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Original Article

Pathology Section

Quality Audit Towards Improvement of Transfusion Services: An Institutional Assessment

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ABSTRACT

Introduction: Maintaining quality in transfusion services is a vital cogwheel of Quality Management System (QMS) in a hospital to impart safe blood to the patients. Quality Indicators (QI) play a pivotal role in quality management as they dispense imminent information regarding the execution of transfusion services and could help in utilising QI as a benchmark for safe quality of blood. Less is known about the authentic utilisation of QI in hospitals.

Aim: To assess the comprehensive quality performance of the blood centre and evaluating the five obligatory QIs as per National Accreditation Board for Hospitals and Healthcare Providers (NABH) and make necessary suggestions for refinement of the same.

Materials and Methods: The cross-sectional study was conducted at the blood bank attached to RL Jalappa Hospital, Tamaka, Kolar, Karnataka, India. The five compulsory QIs, as defined by NABH, were noted and monitored on monthly basis, from December 2019 to December 2020. The particulars were collected in a methodical outline and root causes for any deviation were assessed. Accordingly, particular corrective and preventive measures were taken. Data was entered in Microsoft excel spreadsheets and analysed using Statistical Package for Social Sciences (SPSS) v22 software.

Results: The mean transfusion reaction rate was 0.18 in patients, with a highest value of 0.9 noted in the month of March-2020; there was no transfusion reaction at all in the month of February, April, June, July, October, November and December-2020. The mean wastage rate was 12.9. The maximum wastage was noted in August-2020 (21.7%) and was least in October 2020 (7.2%). Turnaround Time (TAT) was <30 minute for emergency cases with a mean of 27.11 minutes. For routine cases mean TAT was 140.9 minutes.

Conclusion: Stringent enforcement of quality indicators, as mandated by NABH, can help in preventing errors in transfusion services. This, in turn, helps in maintaining a better quality and performance of the blood bank.

Keywords: Quality indicators, Quality management system, Transfusion transmitted infections

INTRODUCTION

Over the last decade the pursuit for safe blood supply has led to enormous growth in the context of Transfusion Medicine (TM) practices. Quality indicators are a part of QMS tool. These are implemented in an institution with the intention of collecting proof for the level of quality performances, and the data can also be used to improve performance in an establishment [1]. To ascertain zero-risk blood transfusion, huge efforts were made to increase the quality of the transfusion services, so there was a need to establish substantial parameters for measuring the quality of transfusion services. These colossal efforts have been made by government and non government based blood banks, to collect, create and assess quality QIs for quality healthcare services. Noteworthy considerations were proposed by reputed bodies such as the Agency for Healthcare Research and Quality (AHRQ) and the College of American Pathologists (CAP) [2]. However, these considerations have been addressed to a limited extent for blood banking services. International Society of Blood Transfusion (ISBT) constituted its Working Party on Quality Management (WPQM). Measures for improving blood banking services utilising QIs: Three benchmarks are categorised for selection of QIs: a) importance, b) scientifically sound parameters along with possibility. Various strategies are instituted by organisations for constant improvement of quality services. Most common strategies utilised are 1. FOCUS-PDCA (Find, Organise, Clarify, Understand and Select-Plan, Do, Act and Check), and 2. Six-sigma. The FOCUS-PDCA had proven considerable benefit in QI projects of blood banking services [3,4]. Here, FOCUS means to find or search what is required for improvement, organisation of team with sound knowledge, clarification of the knowledge in relation to the process implied, understanding factors leading to variations in the process, selection of interventions that may help in improvement of the process. Here, PDCA means planning for improvement, doing the required changes at a very small level on trial basis, checking to note if the changes of data are efficacious or not and acting accordingly to collate the benefits obtained. Six-sigma means that 99.99966% of the process results are anticipated to be free of defects (meaning <3.4 defects per million cycles of the procedure).

Data analysis and collection are also considered as a crucial benchmark for QIs and QIs projects. For obtaining data of QIs usually routine sources are utilised. Computers are considered for storing of data, retrieval of data along with evaluation QIs data. Manual collection of data by manual method is also possible but is slower and has less accuracy. A noteworthy implementation that can augment data collection for QIs manually is the “check sheet”. So, these measures can be implied to enhance quality of QIs for blood banking services. Subsequently this led to the development of QIs in blood banking system. Implementing QMS in all the phases of transfusion services such as blood collection, processing and storage can help in achieving Blood Transfusion Services (BTS) with greater degree of efficacy [5]. Eleven QIs are defined by NABH, of which the first five indicators are compulsorily accredited for blood bank to report and monitor quarterly to NABH [6]. The main goal of BTS is to maintain and provide superlative quality standards in every facet of patient care.

The present study was conducted to evaluate the quality performance as well as to inspect the preparedness of the blood bank of a rural tertiary care hospital and make necessary recommendations required for betterment of the same.

MATERIALS AND METHODS

The cross-sectional study was conducted at the blood bank centre attached to RL Jalappa Hospital Kolar, Karnataka, India. The first five mandated QIs by NABH [6] were documented on a monthly basis, from December 2019 to December 2020. Ethical clearance was obtained for the study from Institutional Ethical Committee with IEC.No DMC/KLR/IEC/480/2022-23).

Study Procedure

The particulars were collected in a methodical manner and root causes for any deviation were assessed, and accordingly particular measures were taken. Essential information with regards to QI parameters were gathered monthly from all the wards, Intensive Care Units (ICUs), Operation Theatre (OT), and also from the blood storage unit itself by blood bank technicians. The whole procedure was carried out under supervision of "incharge" of blood storage unit.

The QIs noted were as follows:

1. Percentage of Transfusion Transmitted Infection (TTI%)

   Calculated as:

   TTI%=Total combined TTI cases inclusive of Human Immunodeficiency Virus (HIV)+Hepatitis B Virus (HBV)+Hepatitis C Virus (HCV)+Syphilis+Malarial Parasite (MP)×100 divided by total numbers of donors in that month.

2. Percentage of adverse transfusion reactions

   Calculated as :

   Percentage of adverse transfusion reactions=number of adverse transfusion reactions multiplied by 100 divided by entire number of blood or component units issued in that particular month

3. Percentage of outdated whole blood or concentrated Red Blood Cells (RBCs) (wastage rate):

   Number of whole blood or concentrated RBC discarded (outdated)/by the entire (total) number of whole blood and concentrated RBC collected or prepared in that month×100

4. Turnaround time was derived as follows:

   TAT=Sum of the time acquired divided by the grand total number of times whole blood or RBC issued.

   Time taken was derived from the time of issue of request or receiving of sample in the blood bank to the time until the blood was cross-matched and made available for transfusion.

5. Percentage of component Quality Control (QC) failures (for each component) was derived as follows:

   Number of a particular component QC failures×100 by total number of that component tested in that month.

STATISTICAL ANALYSIS

Data was entered in Microsoft excel sheet and analysed utilising SPSS Software 22. The unpaired Student's t-test was applied.

RESULTS

Total donors who enrolled for blood donation during the study period was 26,200, of which 575 donors (2.19%) were deferred, 488 donors (84.86%) were temporarily deferred, and 86 donors (14.95%) were permanently deferred as per the DGHS criteria [7]. The total blood collection for the one year study period was 25,625 blood units with 100% component separation. Among the donor population the voluntary blood donors constituted 25,112 (98%), and the relative blood donors were 513 (2%).

[Table/Fig-1] The most common reason for discarding Packed Red Blood Cells (PRBCs) was underweight 600 units (46.54%). The most common cause for discarding Fresh Frozen Plasma (FFP) was lipemic 800 units (43.36%). The most common cause for discarding Platelet Concentrates (PCs) was leakage in 90 units (36%).

Blood component	Total units present	Number of units discarded and the reasons
PRBCs	1289	Clot formation (20) Hemolysis (29) Overweight (500) Underweight (600) Leakage (100) Lipemic (40)
FFPs	1845	Leakage (780) Lipemic (800) Greenish dicolouration (8) Icterus (20) RBC Contamination (237 Units)
PCs	250	Leakage (90) RBC contamination (80) Lipemic (80)

[Table/Fig-1]: The number of discarded units along with reasons for discarding.

The final decision for discarding blood unit was done as per the Standard Operating Procedure (SOP) with prior knowledge and permission from Blood Bank Officer (BBO) along with proper documentation mentioning the date, units involved, and the cause of discard.

The [Table/Fig-2] represents TTI% with maximum TTI% noted in the month of May 2020, (4.2%) followed by October 2020 (3.2%) and December 2019 with TTI% of 2.7%, lowest value was noted in the month of July 2020 (0.2%) with mean TTI of 1.87. The [Table/Fig-3] demonstrates adverse transfusion reaction rate%, maximum adverse transfusion reaction rate was noted in the month of March 2020 (0.9%) and no transfusion reaction was noted in the months of February, April, June, July, October, November and December-2020.

The [Table/Fig-4] depicts wastage rate %, maximum wastage rate was observed in the month of August 2020 (21.7%) and minimum wastage rate was noted in the month of October 2020 (7.2%) with mean wastage rate of 12.9%.

The [Table/Fig-5] represents TAT, TAT was found to be <30 minute for emergency cases except in month of February and May 2020 with TAT value being 40.2 minutes and mean TAT value was 27.11. For routine cases mean TAT was noted 140.9 minutes. The [Table/Fig-6] represents number of TTI's, maximum TTI's were observed in the month of May 2020 (29 units) and least TTI's were noted in the month of December 2020 (11 units). For routine cases mean TAT was noted 140.9 minutes. For Percentage of component quality control (QC) failures: PRBC (Packed RBC) QC failure and FFP (fresh frozen plasma) QC failure were entirely zero during the whole study duration.

DISCUSSION

It is vital to have a strict quality program which must be safe and effective for transfusion services. The present research assessed the five compulsory QI to evaluate the quality control of transfusion services in the study institution. The QC of blood banking was based on these parameters. Published QIs globally are mainly based on Cross match Transfusion ratio (CT ratio), expiration rate and wastage rate of RBC. These services gives only estimation about the utilisation of blood [8]. So, the current study evaluated the obligatory QIs comprehensively for assessing the quality performance of blood bank in the institution.

In current study, the overall TTI% observed 1.87%. The most common TTI observed in the present study was HIV, followed by most seropositive cases in Hepatitis B. Contrary to the present study, the TTI prevalence was 0.6% and 0.6% as reported by Fernandes H et al. and Hariharan A et al., [9,10]. Zulfikar A et al., and Varshney L et al., reported TTI to be 0.93% and 0.82%, respectively [11,12]. Reason for increased TTI% in the current study can be attributed to usage of chemiluminescence in the current blood centre which has increased sensitivity for detection of viral markers. Average

Month	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	June-20	July-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Mean
TTI%	2.7 (200/740)	0.8 (1900/2370)	1 (2000/2000)	1.6 (1700/1062)	2.1 (1900/900)	4.2 (1900/680)	1.7 (1900/1117)	0.2 (2300/1150)	1.4 (1700/1214)	2.2 (1900/863)	3.2 (2600/863)	2.1 (2800/857)	1.2 (1100/917)	1.87 (1976.9/1730.2)

[Table/Fig-2]: TTI percentage (%)

Month	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	June-20	July-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Mean
Adverse transfusion reaction rate %	0.6 (100/166)	0.4 (100/250)	0	0.9 (200/222)	0	0.1 (200/2000)	0	0	0.2 (200/1000)	0.2 (100/500)	0	0	0	0.18 (69.2/318.3)

[Table/Fig-3]: Adverse transfusion reaction rate percentage (%).

Month	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	June-20	July-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Mean
Wastage rate%	11.8 (425/36)	13.0 (327/25)	14.2 (413/29)	10.3 (290/28)	17.0 (205/12)	19.0 (210/11)	21.5 (602/28)	7.8 (157/20)	21.7 (196/9)	8.7 (201/23)	7.2 (116/16)	8.5 (103/12)	7.3 (139/19)	12.9

[Table/Fig-4]: Wastage rate percentage (%).

Month	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	July-20	Aug-20	Sept-20	Oct-20	Nov-20	Dec-20	Mean
TAT (emergency) in minutes	27.2	28.4	40.2	24.2	26.2	40.2	24.2	26.1	22.1	23.2	24.3	22.1	24.1	27.11
TAT (routine) in minutes	140.2	137.3	160.2	134.2	134.2	159.4	140.2	132.3	140.2	144.2	156.2	140.2	114.1	140.9

[Table/Fig-5]: Demonstrates TAT in emergency and routine in minutes with its numerator and denominator along with mean value.

Month-year	Number of units	Seropositive units
Dec-19	20	HIV-8/HBV-4/HCV-5/VDRL-3
Jan-20	19	HIV-7/HBV-4/HCV-5/VDRL-3
Feb-20	20	HIV-8/HBV-4/HCV-5/VDRL-3
Mar-20	17	HIV-7/HBV-3/HCV-5/VDRL-2
April-20	19	HIV-8/HBV-3/HCV-5/VDRL-3
May-20	29	HIV-10/HBV-6/HCV-9/VDRL-4
June-20	19	HIV-8/HBV-3/HCV-5/VDRL-3
July-20	23	HIV-8/HBV-5/HCV-8/VDRL-2
Aug-20	17	HIV-6/HBV-3/HCV-6/VDRL-2
Sep-20	19	HIV-8/HBV-3/HCV-5/VDRL-3
Oct-20	26	HIV-9/HBV-5/HCV-8/VDRL-4
Nov-20	18	HIV-8/HBV-3/HCV-4/VDRL-3
Dec-20	11	HIV-5/HBV-4/HCV-1/VDRL-1

[Table/Fig-6]: Number of TTI's from December 2019 to December 2020.

TAT for routine cases in current study was 140.9 minutes whereas Average TAT was 153 minutes in the study done by Gupta A and Gupta C [13] which was higher in comparison to the current study and Average TAT reported in the study done by Varshney L et al., [12] was 135.8 minutes which was lower in value being contrary to the present study. Average for TAT emergency cases was 27.11 minutes in the current study, which is comparable to study done by Varshney L and Gupta S (29.87 minutes) [12]. In the current study there was no delay in TAT and the recommended AT time was less than 30 minutes [7]. There are no available comparable studies published in English scientific literature with respect to TAT.

Delay (>30 min) in the TAT for emergency cases was observed in the month of February and May 2020. When Root Cause Analysis (RCA) was done for the same it showed that the current blood bank was running short of staff due to some unavoidable leaves of the BTS staff. To resolve the same the technical manager of blood bank was advocated to conduct and manage BTS employees in an appropriate manner so it does not affect the working pattern in the centre. Another quality parameter noted in the current study was adverse transfusion reaction rate, which was 0.18, with a maximum of 0.90 observed in March 2020. Contrary to the present study, Bhattacharya P et al., and Hariharan A et al., reported adverse transfusion reaction rate 0.16 and 0.14, respectively [14,10]. There was no transfusion reactions at all in the month of February, April, June, July, October, November and December-2020. Bulk of the cases which showed transfusion reaction were allergic reactions followed by Febrile Non Haemolytic Transfusion Reactions (FNHTR).

In the present study, the mean wastage rate was 12.9%. Maximum wastage rate was observed in the month of August 2020 around 21.7% and minimum in the month of October 2020 (around 7.2%) which was higher in value as compared to the study done by Mukherjee G et al., [5] and Hariharan A et al., [10] which reported wastage rate value of 13.5% and 15.93%, respectively. The most common cause of wastage was TTI reactivity in the index study; other causes were excess collection or decreased volume collection. Other reasons for wastage were breakage of blood bags during processing and storage. Regular auditing was organised and adopting of "first in first out policy" for issuing of blood. A schedule was chalked out for" maximum blood order schedule" after discussing with the operating surgeons and hospital transfusion committee to prevent further wastage. The study noted that stringent enforcement of quality indicators as mandated by NABH can help in preventing errors in transfusion services and thus in turn helps in maintaining a better quality and performance of the blood bank.

Limitation(s)

This was a unicentric study and only five mandated QIs were evaluated.

CONCLUSION(S)

In the index study TTI% was 1.87% which was higher in comparison to other studies because usage of chemiluminescence in the current blood centre increasing the sensitivity for detection of viral markers. In current centre mean wastage rate was noted to be higher in month of August 2020 which was higher in comparison to the other studies. So, well constructed transfusion strategies can help in decreasing the discard rate of blood bags due to expiry as whole blood is not indicated frequently. So collection of whole blood should be reduced to prevent expiry due to non-utilisation along with connecting and networking to other blood banks for outsourcing of the components when needed can help in efficient usage of blood components and hence preventing wastage. In the current study emergency TAT was found to be more than 40.2 minutes in the month February 2020 and May 2020. It should be ensured that properly trained BTS staff must be available for issuing of blood and its components by strictly following the TAT policy as per institute norms. This study concludes that every hospital should have stringent quality control assurance program for transfusion services and to develop a core committee of transfusion members.

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