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Recommendations for the electronic pre-transfusion check at the bedside

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Pls verify the correctness of the references: the websites previously quoted in the text have been properly added to the list (ref. 17 onwards).

Introduction

The current risk of acquiring viral transmission through blood components is very small[1]. Thus, serious non-infectious hazards of transfusion have emerged as the most common complications[2]. The risk of non-infectious complications, including risks related to hospital-based steps in transfusion care, is at least 100 times greater than the risk of acquiring human immunodeficiency virus or hepatitis C virus infection through blood components[3]. One of the most frequent causes of transfusion-associated morbidity or mortality is mistransfusion, when the wrong blood is transfused to the wrong patient. Mistransfusion is the final outcome of one or more procedural errors or technical failures in the transfusion process, starting with the decision to transfuse a patient and ending with the actual administration of blood components[3]. In particular, ABO-incompatible transfusions attributable to incorrect identification of the patient or the blood unit are among the most serious transfusion hazards[3-5]. The Japan Society of Transfusion Medicine and Cell Therapy (JSTMCT) conducted nationwide surveys in Japan regarding ABO-incompatible blood transfusions (1st survey: January 1995-December 1999; 2nd survey: January 2000-December 2004). They found that the main cause of ABO-incompatible transfusion was identification error between the patient and blood unit[6]. These two surveys reported 9 and 8 "preventable" fatalities, respectively. Mislabelled and wrongly collected patient samples (wrong blood in tube [WBIT]) can also initiate a chain of events leading to mistransfusion[3]. Thus, correct patient identification at the time of sample collection and administration of blood components is critical.

The Serious Hazards of Transfusion (SHOT) scheme in England showed that approximately 70% of incorrect blood component transfused (IBCT) errors take place in clinical areas, with the most frequent error being failure of the final patient identification checking procedure at the bedside; the frequency of IBCT events was calculated as 7 per 100,000 components[7]. However, the true incidence of mistransfusion seems to be even higher due to a failure to recognise many of the errors, and because complete data on transfusion episodes are not available. Thus, the pre-transfusion checking procedure at the bedside is the most critical step to prevent mistransfusion, and represents the final opportunity to prevent blood component misuse. However, a large observational audit revealed a failure to perform the final bedside checking procedure[8], in which the practice compliance of healthcare workers for identification and vital sign monitoring of patients receiving blood transfusions were substandard in many hospitals.

Machine-readable identification technology, especially a bar code-based electronic identification system (EIS), is ideally suited for pre-transfusion checking procedures and has been reported to significantly improve transfusion practice[9-15]. The British Committee for Standards in Haematology (BCSH) Guidelines for the Use of Information Technology (IT) in blood transfusion laboratories were recently up-dated[16], providing mainly guidance on the operational use of laboratory information management systems (LIMS). Thus, to our knowledge, there are no available recommendations addressing the issues regarding the pre-transfusion check procedures at the bedside employing an EIS. The JSTMCT Task Force

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proposed the original draft of recommendations for the electronic pre-transfusion check procedures at the bedside and raised public awareness regarding the draft of recommendations on the home page of the JSTMCT[17]. The draft of the current recommendations developed by the Task Force adopted the opinions were submitted without major changes to the description. The objective of this study was to establish recommendations for the electronic pre-transfusion checking procedures at the bedside, appropriate for clinical situations, where a bar code-based EIS is used.

Purpose of the recommendations

This document sets out recommendations specifically addressing the issues regarding the electronic pre-transfusion checking procedures at the bedside using an EIS. The main body of recommendations includes: 1) pre-transfusion checking procedures at the bedside; 2) requirements for electronic pre-transfusion checking procedures at the bedside; 3) pre-transfusion checking procedures at the bedside for a conscious patient; 4) pre-transfusion checking procedures at the bedside for an unconscious patient or child; 5) pre-issuing checking procedures at the transfusion service; and 6) monitoring of the bedside use of issued blood components.

Transfusion policy

Although blood components are administered to patients in most large-scale community and university hospitals in Japan, some hospitals have no transfusion services and do not employ laboratory technologists licensed by the JSTMCT. It is recommended that hospitals where blood transfusions are frequently performed have a transfusion service or appropriate system with a professional medical doctor(s) responsible for managing the overall safety of blood transfusions. Such hospitals should have a multidisciplinary hospital transfusion committee to oversee the provision of safe and appropriate transfusion support. The hospital transfusion committee may be made up of doctors and nurses from clinical departments where blood administrations are frequently required, pharmacists, laboratory technologists, as well as hospital representatives.

Finally, transfusion practices should be performed in accordance with the transfusion policy, approved by the hospital transfusion committee, and should comply with the Guidelines and Information for Using Blood Products and Blood Transfusion Therapy (Japan Guidelines), issued by the Ministry of Health, Labour and Welfare in Japan (September 2005, partially updated in March 2012)[18], and also consider the number of people requiring electronic pre-transfusion checking procedures at the bedside.

Pre-transfusion checking procedures at the bedside

Current recommendations

Regarding the pre-transfusion checking procedures at the bedside Japan Guidelines recommend that: 1) blood components should be preserved under appropriate conditions; 2) the transfusionist (doctor or nurse) should check the appearance of blood components before initiating blood administration; 3) organisation and initiation of blood administration should be performed individually for each patient; 4) in order to prevent mistransfusion attributable to clerical errors, the transfusionist should check the information regarding both the patient and blood unit, i.e. the patient's name, blood group, product lot number, date of collection, results of compatibility testing, and whether or not blood components have been gamma irradiated; 5) a standard 2-person visual and verbal double-check should be performed regarding the above issues before initiating blood administration at the bedside; and 6) the transfusionist should check the patient's vital signs, including body temperature, blood pressure, pulse, and, if possible, oxygen saturation by pulse oximetry (SpO_2) before initiating blood administration. Finally, Japan Guidelines recommend the use of an EIS to ensure the safety and effectiveness of the pre-transfusion check at the bedside.

Number of people requiring pre-transfusion checking procedures

When an EIS is used in a hospital, the pre-transfusion checking procedures at the bedside may involve one or two healthcare professionals. Potential errors can be minimised if one individual carries out the pre-transfusion checking procedure using an EIS. However, if the electronic pre-transfusion check at the bedside fails because of human error[19], a 1-person pre-transfusion check without the new technology may present a higher risk of mistransfusion than a standard 2-person double-check, although the number of people required to check the identity of the patient and blood unit at the bedside is a subject of debate[20]. If an electronic pre-transfusion check is combined into a standard 2-person double-check it may help reduce confusion among healthcare professionals if the system malfunctions. Japan Guidelines recommend a standard 2-person visual and verbal double-check for pre-transfusion checking procedures at the bedside, as described above. In addition, the recent BCSH Guidelines stated that "the use of a bedside blood tracking system does not replace the role of the well trained and competency assessed clinician who administers blood components"[16].

Current recommendations do not positively recommend a 1-person pre-transfusion check at the

bedside, even if an EIS is used. Thus, the current recommendations state that the electronic pre-transfusion checking procedures at the bedside should be carried out by a 2-person team, one of whom should be the transfusionist and the other should be someone who carries out a second check (second checker); this need not necessarily be a healthcare professional but could be the patient her/himself. When the patient is conscious, the transfusionist (nurse or doctor), together with the patient, conducts the pre-transfusion checking procedures at the bedside using an EIS. When the patient is unconscious or a child, two nurses (or a doctor/nurse pair) can also conduct the pre-transfusion checking procedures. In this case, another healthcare professional, such as the staff member of the transfusion service who delivered the issued blood component into the clinical area, instead of the patient, may be available as the second checker.

Principle of the pre-transfusion checking procedures at the bedside using an EIS

The current recommendations state that: 1) the pre-transfusion checking procedures at the bedside should include, first, a standard 2-person visual and verbal double-check, followed by an electronic pre-transfusion check using a hand-held device "just" prior to the initiation of blood administration; 2) the electronic pre-transfusion checking procedures at the bedside should be carried out by a 2-person team, of whom one should be the transfusionist and the other should be the second checker; and 3) the second checker may change according to patient condition, and does not have to be a nurse or doctor.

Requirements for the electronic pre-transfusion check at the bedside

a) EIS

A bar code-based EIS: several vendors offer a bar code-based EIS, which may be a stand-alone configuration or a built-in product in an electronic medical chart. In Japan, a bar code-based EIS is based on the employment of the linear bar code (NW7), because it has been added to labels attached to all allogeneic blood components supplied from branches of the Japanese Red Cross Blood Centre. The bar code on allogeneic blood components identifies the blood group, product type, unit of blood, product number depending on the donor, and date of collection. In the case of autologous blood components, in-house barcodes identifying the product type and product number should be used. An EIS should be used on all inpatient wards, and in operating rooms and outpatient units. Inpatient wards with an infrequent need for blood transfusions, i.e. psychiatric and dermatology wards, may be excluded from using an EIS.

A hand-held device: a hand-held device is fitted with a laser bar code scanner and linked to an EIS with wireless or wired technology with a docking device, depending on its vendor. It is capable of reading bar codes during pre-transfusion checking procedures at the bedside, receiving transfusion data including the patient's surname, first name, ID number, and blood group via a network and sending data regarding the bedside verification procedure (e.g. name of transfusionist, time of verification) to the host computer at the transfusion service. According to the general specifications of an EIS, if the bar codes of the wristband and blood are identical, the screen of the hand-held device displays "OK". Non-matching data result in a warning on the screen ("NG") with an alarm sound. The same process is used for the pre-issuing checking procedures at the transfusion service. A match/non-match is identified by the software installed in the hand-held device.

Link to a hospital information system: a bar code-based EIS should be linked to the hospital information system, as well as to the transfusion management system (or LIMS) via a network in order to be fully effective[12] The host computer at the transfusion service is linked to the hospital information system via a network and can: 1) store data for transfusion (patient's details, details of blood component, results of pre-transfusion testing); 2) search for the stored data; 3) send the transfusion data to hand-held devices at the bedside; 4) receive the data on the pre-transfusion check at the bedside from hand-held devices; and 5) monitor the bedside use of the issued blood component.

Using an EIS: use of an EIS is recommended on all inpatient wards, except for those that do not frequently require blood transfusions, and in operating rooms and outpatient units. Among blood components, autologous blood components should be used on the basis of EIS readings, as well as allogeneic blood components[21]. Finally, paediatric patients should receive blood transfusions based on an EIS, because of special requirements regarding the administration of blood components, including small-volume transfusions and dispensing blood in plastic syringes, where the management is more likely to be inappropriate compared to that of blood bags[22].

b) Wristbands

All patients, who are admitted to the hospital or who are scheduled to receive blood transfusions should be given wristbands with a bar code and eye-readable identification, including their surname, first name, gender, date of birth, patient identification number, and blood group ABO/RhD. When the wristband is attached to the patient, two nurses should carefully perform a visual and verbal double-check. If the wristband needs

to be cut for venous access, or in the case of surgical intervention, the wristband should then be reattached. Therefore, multiple wristband printers may be needed, as described below.

c) Wristband printer

A wristband printer is specially designed to print the patient's details, as described above. One should be installed at the check-in counter for admission, in operating theatres, and on some inpatient wards where cutting and re-attachment of wristbands are frequently required, i.e. obstetrics wards with a delivery room, and at the transfusion service.

d) Compatibility label and compatibility report form

The compatibility label attached to the blood unit should be printed with bar codes providing data of the pre-transfusion compatibility testing. The compatibility report form, which can be duplicated, should be printed with the same bar code as the compatibility label. A copy should be sent to the transfusion service irrespective of whether or not the description includes adverse events. Both bar codes providing data on the compatibility testing are used during the electronic pre-transfusion checking procedures at the bedside, as well as at the transfusion service.

e) Identification badge for staff members

Identification badges for staff members involved in the electronic pre-transfusion checking procedures at the bedside and the transfusion service should be printed with individual bar codes.

Pre-transfusion checking procedures at the bedside for a conscious patient

This may be the most common situation in most hospitals. The entire process of the electronic pre-transfusion checking procedures for a conscious patient should be conducted by one nurse (or doctor) and the patient together, and should be carried out at the bedside using an EIS. The patient is expected to act as the second checker. Given this, another healthcare professional, such as the staff member of the transfusion service who delivered the issued blood component into the clinical area, should also be available.

The transfusionist:

- asks the patient to state his/her full name and date of birth;
- together with the patient, checks the information and reviews both the blood unit and compatibility report form;
- sequentially scans the bar codes of his/her own identification badge, the patient's wristband, and the blood unit using the hand-held device;
- together with the patient, verifies the data displayed on the hand-held device and assesses whether or not the bar codes on the wristband and blood unit match;
- if the hand-held device displays "OK", blood administration is initiated "immediately".

Pre-transfusion checking procedure at the bedside for an unconscious patient or child

This case may be a common situation in intensive care units (ICUs), emergency rooms, and on inpatient wards for children. The entire process of the electronic pre-transfusion checking procedures for an unconscious patient or child should be conducted by two nurses (or a doctor/nurse pair) and carried out at the bedside using an EIS. If two nurses conduct these, one should act as the transfusionist and the other as the second checker. In the case of a doctor/nurse pair, a nurse may act as the transfusionist and a doctor as the second checker. The second checker may also be another healthcare professional, such as the staff member of the transfusion service who delivered the issued blood component into the clinical area.

The transfusionist:

- together with the second checker, checks the patient's full name and date of birth and reviews the patient's wristband;
- together with the second checker, checks the information and reviews both the blood unit and compatibility report form;
- sequentially scans the bar codes of his/her own identification badge, the patient's wristband, and the blood unit using the hand-held device;
- together with the second checker, verifies the data displayed on the hand-held device and assesses whether or not the bar codes on the wristband and blood unit match;
- if the hand-held device displays "OK", blood administration is initiated "immediately".

Pre-issuing checking procedure at the transfusion service

The SHOT scheme reported that approximately 30% of errors pertaining to IBCT events occur in the hospital transfusion laboratory[7]. These may involve the selection of the wrong sample for testing, transposition of labels, technical or transcription errors in manual pre-transfusion testing, or knowledge-based errors, such as the selection of components of an inappropriate specification. This may lead to a need for the electronic pre-issuing check at the transfusion service. The electronic pre-issuing checking procedures should be performed to ensure that the transfusion service staff member has attached the right compatibility label to the right blood unit after completing compatibility testing.

Although this process is optional and does not play an essential role in the electronic pre-transfusion check at the bedside, it may prevent mislabelling and selection of the wrong blood unit. All blood components should be delivered from the transfusion service after completing the electronic pre-issuing check procedure.

The staff member of the transfusion service:

- attaches the compatibility label printed with the bar codes providing data on the pre-transfusion testing to the blood unit after completing compatibility testing;
- uses a hand-held device to sequentially scan the bar codes of his/her own identification badge, the "original" label of the blood unit, and the newly attached label of the blood unit (both sides of the blood unit should be scanned);
- uses a hand-held device to scan the bar codes of the "original" label of the blood unit and the compatibility report form, on which the same bar code as the compatibility label is printed;
- together with another staff member of the transfusion service, verifies the data displayed on the hand-held device, and assesses whether or not the bar codes on both sides of the blood unit match, and whether or not the bar codes on the blood unit and the compatibility report form match;
- if the hand-held device displays "OK", the blood unit is issued.

Monitoring of the issued blood components at the bedside

The BCSH has recommended that transfusion of blood and blood components should begin as soon as possible after their delivery to the ward or operating theatre[23]. The risk of mistransfusion may increase when the issued blood unit remains unused for an extended period of time at the nursing unit or at the bedside. Therefore, it may be important to pay special attention to how the issued blood unit is used at the bedside in order to improve transfusion safety. When an EIS is used in most clinical areas in a hospital, it can facilitate use of a hand-held device as an electronic pre-transfusion check at the bedside to up-date the information contained in the host computer at the transfusion service, thereby allowing bedside use of the issued blood unit to be monitored. Communication between the transfusion service and the bedside via a network allows compliance with the electronic pre-transfusion checking procedures at the bedside to be monitored[12]. Time after issuing (TAI) is defined as the time from issuing the blood unit at the transfusion service to initiating blood administration at the bedside. TAI can be calculated by a staff member of the transfusion service checking the time the blood unit is issued and also the time the electronic pre-transfusion checking procedure is performed by viewing the monitor of the host computer in the transfusion service. Although this calculation requires the electronic pre-transfusion checking procedures to be carried out "just" prior to the initiation of blood administration, TAI on inpatient wards has been reported to be shortened after initiating TAI monitoring and the immediate notification to use the issued blood unit by the transfusion service by phone[12]. Although this secondary function is not an essential feature of an EIS, it may help improve transfusion safety in the hospital.

How prevalent is use of an EIS in Japan?

The Association of Transfusion Division of University Hospitals (ATDUH) issued questionnaires to a small group of the transfusion service of university hospitals in Japan (n=91). The members of the ATDUH are teaching hospitals and representatives of regions distributed widely across in Japan, and also those of the JSTMCT. All transfusion service members in university hospitals were registered. The questions referred to transfusion practices and use of IT systems, including a transfusion management system and a bar code-based EIS: system vendor, who applied for the system, date of initiation of the system, and compliance with the electronic pre-transfusion checking procedures at the bedside. Of the questionnaires sent to 91 transfusion services, 90 (99%) were returned fully completed. Eighty-one (90%) transfusion services answered that the pre-transfusion checking procedures had been carried out using a bar code-based EIS. At present, the overall prevalence rate of an EIS for pre-transfusion checking procedures at the bedside in Japanese university hospitals is 90%. Further studies, including a nationwide survey, are needed to explore the prevalence of EIS use in Japan.

Conclusions

The current recommendations may be appropriate for clinical situations, where a bar code-based EIS for the pre-transfusion checking procedures at the bedside is used. Although bar code technology is a widely used, reliable, and inexpensive machine-readable identification system, bar code-related patient misidentifications have been reported when a linear bar code is used[24]. More advanced systems, such as radiofrequency identification (RFID), will be introduced in the near future. RFID may have advantages over bar code-based technology, i.e. more user-friendly, allowing more information to be recorded, allowing blood components to be traced. Technology-based solutions designed to prevent mistransfusion have recently been developed, and the effectiveness of the different systems in detecting errors has been reported[25]. To reduce human error and the risk of mistransfusion, we have to address the issue at a hospital level, using a system-based approach.

Disclaimer

Although the recommendations and information were believed to be true and accurate at the time of the preparation of the recommendations, neither the Authors nor the JSTMCT accept any legal responsibility for the content of the current recommendations.

The Authors declare no conflicts of interest.

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Open Forum

輸血副作用サーベイランスにおける underreporting

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キーワード：ヘモビジランス，過少報告

はじめに

輸血療法の安全な実施のためには輸血の副反応の発生状況を把握することが必要であり，ヨーロッパではHIV感染が問題となって以降，輸血の安全監視体制であるヘモビジランス（hemovigilance）が構築されている[1)]．ヘモビジランスの実施が法的に規定されているフランスでは，輸血使用量は1994年の約320万から1998年には約270万本に減少したが，輸血副反応の報告件数は1994年の436件から1998年の6,793件まで増加している[2)]．日本では，日本赤十字社が世界に先駆けて1993年から副作用・感染症情報の収集を行っているが，重症副作用症例の原因検索依頼を兼ねた医療機関からの自発報告が中心であり，必ずしも軽症例を含めた輸血副作用の全容が把握されているわけではない．また，蕁麻疹や掻痒感などの軽症副作用でも輸血療法に支障をきたす場合があり，輸血の安全性の検証や副作用防止対策を考える上でも軽症を含めた輸血副作用全体の状況の把握が重要である．

そこで，我々は全ての輸血副作用症例を報告対象として，インターネットを利用した全国的な簡便かつ迅速な報告体制の構築を目指し，オンラインによる「輸血製剤副作用情報収集システム」のパイロット研究を開始した[3)4)]．参加施設から多くの輸血副作用情報の収集が可能になったが，一方で新たな課題が認められるようになった．今回は2010年から2011年までに本システムで収集した輸血副作用情報の解析結果と現状の課題を報告する．なお，本稿では輸血時のあらゆる有害事象を「副反応」，後述する診断項目表で規定されている輸血関連の症状を「副作用」と記述する．

参加施設数と方法

パイロット研究には2007年の開始時点で7施設が参加し，2009年から5施設，2010年から33施設，2011年から6施設，総計51施設が参加した．

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6）山口大学
7）熊本大学
8）東京医科大学八王子医療センター
9）東京大学
10）埼玉医科大学
11）三楽病院
12）士別市立病院
13）黒石病院
14）南多摩病院
15）八尾総合病院
16）順天堂大学
〔受付日：2015年6月21日，受理日：2015年9月3日〕

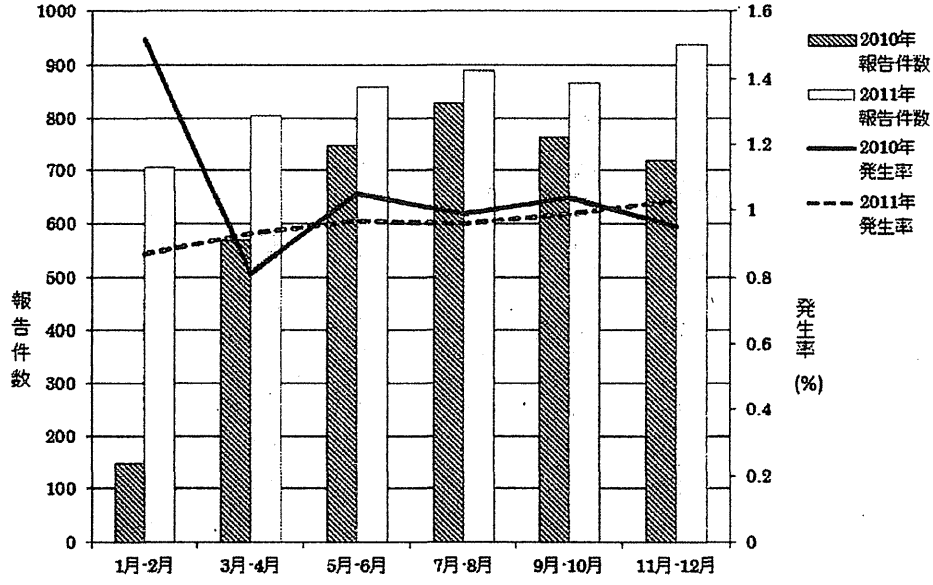

図1 非溶血性輸血副作用の報告件数と発生率の推移

参加施設の輸血部門が輸血実施部署から輸血副作用報告を収集し，「輸血製剤副作用情報入力システム」を使用して2カ月毎に自施設の輸血副作用の発生状況をオンライン登録した．登録項目は輸血製剤の各使用単位数と各使用バッグ数・製剤別の副作用症状の発生件数・製剤別の副作用の発生件数である．副作用の症状と診断は「輸血副作用把握体制の確立　特に免疫学的副作用の実態把握とその対応（研究代表者　高本滋）」で作成された16項目の症状別分類と診断項目表[5]に基づいている．今回は2010年1月から2011年12月までの2年間に収集された輸血副作用データを解析した．

結　果

1. 参加施設の輸血使用量

2010年の参加施設数は45施設で，輸血使用バッグ数は赤血球製剤(RBC)が198,380バッグ(380,261単位)，血小板製剤（PC）が87,096バッグ（881,801単位），血漿製剤（FFP）が97,731バッグ（262,115単位）であった．2011年の参加施設数は51施設で，輸血使用バッグ数はRBCが269,394バッグ(515,060単位)，PCが116,082バッグ(1,214,042単位)，FFPが142,439バッグ(368,644単位）であった．これらの使用量は日本赤十字社から全国の医療機関に供給されたRBC，PC，FFPの使用単位数の5.9%，10.0%，8.2%(2010年)，及び7.9%，13.8%，11.3%（2011年）に相当した．

2. 輸血副作用の発生状況

2010年の副作用報告は非溶血性副作用が3,775件，溶血性副作用が6件，感染症が1件で，バッグあたりの非溶血性副作用の発生率は1.06%であった．2011年の副作用報告は非溶血性副作用が5,065件，溶血性副作用が3件，バッグあたりの非溶血性副作用発生率は0.96%であった．非溶血性副作用の報告件数と発生率の推移を図1に示す．

3. 製剤別の副作用発生状況

RBCとFFPの2カ月あたりの副作用の平均発生率は2010年；0.54%と0.94%，2011年；0.47%と0.67%に対してPCでは2010年；2.53%，2011年；2.46%であった（表1）．

4. 症状別の副作用発生状況

RBCでは「発熱」と「発疹・蕁麻疹」が副作用件数の半数近くを占めていた．一方，PCとFFPでは「発疹・蕁麻疹」と「掻痒感・かゆみ」が副作用件数の半数以上を占めていた（表2）．

重篤な輸血副作用の発生状況（表3）は，重篤な非溶血性副作用の中で重症アレルギー反応が全ての製剤で70%以上を占め，輸血関連急性肺障害（TRALI），輸血関連循環過負荷（TACO）の報告は各製剤で1〜3件であった．輸血後移植片対宿主病（PT-GVHD），輸血後紫斑病（PTP）の報告は無かった．また，溶血性副作用は2010年に急性溶血2件，遅発性溶血4件，2011年に急性溶血3件の報告があった．

5. 施設別の輸血副作用発生状況

参加時期の異なる施設別の輸血副作用発生率を示す（図2）．施設の製剤別の輸血副作用発生状況を発生率〔副作用件数，使用バッグ数〕で比較すると，2007年より参加した7施設では2010年；RBC 0.50%〔172件，33,780バッグ〕，PC 3.76%〔482件，12,815バッグ〕，FFP 1.22%〔160件，13,023バッグ〕，2011年；RBC 0.60%

表1　輸血製剤別の副作用の発生件数とバッグあたりの発生率

		RBC			PC			FFP		
		報告件数	輸血バッグ数	発生率(%)	報告件数	輸血バッグ数	発生率(%)	報告件数	輸血バッグ数	発生率(%)
2010年	1月～2月	49	5,804	0.84	65	1,820	3.57	34	2,122	1.60
	3月～4月	155	37,239	0.42	308	15,435	2.00	107	17,653	0.61
	5月～6月	188	36,887	0.51	411	16,333	2.52	152	17,891	0.85
	7月～8月	205	40,865	0.51	441	20,866	2.15	183	21,680	0.87
	9月～10月	192	38,417	0.50	418	16,248	2.57	153	18,289	0.84
	11月～12月	170	39,168	0.43	387	16,374	2.36	164	20,096	0.84
	合計	959	198,380		2,030	87,076		793	97,731	
	平均/2カ月	159.8	33,063.3	0.54	338.3	14,512.6	2.53	132.2	16,288.5	0.94
2011年	1月～2月	195	41,555	0.47	359	18,595	1.93	152	20,602	0.74
	3月～4月	177	45,280	0.39	451	18,156	2.48	176	23,010	0.76
	5月～6月	220	44,792	0.49	481	19,583	2.46	161	24,628	0.65
	7月～8月	220	45,344	0.49	519	20,841	2.49	151	26,797	0.56
	9月～10月	209	44,526	0.47	504	19,198	2.63	153	23,683	0.65
	11月～12月	247	47,897	0.52	544	19,709	2.76	149	23,719	0.63
	合計	1,268	269,394		2,858	116,082		942	142,439	
	平均/2カ月	211.3	44,899	0.47	476.3	19,347	2.46	157	23,739.8	0.67

2010年の参加施設数は1～2月：12，3～4月：43，7～12月：45であり，2011年は51である．

表2　症状別の輸血副作用の発生件数と割合

	2010年						2011年					
	RBC		PC		FFP		RBC		PC		FFP	
	報告件数	割合(%)	報告件数	割合(%)	報告件数	割合(%)	報告件数	割合(%)	報告件数	割合(%)	報告件数	割合(%)
1）発熱	280	22.2	144	5.2	42	3.8	400	23.4	220	5.1	55	3.6
2）悪寒・戦慄	71	5.6	66	2.4	32	2.9	96	5.6	108	2.5	25	1.6
3）熱感・ほてり	75	6.0	62	2.3	25	2.3	110	6.4	99	2.3	38	2.5
4）掻痒感・かゆみ	123	9.8	710	25.8	239	21.7	125	7.3	1,109	25.5	346	22.4
5）発赤・顔面紅潮	91	7.2	198	7.2	88	8.0	120	7.0	326	7.5	141	9.1
6）発疹・蕁麻疹	270	21.4	1,376	50.1	516	46.8	393	23.0	2,168	49.8	732	47.4
7）呼吸困難・呼吸障害	35	2.8	45	1.6	25	2.3	52	3.0	77	1.8	32	2.1
8）嘔気・嘔吐	58	4.6	25	0.9	16	1.5	61	3.6	46	1.1	29	1.9
9）胸痛・腹痛・腰背部痛	35	2.8	12	0.4	13	1.2	21	1.2	16	0.4	6	0.4
10）頭痛・頭重感	14	1.1	6	0.2	1	0.1	20	1.2	10	0.2	8	0.5
11）血圧低下	63	5.0	36	1.3	54	4.9	95	5.6	78	1.8	75	4.9
12）血圧上昇	60	4.8	18	0.7	14	1.3	110	6.4	24	0.6	21	1.4
13）動悸・頻脈	32	2.5	17	0.6	22	2.0	38	2.2	35	0.8	18	1.2
14）血管痛	28	2.2	2	0.07	0	0.0	38	2.2	1	0.02	0	0.0
15）意識障害	2	0.2	3	0.1	0	0.0	1	0.1	4	0.09	0	0.0
16）血尿（ヘモグロビン尿）	6	0.5	1	0.04	1	0.1	9	0.5	1	0.02	0	0.0
17）その他	17	1.3	27	0.98	14	1.3	22	1.3	32	0.7	19	1.2

〔210件，34,427バッグ〕，PC 4.61%〔634件，13,705バッグ〕，FFP 0.97%〔134件，13,711バッグ〕であった．2009年より参加した5施設では2010年：RBC 1.52%〔65件，4,250バッグ〕，PC 0.24%〔1件，416バッグ〕，FFP 1.26%〔9件，711バッグ〕，2011年：RBC 2.54%〔98件，3,847バッグ〕，PC 5.21%〔12件，230バッグ〕，

表3 重篤な輸血副作用の発生件数

	2010年			2011年		
	RBC	PC	FFP	RBC	PC	FFP
非溶血性副作用	発生件数			発生件数		
重症アレルギー反応	15	11	17	12	20	22
輸血関連急性肺障害（TRALI）	1	1	1	3	2	0
輸血関連循環過負荷（TACO）	3	1	0	2	0	1
輸血後移植片対宿主病（PT-GVHD）	0	0	0	0	0	0
輸血後紫斑病（PTP）	0	0	0	0	0	0
溶血性副作用	発生件数			発生件数		
急性溶血	2	0	0	3	0	0
遅発性溶血	4	0	0	0	0	0

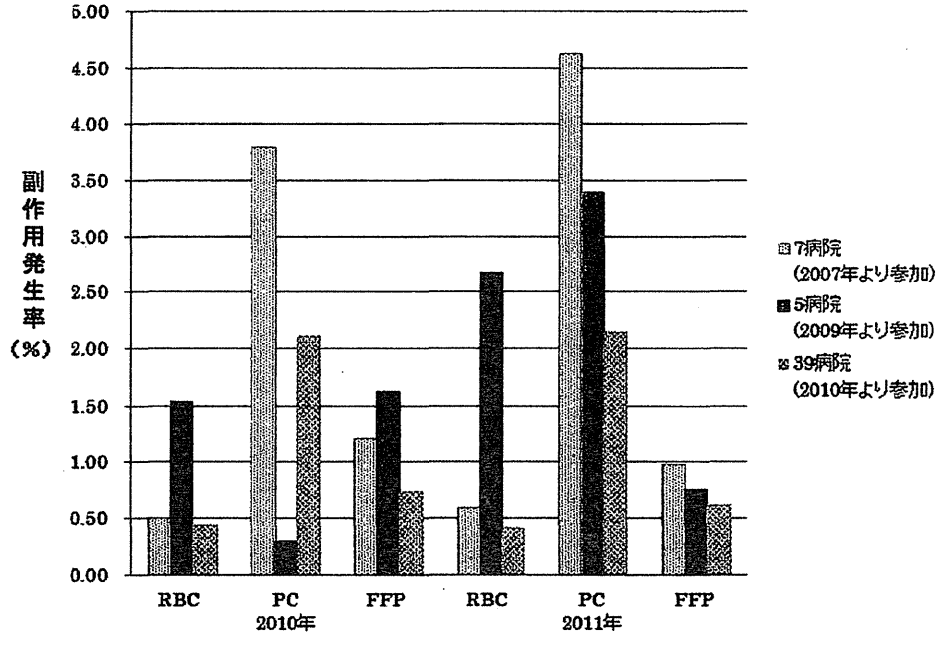

図2 参加時期の異なる施設間の輸血副作用の発生率

FFP 0.78%〔4件，512バッグ〕であった．2010年より参加した39施設では2010年：RBC 0.45%〔722件，160,350バッグ〕，PC 2.09%〔1,547件，73,845バッグ〕，FFP 0.74%〔622件，83,997バッグ〕，2011年：RBC 0.41%〔960件，231,120バッグ〕，PC 2.16%〔2,212件，102,147バッグ〕，FFP 0.62%〔804件，128,216バッグ〕であった．参加時期の異なる施設で製剤別の副作用発生率に差が認められたため各施設のデータを確認したところ，『血小板製剤バッグ使用数1,152に対して副作用1件』，『血漿製剤バッグ使用数668に対して副作用1件』と副作用報告数が極めて少ない施設があることが判明した．このことから，輸血副作用の発生率に差が生じる原因として輸血副作用の過少報告（underreporting）の可能性が考えられた．

2010年以降の新規参加施設に本システムにデータ登録する際の問題点をアンケート形式で尋ねたところ，参加施設からは「軽症例の副作用の報告が少ない．」，「軽症に該当する副作用項目の院内周知不足のため情報を収集できていないかもしれない．」，「輸血副作用の判定に個人差があり，収集漏れの可能性がある．」，「輸血副作用の報告が一部の診療科からしか出されておらず，全ての診療科から報告されているのか疑問である．」などの意見が出された．

考　察

輸血副作用の実態把握は輸血の副反応を防止して輸血製剤の安全性を向上させるために有用である．2007年にスタートしたオンラインによる「輸血製剤副作用

情報収集システム」は，2011年には日本赤十字社から全国の医療機関に供給された輸血製剤の約10%量での副作用データ収集が可能になった．軽症・重症にかかわらず，輸血副作用の全数把握を目的として「輸血副作用の症状項目」が明確化されたので副作用症状を見落としにくくなると考えられる．比較的小規模の施設では，輸血件数が少ないために副作用発生率が見かけ上高くなることもあるが，輸血副作用の情報収集が確実に実施されているとも考えられる．本システムへの参加施設が増加し，より多くの副作用情報の収集が可能になることが期待される一方で，施設間で副作用発生率に差があることや，同じ製剤でも調査時期で副作用発生率が異なることが認められた．これは輸血副作用の過少報告(underreporting)の可能性があり，軽症の副作用が報告されないことがその要因と考えられる[6][7]．薬物有害事象報告システムpharmacovigilanceにおいても軽症の有害事象が報告されないために報告数が21%減少したとされている[8]．この過少報告の原因としては「薬物有害事象に気づかない」,「患者観察の時間が足りない」,「報告システムが医療者に周知されていない」,「薬物有害事象の報告が重視されていない」，等が挙げられている[9][10]．輸血では過少報告の背景要因として，輸血副作用の不十分な監視体制（輸血実施後の患者観察の手順が定められていない，施設内の副作用報告体制が構築されていない，副作用報告体制が活用されていない等)と，医療者の輸血副作用への意識の低さ(「副作用の症状項目」を知らない，軽症副作用を見過ごしている等）が考えられるので，副作用報告件数の少ない参加施設に問い合わせを行い，過少報告の原因を明らかにして改善策を講じる必要がある．また，pharmacovigilanceでは報告状況の改善を図るために医師に対して薬物の有害事象に関する教育・トレーニングが行われているので[10][11]，輸血副作用においても本システム参加施設における情報収集体制の整備だけでなく，輸血副作用報告について医療者へ再教育等が必要と思われる．そして輸血副作用情報を適切に収集できれば，本システムは輸血製剤の副作用の実情を把握するために有用であり，副作用防止策の評価も可能なので，日本のヘモビジランスの確立に貢献できるものと考えられる．

著者のCOI開示：本論文発表内容に関連して特に申告なし

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UNDERREPORTING IN REPORTING SYSTEM FOR ADVERSE TRANSFUSION REACTIONS

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