

Evaluation of the in-hospital hemovigilance by introduction of the information technology-based system

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BACKGROUND: Hemovigilance is an important aspect of transfusion medicine. However, the frequency of the adverse reactions often varies using different reporters. Recently, we have employed a new information technology (IT)-based in-hospital hemovigilance system. Here, we evaluated changes in practice after implementation of an IT-based reporting system.

STUDY DESIGN AND METHODS: We compared the rate of frequency and details of blood transfusion-related adverse reactions 3 years before and after introduction of the IT-based reporting system. Contents and severity of the adverse reactions were reported in a paper-based reporting system, but input by selecting items in an IT-based reporting system. The details of adverse reactions are immediately sent to the blood transfusion unit online.

RESULTS: After we introduced the IT-based reporting system, the reported rate of transfusion-related adverse reactions increased approximately 10-fold from 0.20% to 2.18% ($p < 0.001$), and frequencies of urticaria, pruritus, rash, fever ($p < 0.001$), hypertension ($p = 0.001$), tachycardia ($p = 0.003$), and nausea and vomiting ($p = 0.010$) increased significantly. Although there was no error report in the paper-based reporting, incorrect reports were observed in 90 cases (0.52%) in the IT-based reporting ($p < 0.001$).

CONCLUSION: The advantages of IT-based reporting were: 1) a significant increase in the frequency of adverse reaction reporting and 2) a significant decrease in underreporting, although the true frequency has yet to be clarified. The disadvantage of the IT-based reporting was an increased incidence of incorrect inputs, all of which was unnoticed by the reporters. Our results showed several important points in need of monitoring after introduction of an IT-based reporting system.

There have been numerous reports on blood transfusion-related adverse reactions, including immunologic reactions, cardiorespiratory distress, and infections.^{1,2} However, the causes of these reactions are diverse and may be difficult to understand. Thus, a better understanding and common grouping of these types of adverse reactions has been proposed.²⁻⁵ Moreover, hemovigilance has been recognized as being essential for the safety of patients.⁶⁻¹⁰ Indeed, hemovigilance helps to analyze transfusion-related reactions and reduce the risks associated with this procedure.⁵ As such, adverse reactions should be quickly and correctly reported.¹¹

An online surveillance system, between each hospital and the Japan Society of Transfusion Medicine and Cell Therapy, was initially created in Japan in 2007. Introduction of this system has improved the efficiency and reliability of collecting data on transfusion-related reactions.¹² The new method of reporting also showed that the frequency of adverse reactions varied between hospitals according to their size, patient characteristics, and the types of systems adopted. However, the effect of the in-hospital reporting

ABBREVIATIONS: IT = information technology; PC(s) = platelet concentrate(s); PDA(s) = personal digital assistant(s).

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method, that is, paper-based versus information technology (IT)-based reporting, on adverse reactions has not been fully elucidated.

In this study, we analyzed the frequency of adverse reactions on blood transfusion before and after introduction of the IT-based reporting system using personal digital assistants (PDAs) and tried to clarify the observed differences. We also evaluated the advantages and disadvantages of the IT-based hemovigilance system.

MATERIALS AND METHODS

The frequency and details of blood transfusion-related adverse reactions were collected by paper-based reports from 2008 through 2010 and then by a new IT-based reporting system from 2011 through 2013. Here, we have analyzed and compared these two different reporting systems.

In the paper-based reporting system, doctors and nurses who had observed adverse reactions in recipients after starting a blood transfusion telephoned their concerns to the transfusion unit, filled out a predetermined form, and sent it to the transfusion unit. Medical symptoms were checked 5 and 15 minutes after starting the transfusion as well as at the end of the transfusion. Late-onset adverse reactions were updated by the doctors in their round. After receiving the reports, members of the transfusion unit immediately confirmed their contents and graded the adverse reaction.

The IT-based reporting system, including the PDA and the application software for medical practice assistance, was made by NEC Corporation (Tokyo, Japan). Doctors and nurses scanned both the identification bar code on the patient's wristband and the product bar code on the blood bag by the PDA at regular intervals and input the presence or absence of any adverse reaction. However, scanning was not enforced by the IT-based reporting system and could be omitted on a case by case basis depending on the individual situation with the patient, for example, emergency transfusion. In such cases, the transfusion unit conducted a postsurvey for adverse reactions. The information was electronically sent to the transfusion unit and automatically printed out. Members of the transfusion unit confirmed adverse reactions in a similar way as previously described. According to whether the IT-based reporting system was adopted, we participated in the national hemovigilance using the IT-based reporting system.¹² We also educated reporters concerning the proper method for using IT-based reporting and reeducated them about the classification and severity of adverse reactions.

Examined items and the severity score of transfusion-related adverse reactions were classified according to the proposed standard definitions for surveillance of noninfectious adverse transfusion reactions.^{13,14} Examined items include fever, chill rigor, feverishness, pruritus, rash, urticaria, respiratory distress, nausea and vomiting, headache,

chest or flank or back pain, hypotension, hypertension, tachycardia, vein pain, disturbance of consciousness, or hemoglobinuria. These reactions were analyzed for platelet concentrate (PC), red blood cell (RBC), and fresh-frozen plasma (FFP) transfusion. Clinical evaluation was based on the issues and the classification of the ISBT Working Party on Haemovigilance.¹³ The severity score has four grades: Grade 1 = nonsevere, Grade 2 = severe, Grade 3 = life-threatening, and Grade 4 = death. We defined Grade 2, 3, and 4 as a severe adverse reaction. Severe adverse reactions were subsequently reported to the Blood Products Research Organization in the Japanese Red Cross and evaluated with samples taken from the patients. The same definitions were used for both the paper-based and IT-based reporting system.

Items analyzed

We analyzed the frequencies and details of transfusion-related adverse reactions for three types of blood transfusion using both reporting systems. We also analyzed differences between the paper-based and IT-based reporting systems in the hospital. Finally, we attempted to clarify the advantages and disadvantages of each reporting method.

Statistical analysis

All statistical analyses were performed by the chi-square test using computer software (SAS analysis suite, SAS, Tokyo, Japan). *p* values of less than 0.05 were considered significant.

RESULTS

Frequencies reported as transfusion-related adverse reactions

The numbers of patients transfused before and after introduction of the IT-based reporting system were 12,293 and 17,178 cases, respectively. The frequencies of adverse reactions in the transfusion of each blood component are shown in Table 1. After introduction of the IT-based reporting system, the frequency of PC transfusion-related adverse reactions significantly increased from 0.22% (10/4626 cases) to 3.33% (233/7005 cases; *p* < 0.001), RBC transfusion-related adverse reactions from 0.15% (9/6086 cases) to 1.02% (86/8395 cases; *p* < 0.001), and FFP transfusion-related adverse reactions from 0.38% (6/1581 cases) to 3.15% (56/1778 cases; *p* < 0.001). The number of cases and frequencies of severe adverse reaction for each blood component were unchanged between the paper- and IT-based reporting systems (Table 2).

The frequency of each transfusion-related adverse reaction

The frequency of adverse reactions was higher in the IT-based reporting system than in the paper-based reporting

TABLE 1. Frequency of each adverse reaction after PC, RBC, and FFP transfusion: comparison between paper- and IT-based reporting systems*

Adverse reactions	Paper vs. IT			
	PC	RBCs	FFP	Total
Allergic cutaneous reaction	9 vs. 213 (0.19 vs. 3.04) $p < 0.001$	2 vs. 35 (0.03 vs. 0.42) $p < 0.001$	3 vs. 56 (0.19 vs. 3.15) $p < 0.001$	14 vs. 297 (0.11 vs. 1.73) $p < 0.001$
Urticaria	9 vs. 164 (0.19 vs. 2.34) $p < 0.001$	2 vs. 32 (0.03 vs. 0.38) $p < 0.001$	3 vs. 37 (0.19 vs. 2.08) $p < 0.001$	14 vs. 233 (0.11 vs. 1.36) $p < 0.001$
Pruritus	2 vs. 135 (0.04 vs. 1.93) $p < 0.001$	0 vs. 12 (0 vs. 0.14) $p < 0.001$	0 vs. 17 (0 vs. 0.96) $p < 0.001$	2 vs. 164 (0.02 vs. 0.95) $p < 0.001$
Rash	2 vs. 19 (0.04 vs. 0.27) $p = 0.002$	0 vs. 10 (0 vs. 0.12) $p = 0.001$	0 vs. 11 (0 vs. 0.62) $p < 0.001$	2 vs. 40 (0.02 vs. 0.23) $p < 0.001$
Fever	2 vs. 8 (0.04 vs. 0.11) $p = 0.180$	3 vs. 25 (0.05 vs. 0.30) $p < 0.001$	1 vs. 3 (0.06 vs. 0.17) $p = 0.363$	6 vs. 36 (0.05 vs. 0.21) $p < 0.001$
Tachycardia	2 vs. 5 (0.04 vs. 0.07) $p = 0.536$	1 vs. 12 (0.02 vs. 0.14) $p = 0.005$	0 vs. 3 (0 vs. 0.17) $p = 0.051$	3 vs. 20 (0.02 vs. 0.12) $p = 0.003$
Nausea/vomiting	1 vs. 7 (0.02 vs. 0.10) $p = 0.088$	1 vs. 7 (0.02 vs. 0.08) $p = 0.068$	1 vs. 3 (0.06 vs. 0.17) $p = 0.363$	3 vs. 17 (0.02 vs. 0.10) $p = 0.010$
Hypertension	0 vs. 2 (0 vs. 0.03) $p = 0.154$	0 vs. 7 (0 vs. 0.08) $p = 0.006$	0 vs. 1 (0 vs. 0.06) $p = 0.259$	0 vs. 10 (0 vs. 0.06) $p = 0.001$

* Data are reported as cases (%). Urticaria, pruritus, and rash were calculated as an allergic cutaneous reaction. The numbers of patients transfused before and after introduction of the IT-based reporting system were 12,293 and 17,178 cases, respectively. If a patient showed multiple adverse reactions, the total number of adverse reactions was counted as one. p values were calculated with chi-square by comparison of the frequencies between paper- and IT-based reporting systems.

system for all adverse reactions. In particular, the frequency of urticaria ($p < 0.001$), pruritus ($p < 0.001$), rash ($p < 0.001$), fever ($p < 0.001$), tachycardia ($p = 0.003$), nausea and/or vomiting ($p = 0.010$), and hypertension ($p = 0.001$) was significantly higher in the IT-based reporting system. For PC transfusion, the frequency of urticaria

($p < 0.001$), pruritus ($p < 0.001$), and rash ($p = 0.002$) was significantly higher in the IT-based reporting. In RBC transfusion, the frequency of urticaria ($p < 0.001$), pruritus ($p < 0.001$), rash ($p = 0.001$), fever ($p < 0.001$), tachycardia ($p = 0.005$), and hypertension ($p = 0.006$) was significantly higher using the IT-based reporting system. Likewise, the

TABLE 2. Number (%) of patients transfused and reported ARs for each blood component*

Blood components	Paper-based reports (2008-2010)	IT-based reports (2011-2013)	p value
PC			
Transfused cases	4,626	7,005	
Reported on ARs	10 (0.22)	233 (3.33)	< 0.001
With severe ARs	2 (0.04)	1 (0.01)	0.347
RBCs			
Transfused cases	6,086	8,395	
Reported on ARs	9 (0.15)	86 (1.02)	< 0.001
With severe ARs	3 (0.05)	2 (0.02)	0.419
FFP			
Transfused cases	1,581	1,778	
Reported on ARs	6 (0.38)	56 (3.15)	< 0.001
With severe ARs	2 (0.13)	2 (0.11)	0.907
Total			
Transfused cases	12,293	17,178	
Reported on ARs	25 (0.20)	375 (2.18)	< 0.001
With severe ARs	6 (0.05)	5 (0.03)	0.392

* p values were calculated by the chi-square test.
ARs = adverse reactions.

frequency of FFP transfusion, urticaria ($p < 0.001$), pruritus ($p < 0.001$), and rash ($p < 0.001$) was significantly higher when employing the IT-based reporting system (Table 1).

Additionally, we compared the frequencies of adverse reactions among the three transfusion procedures (PC, FFP, and RBCs) separately in the IT-based reporting system (Table 3). Allergic cutaneous reactions including urticaria, pruritus, and rash were more frequently reported in PC and FFP transfusions than in RBC transfusion ($p < 0.001$ and $p < 0.001$, respectively). However, the frequency of fever was significantly higher in RBC than PC transfusions ($p = 0.011$). The frequency of tachycardia and hypertension was not significantly different between the three transfusion procedures.

The frequencies of allergic cutaneous reaction in transfusion of each blood component

The frequencies of allergic cutaneous reactions, including urticaria, pruritus, and rash, in the transfusion of each blood component were compared between the paper- and IT-based reporting systems. Allergic cutaneous reactions account for 0.19% versus 3.04% of total adverse reactions reported for PC transfusion ($p < 0.001$), 0.03% versus 0.42% for RBC transfusion ($p < 0.001$), and 0.19% versus 3.15% for FFP transfusion ($p < 0.001$) using the paper- and IT-based reporting systems, respectively (Table 1). Allergic cutaneous reactions were the most frequently reported adverse reaction in transfusions for all three blood components. Fever, hypertension, and tachycardia were more frequently reported in RBC transfusion.

Accuracy of the reporting in both systems

Incorrect reports were observed in 90 cases, which include 58 clerical errors in reaction entry (clerical errors; 64%) and 32 reported symptoms unrelated to the transfusion such as fever (17%, 15 cases), trouble in instillation procedure (4%, four cases), and existing hypertension (3%, three cases) and hypotension (2%, two cases). In all cases the reporters failed to notice incorrect inputs themselves. All of the incorrect inputs were corrected after confirmation by members in the blood transfusion unit. By contrast, there was no error report in the paper-based reporting ($p < 0.001$).

DISCUSSION

In this study, we analyzed the effect of changing the adverse reaction reporting protocol from a paper-based system to an IT-based system and assessed the influence of this change on hemovigilance in our hospital. The total number of cases transfused between the two study periods is different. The reasons might be explained by the fact that the number of operations was increased mainly because there was a revision of the health insurance sys-

tem and that the number of patients with hematologic disorders increased in our hospital because of a shortage of hematologists in nearby hospitals.

Initially, we examined the difference in the reported frequency of adverse reactions before and after changing the reporting system. The reported frequency of adverse reactions in the IT-based reporting system was significantly higher (2.18%) than in the paper-based reporting system (0.20%). Yeh and colleagues¹⁵ described a similar trend, where the reported frequency of adverse reactions increased from 0.21% to 0.61% after a change in the reporting procedure from a paper-based reporting system to an IT-based reporting system. However, Yeh and colleagues did not specifically report the frequencies of reaction after transfusion for each blood component nor report the frequencies in relation to the severity of reaction. They mainly reported results based on a questionnaire from 40 nurses experienced in using both reporting systems. In their survey, 78% of nurses did not report adverse reaction in the paper-based reporting system, and the proportion of nurses not reporting adverse reaction decreased to 6% in the IT-based reporting system.

There are three possible reasons for the observed increase in the reported incidence of adverse reactions upon introduction of an IT-based reporting system. First, the introduction of an IT-based reporting system made adverse reaction reporting easier and more convenient. In a paper-based reporting system, doctors and nurses who found an adverse reaction had to notify the event to the transfusion unit, enter the symptoms in an adverse reaction report, and then describe details of the adverse reaction in a medical record. By contrast, using an IT-based reporting system, doctors and nurses who found an adverse reaction only need select applicable symptoms from a list on a PDA screen and the adverse reaction is automatically included in the medical records of the patient as well as being simultaneously reported to the transfusion unit. Thus, adverse reactions that had not been reported in the paper-based reporting system might be recorded in the IT-based reporting system because of the reduced workload associated with documenting such events.

Second, doctors and nurses taking blood transfusions must have a PDA, which is used to record details of each patient. As such, regular reports of the transfusion with an evaluation for the presence or absence of adverse reactions are recorded.

Finally, because all symptoms related to adverse reactions are listed on a PDA screen in an IT-based reporting system, the item that should be checked can be selected at the bedside. Doctors and nurses with limited knowledge of complications arising from blood transfusions can confirm possible adverse reactions by simply checking a PDA screen.^{16,17} Thus, unreported adverse reactions in a paper-based system tend to be reported after introduction

TABLE 3. Comparison of the frequency of adverse reactions among different blood components in IT-based reporting system (PC vs. RBCs, RBCs vs. FFP, and PC vs. FFP)*

Adverse reactions	PC vs. RBCs	RBCs vs. FFP	PC vs. FFP
Allergic cutaneous reactions	213 vs. 35 (3.04 vs. 0.42) $p < 0.001$	35 vs. 56 (0.42 vs. 3.15) $p < 0.001$	213 vs. 56 (3.04 vs. 3.15) $p = 0.813$
Urticaria	164 vs. 32 (2.34 vs. 0.38) $p < 0.001$	32 vs. 37 (0.38 vs. 2.08) $p < 0.001$	164 vs. 37 (2.34 vs. 2.08) $p = 0.508$
Pruritus	135 vs. 12 (1.93 vs. 0.14) $p < 0.001$	12 vs. 17 (0.14 vs. 0.96) $p < 0.001$	135 vs. 17 (1.93 vs. 0.96) $p = 0.003$
Rash	19 vs. 10 (0.27 vs. 0.12) $p = 0.030$	10 vs. 11 (0.12 vs. 0.62) $p < 0.001$	19 vs. 11 (0.27 vs. 0.62) $p = 0.038$
Fever	8 vs. 25 (0.11 vs. 0.30) $p = 0.011$	25 vs. 3 (0.30 vs. 0.17) $p = 0.316$	8 vs. 3 (0.11 vs. 0.17) $p = 0.576$
Tachycardia	5 vs. 12 (0.07 vs. 0.14) $p = 0.175$	12 vs. 3 (0.14 vs. 0.17) $p = 0.800$	5 vs. 3 (0.07 vs. 0.17) $p = 0.261$
Hypertension	2 vs. 7 (0.03 vs. 0.08) $p = 0.146$	7 vs. 1 (0.08 vs. 0.06) $p = 0.699$	2 vs. 1 (0.03 vs. 0.06) $p = 0.596$

* Data are reported as cases (%). Significance was analyzed by the chi-square test. p values were calculated by comparison among the three blood components

of an IT-based system, which, in turn, results in an increase in reported frequencies.

Although reports of adverse reactions increased in transfusions for all three blood components using the IT-based reporting system, those related to PC transfusions increased the most. The reasons might be speculated by the previous reports, which showed adverse cutaneous reactions associated with PC transfusion were found to be more frequent than for RBC or FFP transfusion.^{12,18,19} Moreover, there were a considerable number of mild adverse reactions which were neither reported to the transfusion unit nor evaluated by the specialists for transfusion medicine.¹⁹

While the frequencies of severe adverse reactions were not significantly different between the two different reporting methods, the IT-based reporting system has a number of important merits over a paper-based reporting system. For example, the IT-based reporting system reduces the burden of doctors and nurses who have a heavy workload. Furthermore, the IT-based reporting system allows the specialist in a transfusion unit to receive prompt information for adverse reactions and intervene in the treatment regime at an earlier stage.

Using the paper-based system, cases of adverse reactions were reported to the transfusion unit on paper only after an initial description of symptoms by telephone. In these circumstances, the initial reporter will briefly explain the symptoms in relationship to the transfusion, and may discuss a possible association. Thus, the paper-based reporting system appears to be inconvenient to the reporters and resulted in an increase of underreporting of

adverse reactions. By contrast, IT-based reporting quickly and directly describes any such adverse reaction by digital transmission. Any errors in the initial report should be subsequently confirmed and corrected when necessary. It is important to differentiate the underlying basis of a patient's symptoms because the ensuing treatment may vary depending on their cause. Therefore, the staff of the transfusion unit may telephone the reporter and discuss the symptoms in detail, especially if they are of uncertain origin. In this study, even if there was only a slight possibility of a symptom being caused by the transfusion procedure, we counted it as an adverse reaction.

Next, we assessed the influence of the introduction of the IT-based reporting system on the definitive diagnosis of adverse reactions. The reported number of cases of urticaria, pruritus, rash, fever, nausea, and vomiting, which are generally described as mild adverse reactions, significantly increased upon introduction of the IT-based reporting system in this study. Therefore, any difference in the reported frequency of adverse reactions between the two systems is attributable to variation in the reporting rate of mild adverse reactions between the reporting systems. Mild reactions can often be missed or downgraded and result in underreporting. Narvios and coworkers¹⁹ analyzed underreported adverse reactions in patients receiving a blood transfusion and found that underreported adverse reactions included urticaria (41%), fever (19%), chill (19%), vomiting (2%), and others (19%). All of these adverse reactions were mild. However, many adverse reactions begin with mild symptoms of varying duration.²⁰ For example, symptoms related to allergic cutaneous reactions

including urticaria, pruritus, and rash, which were frequently underreported, can be an early sign of anaphylactic shock.^{21,22} In addition, fever, nausea, and vomiting could be symptoms related to hemolytic transfusion reactions^{13,14} or bacterial infection.²³ Furthermore, transfusion malpractices, such as ABO major mismatch, sometimes begin with mild symptoms and hematuria.²⁴ Indeed, the reporting of mild symptoms at an early phase of the transfusion procedure may be one of the most important merits of the IT-based reporting system.

Nonetheless, the reports generated from the IT-based system in this study included 0.52% of misidentified adverse reactions. We believe that incorrect reports frequently arise due to two distinct reasons. First, a reporter may select a wrong item when inputting it on the PDA. Almost all of the clerical errors were unrecognized by the reporters themselves until pointed out by the transfusion unit. We should be aware of incorrect selections that can easily be made in an IT-based reporting system.

The second commonly observed misreporting involves inappropriate recording of symptoms that are unrelated to the transfusion procedure. It is sometimes difficult to decide whether symptoms observed during a transfusion are related to adverse reactions or to an underlying disease or complication other than the transfusion. The most frequent example of inappropriate reporting of adverse reactions in this study was that of fever, which accounted for 17% of such cases. The definition of fever caused by a transfusion is “an increase in body temperature above 38°C after starting a transfusion or a 1°C or more increase in body temperature after starting a transfusion” and that of hypotension is a “30 mmHg or more reduction of systolic blood pressure after starting a transfusion.” Similar criteria for symptoms are set to other adverse reactions related to transfusion.^{13,25} The frequency of incorrect reports probably increased because reporters input the occurrence of an adverse reaction when they observed the symptom listed on PDA without considering carefully whether it was caused by the transfusion or not. Incorrect reports not only make the true frequency of adverse reactions unclear but may also lead to misdiagnosis and wrong treatment.¹² Transfusion specialists should verify the facts together with the reporter. Moreover, reporters must learn their role in relaying information in addition to proper usage of the system. The reporter must also learn about the variation and severity of adverse reactions because this information is needed to properly fill out the report. Indeed, mild symptoms can sometimes lead to a critical reaction.

We should note that it is not possible to ascertain the true frequency of adverse reactions without performing lengthy reviews of the medical reports extensively. Furthermore, some reporters might not completely describe adverse reactions on medical reports. The IT-based system was found to increase the reporting of mostly benign reac-

tions, but not the rate of reporting of severe reactions. Moreover, there are possibly additional reactions that were unreported despite the use of the IT-based reporting system.

In conclusion, introduction of an IT-based reporting system and its effective use might lead to the quick response of the transfusion unit and initiation of treatment for adverse reactions. An understanding of the shortcomings of an IT-based reporting system allows us to complement the data, which will reinforce the standard of in-hospital hemovigilance. The transfusion unit should frequently monitor whether in-hospital hemovigilance is functioning appropriately after the introduction of an IT-based reporting system. Additionally, we should continue educating medical staff on adverse reactions related to transfusion.

CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

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