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Original Article

Code development of the national hemovigilance system and expansion strategies for hospital blood banks

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Abstract:

Objectives: The aims of this study were to develop reportable event codes that are applicable to the national hemovigilance systems for hospital blood banks, and to present expansion strategies for the blood banks. **Materials and Methods:** The data were obtained from a literature review and expert consultation, followed by adding to and revising the established hemovigilance code system and guidelines to develop reportable event codes for hospital blood banks. The Medical Error Reporting System-Transfusion Medicine developed in the US and other codes of reportable events were added to the Korean version of the Biologic Products Deviation Report (BPDR) developed by the Korean Red Cross Blood Safety Administration, then using these codes, mapping work was conducted. We deduced outcomes suitable for practice, referred to the results of the advisory councils, and conducted a survey with experts and blood banks practitioners. **Results:** We developed reportable event codes that were applicable to hospital blood banks and could cover blood safety - from blood product safety to blood transfusion safety - and also presented expansion strategies for hospital blood banks. **Conclusion:** It was necessary to add 10 major categories to the blood transfusion safety stage and 97 reportable event codes to the blood safety stage. Contextualized solutions were presented on 9 categories of expansion strategies of hemovigilance system for the hospital blood banks.

Key words:

Biologic products deviation report, hemovigilance, medical error reporting system-transfusion medicine, reportable event code

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Introduction

In 2008, hospital blood banks in Korea were observed for being poorly managed and having a high frequency of deviation occurrences. Hospital blood banks take charge of supplying only 0.6% of the total amount of blood product, but blood transfusion safety has a direct impact on people's life and health, and thus requires secure management.[1] In 1970, a domestic law of Korea on blood safety was enacted, and Section 2 Part 5 of the first regulation on hemovigilance (specific transfusion reaction) law was added in 1999 and revised in January 2005. However, as only obligatory provisions require reporting to the government, a voluntary agency or system for guaranteeing quality is insufficient. According to reports from the UK and Ireland, from October 1996 to September 1998, a total of 366 cases of mortality and major complications associated with blood transfusion in hospitals had been reported to the Serious Hazards of Transfusion (SHOT). According to the operating results of Medical Error Reporting System-Transfusion Medicine (MERS-TM) in 2001, 61% of transfusion related events occurred at the bedside, 35% occurred in the laboratory, and 4% occurred in blood banks or other institutions.[2] According to a SHOT report, 61% of the cases were related to blood collection, blood transfusion orders, and transfusion; 36% were related to the clinical laboratory; and 3% were related to deviation in blood banks.[3] Some efforts have been made to scale measurements of noninfectious transfusion-related events, including MERS-TM,[2] the voluntary program SHOT,[4] the mandatory transfusion-related incidents/accidents/medical errors reporting system of the New York State Department of Health,[5] the French Haemovigilance System,[6] and Belgium's SANGUIS Group.[7] Near-miss events were estimated to be five times that of the actual events.[8] Although the hemovigilance system managed by the Red Cross is being demonstrated and executed as the primary reporting system, it cannot be established as a complete hemovigilance system without relationships to hospital blood banks. Therefore, it is necessary to develop codes of reportable events to expand the national hemovigilance system to hospital blood banks.

Materials and Methods

We investigated the transfusion-related deviation reporting systems of other countries, as well as the applicable laws and types of reporting used in those countries, in order to develop a bill appropriate for domestic use. In 2006, the Red Cross Blood Safety Administration developed a hemovigilance system

based on Biological Product Deviation Report (BPDR), which was developed by the Food and Drug Administration (FDA) and the Department of Health and Human Services in the US. Then revision was performed twice—in 2007 and 2009. The system is sufficient for guiding the hemovigilance of blood product safety for blood banks, but not for blood transfusion safety for hospital blood banks. In this study, we used the reporting system developed by the Red Cross Blood Safety Administration, and added to it the MERS-TM, which is a voluntary reporting system developed by the US National Institutes of Health in 1995; we then reviewed and revised it. The data were obtained through a literature review on MERS-TM, SHOT, and Serious Hazards of Transfusion (SABRE) in several countries, and gathered advisory councils together by constructing a network of professionals to identify domestic status of reporting system in Korea. In the advisory councils, we obtained consultations regarding the literature review, case review, and code organization for early expansion of the hemovigilance system for the hospital blood banks. Specifically, 1) reviewed the revision of hemovigilance reporting provisions and guidelines; 2) deduced from international case reports (BPDR, eBPDR, MERS-TM, and report forms) for reviewing the reporting methods for hemovigilance systems; 3) referred to the development of the hospital blood bank hemovigilance system demonstration plan, according to the comments from unstructured discussion; and 4) reviewed the temporary proposal for the standard education program. The standard education program was implemented for 47 practitioners in the Red Cross and hospital blood banks in order to introduce the significance and advance cases of blood safety management, and describe 'Errors in Transfusion-related Activities' reporting and processing guidelines to introduce them to the background and status. We also educated them on the development process and instructions on reportable codes for the hemovigilance system. Finally, we gathered comments from the advisory councils and mail survey to collect and analyze opinions of the practitioners. The subjects of mail survey were the practitioners in 21 hospital blood banks where blood collection records exceeded 100 cases in 2008. Survey materials, including the 'preliminary code comparison matrix' and the 'review forms' were distributed to them. The mail survey was carried out from October 15 to November 11, 2009.

Results

Development of reportable event codes

The hemovigilance reporting system developed by the Red Cross Blood Safety Administration in 2009 was classified into three levels—major, medium, and small; within these, there were 9 major, 43 medium [Tables 1 and 2], and 351 small categories. MERS-TM was classified into two levels. Subsequently, the types of blood safety were classified into two stages: blood product safety and blood transfusion safety. The 9 major categories of the reporting system of the Red Cross Blood Safety Administration were included in the blood product safety stage, which is currently employed by the Red Cross Blood Bank. The 10 major categories of MERS-TM, excluding those that duplicate the reporting system of the Red Cross were included in the blood transfusion safety stage; these will be employed by hospital blood banks after the final decision made by the Department of Blood Safety Supervision, Korea Centers for Disease Control and Prevention (KCDC). The code mapping was performed between the two reporting systems. As a result, it was necessary to add 10 major categories for the blood transfusion safety stage, such as Product Check-in, Product Storage (Unit Storage), and Product Manipulation (Unit Manipulation). The medium categories were consolidated into six-digit codes by inserting 00 in the MERS-TM code. Finally, 97 reportable event codes were added to the blood safety stage. The codes of the major categories are presented in Table 1.

Expansion strategies for the hospital blood banks

Expansion strategies were developed by collecting and analyzing the opinions of the advisory council and practitioners from the methods above. We organized the results according to a 'Situations and Solutions' structure. In this study, the situations and solutions are presented for 9 categories on expansion strategies for hospital blood bank hemovigilance systems. We organized these strategies by stage of Information Strategic Planning (ISP): the planning stage, analysis stage, design stage, implementation stage, and support stage as detailed below. These stages are summarized in Figure 1.

Planning stage

Cultivate an appropriate culture suitable for implementation by adopting the survey results, distribution of the code booklet, provision of incentives for promotion, changes in the participants' recognition, and creation of consensus.

Situations

- Provide a pre-demonstration guide and confirm agreement to participate, create awareness of the new policy, and consensus among practitioners about the need to manage 'Errors in Transfusion-related Activities'.
- Recognize that following the report protocols in 'Errors in Transfusion-related Activities' may present some disadvantages, so it is crucial to create an atmosphere conducive to voluntary reporting.

Solutions

- Survey the staff to identify required information and training for proper error reporting.
- Divide the 'Errors in Transfusion-related Activities' reporting

Table 1: Codes of major categories

Type of blood safety			Major category	Work classification
Blood product safety (Blood donation safety)	1	PD	Post donation	For reporting from Red Cross blood services
	2	DS	Donor screening	
	3	DD	Donor deferral	
	4	BC	Blood collection	
	5	CP	Component preparation	
	6	LT	Laboratory testing	
	7	LA	Labeling	
	8	QC	Quality control	
	9	MI	Miscellaneous	
Blood transfusion safety	10	PC	Product check-in	For reporting from hospital blood banks
	11	US	Product storage, unit storage	
	12	UM	Product manipulation, unit manipulation	
	13	SE	Product selection, unit selection	
	14	SH	Sample handling	
	15	AV	Available for issue	
	16	PR	Product/patient request	
	17	OE	Order entry	
	18	UI	Product issue, unit issue	
	19	UT	Product administration, unit transfusion	

Table 2: Codes of medium categories

PD	Not specified Information provided by donor or third party; includes true-positive and false-positive test results Reason for deferral, types of behavior, and history prior to donation (deferral by the criteria at that time, history of diagnosis, and treatment) Products issued with types of risk behavior or history unknown or not specified
DS	Not specified Preliminary inspection not done, donor record incomplete or incorrect, and donor did not meet acceptance criteria Donation with donor information incorrect, donor record incomplete (includes donor records not found or missing) Deferral donation by missing donor history search Missing reason for Donor Deferral, legal communicable disease information, drug information, and other specification by missing donor history search Deferral of donation even with donor history search Missing reason for Donor Deferral, legal communicable disease information, drug information, and other specification even with missing donor history search Donor Deferral donation by missing inspection record Ban on donor individual criteria
DD	Not specified Donor missing or incorrectly identified on deferral list Legal communicable disease, deferral history, drug history, and other specifications missing or incorrectly identified
BC	Not specified Contamination or damage of products and samples Soft goods defect (bags, tubing, etc) (include anticoagulant) Deviation in blood collection
CP	Not specified Contamination or damage of products during component preparation Components not acceptable for standard Components from deferral whole blood issued Request for exchanging the products issued Component preparation process not performed in accordance with specifications
LT	Not specified Testing performed, interpreted, or documented incorrectly or work process violation Sample related Reagents related (abnormal reagents, untested reagents, expired reagents were used) Other impact test (prior to result of screening final sending)
LA	Not specified Labeling incorrect or missing information
QC	Not specified Deferral products issued due to delayed recovery and disposal with post-donation information Testing incompletely performed or distribution of product that did not meet specifications (include no testing document) (classify into LT with deferral in testing) Incorrect product issued Distribution, storage, and transition-related checklist Incorrect blood product supply process
MI	Not specified Computer entry related Hospital blood bank computer entry related Other administration related

system into mandatory and voluntary sections because it will not be easy to get legislation passed to make the whole document compulsory right away.

- Publish and distribute the 'Errors in Transfusion-related Activities' codes booklet. After pre-application, investigate participants' reactions after a period of time, and then publish a revised version for all users.
- Provide incentives for management of 'Errors in Transfusion-related Activities': For example, incentives such as advantages in the hospital accreditation process for agencies that make ample effort toward compliance, providing an information and management plan for 'Errors in Transfusion-related Activities', and education program.

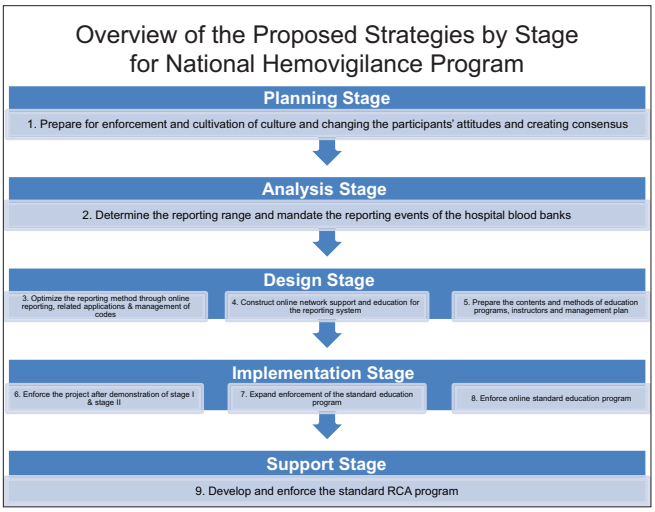

Figure 1: Proposed strategies by stage

Analysis stage

Determine reporting range and mandate the reporting events of the hospital blood banks.

Situations

- Clarify the scope of blood safety management work in KCDC in order to expand the 'Errors in Transfusion-related Activities' of the hemovigilance system among hospital blood banks.
- Construct a reporting system that encompasses both the Red Cross Blood Services and hospital blood banks in order to create a comprehensive blood safety error reporting program.
- Add a blood transfusion safety stage to BPDR for reporting organizations that manage transfusion activities.
- Avoid making reporting exceptions for hospital blood banks or creating streamlined reporting that neglects to cover all details in the Red Cross reporting system. Complete reporting should be performed even though the workload may be increased by additional 'Errors in Transfusion-related Activities' reporting tasks.
- The US FDA should create codes for errors occurring in hospital and transfusion settings (wards, intensive care unit, operating room, emergency room, etc).

Solutions

- Prioritize the inclusion of 'Errors in Transfusion-related Activities' into compulsory activities, and provide adequate education about the necessary procedures.
- Include the 'Errors in Transfusion-related Activities' reporting in the evaluation criteria for hospital accreditation because KCDC makes regulation of blood bank activities a required

part of evaluation once every year or two years.
- If a demonstration is needed, include evaluation criteria and recommendations for 2010 and enforce compulsory participation in 2011.
- Collect opinions of the directors of the hospital blood banks and revise accordingly the level of detail of items in the 'Errors in Transfusion-related Activities'.

Design stage

Optimize the reporting method through an online reporting system, development of related applications, and classify reportable codes for both Red Cross blood services and hospital blood banks.

Situations

- Excessive workload was reported because of the 'Errors in Transfusion-related Activities' implementation. There was also a report regarding inefficient time management due to complicated 'Errors in Transfusion-related Activities' and a reporting system that makes work more difficult to perform.
- Eliminate the evaluation items in the 'Errors in Transfusion-related Activities' that duplicate items required by certification of the laboratory, hospital accreditation process, hemovigilance evaluation for KCDC, and other evaluation activities.
- Simplify the reporting authorization process so that it becomes more convenient.
- Plan deliberately for the inevitable adoption of an online reporting system.

Solutions

- Improve the current report format, borrowed from subject blood banks by developing an additional online report system to make the reporting process much faster and easier.
- Develop an efficient online reporting system to reconcile the considerable differences between the two computer systems being used by the Red Cross and hospital blood banks, which currently makes the implementation of 'Errors in Transfusion-related Activities' challenging.
- Since the reporting scheme was originally developed by supply blood banks such as the Red Cross and BloodNet, allow hospital blood bank staff to check 'N/A' when an item in the 'Errors in Transfusion-related Activities' is not applicable to blood banks.
- Classify codes that are common to supply institutions (Red Cross blood services) as well as self-consuming institutions (hospital blood banks) and those that are unique to each, in order to prevent confusion.
- Due to the existence of ambiguous cases and sheer quantity of cases, which make entry challenging, develop a Clinical Decision Support System (CDSS) with auto detect and entry functions, as well as a revision function for incorrect entries.
- Revise reportable codes. The current codes are appropriate for the Red Cross (ie, for blood product safety), but additional codes that are appropriate for the hospital blood banks (ie, blood transfusion safety) are needed.

Construct online network support and education for the reporting system.

Situations

Promote education for users, in order to implement the reporting system appropriately.
- Implement a sharing system that can exchange the feedback on reported information, in order to maintain the reporting activities.
- Initiate collaboration among hospital blood banks and regional Red Cross blood services, as well as the place for education and information exchange, to communicate closely with each other on issues such as blood information and inspection information.

Solutions

- Develop content for enriching the existing KCDC website to share the experiences of the practitioners.
- Utilize more actively the current online reporting system developed by the Red Cross blood services.
- Provide a professional training program on efficient staffing for hospital blood banks with a poor work environment due to limiting staffing.

Develop education program goals and curriculum, train instructors, and implement the plan.

Situations

- Staff (1-2 people) in hospital blood banks communicate the information through individual discussion and reading, but it is challenging to plan and execute the education program independently.
- Find a way to recognize participation in education programs, even if there are many practical difficulties.

Solutions

- Provide an education program with content based on practitioners' needs.
- Provide both regular education and supplemental impromptu education as needed.
- Choose instructors who are practitioners and can educate properly based on extensive practical experience in the field, or who are in management in the KCDC.
- Require education in regional Red Cross blood services nearby, and conduct the training 1-2 times annually with the Society of Blood Transfusion and practitioners as leaders.

Implementation stage

Enforce the project after demonstration of stages I and II.

Situations

- Implement the project in stages. Full implementation from the beginning would be difficult.
- Make an effort over the long term to aggregate cases that have not been done by the pilot project hospitals at all so far.

Solutions

- Classify implementation tasks into stages I and II, accumulate data for at least more than a year, and then confirm the enforcement plan.
- Stage I pilot project: Analyze the data collected for blood banks in which blood collection records account for more than 1,000 cases annually as the pilot project.
- Stage II pilot project: Implement based on analysis from Stage I, demonstrate and expand for the hospital blood banks in which blood collection records account for more than 500

cases, which means expanding the scope of demonstrating institutions.
- Implementation of the project: Aim to have all hospital blood banks adopt the procedure starting within 2 years and mandate this requirement.

Enforce the standard education program.

Situations
- If there is no correct understanding of 'Errors in Transfusion-related Activities', interpretations made in each hospital and practitioner will be different, and consensus cannot be made.
- Support quality improvement of the information exchange among the staff by continuous and standardized education because staff assigned for transfusion-related activities may change periodically.
- Provide continuous education for small-scale blood banks because these institutions may find it difficult to understand each other's practice due to unfamiliar practices.

Solutions
- Implement workshops and training in all blood banks by region, with fundamental education for practitioners in blood banks.
- Enforce joint education with fundamental education of practitioners as needed.
- Recognize and enforce the standard education program as mandatory continuous education.

Enforce an online version of the standard education program.

Situations
- Present alternatives for people who cannot participate in the offline program in order to reduce the burden and make it more practical.
- Currently, the participation rate is poor because it is not mandatory and motivated only by self-direction.
- The KCDC provides small-scale continuous education through the e-Learning program, which is one of the more effective ways than traditional education program.
- Publicize the current online education and information (e-Learning) to maximize utilization, making efficient use of the existing system.

Solutions
- Develop a Learning Management System (LMS) for operation and management of the current e-Learning of 'Errors in Transfusion-related Activities' provided from the KCDC website.
- Retain records on participant completion and grades in the LMS. If online education is completed, it can serve as a substitute for offline attendance.
- Enforce good utilization plans for recipients, utilize hemovigilance education for in-service education, and then make it a mandatory program by enforcement.
- Enrich the content of the education and develop it in stages in the future.

Support stage

Develop and enforce the Root Cause Analysis (RCA) training program.

Situations
- Include RCA in operating the 'Errors in Transfusion-related Activities' reporting system, thus improving the quality and efficiency of the hemovigilance system.
- Develop and disseminate systematic RCA methods continuously.
- Use practice centered workshops instead of large-scale lecture because of the professional characteristics of the content.

Solutions
- Give a standard definition and provide continuous education and training on RCA.
- Promote and educate on the feasibility and urgency of RCA.
- Hold small-scale workshops for groups of 10-20 people each year by region in order to improve regional accessibility. For example, using the regional Red Cross blood services as bases, go to the nearest blood banks to encourage as much participation as possible. Notify them of the full-year plan, so the staff can prepare ahead of time.
- Develop and present a systematic management plan for RCA workshops.

Discussion

The ultimate aim of hemovigilance is to improve the safety of the blood transfusion chain from donor to patient. Some medical error reporting systems for collecting and analyzing adverse events including transfusion errors already exist. For example, in Australia, over 200 healthcare organizations or health services voluntarily send incident reports to the Australian Incident Monitoring System (AIMS).[9] The Japan Council for Quality Health Care collects voluntarily reported adverse events from healthcare organizations in Japan, particularly sentinel cases with RCA.[10] The National Reporting and Learning System (NRLS) in England and Wales is another example of a learning system. NRLS receives reports of patient safety incidents from local healthcare organizations.[11] A World Health Organization (WHO) guideline on adverse event reporting and learning systems states that the effectiveness of the systems is measured not only by accurate collection and analysis of data but also by its usefulness in making recommendations that improve patient safety.[12]

The challenge for hemovigilance is to make independent evidence-based recommendations, supported by robust and meaningful data from the reporting system.[13] Therefore, it is necessary to expand the reporting and learning system to foster continuous improvement in blood product safety and transfusion safety for rapid identification of serious risks related to blood components at both local and national levels and a rapid initiation of appropriate risk minimization activities. Also, the systems should be operated such that they facilitate sharing of best practices and stimulate system-wide improvements.

Conclusion

In this study, 10 major categories were added to the blood transfusion safety stages, such as Product Check-in, Product Storage (Unit Storage), and Product Manipulation (Unit Manipulation). The medium categories were consolidated into six-digit codes by inserting 00 into the MERS-TM code. Finally, 97 reportable event codes were added to the whole blood safety stage. The situations

and solutions were presented on 9 categories for expansion strategies of the hemovigilance system for the hospital blood banks. Through this study, we hope to foster improvement and standardization of the quality of blood distribution, and also create a consensus for expanding the hemovigilance system for hospital blood banks. Furthermore, we expect that this can be utilized as a reference for expansion strategies for other institutions reporting on blood safety. Improvement of blood transfusion safety will improve the quality of patient safety and become the foundation of international blood safety activities and research collaboration.

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