was no uniform standard for the scope, definition and diagnosis of AR/AE, making it difficult to compare and analyse the data of different organizations.

In 2012, the Blood Quality Management Committee of CSBT, the secretariat of which was located in Shanghai Blood Center, organized a HV work group to draft a guideline for HV. The group is composed of transfusion medicine experts from both blood centres and hospital blood banks and clinical experts. The objects of the workgroup were as follows: (1) the guideline was for providing technical support for developing HV system, not a uniform standard for the models or ways of HV; (2) the guideline should be able to adapt to different regions and different levels of blood services with both conciseness and sufficiency; (3) the guideline should be conform to international standards and in line with academic progress, especially the definitions and diagnostic criteria of donation reactions and transfusion reactions. After a year of work, the work group completed the draft for comment of HV guideline and organized a series of seminars to solicit the opinions of stakeholders. The first edition of the guideline was released in September 2013.

The guideline consists of five parts: Basic Concepts, Forms of Operating, Donation Reactions, Transfusion Reactions and Adverse Events. The part of Adverse Events includes the Events related to Blood Donation and the Events of Blood Transfusion. It was assigned a unique code for each Reaction or Event to facilitate the processing and analysis of information system. The part of Transfusion Reactions contains the Classification and Coding, Definition, Severity, Imputability, Observation Form, Summary Form and Diagnostic Criteria. The Observation Form has both mandatory and optional items to meet the needs of hospitals with different levels, in which the hospitals can fill in the reaction diagnosis, relevant laboratory testing results, therapy and outcome, or only the necessary items such as the patient general conditions, clinical manifestations of the reaction and the relevant blood unit information. In 2013, the WHO China Consultation on Haemovigilance was held in Shanghai to promote HV and the Guideline.

In 2015, according to the revised ISBT & IHN & AABB Standard for Surveillance of Complications related to Blood Donation, and the HV pilot experience in Shanghai, the work group revised the guideline into HV guideline 2nd edition, which was released by the Blood Quality Management Committee of CSBT on October 2015 [9].

Developing the training programme and pilots

HV is also considered to be used for other important objectives, such as the training of transfusion practitioner, the implementation of patient blood management (PBM)

and the development of clinical guidelines. Appropriate education and training of all personnel involved in the blood transfusion chain, from the blood transfusion service, the hospital blood bank through to the clinical areas, are essential to HV. In 2008, Shanghai Blood Center launched a national training programme, the Education Course for Leadership of Blood Services (ECLBS), in collaboration with CSBT, AABB and ISBT, to provide comprehensive transfusion medicine training to blood services management personnel [10]. From 2012 to present, HV education was included in the course of ECLBS. In addition, the HV work group also conducted an annual continuing educational programme. These education and training were aimed at national blood system to promote the general principles of HV, its objectives and benefits, and individual roles and responsibilities. With the integration of HV into the existing expert symposiums and education courses in the past few years, hundreds and thousands of clinicians and blood bank practitioners got training and the importance of HV were recognized widely, and the principles of nonpunitive principle and learning from errors.

Based on the guideline, a HV pilot programme was launched in Shanghai, which covered several hospitals. In addition, a few other pilots were carried out at some institutes. The next step is to develop HV information system to facilitate the reporting procedure.

The Challenges at present

HV has been introduced to China a dozen years, but it was still in an initial stage. The reasons or challenges might be as follows:

(1) Insufficient of attention and understanding. Transfusion medicine and HV have not got enough attention and understanding from clinicians and hospital managers. From the viewpoint of many clinicians and hospital managers, blood transfusion is only one of clinical therapy procedures, of which the most important issue is the supply and the risks of TTI.
(2) Inadequate of competent staff. It is a general fact that most of hospital blood banks are short of personnel, especially transfusion physician. One of the main reasons is that transfusion medicine education is insufficient and incompetent in the medical education system and there is a serious lack of transfusion physicians to meet the need of clinical transfusion services.
(3) Lack of practice atmosphere. HV require blood services and hospital to reveal the problems in themselves on their own initiative, which need an atmosphere of tolerance and learning from errors. However, the fact is that report of AR/AE might become a cause of medical dispute in hospital, especially in the present serious medical practising environment in China. Another obstacle to HV comes from that the reporting institutes worry about the punishment from administration authority.

Discussion on the strategies

To develop HV in China, should the mode be centralized or decentralized, mandatory or voluntary? The view of stakeholders is not consistent. A popular belief is that HV should be carried out compulsively by central authority, such as NHFPC. However, the variety of different level of medical care and blood service between different areas may restrict the feasibility and effectiveness of a centralized mandatory HV system. To promote HV by the power and resource of government might be quickly and efficiently, but there also might be negative results, especially the truth of data could be affected. Stakeholders as hospitals could hide unfavourable information to avoid the punishment.

The Measures for Administration of Clinical Use of Blood, which was issued by MOH in 2012, ruled that medical institutions should establish the adverse events monitoring and reporting system of clinical use of blood in accordance with national relevant laws, regulations and standards [11]. According to the Measures, the forms of reporting system were generally founded in hospitals, but in fact, the data reported are seriously incomplete and cannot reflect the reality of clinical transfusion safety. Which also gave the support to the view above.

An efficient and sustainable HV system must base on a nonpunitive, learning from error environment and culture, and confidentiality and security of reported data. A voluntary mode will be promoted step by step with pilot and practice by means of joint efforts of education and training. The strategy makes HV separate from assessment and commenting system of administration and is beneficial to the reliability and sustainability of HV, as while less worry about being punished. Above all, it is important to avoid decision-making mistake as a result of fake information [12].

In 2017, the Haemovigilance Committee of CSBT was set up, which could be a milestone in the development of HV in China. Through the committee, we can study the practices of antecedence countries and learning their experiences, by formulating policies, evaluating modes and mechanisms, compiling standards and guidelines, improving information management and standardization from one region to the other, to establish a national HV systems step by step in China.

Conflict of interests

The author declares no conflict of interests.

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