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Research Paper

Author should provide Figures 1 to3 and Tables 1-2

"Status analysis and evaluation of the blood scrap rate from 2015-2017 for a blood center in China"

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ABSTRACT

Introduction: The objective of this study was to obtain full knowledge of current conditions and development in the past three years of clinical transfusion practice in Nanjing, Jiangsu province, China. The recent situation of blood quality control and blood production scrap rate from 2015-2017 were monitored and measured through different quality statistics and management tools. The causes of unqualified and scrapped blood during blood collection and supply were analyzed and evaluated. The analysis of the key indexes for blood component quality control showed that the qualified rate of the FVIII activity (FFP) was 54.55%, which failed to meet the requirements of at least 75%. Retrospective analysis of conventional blood scrapping factors showed that the ratio of laboratory scraps was the first. Composition ratio of TTI screening results showed ALT of 31.91%, HBV21.92%, TP12.15%, NAT10.78%, HCV8.45%, HIV7.43% respectively. Retrospective analysis of unconventional blood scrapping factors showed that the total unconventional blood depletion rate was 0.565%. Small amount was the most important factor of causing unconventional scrapping. The blood donor service satisfaction rate and the blood hospital service satisfaction rate was over 95 and 90% respectively which achieved the quality target. Nonconforming product control was proposed and determined as the urgent theme of the first QCC. It is very necessary for blood stations to effectively control blood scrapping, which can reduce the cost of blood collection, protect the blood donation of unpaid blood donors, increase the rate of repeated blood donation, and improve blood safety.

Key words: Blood quality control, monitoring, measurement, analysis, evaluation.

INTRODUCTION

In China, International Organization for Standardization (ISO) 9000 was introduced into Blood Transfusion Services (BST) since 1999. BST evaluates the performance and effectiveness of the quality management system. Performance of the quality management system for a blood bank includes the contents of blood products and services, as well as the contents related to process operation and system operation, such as the blood pass rate, customer return visit and satisfaction survey, and the clinical hospital complaint rate. Performance evaluation usually includes activities such as data acquisition, analysis and conversion, and implementation evaluation. The usage and discard, infectious and noninfectious adverse events, Near-miss events, the ability of services to meet patient needs shall be monitored to confirm blood utilization. Quality management staffs participate in the examination of blood scrapping in the whole process, master the dynamic quality status, and also implement the blood sampling. This article selected the blood component qualification rate, blood scrap rate and customer satisfaction rate as indicators to analyze the effectiveness of the quality management system for BST. The quality statistic methods were used for

monitoring and measurement. Survey results from the blood bank (Nanjing, Jiangsu, China) were reported and discussed here.

MATERIALS AND METHODS

Ethical compliance

This study was approved by the independent ethics committee of Nanjing Red Cross Blood Center. There are no conflicts of interest in the present article. Blood samples used were collected from the blood donors who voluntarily donated whole blood at our blood center. All volunteers signed an informed consent statement to approve the use of their remaining sample.

Data sources of quality control (QC)

The trend analysis was used to evaluate the quality of blood and blood components. The quality control data of seven kinds of blood components, which were tested every month, were collected. According to the blood quality control program in the "Blood Station Technical Operation Regulations" (2015 Edition, China) and GB18469-2012"Quality Requirements For Whole Blood And Blood Components (Blood Station Technical Operation Regulations, 2015; GB18469-2012), red blood cells in additive solution, red blood cells in additive solution leukocytes reduced, washed red blood cells(Washed RBCs), apheresis platelets, fresh frozen plasma(FFP), fresh frozen plasma methylene blue treated and removed and Cryoprecitation were sampled. Seven key indexes(HB, HCT, Platelet content, pH, Factor VIII activity, Fibrinogen content, Methylene blue residue), which are related to clinical infusion efficacy or reflected the preparation process, were recorded and analyzed from 2015-2017.

Data sources of blood rejection rate

In 2016 and 2017, all blood products were collected and prepared, with a total of 489,735 cases, that is, 239,962 and 249,773, respectively. The quantity of clinical transfused bloods was 235,987and 244,771, respectively. The quantity of scrapped bloods was 3,965 and 5002, respectively. The classification of causes of blood scrapping comprises normal causes and abnormal causes. Normal causes involve laboratory scrap (Inspection failed, Irregular antibody) and testing scrap (Blood sampling). Abnormal causes involve non-qualified scrap, Raw material issues and other non-laboratory scrap. Different causes were classified, covering the whole process for blood collection, separation, detection, preservation, and transportation. They include Transfusion transmitted infection (TTI) blood sieve, moderate to severe lipid plasma, insufficient blood volume, expired blood, damage, hemolysis and so on.

Data sources of customer satisfaction

The customers' perceptions of the degree to which their needs and expectations have been fulfilled were monitored. Here customer satisfaction included satisfaction with blood supply services and satisfaction with blood donation services. The satisfaction survey was conducted in the region and the areas under its jurisdiction. From 2015 to 2017, taking the Nanjing Red Cross Blood Center as the respondent, the past three years' survey content included the main service elements and processes of the industry. Satisfaction was divided into three levels: satisfaction, basic satisfaction, dissatisfaction. Satisfaction rate = (satisfactory number × 100 + basic satisfactory number × 70) / (satisfactory number + basic satisfactory number + unsatisfactory number). The survey was conducted irregularly throughout the year, the statistical analysis results reported once every 6 months. The clinical blood quality feedback from 2015-2017 was reported here.

RESULTS

Analysis of the key indexes for blood component quality control

The sampling results of the six blood components from 2015-2017 showed that there were eight key indexes which could not meet 100% of the GB18469-2012 (Quality requirements for whole blood and component blood), such as Factor VIII(FVIII) activity (FFP), HB(Washed red blood cells)、FVIII activity (Cryoprecitation), Methylene blue residue, HCT(Red blood cells), Platelet content, Fibrinogen content(Cryoprecitation), HB(Red blood cells). The qualification rate of FVIII activity (FFP) failed to meet the requirements, which was at least 75% under control per month. Statistical analysis is shown in Table 1. The qualified rate of the FVIII activity (FFP) was 54.55% only. According to the Pareto curve (Figure 1: Pareto chart was used to analyze the unqualified reasons for the quality of blood components from 2015-2017 (Pareto analysis: 0-80% as the main factor, 80-90% as the secondary factor, 90-100% as the general factor)). FVIII activity (FFP)、HB(Washed red blood cells) and FVIII activity(Cryoprecitation) were the main factors affecting the sampling pass rate. The composition ratio was 41.31, 15.70 and 14.13%, respectively.

Analysis of the conventional blood scrapping factors

From 2016-2017, retrospective analysis of conventional

blood scrapping factors showed that the ratio of laboratory scraps was the first, the factor of unqualified inspection caused scrap rate was 1.02% (= Scraps / (Total Scraps + Outbound),= 5010/489725). Irregular antibody scrap rate was 0.07% (= Scraps / (Total Scraps + Outbound),= 358/489725). The total conventional scrap rate was 1.27%(= ConventionalScraps / (Total Scraps + Outbound),= 6202/489725). The average inspection failure rate of the laboratory was 1.313% (= unqualified number/ the number of people collected,= 2272/173056). Composition ratio of TTI screening results showed that the main factors contained ALT 31.91%, Hepatitis B Virus (HBV) 21.92%, TP12.15%, Nucleic Acid Amplification Techniques (NAT) 10.78%. Hepatitis C Virus (HCV) 8.45% was a secondary factor (Figure 2: Pareto chart was used to analyze the conventional blood scrapping factors from 2016-2017 (Pareto analysis: 0-80% as the main factor, 80-90% as the secondary factor, 90-100% as the general factor)).

Analysis of the unconventional blood scrapping factors

From 2016-2017, Retrospective analysis of unconventional blood scrapping factors showed that the total unconventional blood depletion rate was 0.565% (=Scraps/(Total Scraps+ Outbound), =2765/489725). Unconventional reasons for scrapping included Small amount, Lipemia, Clot, Precipitate, Centrifugal leakage, Frozen leakage, Over preserved blood, Confidentiality discarding blood, Heat leakage, Hemolysis, Contamination, Transport discarding, Excess etc. Small amount was the most important factor of causing unconventional scrapping, and the composition ratio was 52.84%. The incidence rate was 0.872% (=small amount number/(whole blood collection number),=1350/154743) (Figure 3: Pareto chart was used to analyze the unconventional blood scrapping factors from 2016-2017 (Pareto analysis: 0-80% as the main factor, 80-90% as the secondary factor, 90-100% as the general factor)).

Analysis of customer satisfaction

The quality target of blood donor service satisfaction rate and the blood hospital service satisfaction rate was over 95 and 90%, respectively. For 2015, the result was 99.85 and 97.6%, respectively; for 2016, the result was 99.48 and 100%, respectively; and for 2017, the result was 98.00 and 99.78%, respectively. The clinical blood quality feedback results are shown in Table 2. The main adverse reactions of transfusion were fever reaction, allergy and rash reaction. After investigation, there was no quality problem with the blood involved. In 2017, one case of shock after transfusion occurred. Establishment of performance goals and analyzes of the evaluation system help in the improvement and increase of customer satisfaction.

DISCUSSION

Current situation grasp

The author reported the blood quality control in detail for the year 2015 (Shi et al., 2017a). Combined with 10 clinical blood components that our center supplied, quantitative items which are relevant to clinical infusion efficacy or reflect the manufacturing process were selected as key indicators to draw line charts for trend analysis further. The eligibility criteria for key indicators were set as action limits, which were used as the boundaries that retrospective researches were required or measures were taken when necessary. A threshold of 120% (> eligibility criteria are met) or 80% (< eligibility criteria are met) of key-indicator eligibility criterion was set as a warning limit, which was served as a threshold for attention. The method of continuous trend analysis based on trend analysis chart was suitable for blood component quality control project. It provided reference for the stability evaluation of blood products. Timely analysis of deviation data, that provides guidance and supervision of each position to take corrective and preventive measures, can effectively prevent quality non-compliance caused by improper process control or system deviation. The process of blood collection, preservation, preparation, release, and quality control was backward. The stability of Factor VIII activity (FFP) was poor, and it was closely related to the preparation procedure of the component preparation department. As a heat labile coagulation factor, Factor VIII was easily reduced or lost due to various factors in different storage and isolation processes. Time temperature control had a great influence on the Factor VIII activity (FFP). Through the trend analysis of quality control department, the Factor VIII activity (FFP) was defined as a key indicator to be observed continuously, and needed corresponding improvement measures.

Blood banks are supposed to perform test using a single ELISA/rapid screening test and units found to be reactive for any of the infections need to be discarded. In China, the strategies of blood screening are two-pass enzyme-linked immunoassay and one-time nucleic acid detection. The ALT (Shi jet al., 2015a) and Hepatitis virus (Hu et al., 2017) positive rate of blood donations was first regarded among the conventional blood scrapping factors. Human immunodeficiency virus (HIV) (Shi et al., 2017b) prevalence is associated with gender, age, characteristics, and repeated blood donation. The increasing MSM prevalence rate is a new feature. In Guangzhou (Ke et al., 2013), the risk of transfusion-transmitted TTI from 2010-2011 was reported, and that after NAT testing the residual risk was HBV 1/46643, HCV 1/723526, HIV 1/1254770.

Line chart was used to analyze the rate of the unconventional blood scrapping each month, respectively 2016 and 2017. The ring and year-on-year analysis showed a significant growth in February and December, 2017. Then

it was found that the unconventional scrapping of blood quality abnormalities such as lipemia and color abnormalities in 2017 was concentrated after a period of accumulation, and corresponding corrective measures were taken to require relevant departments to find problems and promptly report them. The author reported that 184 cases in 19,921 blood donors were statistically analyzed from Jan to May in 2014 in Nanjing. The rate of inadequate blood was 0.92%, the mainly abnormal reason was poor bleeding (Shi et al., 2015b). Similarly, this article showed that from 2016-2017 the main factor of unconventional blood scrapping was a small amount of blood collection. Line chart was used to analyze the proportion of small amount in blood collection each mouth in respectively 2016 and 2017. The result showed that there was no significant difference for the incidence of inadequate blood.

Haemovigilance (HV) is an effective tool for improving transfusion safety. In France, Singapore, Japan, the United Kingdom, the Netherlands, Canada and the United States, there are different forms of HV operations: full-time administrative departments, blood supply agencies, professional organizations, public health departments, government and civil cooperation. The National Blood Collection and Utilization Survey (NBCUS) showed decline in blood collection and transfusion in the United States (Ellingson et al., 2017). HV is the only way for China's blood industry to reach the international advanced level. The defect of this article was that the current situation of the clinical blood quality feedback was imperfect mechanism.

Selection of subjects and analysis of causes

The blood banks ensured that blood and blood components that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. Appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services shall be taken. The organization shall evaluate the performance and the effectiveness of the quality management system. Monitoring, measurement, analysis and evaluation were required in performance evaluation in ISO 90001. What need to be monitored and measured? The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results. The monitoring and measuring shall be performed. The results from monitoring and measurement shall be analysed and evaluated. Statistical quality control and analysis were effective management tools and measures in the comprehensive management of blood stations presently.

Total Quality Management (TQM) was described in the ISO, Risk Management for BTS, AABB Standards for Blood Banks and Transfusion Services. Control of nonconforming product was urgently required to allow transfusion services strategic planning for securing future blood supply.

Quality Control Circle (QCC), a kind of active TQM tool and a lively quality control form, can be used as an effective tool to improve medical quality, organized and planned to promote the reasonable application of limited resources. Based on the current situation for our blood station and using brainstorming analysis, topics were proposed. “Reduction of blood scrap rate” was proposed and determined as the urgent theme of the first QCC. Unconventional scrap rates provided basic monitoring goals for decision analysis. It was very necessary for blood stations to effectively control blood scrapping, which can reduce the cost of blood collection, protect the blood donation of unpaid blood donors, increase the rate of repeated blood donation, and improve blood safety. Using the rejection rate of blood product to evaluate the effectiveness of non-conforming product control was a very important, product-related performance indicator in blood station. These benefit the quality control (QC) of blood critical links, provide the basis for corrective and preventive measures.

Conclusions

The use of quality tools to assess, develop, implement, and monitor work process design can assist staff by modifying QI processes that promote efficiency, effectiveness, and patient safety (Goodnough et al., 2011). In the past 10 years, with the development of China's medical and health services, blood collection and supply issues have also increased significantly. Blood and blood products should be considered as a public resource. An overall focus on risk-based thinking is essential for achieving an effective quality management system. To protect limited blood resources, the control of nonconforming blood and blood components covers all activities of the blood transfusion chain, from donors to recipients. This study laid the foundation for the key factor analysis. It was beneficial to draw fishbone diagram, and whole reasons were discussed and analyzed. QC procedures have been implemented for consumables, blood components, critical equipment and so on. Setting plan, improvement measures and achieve set goals were the next steps.

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REFERENCES

Blood Station Technical Operation Regulations, 2015 Edition, China.

GB18469-2012 Quality Requirements For Whole Blood And Blood Component. Beijing:China Standard Press,2012.

Shi J, Jia L, Duan Z et al (2017). Trend analysis of the key indexes for blood component quality control. Chin. J. Blood Transfusion. 30(09):1057-1059.

Shi J, Zheng J, Luo Y et al (2015). Investigation and analysis of unqualified detection of alanine aminotransferase (ALT) in unpaid blood donors. Medical Information. 28(5): 235.

Hu B, Bao J, Shi J et al (2017). Investigation of HBV infection among eligible volunteer blood donors in Nanjing City [J]. Chin. J. Blood Transf . 30(05): 448-451.

Shi J, Jia L, Luo Y et al (2017). Investigation and analysis of HIV infections among voluntary blood donors in Nanjing, Jiangsu province from 2013 to 2015.J. Clin. Transfus. Lab. Med. 19(01): 34-36.

Ke Huang, et al (2013). Residual risk assessment of HBV, HCV and HIV in transfusion in Guangzhou from 2010-2011. Chin. J. Blood Transf. 26(2):128-131.

Shi J, Zheng J, Luo Y et al (2015). Case analysis of 184 cases of insufficient amout blood. J Clin Hematol (China).28(10): 884-885.

Ellingson KD, Mrp S, Haass KA, et al (2017). Continued decline in blood collection and transfusion in the United States-2015.[J]. Transfusion. 42(10):1588-1598.

Goodnough LT, Viele M, Fontaine M, et al (2011). Quality management in the transfusion service: case studies in process improvement.[J]. Transfusion. 51(3): 600–609.