Electronic transfusion consent and blood delivering pattern improve the management of blood bank in China

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Abstract

Background

The aim of this study was to improve the accuracy of blood transfusion treatment consent, simplify the verification process, prolong the temperature control time before blood transfusion, and save the labor cost of blood transportation.

Methods

We designed the electronic signing process of blood transfusion consent, which can generate personalized text content and automatically check the accuracy of filling. The signal can be transmitted to the blood transfusion management system (TMS) to relieve the blood distribution. For blood delivering, we established the blood transport center, recruited full-time nurses and used temperature-controlled blood transfer boxes to deliver blood in batches on a regular basis.

Results

Quarterly analysis of blood transfusion quality data showed that the accuracy of blood transfusion consent was 100% after electronic consent process implemented. The average savings of confirmation time between electronic content and papery content was 26min for Department of Emergency (Estimated Difference (95% CI) = 26 (20 to 36), $p < 0.05$). The pattern of blood delivering reduced the time for each unit of leaving temperature control by 7.24min on average (Estimated Difference (95% CI) = 7.24 (6.92 to 7.56), $p < 0.05$), and saved $3.67 of labor cost for each unit as well.

Conclusion

Electronic transfusion consent process not only ensures the accuracy, but also saves the verification time. Moreover, the blood delivering pattern prolongs the temperature control time of blood, and saves labor costs. These two improvements could enhance transfusion management.

Background

Blood transfusion is a major lifesaving frontline procedure in majority of clinical wards [1]. According to *Annual SHOT Report 2019*, errors are still the main cause of the majority of serious transfusion hazard incidents, accounting for up to 84.1% (2857/3397) in 2019 [2]. Quality management is the key to blood transfusion safety [3]. In China, the transfusion process starts with doctor's assessment of the patient's condition, then the patient is informed and signs consent, and doctor applies for blood. For nurses, they need to collect the specimens, notice for specimen distribution, and check the blood that has been confirmed by the cross-match tests, transfuse and monitor for transfusion reactions [4]. After transfusion,

the doctors and nurses need to finish post-transfusion evaluation and the medical records. The blood transfusion process is complicated, it involves the interaction of doctors, nurses, blood transfusion staffs and caregivers. They need to comply with all the laws and regulations [5].

In year of 2011, the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) made recommendations on patient consent for blood transfusion [6]. Patients should be fully informed of the reasons for blood transfusion, its benefits, risks alternatives, and give their consent [6]. According to the *Technical Specifications for Clinical Blood Transfusion adopted by the Ministry of Health of the People's Republic of China*, physician should explain to the patient or his/her family members the adverse reactions of allogeneic blood transfusion, and the possibility of blood-transmitted diseases, obtain the consent of the patient or his/her family members, and sign on the consent of blood transfusion treatment when deciding the blood transfusion treatment [7]. The form should be put into the medical record. This provision has become a monitoring indicator for evaluating transfusion management and hospital management [8]. But it’s hard to reach 100%.

The transportation and temperature control management after blood leaving the blood bank are the difficult problems in blood transfusion process management [9]. According to the *Technical Specifications for Clinical Blood Transfusion*, after blood matching test, medical staff (doctors and nurses) should go to the blood bank to collect the units [7]. They need to check the blood information with staffs of department of transfusion medicine. And once the unit of blood left the blood bank, it is not allowed to return [7]. Doctors and nurses in China are often very busy, and it takes time and effort to get blood back and forth, especially when waiting for elevators. Due to the lack of cold chain temperature monitoring, the units of blood that leaves the temperature control of the blood bank cannot be returned for reuse [10, 11]. This also makes staffs very cautious about taking blood, often carrying only one unit for a patient at a time, which requires a longer round trip.

Our hospital is a large comprehensive grade III class A hospital with 3000 beds in Zhejiang Province of China. The annual red blood cell dosage is about 16,000 U, and the plasma dosage is about 2,300,000 ml. In order to improve the blood transfusion management and speed up the efficiency of blood transfusion process, we tried to improve the flow of blood transfusion consent and blood transport in our hospital.

Methods

Data collection

Our study was conducted during June to December in 2019. We collected all the process management data of blood transfusion patients in these 7 months from hospital information system (HIS) and blood transfusion management system (TMS), including the blood transfusion application time, the delivery time of paper consent, the signing time of electronic consent, the printing time of blood receipt by the ward nurse, the sending time for distribution, the blood leaving time, the blood checking time and the

blood infusion time, etc. The data before and after the improvement were all involved. We also collected salary information for staffs. The ethical approval and consent to participate were supported by the Ethics Committee for Zhejiang Provincial People's Hospital in Hangzhou, Zhejiang, China (2022QT007).

Optimize the consent verification process by using electronic transfusion consent

Based on the Certificate Authority certification technology, the hospital achieved paperless medical record management. We designed the electronic process of the transfusion treatment consent, which covered the contents of the paper consent and added optional special circumstances, such as the risks of emergency mismatch transfusion of rare blood type, carrying drug antibodies or autoantibodies or isoantibodies. Doctors could choose the optional special circumstance, and consent would increase the text of corresponding risk. When the doctors opened the patients' blood transfusion treatment consent forms, the system automatically extracted the data of patients' blood transfusion and lab test and generated pre-printed form document according to the paper forms. Once they signed on the electronic signature board or tablet, and saved the files, the electronic consent document generated, then kept in the electrical medical record.

Prior to the introduction of electronic consent forms, the patients signed the papery forms, caregivers need to deliver the forms to the blood bank. The staffs check whether the blood transfusion consents were signed correctly, then released blood after confirming. We completed 100% of the signing requirement, but it took a lot of time and manpower. The flow of electronic consents was quite different from the previous paper forms, which need not to be delivered to the blood bank after signed. It had automatic verification function. If the electronic consent was not filled with the standard format or incomplete, it would not be saved and required correction. If it was corrected, the file would generate confirmation message and transmit it to the TMS. Blood distribution was no longer blocked when the TMS obtained the message.

Flowchart of transfusion consent verification process is illustrated in Fig. 1.

Optimize the blood delivering pattern from blood bank to ward

Establish a blood transport center to provide full-time blood distribution services

The traditional way of taking blood was very time consuming. The staff of blood bank reviewed the experimental results and uploaded the blood pre-outbound information. After receiving the information, the ward nurses selected the blood to be transfused according to the patient's condition and print the blood receipt. They need to bring the blood transfer boxes to the blood bank, checked the units with the staff, took the units back to the ward, examined again, and prepared for blood transfusion. Due to China's

existing blood transfusion regulations and lack of monitoring of the cold chain of blood, medical staff usually only took one bag of blood for a patient. Medical staff often complained that the traditional way was a waste of time, especially in high-floor wards, where they had to wait extra time for lifts.

The hospital set up an in-hospital blood transport center in October 2019. The center was located in the blood bank and equipped with 5 nurses who were responsible for blood distribution throughout the hospital. The blood distribution process went like this: The ward nurse selected the blood to be transfused, they sent the distribution information. The nurses in the blood transport center check the information, printed out the outbound receipt, completed the units of blood outbound check, packed and delivered the units of blood to the ward on time. They checked and handed over units in the ward with ward nurses. When the patient needs blood transfusion, the ward nurses took the blood from the transfer boxes which had temperature monitoring and rewarmed it for transfusion. We always had a nurse in charge of delivering emergency blood for operating rooms and emergencies. Flowchart of blood transport is illustrated in Fig. 2. We still reserve the path of ward doctors and nurses going to the blood bank by themselves to take blood for emergency rescue.

Replace the blood transfer box, realize the whole blood temperature control coverage

Once the unit of blood left the blood bank, it went off the temperature monitor. The unit of blood was not allowed to be returned to reuse [7]. In order to extend the blood cold chain temperature control to the bedsides of patients, we replaced the blood transfer boxes and implemented the temperature control information system management. The transfer box used cold storage agent to keep low temperature. A visual temperature monitoring interface was set outside the box, which can read the temperature inside the box in real time and uploaded the temperature to the temperature control information system every 10 minutes. Temperature control information system was equipped with warning device. Once the temperature exceeded, the transfer box and temperature control information system will alarm immediately. This type of transfer boxes was mainly used for blood transport in hospital or blood storage in ward less than 1 hour. Another type of blood storage tank can be connected to the power supply, just like a refrigerator with refrigeration device, which could store blood that cannot be transfused temporarily in the area for a long time. In order to ensure the permission of blood use, the transfer box was equipped with a two-dimensional combination lock, therefore, authorized mobile phones can scan the code to open it.

Quality data calculation

Time difference between blood application and consent verification

We collected monthly transfusion quality data, including the accuracy rate of transfusion consents. To evaluate the effect of process improvement, we also calculated the time difference between the

application for blood transfusion and the consent confirmation for blood distribution in the emergency department during June to December. Calculation formula was as follows:

Time difference of papery consents= Confirmation consents time - Blood application time

Time difference of electronic consents= Successful submission of electronic consents times - Blood application time

Time of blood leaving temperature control

Time of blood leaving temperature control before transfusion is an important quality parameter. In general, the units of blood need to be rewarmed at room temperature before transfusion, private storage of blood in the ward is not allowed. We calculated the time of blood leaving temperature control as follows:

For issuing the units of blood,

Time of blood leaving temperature control= Start time of blood transfusion - Time of blood outbound

For delivering blood,

Time of blood leaving temperature control= Start time of blood transfusion - Time of blood receiving

(Note: Blood receiving means removal of blood from the temperature- Controlled transfer boxes by ward nurses)

The labor cost between issuing and delivering the units of blood

We recorded the staff time for issuing and delivering the units of blood. For issuing the units of blood, data was collected on the time taken for the ward nurses to perform a return journey to the blood bank. The time record is from when the ward nurse to print the blood receipt to when they return to the ward to check the blood information. For delivering the units of blood, nurses of blood delivery center recorded the time from printing receipt of a delivering request to the time the blood was checked by ward nurses. The labor cost for performing was calculated using the average time taken to perform multiplied by the hourly cost for the grade of staff.

Statistical analysis

Statistical analysis was performed by SPSS 22.0 software package. Because the data was skewed, the measurement data was expressed as Median (P25, P75). The two group of data were compared based on the Mann-Whitney U test. Multiple comparisons were based on the Kruska Wallis method. The *p*-value of < 0.05 was considered statistical significance.

Results

Electronic transfusion consent process ensured the accuracy and saved confirmation time

We gradually introduced electronic consents from August 2019, it accounted for more than 97% till November and December (Fig. 3A). Because of the system's interception, valid consent was obtained and documented for each blood transfusion during electronic consents implementation. Quarterly analysis of blood transfusion quality data showed that the accuracy of blood transfusion consent was 100%.

We also analyzed the time difference between consents confirmation and blood transfusion application in the emergency department every month. The time difference was significantly reduced since September when the ratio of electronic consents was 71.43% (Fig. 3B). The average electronic time difference was negative, because consents were always signed before the application for transfusion, and the electronic consents were confirmed by the system automatically. They did not delay the distribution of emergency blood. We also compared the time differences of all electronic consents and paper consents (Table 1, Supplementary Table 1), and found that electronic consents save the confirmation time significantly, the average savings was 26 minutes (Fig. 3C).

Table 1
Time differences between the papery and electronic consents

	M (P25, P75)	Estimated Difference (95% CI)	Mann-Whitney U test	
			Z value	*p* value
Papery	21 (12, 53)	26(20 to 36)	-11.398	<0.001
Electronic	2 (-4.75, 8.80)			

Pattern of delivering blood increased blood temperature control time

We established the blood transport center in October 2019.The mode of blood transport from blood bank to wards was changed, while the proportion of blood delivered was 53.14% in October and 93.64% in December (Fig. 4A). We found that the average time for blood leaving temperature control was significantly reduced (Fig. 4B). We analyzed the difference of blood temperature control time between the two modes of blood transportation (Table 2, Supplementary Table 2), delivering the units of blood increased temperature control time significantly ($p < 0.05$) (Fig. 4C).

Table 2
Leaving temperature control time of issuing and delivering the units of blood

	M (P25, P75)	Estimated Difference (95% CI)	Mann-Whitney U test	
			Z value	*p* value
Issue	18.48 (12.12, 27.43)	7.24 (6.92 to 7.56)	-41.98	<0.001
Delivery	10.53 (5.68, 18.91)			

Delivering blood reduced the labor cost

We calculated the staff time of delivering and issuing for each unit of blood. For delivering, the average time was 0.26hrs, comparing the issuing time was 0.62hrs. The ward nurses time cost was $7.48/hour, while the time cost of blood delivery nurses who delivering blood only was $3.74/hour. The cost of staff time was saved $3.67 for each unit of blood. According to the blood consumption of our hospital in 2018 and 2019, the savings are estimated at $99,000. (Table 3)

Table 3
Cost comparison of different mode of transporting blood

Items	Issuing	Delivering
Average time for each unit (hrs)	0.62	0.26
Ward nurses time cost ($/hr)	7.48	-
Transport center nurses time cost ($/hr)	-	3.74
Total cost of staff time for each unit ($)	4.64	0.97
Annual saving in staff time costs that delivering blood contributed ($)	-	99,000

Discussion

The safety of blood transfusion concerns the safety of life. Improving transfusion management can improve the safety and effectiveness of blood transfusion [12]. A number of clinical applications have benefited from the implementation of transfusion information management or transfusion information process improvement [13-15]. Since year of 2017, our hospital had implemented the electronic information management of blood transfusion through the whole process. Since 2019, Zhejiang Provincial Health Commission released “Without the Need for A Second Visit” reform for improving health care services [16], including the item of “No need to run for blood service”, and the main purposes of the reform are making full use of Internet and big data to comprehensively promote good medical services. At the second half of 2019, we have improved the electronic blood transfusion consent process and the blood delivery process to complement the management of blood transfusion. We’ve found that electronic transfusion consents not only guaranteed the signing accuracy, but also saved the confirmation turnaround time. Each consent form saved an average of 26 minutes. The pattern of blood delivering

reduced the time for each unit of leaving temperature control by 7.24 minutes on average, and saved $3.67 of labor cost for as well.

Before the blood transfusion, patients should be fully informed [17]. Different countries have different policies and realities [17-21]. The lack of consents for blood transfusion, or lack of documentation which only had verbal consents remained a problem in some areas [18, 19]. This problem could be solved by using a pre-prepared paper consent form in a standard format and checking that the consent was completed before transfusion [20, 21]. But it also brought other problems. These problems could be classified into three categories: 1. The paper consent form was incomplete [20, 22, 23]; 2. The content was outdated, the risks involved were not detailed enough, and the content of patient blood management was not reflected [21]; 3. Low efficiency and manpower consumption [24].

We implemented pre-printed transfusion consent forms before, but were plagued by these three problems. Therefore, we designed and operated electronic blood transfusion treatment consent process, which can automatically extract laboratory test data of patients, set standard format, automatically complete the format review, and refuse to save and submit the incomplete consents. According to different conditions of patients, doctors can choose different risk content text. The content of autologous transfusion is highlighted in bold and underlined font. Since the implementation of electronic consent, transfusion consent filling accuracy rate was always 100% in quarterly blood transfusion quality sampling. This greatly saved the verification time of transfusion consent and improves the efficiency as well. At present, we had only solved the problem of "yes", how many patients had been effectively informed and how many patients had truly understood the content of blood transfusion consent and participated in the decision is what we need to pay attention to in the follow-up investigation [24]. Maybe video animation and other forms will be more helpful for patients to understand [17].

Improper storage and transportation of blood can result in blood wastage [25, 26]. Delayed infusion and improper storage after blood issued also lead to higher transfusion adverse reactions [1]. Temperature monitoring of blood products in hospitals is usually performed only in the blood bank for blood storage [10, 11, 26]. The units were in state of unmonitored conditions in clinical wards and theatres after blood issued [1]. Therefore, extending the temperature control of blood products to wards and theatres can improve blood transfusion safety. Electronic remote blood issue (ERBI) technology is thought to rely on TMS, automated refrigerators and electronic cross-matching to enable remote self-service blood collection [27, 28]. The refrigerator is usually placed in the theatres or wards far away from the transfusion department to ensure the timely supply of blood for emergency use [28]. This is also a way of extending temperature control to the ward. But it costs a fortune to equip each ward. Moreover, ERBI is not suitable for areas where blood resource is relatively scarce or electronic cross-matching has not been carried out. We focused on the blood transfer boxes. The boxes can be refrigerated, can realize temperature monitoring and data transmission. For safety reasons, they can be opened by scanning code. The nurses in the blood transport center delivered blood with different types of blood transfer boxes according to the different needs of the ward. According to the storage time, nurses could flexibly allocate

the transfer boxes, realized the management of blood left the blood bank. The temperature control time of blood was significantly increased.

Another problem with blood transporting is the cost of manpower [29]. In a study quantifying the cost of care in patients with transfusion-dependent thalassemia, procedure costs (55%) were higher than blood costs (40%) [30]. In the United Kingdom, the nurses needed to collect samples, place requests for blood transfusion and administer transfusion [31]. Specimen delivery and blood delivery were done by workers and cost only $9, but nursing inputs was still the most important part of the whole chain of blood transfusion management [32]. In China, regulations clearly state that trained medical personnel (usually nurses) should be responsible for blood delivery [7]. This undoubtedly increases the nursing inputs. We changed the blood transport mode and replaced ward nurses with dedicated blood delivery nurses. We delivered blood in batches on a regular basis, saved $3.67 per unit on average. The annual savings is also substantial, comparable to ERBI brings($5,000 - $10,000) [32].

We reported the benefits of electronic consent process and blood delivery model in our hospital. Each hospital has different status and regulations, and it is unknown whether they apply to other hospitals. As previously described, the current electronic informed consent signing process was convenient, but it was uncertain how many patients truly understood and participated. It is also unknown whether there was over signing, which caused fatigue in patients or family members [24]. Our current blood delivery model was suitable for the correction of anemia in clinical general conditions, but not for emergency treatment. Due to our original regulations, blood left the blood bank can not be returned [7, 8], therefore, the situation of clinical blood withdrawal and scrapping was very rare, and it was impossible to compare the data at the present stage whether the increase of blood temperature control coverage brings about the decrease of blood bag scrapping.

Conclusion

Blood transfusion is an important means of clinical treatment. The information management of blood transfusion process can help standardize the implementation of blood transfusion process and improve blood transfusion safety. We used information management technology to improve two transfusion processes: electronic consent verification and blood delivery pattern. The automatic check function of the system not only ensured the accuracy of the consents filling, but also saved the manual check steps and speed up the blood transfusion process. We had established a blood transport center and combined with the use of temperature-controlled blood transfer boxes, solved the problem of cold chain control after blood leaving the blood bank, and also saved a considerable amount of labor costs. We recommend more transfusion management improvements to improve transfusion safety.

Abbreviations

SHOT
Serious hazards of transfusion

SaBTO
the advisory committee on the safety of blood, tissues and organs
Ele
Electronic content
Pap
Papery content
ERBI
Electronic remote blood issue

Declarations

Authors' contributions

L.J., Y.D. and B.C. conceived and designed the study. Z.W., Q.Z. and G.Z. supervised the study. L.J., Y.D. and Z.W. did the statistical analysis. K.H. and W.X. drafted the report. K.H., W.X., and Y.X. contributed to data collection and analysis. Y.D. and Z.W. interpretation of data. L.J., Y.D. and B.C. revised the manuscript. All authors approved the final version of submission.

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Availability of data and materials

The datasets used and/or analyzed during the current study are all available in the supplementary files.

Ethics approval and consent to participate

All methods were carried out in accordance with relevant guidelines and regulations, and we didn't involve the experiments on humans and/or the use of human tissue samples. The verbal informed consents were obtained from all participants when we collect all information of patients in our hospital. Ethical approval and consent to participate were supported by the Ethics Committee for Zhejiang Provincial People's Hospital in Hangzhou, Zhejiang, China (2022QT007).

Competing interests

The authors declare that they have no competing interests.

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Figures

Figure 1

Flowchart of transfusion consent verification process. The thickness of lines and arrows are representing an improved electronic consent process. The double arrow dotted line path, represents two ways of calculating the spent time for consent confirmation

Figure 2

Flowchart of blood transport process. The thickness of lines and borders were representing the blood delivering pattern

Figure 3

The changes in transfusion informed consent form and consents confirmation time. **A** Ratio of blood transfusion consent forms from June to Dec. 2019. Ele: electronic, Pap: papery. **B** Time difference between consents confirmation and blood transfusion application in the department of emergency from Jun. to Dec., compared with Jun., Jul. and Aug. the difference was significant (**: $p < 0.001$). **C** Time difference of electronic and papery consents, the difference was significant (**: $p < 0.001$)

Figure 4

The changes of blood transport pattern and temperature control time. **A** Ratio of blood transport pattern from Jun. to Dec. 2019. **B** Time for blood leaving temperature control from Jun. to Dec. 2019, compared with Jun., Jul., Aug., Sep., the difference was significant (**: $p < 0.001$). **C** Leaving temperature control time between issuing and delivering blood, the difference was significant (**: $p < 0.001$)

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryTable1.Rawdatasetsoftheconsents.xls
- SupplementaryTable2.Rawdataofbloodtransportpattern.xls