



A survey of blood transfusion errors in Aichi Prefecture in Japan: Identifying major lapses threatening the safety of transfusion recipients



Masaki Ri^{a,b,*}, Masanobu Kasai^{a,c}, Akio Kohno^{a,d}, Masaru Kondo^{a,e}, Masashi Sawa^{a,f}, Tomohiro Kinoshita^{a,g}, Isamu Sugiura^{a,h}, Yasuo Miura^{a,i}, Kazuhito Yamamoto^{a,j}, Toshiki I. Saito^{a,k}, Yukiyasu Ozawa^{a,l}, Tadashi Matsushita^{a,m}, Hidefumi Kato^{a,n}

^a Aichi Prefectural Joint Committee of Blood Transfusion Therapy, Nagoya, Japan

^b Department of Blood Transfusion and Cell Therapy, Nagoya City University Hospital, Nagoya, Japan

^c Department of Hematology and Oncology, Japanese Red Cross Nagoya Daini Hospital, Nagoya, Japan

^d Department of Hematology and Oncology, Konan Kosei Hospital, Konan, Japan

^e Okazaki City Hospital, Okazaki, Japan

^f Department of Hematology and Oncology, Anjo Kosei Hospital, Anjo, Japan

^g Japanese Red Cross Aichi Blood Center, Seto, Japan

^h Blood Transfusion and Cell Therapy Center, Toyohashi Municipal Hospital, Toyohashi, Japan

ⁱ Department of Transfusion Medicine and Cell Therapy, Fujita Health University Hospital, Toyoake, Japan

^j Department of Hematology and Cell Therapy, Aichi Cancer Center Hospital, Nagoya, Japan

^k Clinical Research Center, National Hospital Organization Nagoya Medical Center, Nagoya, Japan

^l Department of Hematology, Japanese Red Cross Nagoya Daiichi Hospital, Nagoya, Japan

^m Department of Transfusion Medicine, Nagoya University Hospital, Nagoya, Japan

ⁿ Department of Transfusion Medicine, Aichi Medical University Hospital, Nagakute, Japan

ARTICLE INFO

Keywords:

Transfusion survey
Questionnaires
Malpractice
Aichi Prefecture
Japan
Human error

ABSTRACT

Background: Despite recent progress in blood systems, transfusion errors can occur at any time from the moment of collection through to the transfusion of blood and blood products. This study investigated the actual statuses of blood transfusion errors at institutions of all sizes in Aichi prefecture.

Materials and methods: We investigated 104 institutions that perform 98 % of the blood transfusions in Aichi prefecture, and investigated the errors (incidents/accidents) that occurred at these facilities over 6 months (April to September, 2017). Incident/accident data were collected from responses to questionnaires sent to each institution; these were classified according to the categories and risk levels.

Results: Ninety-seven of the 104 institutions (93.3 %) responded to the questionnaire; a total of 688 incidents/accidents were reported. Most (682 cases; 99.2 %), were classified as risk level 2; however, 6 were level 3 and over, which included problems with autologous transfusion and inventory control. Approximately one-half of the incidents/accidents (394 cases; 57.3 %), were related to verification and the actual administration of blood products at the bedside; more than half of these incidents/accidents occurred at large-volume institutions. Meanwhile, a high frequency of incidents/accidents related to transfusion examination and labeling of blood products was observed at small- or medium-sized institutions. The reasons for most of these errors were simple mistakes and carelessness by the medical staff.

Conclusions: Our results emphasize the importance of education, operational training, and compliance instruction for all members of the medical staff despite advances in electronic devices meant to streamline transfusion procedures.

1. Introduction

Transfusion of blood is widely performed supportive therapy for

patients with active or chronic bleeding, surgical stress, or hematological disorders. In Japan, blood transfusions are routinely conducted across medical institutions, including large hospitals and small clinics.

* Correspondence author at: Department of Blood Transfusion and Cell Therapy, Nagoya City University Hospital, 1 Kawasumi, Mizuho-chou, Mizuho-ku, Nagoya, Aichi, 467-8601, Japan.

E-mail address: rmasaki@ybb.ne.jp (M. Ri).

<https://doi.org/10.1016/j.transci.2020.102735>

Received 18 September 2019; Received in revised form 18 December 2019; Accepted 6 January 2020

1473-0502/ © 2020 The Author(s). Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

However, inappropriate management of a blood transfusion carries a high risk of causing a life-threatening accident in a recipient. Policies and guidelines related to blood transfusions have been established by the Ministry of Health, Labor, and Welfare (MHLW) of Japan [1,2], and used as a reference for the blood transfusion treatment system in each hospital. These guidelines include two scopes, the safety procedures of transfusion medicine and the appropriate use of blood products, thereby focusing on the prevention of side effects triggered by immature blood transfusion systems. These guidelines also recommend the use of blood products based on clinical evidence and transfusion triggers for each disease, such as active or chronic bleeding and hematological disorders, and have wide acceptance in most of the institutions handling blood transfusions. In the last decade, due to the establishment of policies and guidelines, the approach to transfusion-related adverse events have improved, and serious mistransfusions, such as ABO-incompatible transfusion and patient identification errors, have been reduced with the aid of advanced information technology. However, human errors of any dimension in transfusions, reported as incidents and accidents, have neither been reduced considerably nor have shown any improvement so far. To reduce transfusion errors, a practical guide for safe hospital blood transfusions was additionally issued by the Japanese society of blood transfusion and cell therapy under supervision of the MHLW [3]. However, ignorance or poor understanding of the transfusion system among the medical staff having less experience with transfusions may be a critical factor for the generation of transfusion errors, even though practical and detailed guidelines have been established. In addition, the diversity of patient volumes and specialties across these institutions results in disparate incidence or accident rates among them. Therefore, to eliminate errors and improve the safety of blood transfusions, it is necessary to surveil these institution to document any incidents and accidents that occur in order to learn how to prevent them more effectively [4,5].

Owing to advancing technologies, the automation and computerization of blood transfusion procedures have the potential to reduce clerical errors. Using barcode-based coupling of the patient's ID band with blood product labels, as well as radiofrequency identification (RFID), human error rates have been dramatically reduced. However, costs, security, and privacy appear to be the principal barriers to the adoption of these advanced technologies at many institutions [6], especially small-sized facilities. Moreover, no system has been developed that can completely eliminate the incidences of human error to date, as even technologies such as RFID are not fool-proof [7–9].

To ensure the safety of transfusion medicine in Aichi prefecture in Japan, we previously selected 12 major medical institutions that perform abundant blood transfusions, and performed a preliminary analysis of the incidents and accidents reported by these facilities over 6 months in 2016. Our analysis revealed that such incidents/accidents all occurred during the process of blood transfusion, from ordering the blood product to actual infusion by the bedside. The occurrence of these incidents was considered to be due to an insufficient understanding of the operative norms and systems required, as well as careless mistakes by the medical staff at all levels at each institution.

In the current study, we performed an expanded survey of transfusion related incidents that occurred across the entire prefecture of Aichi, analyzed their causes, and identified effective methods to prevent human errors and enhance the safety of transfusion medicine in the era of highly advanced electronic devices.

2. Materials and methods

We performed a retrospective review of transfusion-related events covering the period between April and September, 2017. A total of 104 medical institutes that collectively perform 98 % of all blood transfusions in Aichi prefecture were sent questionnaires to inquire about both their specific transfusion procedures and any related incidents or accidents. This questionnaire collected 5 key pieces of information

Table 1
Classifications of blood transfusion incidents/accidents.

Categories	
1	Ordering pre-transfusion testing
2	Handling labels and collection of specimens
3	Performance of transfusion-related testing
4	Transferring the results of transfusion-related testing
5	Decision to administer blood products and ordering
6	Ordering blood products from the Japanese Red Cross Society
7	Receiving the blood product and irradiation
8	Handling and storing the blood products at the blood transfusion unit
9	Delivering the blood product to the inpatient ward
10	Handling of the blood product at the inpatient ward
11	Preparation and confirmation of the blood transfusion just before the procedure
12	Transfusion of blood products in a bed side
13	Implementation record of transfusion, mainly by electronic device
14	Returning the products
15	Inventory control
16	Self-donated products
17	Stem cell transplantation and cell therapy

including the number of blood products actually transfused, type of transfusion error, number of incidents/accidents that occurred during the surveillance period, impact of the transfusion incident/accident on the recipient, and cause of the incident/accident (supplemental data 1).

Transfusion related incidents/accidents were classified into categories and risk levels according to the guidelines proposed by the MHLW study group 'Research of the Side Effects of Transfusions' (Table 1). Risk assessments for each incident or accident were determined based on the impact on the recipient. As shown in Table 2, events of levels 0–3a were defined as incidents, whereas events of levels 3b and over were defined as accidents that required continuous treatment owing to ensuing illnesses or injuries.

2.1. Statistical analysis

Linear regression analysis was performed to estimate the relationship between the number of blood products and the events per institution.

3. Results

3.1. Total number of supplied blood products and transfusion errors

Of the 104 institutions surveyed, 97 (93.3 %) responded to the questionnaire; the sizes of the responding facilities are summarized in Fig. 1a. Among the 97 institutions that participated, 42.3 % were small-scale (20–299 beds), 28.9 % were median-scale (300–499 beds), and 25.8 % were large-scale (≥ 500 beds). The total number of blood products administrated in these 97 institutions during the survey period was 118,206, including 75,347 red blood cell products, 20,735 platelet products, 17,941 fresh frozen plasma products, and 4183 whole-blood products for autotransfusion. A total of 688 incidents and accidents were reported during the survey period, with an event rate of 0.58 %. In linear regression analysis between the number of blood products and the incidences of transfusion (supplemental data 2), only a poor-to-moderate correlation was observed ($R^2 = 0.406$; $p < 0.0001$).

3.2. Numbers and contexts of transfusion errors at each risk level

All 688 incidents/accidents were categorized according to the stages in which they occurred (Fig. 1b). The highest incidences of these events occurred during implementation/recording at the bedside (category 13), transfusion of blood products at the bedside (category 12), and preparation and verification of blood transfusion (category 11), at 23.3 % (160 events), 17.4 % (120 events), and 16.6 % (114 events),

Table 2
Definitions of blood transfusion incident/accident risk levels.

	Level	Description
Incident	Level 0	Found and corrected a mistake that risked incorrect handling
	Level 1	No consequences for the patient owing to the incident
	Level 2	Patient experienced incident-related consequences that did not require treatment
	Level 3a	Any serious changes requiring transient treatment owing to the accident
Accident	Level 3b	Any serious changes owing to the accident that required continuous treatment
	Level 4a	Any serious changes owing to the accident that required long-term treatment
	Level 4b	Any serious changes that caused subsequent complications because of the accident
	Level 5	Death due to the accident

respectively. These 3 categories, which mainly involved checking and implementing the blood transfusion procedure at the bedside, accounted for half of all the incidents/accidents. Representative examples of such incidents or accidents in each category are shown in Table 3.

The breakdown of all 688 incidents/accidents category-wise is seen in Fig. 2a. As seen in Table 4, there were six events of level 3 and higher including 2 cases related to handling transfusions at the bedside

(category 12), 2 related to autologous transfusion (category 16), 1 involving inventory control (category 15), and 1 involving internal handling (category 10). In 2 cases, autologous blood samples were spoiled owing to incorrect handling of the storage bag, and spoilage of a cord blood stem cell product also occurred because of inefficient handling of the refrigerator. Incidents or accidents occurred across all stages of blood transfusion, and the main reasons for their occurrence

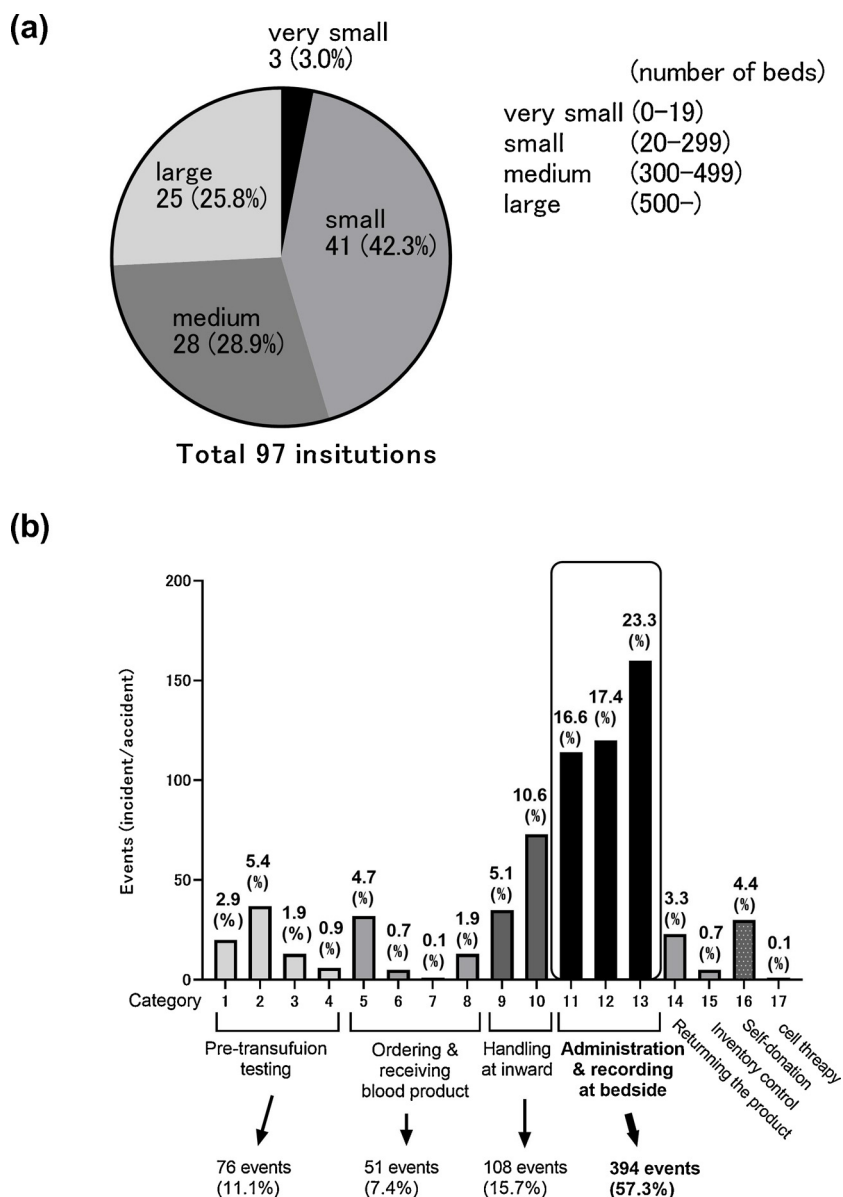


Fig. 1. Types of institutions enrolled in this study and classification of transfusion incidents/accidents. (a) The sizes of the 97 institutions enrolled in this study. (b) Numbers and percentages of transfusion incidents/accidents in each category.

Table 3
Representative cases of incidents/accidents from the error 3 categories that occurred most frequently.

Category	Representative case
11	Lack of informed consent for transfusion Lack of confirmation just before administering the product, such as coupling the patient's ID band with the blood product label Wrong setting of the speed of the administration
12	Forgetting to administer the blood product at a planned time or date. A root error resulting in mixing the blood product with other drugs
13	Administration of the wrong blood product volume Forgetting to record the administered blood product Recording the ID of an unused product No observation or recording of side effects following blood transfusion

were either a poor understanding of (or insufficient compliance with) operational procedures, insufficient collaboration between the medical staff, and human errors attributable to work fatigue.

Finally, we analyzed the categories of incidents/accident as a function of institution size (Fig. 2b and c). Among all groups, a high incidence of category 11–13 errors was observed (62.4 %, 46.9 %, and 48.0 % in large-, medium-, and small-sized institutions, respectively; Fig. 2c). However, when focusing on the early processes of blood transfusions (categories 1–4), small- and medium-sized institutions showed higher incident rates (17.9 % and 13.3 %, respectively); large-sized institutions had a rate of 8.6 %.

4. Discussion

In our study, responses to the questionnaires were obtained from most of the institutions that perform blood transfusions in Aichi

prefecture. Therefore, our retrospective study includes almost all cases of transfusion errors that occurred across institutions of all sizes, and may thus provide actionable data that can be used to prevent future transfusion errors.

A total of 688 transfusion-related incidents/accidents occurred over 6 months in Aichi prefecture; as such, the rate of incidents/accidents was 0.58 %. This rate was relatively higher than those found in 2 previous studies conducted in Japan, including a survey of incidents/accidents at 12 major institutions in Aichi prefecture (0.38 %) and a 7-year survey of a single institute (0.51 %) [10]. Unlike these previous studies, ours included a high number of small- or medium-sized institutions; these showed rates of incidents/accidents per transfused blood sample (1.16 % and 0.56 %, respectively), which were higher than the rates observed in large-sized facilities. Among all the processes related to blood transfusion procedures, those involving pre-transfusion tests (categories 1–4) showed a lower frequency of incidents/accidents than did other processes. However, a relatively high rate of incidents during pre-transfusion testing was observed in small- or medium-sized institutions, indicating the lack of a well-constructed system or inexperience in handling pre-transfusion testing in such facilities. The establishment of a well-planned system that takes into account the characteristics and size of each individual facility is required to ensure patient safety during pre-transfusion testing [6].

Consistent with previous reports [11,12], approximately one-half of the incidences/accidents observed in our study were from categories 11–13, which involved bedside procedures. Therefore, retraining of personnel for proper compliance with transfusion procedures, especially physicians and nurses, is needed to reduce bedside errors. Several errors related to the recording of administered blood products (category 13), such as documenting unused blood samples, neglecting to record transfusion-related side effects, and forgetting to document the transfusion altogether, were observed. Although the development of

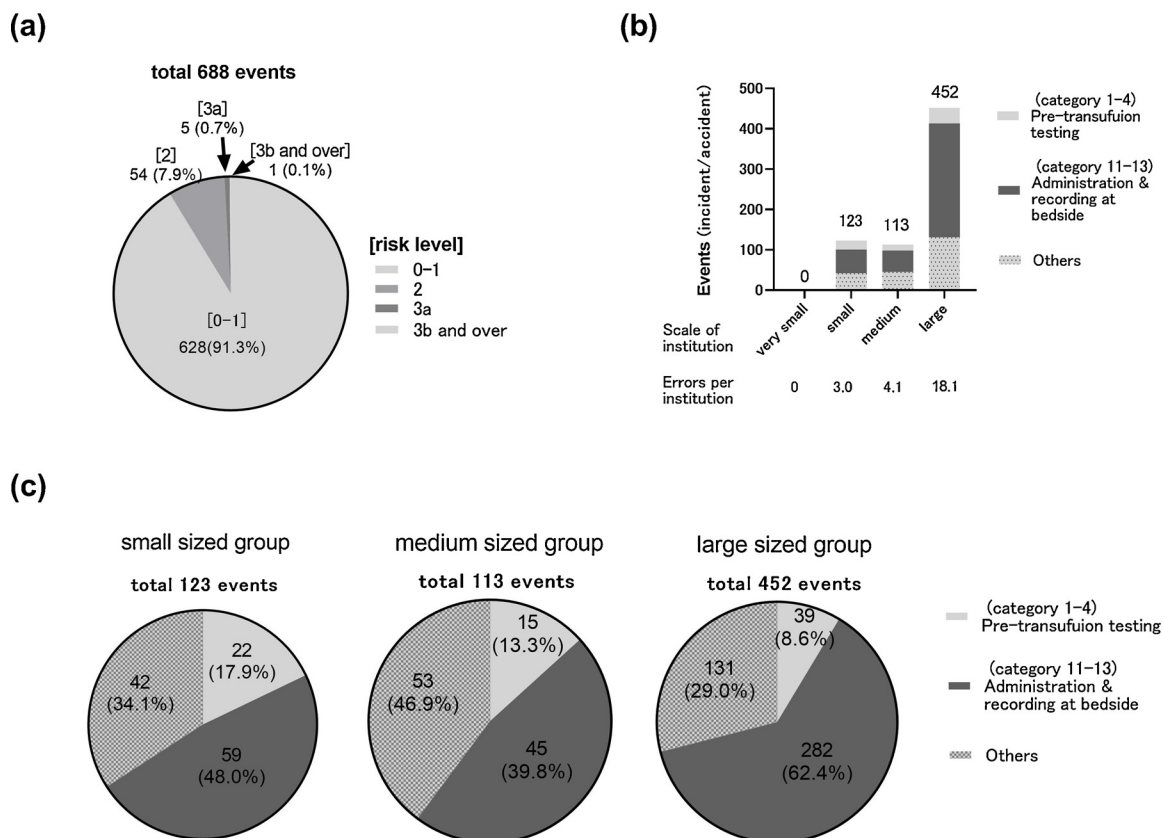


Fig. 2. Classification of transfusion incidents/accidents according to risk level and category. (a) The numbers of incidents/accidents in each risk level. (b) & (c) Populations that experienced incidents/accidents of categories 1–4, categories 11–13, and other categorizes per size of facility.

Table 4
Cases of error category level 3 and higher.

Category	Level	Case
10	3a	Blood products sent from blood transfusion unit to the ward were missing resulting in worsening of anemia in the patient.
12	3a	Administration of multiple blood products within a short period without planned interval between the products, resulting in heart failure of the patient due to overdose.
	3a	Missed observation of the patient with history of transfusion allergy during administration of blood product, resulting in worsening of the transfusion allergy and the need for intensive medication.
15	3b	Missed closing the lid of liquid nitrogen freezer used for preservation of cord blood stem cells, resulting in spoiled cord blood cells. This accident resulted in termination of allogeneic stem cell transplantation and subsequent progression of the hematological disease in the patient.
16	3a	Spoiled autologous blood samples just before the transfusion due to incorrect handling of the storage bag in the postoperative patient. Emergency transfusion was performed.
	3a	Excessive blood collection from the patient for autologous blood transfusion due to missing confirmation of planned volume, leading to the development of vasovagal reaction and the need for medication.

electronic equipment enables the establishment of well-planned blood transfusion procedures, human errors still occur [6,9,13]. To prevent this, training of the medical staff to comply with transfusion procedures should be prioritized [11,14].

In our study, the main causes of incidents/accidents were attributed to simple mistakes such as the lack of documentation or carelessness. Transfusion-related errors can be serious in nature, such as when incompatible blood is administered. Excess dependence on electronic devices may also trigger human errors and/or prevent their early detection; therefore, essential preventive precautions, compliance with operating procedures, and verifying that the blood product matches the intended recipient at the bedside should all be emphasized via educational or retraining programs targeting the medical staff. In most academic institutions, lectures on transfusion medicine and practical examinations on transfusion-related training are conducted for both the undergraduate and graduate students; however, in Japan, no systematic evaluation of comprehension and attainment of transfusion procedures in students are conducted before they begin working. Therefore, to reduce errors caused by lack of knowledge and experience among the medical staff, well-planned training and pre-work evaluation of the performance of the transfusion procedure should be conducted.

With respect to the risk level of incidents/accidents, most cases were assessed as levels 0–2, suggesting that the risk to the patients' safety was minimal. However, level 3 events occurred in 6 cases, among which 5 transpired in large-sized institutions. These included 1 event related to the handling of a blood product at an inpatient ward (category 10), 2 events related to errors at bed side (category 12), 1 event related to the inefficient handling of a refrigerator (category 15), and 2 events related to autologous transfusion (category 16). Among them, two serious incidents occurred at a bed side (category 12), a heart failure due to an overdose of blood products, and worsening of a transfusion allergy in a patient with a history of transfusion allergy, that could have been prevented if multiple checks had been conducted by the staff. While administering two or more blood products, the planned interval between the products and the dosing rate of administration should be carefully confirmed before the start of the procedure. In addition, history of side effects and allergy related to transfusion in the patient should be shared and re-confirmed by the staff. Lacking confirmation of these fundamental matters is likely to trigger other serious malpractices, and therefore should be corrected by re-training the medical staff and re-confirming the checking procedure. In case of the spoiled cord blood (level 3b, category 16), a simple mistake of forgetting to close the lid of the refrigerator caused a serious consequence of cancellation of the allogeneic transplantation and subsequent worsening of the hematological disorder. The reason for this error may be the lack of experience of the staff handling the liquid nitrogen tank, and inadequate setting of the temperature monitoring system. In Japan, stem cell transplantations are performed even in small-sized institutions, and the employment of specialized technical staff for transfusion and cell therapy has been insufficient in most of the institutions. Therefore, further improvement in handling the preservation of blood and cell

products and preserving the quality of these products is required to avoid serious errors and secure the safety of the transfusion recipients.

Recent advantages of the risk management system has encouraged all the staff in healthcare institutions to voluntarily report medical adverse events, incidents and accidents, promptly. Most medium- to large-sized institutions have formed a medical safety committee with a safety manager for each department, to collect and evaluate all the incidents/accidents occurring in the institution. Reporting of critical incidents can provide an important learning effect from the errors as it helps to unmask potentially critical weak points. In Japan, most of the institutions handling blood transfusions hold a conference for the safety managers and Transfusion Therapy Committee once a month, to evaluate all the events related to transfusion errors, and submit a report of the transfusion errors to the regional bureau of health and welfare. Recently, several large institutions have developed computerized incident reporting, which can detect preventable events from the medical records, and operate the critical incident reporting system (CIRS) uniquely. However, these systems have been introduced in limited institutions, mainly large-sized institutions, and no data are available on how the CIRS is used within the healthcare facilities in Japan. CIRS can be regarded as a helpful and supportive tool in clinical risk management. Sharing all transfusion errors among the institutions by a well-established CIRS is desirable to support organizational learning and collective knowledge management.

As a limitation of our study, transfusion errors were retrospectively analyzed, and replies in the questionnaire may be subject to recall or other biases. In addition, our study had several other issues that required improvement: the number of institutions investigated was small, duration of the investigation period was limited, and there was a lack of critical content related to each incident/accident, such as the kind of medical staff responsible for the incident/accident and the adequacy assessment of the blood transfusion training pathway at each institution. A well-planned prospective survey is desirable to resolve the bias and elucidate the fundamental issues triggering blood transfusion errors at each institution more accurately.

Results of the current study were reported to the Aichi Prefectural Joint Committee of Blood Transfusion Therapy. After evaluation and approval by the committee, these results were posted on the homepage of the regional bureau of health and welfare in Aichi prefecture, and also sent to all the institutions handling blood transfusions. Several institutions adopted the results of the current study to educate and train all the medical staff handling blood transfusions. In addition, a survey of the transfusion system and related problems in small-sized institutions and home medical care centers such as clinics has now been proposed based on the result of our study, which will be conducted by the Aichi Prefectural Joint Committee of Blood Transfusion Therapy.

In conclusion, errors were observed during all stages of the blood transfusion process, mainly during the confirmation, handling, and documenting of transfusions by the bedside. Most were simple mistakes committed by the medical staff. Education, training, and assuring compliance with proper transfusion procedures for all the involved

personnel should be prioritized to prevent such human errors and ensure the safety of transfusion medicine.

Authorship contributions

Study conception and design: T.M., H.K.

Acquisition, analysis, and interpretation of data: M.R., M.K, A.K., M.K., M.S., T.K., I.S., Y.M., K.Y., T.I.S., Y.O., M.T., H.K.

Drafting of manuscript: M.R., H.K,

All Authors reviewed and edited the manuscript.

Declaration of Competing Interest

None of the Authors has a conflict of interest with any of the subject matter of this work.

Acknowledgements

We thank all institutions in Aichi Prefecture that participated in the survey for transfusion errors.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.transci.2020.102735>.

References

- [1] Handa M. Safer and more appropriate blood transfusion therapy. Rinsho Ketsueki [Jpn J Clin Hematol] 2015;56(10):2170–9.
- [2] Research on regulatory science of pharmaceuticals and medical devices study on transfusion reaction monitoring system in medical institutions. Practical guide for safe hospital blood transfusion. The japan society of transfusion medicine and cell therapy. 2012. 1st version <http://yuketsu.jstmct.or.jp/wp-content/themes/jstmct/images/medical/file/reference/Ref22.pdf>.
- [3] Makino S. Transfusion medicine in practice. Rinsho Ketsueki [Jpn J Clin Hematol] 2016;57(10):2232–40.
- [4] Hensley NB, Koch CG, Pronovost PJ, et al. Wrong-patient blood transfusion error: leveraging technology to overcome human error in intraoperative blood component administration. J Commun. J Qual Patient Saf 2019;45(3):190–8.
- [5] Strauss R, Downie H, Wilson A, et al. Sample collection and sample handling errors submitted to the transfusion error surveillance system, 2006 to 2015. Transfusion 2018;58(7):1697–707.
- [6] Coustasse A, Cunningham B, Deslich S, Willson E, Meadows P. Benefits and barriers of implementation and utilization of radio-frequency identification (RFID) systems in transfusion medicine. Perspect Health Inf Manag 2015;12. 1d.
- [7] Clifford SP, Mick PB, Derhake BM. A case of transfusion error in a trauma patient with subsequent root cause analysis leading to institutional change. J Investig Med High Impact Case Rep 2016;4(2). 2324709616647746.
- [8] Heddle NM, Fung M, Hervig T, et al. Challenges and opportunities to prevent transfusion errors: a Qualitative Evaluation for Safer Transfusion (QUEST). Transfusion 2012;52(8):1687–95.
- [9] Nuttall GA, Stubbs JR, Oliver Jr. WC. Transfusion errors: causes, incidence, and strategies for prevention. Curr Opin Anaesthesiol 2014;27(6):657–9.
- [10] Sato Y, Niwa Y, Takahama H, Asazuma N, Murata Y, Sunouchi K. Incidents associated with blood transfusion in Kawakita General Hospital-Seven years' experience. Jpn J Transfus Cell Ther 2009;55(1):43–7.
- [11] Bolton-Maggs PHB. Serious hazards of transfusion - conference report: celebration of 20 years of UK haemovigilance. Transfus Med 2017;27(6):393–400.
- [12] Baele PL, De Bruyere M, Deneys V, et al. Bedside transfusion errors. A prospective survey by the Belgium SAnGUIS Group. Vox Sang 1994;66(2):117–21.
- [13] Mounchili A, Leduc S, Archibald C, Miller J, Hyson C. A summary of the transfusion error surveillance system: 2008–2011. Can Commun Dis Rep 2014;40(18):374–8.
- [14] Myhre BA, McRuer D. Human error - A significant cause of transfusion mortality. Transfusion 2000;40(7):879–85.