Electronic identification systems reduce the number of wrong components transfused

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BACKGROUND: Errors in hospital transfusion may cause wrong (blood) components to be transfused. This study assessed the value of electronic identification systems (EISs) in reducing wrong component transfusions (WCTs).

METHODS: UK hospitals reporting to Serious Hazards of Transfusion were invited to complete an electronic survey about transfusion including the use of EISs. Further information was requested for WCTs and near-miss WCTs.

RESULTS: A response rate of 93 of 222 (42%) hospitals accounted for 38% of UK blood component issues in 2015 and 2016. Thirty-three of 93 (35%) hospitals employ manual procedures and 16 (17%) use EISs throughout the transfusion process; most of the remainder use EISs for blood collection only. Fifty-seven WCTs were identified in approximately two million blood components. The primary error was at blood draw and sample labeling (3), blood collection (15), and administration (2); the remainder were mostly blood bank errors. No WCTs occurred with blood draw and sample labeling or administration with use of EISs. Three WCTs occurred with EISs for blood collection due to incorrect processes for emergency transfusions of group O blood without any adverse effects. Seventeen WCTs occurred with manual processes; one was an ABO-incompatible red blood cell transfusion resulting in renal impairment. Near-miss WCTs were also more frequent with manual procedures than EISs at blood draw and sample labeling and blood collection.

CONCLUSIONS: This is the first multicenter study to demonstrate a lower incidence of WCTs and near-miss WCTs with EISs compared to manual processes, and highlights some limitations of both manual and EIS procedures.

Hemovigilance systems continue to report instances of wrong (blood) component transfusion (WCT), some of which are ABO-incompatible transfusions with serious consequences for patients.[1,2] Since 1996, the Serious Hazards of Transfusion (SHOT) scheme has been collecting and analyzing anonymized information on adverse events and reactions in blood transfusion from all health care organizations that are involved in the transfusion of blood and blood components in the United Kingdom.[1] Where risks and problems are identified, SHOT produces recommendations in its annual reports to improve patient safety. There were four ABO-incompatible red blood cell (RBC) transfusions reported to SHOT during 2016 and 2017.[1,3] However, this was just the tip of the iceberg, as 606 WCT near-miss events were reported that could have led to ABO-incompatible transfusions but were detected and prevented before the transfusion was given. Of the 606 WCT near-miss events, 566 (93%) were "wrong blood in tube" events (WBITs), and if they had not been detected in the blood bank, they may have led to WCTs with the potential to cause patient harm. The US Food and Drug Administration reported two definite and two possible transfusion-related fatalities due to ABO-incompatible transfusion in 2016 and one probable/likely death in 2017.[2]

ABBREVIATIONS: EISs = electronic identification systems; SHOT = Serious Hazards of Transfusion; WBITs = wrong blood in tube events; WCTs = wrong component transfusions.

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Errors at any step of the transfusion process can cause WCTs. These steps include patient registration, blood draw and sample labeling, compatibility testing and issue of blood components from the blood bank, the collection and delivery of blood, and the administration of blood.[4–6] Many efforts have been made to document and/or reduce the errors that cause WCTs, including initiatives for the education and training of the many staff involved at each step of the transfusion process.[7] There have been several studies exploring the value of electronic identification systems (EISs) to reduce WCTs.[8–11] Some have focused on a specific step of the process, and others have explored "end-to-end" electronic processes.

There are significant challenges in developing and implementing an EIS,[12] and there are few data about how widespread the implementation of these systems has been. The studies demonstrating their value in reducing transfusion errors have predominantly been single-center studies,[7–9] the exception being the recent study conducted by the BEST (Biomedical Excellence for Safer Transfusion) Collaborative showing electronic patient identification for sample labeling reduces WBITs.[11] The study reported here used data collected by the SHOT hemovigilance scheme to assess the implementation of EISs and compare the frequency of WCTs and near-miss WCTs in hospitals using standard manual procedures for transfusion and those using an EIS at one or more steps of the transfusion process.

METHODS

All UK organizations reporting to SHOT were invited to complete an electronic survey with questions about their transfusion processes including the use of EISs. Further information was requested for each case of WCT or WCT near-miss reported to SHOT in 2015 and 2016 and if it occurred with an electronic or manual process.

SHOT defines WCT as an incident when a patient was transfused with a blood component of an incorrect blood group, or that was intended for another patient and was incompatible with the recipient, or that was intended for another recipient but happened to be compatible with the recipient, or that was other than that prescribed, for example, platelets instead of RBCs.[1] A WCT near-miss event refers to any error that, if undetected, could result in the determination of a wrong blood group or transfusion of an incorrect component but was recognized before the transfusion took place.

The invitation to hospitals to participate was distributed via email from SHOT. Data collection was divided into two parts, and reporters were given a period of 2 weeks to complete Part 1 and 2 weeks to complete Part 2. Non-responders were followed up on one further occasion and given further time to complete and return the requested data.

The first stage of the study comprised a questionnaire via an online tool (*SurveyMonkey*) (Appendix S1, available as supporting information in the online version of this paper). The survey asked questions in relation to the use of a manual procedure or EIS at the three key steps of transfusion in hospitals, namely:

1) blood draw and sample labeling;
2) at the point of collection and delivery of blood; and
3) at the bedside for the administration of blood.

The questionnaire also asked for information about the proportion of units of blood components using a manual procedure or EIS at each of these steps of the transfusion process in hospitals. SHOT collects data on the issues of blood components from UK blood services to each hospital, allowing a calculation of how many blood components used a manual procedure or EIS at each step of transfusion in each hospital. In turn, a calculation of how many and what proportion blood components used a manual procedure or EIS at each step of transfusion was made for all hospitals reporting to SHOT. Where a hospital provided a range of use of EISs (e.g., 31%-50%), the lower figure was taken to estimate the number of procedures performed using EISs. The total number of blood components issued in the United Kingdom was taken from the SHOT annual reports for 2015 and 2016.[3,13]

In the second stage of the study, those organizations that had reported a WCT or a WCT near miss to SHOT during 2015 or 2016 were asked to complete a spreadsheet providing further information on each case, specifically to provide information about the step of transfusion at which the WCT or near-miss WCT occurred and whether it occurred with a manual procedure or EIS. This enabled estimation of the rate of WCTs or WCT near misses at each step of transfusion, and a comparison of the rate with manual procedures and EISs.

The rates of WCTs and WCT near misses were compared between manual procedures and EISs for each step in the transfusion process where the error occurred. Comparisons were made using a chi-squared test or Fisher's exact test if any cell count of the 2×2 contingency table was less than five. Crude odds ratios (ORs) and their 95% confidence intervals (CIs) were calculated for WCTs and WCT near misses. A continuity correction of 0.5 was applied to each cell count of the 2×2 contingency table if no WCTs or near-miss WCTs were reported to calculate the crude OR.[14]

RESULTS

Survey of practice

Ninety-three of 222 (42%) of the hospitals reporting to SHOT responded to the survey, allowing analysis of 1,946,386 of 5,060,423 (38%) of all units of blood components issued to UK hospitals in 2015 and 2016 and a review of their transfusion processes.

Of 93 hospitals, 33 (35%) indicated they use a manual procedure for all three key steps in the transfusion process (Table 1). Sixteen (17%) use an EIS for all three key steps, eight (9%) for two steps, three (3%) for sample and blood

TABLE 1. Number of hospitals that used various combinations of manual and EIS processes and the calculated number of blood components where manual or EIS processes were used

Combinations of manual and EIS processes	Number (%) of hospitals (denominator: 93 hospitals that responded to the survey)	Number (%) of blood components where manual or EIS processes were used (denominator: 1,946,386 units)
Manual throughout (all 3 steps)	33 (35)	661,380 (34)
Electronic blood draw, sample labeling and blood collection	3 (3)	23,391 (1)
Electronic blood collection only	36 (39)	29,7944 (15)
Electronic blood collection and administration only	5 (5)	57,745 (3)
Hospitals that had all three clinical electronic blood systems: sample, collection, and administration	16 (17)	352,932 (18)
Number of blood components in hospitals with an EIS but where EIS was not used	…	552,994 (28%)

EIS = electronic identification system.

collection, and five (5%) for blood collection and administration. The remaining 36 (39%) use an EIS for blood collection only. No hospitals used combinations of EISs that are not represented in Table 1; for example, no hospitals used EISs for blood sampling and administration only.

The first EIS introduced for transfusion in the hospitals responding to the survey was for blood collection from the designated storage site in 1999, followed by the first bedside administration system in 2005 (Fig. 1). An electronic system for blood draw and sample labeling was first implemented in the hospitals responding to the survey in 2006. The implementation of EISs for administration of blood peaked in 2008 but appears to have slowed since 2014.

In hospitals using an EIS, it is not necessarily used for all transfusions. Figure 2 illustrates this point by showing the range in the proportion of transfusions where an EIS was used for each of the three steps of the transfusion process in 2016. For example, only seven hospitals were using an EIS for more than 90% of blood draw and sample labeling, and only 15 hospitals were using an EIS for bedside administration. There was little change in the use of EISs between 2015 and 2016 (data not shown).

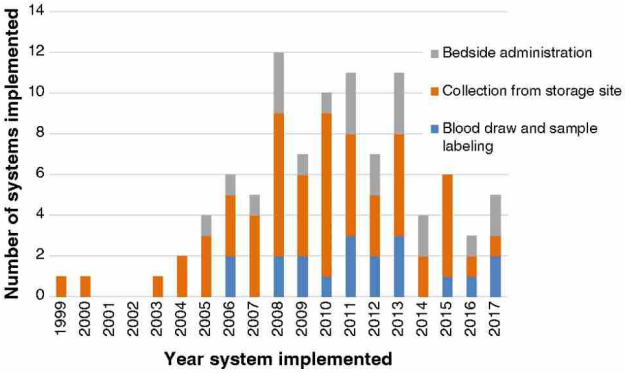

Fig. 1. Number and type of each EIS implemented between 1999 and 2017. [Color figure can be viewed at wileyonlinelibrary.com]

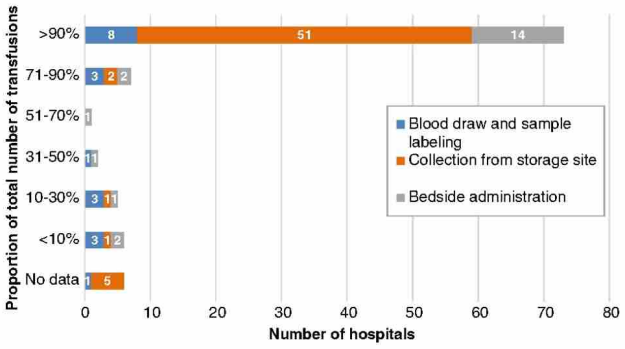

Fig. 2. Proportion of transfusions for each of the three types of EIS (2016). [Color figure can be viewed at wileyonlinelibrary.com]

Transfusions and WCTs associated with either manual procedures or EISs

The number of blood components issued to hospitals using manual procedures for all three steps in the transfusion process was 661,380 of 1,946,386 (34%) during the study period (Table 1). A total of 552,994 of 1,946,386 (28%) blood components were issued to hospitals that had an EIS, although it was not being used at the time that the transfusion procedure was carried out. The remaining procedures occurred in hospitals using an EIS for one or more of the three key steps of the transfusion process, that is, 18% where there was an EIS for all three steps of transfusion, 3% where there was an EIS for blood collection and for administration, 1% where there was an EIS for blood sampling and for blood collection, and 15% where there was an EIS only for blood collection.

In 2015 and 2016, 145 WCTs were reported by 87 hospitals to SHOT, and 57 (39%) of them occurred in the hospitals responding to the survey. Twenty (35%) occurred at blood draw and sample labeling (3), blood collection (15), or bedside administration (2) (Table S1, available as supporting information in the online version of this paper). Seventeen of 20 (85%) occurred with manual procedures in

TABLE 2. Comparison of WCTs occurring with manual and electronic systems

Step in the transfusion process where the error occurred	WCTs associated with a manual process/number of units transfused (%)	WCTs associated with an electronic process/number of units transfused (%)	Crude odds ratio (95% CI), p value*
Blood draw and sample labeling	3/1,570,063 (0.0002) 1 in 523,354 units	0/376,323	0.60 (0.03-11.54) p = 1.00
Collection of blood from refrigerator	12/1,214,374 (0.001) 1 in 101,195 units	3/732,012 (0.0004) 1 in 244,004 units	0.41 (0.11-1.47), p = 0.191
Blood administration	2/1,535,709 (0.0001) 1 in 267,854 units	0/410,677	0.75 (0.04-15.58), p = 1.00

* P values are calculated from two-sided Fisher's exact test.
WCTs = wrong component transfusions.

one of these three key steps of transfusion; three occurred at blood draw and sample labeling, 12 at blood collection, and two at blood administration. Only 3 of 20 (15%) of the WCTs occurring at blood sampling, blood collection, or bedside administration occurred with an EIS, and all three were at blood collection; they were all related to the collection of emergency group O blood. They are described in detail below, and none resulted in harm to the patient.

Case 1

A pediatric emergency O-negative RBC unit was collected and subsequently transfused instead of an adult emergency O-negative unit. In this hospital, the removal of emergency blood is exempt from formal checking by the EIS. The manual administration step also failed to identify the error, and the patient received the wrong blood unit.

Case 2

An adult emergency O-negative RBC unit was collected and subsequently transfused instead of a pediatric emergency O-negative unit. The nurse collecting the blood could not log into the refrigerator in the maternity unit, so a midwife did this for her. Neither the pediatric nor adult unit would scan, and in the confusion the adult unit was taken to the bedside instead of the pediatric unit.

Case 3

A midwife left the door of the delivery suite blood refrigerator open. Another member of staff, untrained in the collection procedure, collected an inappropriate unit of emergency stock (adult O-positive unit rather than O-negative). The patient's blood group was subsequently found to be D positive.

Indeed, none of the 57 WCT cases reported here was associated with the death of the patient. Only one was associated with major morbidity associated with miscollection of the sample using a manual procedure as described below.[3]

Case 4

A 61-year-old male was admitted for coronary artery bypass graft. He received four units of group A-positive RBCs. He had an uneventful stay in the hospital and was discharged home. Fourteen days later he was admitted to critical care via the emergency department with renal impairment and a falling hemoglobin. On this second admission he was grouped as O-positive. The sample used for the compatibility testing 14 days previously had been taken from the wrong patient and labeled incorrectly. A second sample was not obtained to confirm the ABO group, although it was the hospital policy. The investigation revealed that the trolley containing all patient request forms and labels was taken to the bedside. While the sample was being taken, a colleague placed another set of labels on top of the current sets. The staff member then labeled the sample with an incorrect label and did not fully identify the patient.

A comparison of the rate of WCTs with manual procedures and EISs is shown in Table 2. Decreased odds of WCTs were found using EISs compared to manual procedures for draw and sample labeling and blood administration, where there were no WCTs with EISs. A 59% lower odds of WCTs was found using an EIS when collecting blood compared to use of a manual process (OR, 0.41; 95% CI, 0.12-1.47; p = 0.191).

In the majority of the remaining WCTs (31/37 cases) (Table S1, available as supporting information in the online version of this paper), the primary error for the WCT occurred in the blood bank, either at the point of sample receipt (5), testing (17), component selection (8), or component labeling (1).

Near-miss WCTs associated with EISs

The study captured near-miss events that could have led to a WCT if not detected. There were 1713 cases reported to SHOT from 206 hospitals during 2015 and 2016, and 571 (33%) were captured in this study. A total of 484 of 571 (85%) occurred with manual procedures for draw and sample labeling, collection of blood from a refrigerator, or bedside administration, and 37 (6%) with an EIS for these steps (Table S2, available as supporting information in the online version of this paper). A total of 452 of 497 (91%) of the manual process errors were with draw and sample labeling. The 37 errors with EIS occurred at blood draw and sample labeling (17) or bedside administration (20).

Of the primary errors made at the point of sampling with manual systems, 427 of 452 (94%) were detected in the

TABLE 3. Comparison of near-miss WCTs occurring with manual and electronic systems

	Near-miss WCTs associated with a manual process/number of units transfused (%)	Near-miss WCTs associated with an electronic process/number of units transfused (%)	Crude odds ratio (95% CI), p value
Blood draw and sample labeling	452/1,570,063 (0.079%) 1 in 3,474 units	17/376,323 (0.004) 1 in 22,137 units	0.16 (0.10-0.25), p < 0.001**
Collection of blood from refrigerator	30/1,214,374 (0.002) 1 in 41,379	0/732,012	0.03 (0.00-0.44), p < 0.001*
Blood administration	2/1,535,709 1 in 767,854 (0.0001)	20/410,677 1 in 20,533 (0.005)	37.39 (8.74-159.99), p < 0.001*

* P values are calculated from two-sided Fisher's exact test.
** P values are calculated from chi-square test.
WCTs = wrong component transfusions.

blood bank (Table S3, available as supporting information in the online version of this paper). All 17 primary errors that were made at the point of sampling with an EIS were also detected in the blood bank. The collection errors with manual procedures were detected at the point of administration of blood or during collection; there were no near-miss WCTs with collection with use of an EIS. There were 22 errors that occurred during the administration of blood, but they were all detected by use of either manual checking (2) or EIS (20).

A comparison of the rate of near-miss WCTs with manual procedures and EISs is shown in Table 3. An 84% and 97% reduced odds of near-miss WCTs were found when an EIS was used for draw and sample labeling and collection of blood (OR, 0.16; 95% CI, 0.10-0.35; $p < 0.001$; and OR, 0.03; 95% CI, 0.00-0.44; $p < 0.001$), respectively. The reverse was the case for near-miss WCTs at blood administration; there were much higher odds of near miss WCTs with EIS than with a manual process (OR, 37.39; 95% CI, 8.74-159.99; $p < 0.001$).

DISCUSSION

WCT causing morbidity and in some cases death remains an important preventable complication of transfusion.[1,2] Errors leading to WCT occur at every step of the transfusion process in hospitals.[4–6] SHOT previously found that 21% of errors resulting in "wrong blood events" are made at the time of prescription, sampling, and request; 37% in the blood bank; and 40% when blood is collected from the blood bank or administered.[15]

This observational study of WCTs used data from the long-established SHOT hemovigilance scheme to compare the occurrence of WCTs between manual procedures and EISs for blood sampling, blood collection, and its administration. In this study, which uses data from 2015 and 2016, there were no WCTs with an EIS at the bedside, either at blood draw and sample labeling (0 in 376,323 units) or administration of blood (0 in 410,677 units), compared with a rate of 1 in 523,354 units transfused for a manual procedure for draw and sample labeling and 1 in 267,854 units transfused for a manual procedure for blood administration. The rate of WCT for blood collection from a blood refrigerator was less with an EIS than a manual procedure; it was 1 in 101,195 for manual and 1 in 244,004 for EIS.

The WCTs associated with blood collection with use of an EIS all occurred in emergency situations, where the wrong group O blood was collected, either a mix-up of pediatric and adult units or selection of a group O-positive unit rather than O-negative, but there were no adverse effects for the patients. One of the WCTs occurring with a manual procedure due to WBIT resulted in an ABO-incompatible RBC transfusion of four units causing renal impairment.

The three WCTs that occurred with use of an EIS at the point of collection of blood components from the blood refrigerator illustrate some useful points when considering implementation of EISs for blood collection and some potential pitfalls if hospitals currently have EIS for collection. Case 1 demonstrates the importance of ensuring that the EIS procedure is simple to follow and has the capability of being used for collecting emergency units. The EIS in this case was unable to differentiate between different types of components that are removed in emergency situations because the emergency process allowed bypassing the essential scanning step, which would ordinarily detect an error. Cases 2 and 3 both occurred in maternity units, and staff members allowed staff who did not have authorization to collect blood to remove the blood units. All three cases occurred in urgent circumstances, time was pressured, and standard procedures were not followed.

Near-miss WCT cases that used EISs at the point of sampling and administration also illustrate useful points for consideration when an EIS is used at these steps or when implementation is being considered. The rate of near-miss WCTs was 1 in 3,474 for manual blood draw and sample labeling and 1 in 22,137 for EIS. All these cases were identified in the blood bank and did not proceed to actual WCTs. These data confirm the results of a recent study from the BEST Collaborative, which found an approximately fivefold reduction in WBITs with electronic compared to manual procedures.[11] Although near-miss WCTs with use of an EIS for blood sampling were less frequent than with a manual process, the 17 WBIT sampling near-miss cases with use of an EIS demonstrate how easy it can be to generate printed labels from identification bands that are not attached to patients or to use wrong labels that have been generated away from the bedside.

UK guidelines recommend that unless secure electronic patient identification systems are in place, a second confirmatory blood sample should be requested for confirmation of the ABO group of a first-time patient before transfusion, where this does not impede the delivery of urgent blood components.[16] This study did not explore compliance with this recommendation, so it is not known how many WBITs were detected by the second sample policy and how many by other means such as the presence of a historical blood group in the patient's blood bank records.

There were no near-miss WCTs for blood collection with an EIS (0 in 732,012 units) and 1 in 41,379 units for manual blood collection. The rate of near-miss WCTs was 1 in 20,533 units for the administration of blood with an EIS and 1 in 767,854 units with a manual process. This result may at first sight appear surprising, but it illustrates key points about the way that EISs are used in practice. Review of the 20 administration near-miss WCTs with use of an EIS revealed that staff approached the wrong patient in 13 cases. These errors occurred immediately before the pretransfusion checking process and were detected by the EIS alerting them of an error. This demonstrates the value of EISs in the avoidance of WCTs but raises concerns about overreliance on electronic scans of the patient's wristband and the blood unit and that staff are bypassing routine patient identification steps such as asking conscious patients to state their name and date of birth and checking the details on the wristband and the blood unit. These key manual steps of patient identification are prompted by the handheld scanner used for bedside checking with use of the EIS and precede electronic scanning of barcodes on the patient's wristband and the blood unit. The near-miss WCTs at the bedside illustrate the strength of EISs in preventing a WCT, as a WCT would not be prevented if similar patient misidentification had occurred with use of manual procedures, but indicate overreliance on the scanning steps to identify a WCT. The risk of overreliance on EISs has been recognized previously[5] and highlights the importance of thorough training and continued support for the staff undertaking the procedures and follow-up of near-miss events and providing retraining as required.

The limitations of this study include that WCTs and near-miss WCTs were rare outcomes even in this large 2-year data set from a national hemovigilance scheme. This study was not powered to detect meaningful differences between these outcomes for EISs and manual processes, reflected in the wide 95% confidence intervals. In addition, it was not a comprehensive representation of practice in UK hospitals, as the response rate to the survey was 42%, representing 38% of blood components issued to UK hospitals in 2015 and 2016. However, the responders to the survey were representative of hospitals participating in SHOT. Eighty-one of 93 responders to the survey provided sufficient additional information to provide this analysis and showed that they were representative of all participants in the SHOT program with the exception of the minority of hospitals (25%) with either very low blood component usage (up to 1000 units/year) who were underrepresented (1/18, a 6% response rate) or very high usage (over 20,000 units/year) who were overrepresented (22/32, a 69% response rate). The majority of hospitals (75% of SHOT participants) with either low usage (1001-7000 units/year), medium usage (7001-12,000 units/year) or high usage (12,001-20,000 units/year) were well represented, with respective response rates of 18 of 57 (32%), 25 of 57 (44%) and 15 of 39 (39%) compared to the overall response rate of 42%. The response rate in the four countries of the United Kingdom was 69 of 154 (45%) in England, 1 of 5 (20%) in Northern Ireland, 8 of 15 (53%) in Scotland, and 3 of 6 (50%) in Wales.

Some hospitals were unable to provide a precise estimate of the proportion of procedures performed by EISs. Where a hospital provided a range of use of EISs for a specific transfusion procedure (e.g., 31%-50%), the lower figure was taken to estimate the number of procedures performed using an EIS, and this may have resulted in an underestimate of the use of EISs. Finally, the denominator to determine the incidence of WCTs and near-miss WCTs was not the number of transfusions administered in each hospital but the number of blood components provided to each hospital by National Health Service Blood & Transplant and the other UK Blood Transfusion Services. Given that a small proportion of blood components provided to hospitals may not be transfused, the use of the number of blood components issued to hospitals may have resulted in a slight underestimate of the rate of WCTs.

In conclusion, to our knowledge this is the first multicenter study to demonstrate a lower incidence of WCTs with EISs compared to manual procedures. The review of the WCT and near-miss WCT events reported to SHOT over 2 years highlights some limitations of both manual and EIS procedures and emphasizes how positive patient identification remains paramount for patient safety. The study indicates that the implementation of EISs in the United Kingdom has been patchy and is rarely used to its full functionality for all three key steps of the hospital transfusion process. It also shows that the number of hospitals taking up EISs slowed between 2014 and 2017, although more recent informal information from suppliers indicates that uptake has increased since then. Further efforts are needed to hasten the implementation of EISs to improve patient safety in the transfusion process.

CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article.

Appendix S1. Hospital survey tool about transfusion procedures.

Table S1. Step in the transfusion process where the primary error occurred

Table S2. Number of near-miss WCTs using a manual process or EIS and the step in the transfusion process where the primary error occurred

Table S3. Step in the transfusion process where the primary error for near-miss WCTs was detected.