

QUALITY INDICATORS TO ACCESS PERFORMANCE OF BLOOD TRANSFUSION SERVICES OF TERTIARY CARE HOSPITAL IN NORTH INDIA.

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ABSTRACT:

Background and Objectives: Ensuring quality in transfusion services has become an essential part of the hospital quality management system (QMS) to provide safe blood supply to the patients. The present retrospective study was conducted to assess quality performance of the blood center put forward by the National Accreditation Board for Hospitals and Healthcare Providers (NABH). **Methods:** The seven quality indicators (QI) defined by NABH were observed and monitored yearly for a period of four years from January 2019 to December 2022, information was gathered in a structured manner, root causes for any deviation were analyzed, and specific corrective and preventive actions were taken. **Results:** The overall performance was found to be satisfactory with mean transfusion-transmitted infection (TTI) rate being 1.6% and adverse transfusion reaction rate 0.35%, The wastage rate was 1.025% for whole blood & PRBC, 11.7% for platelets and 4.92% for fresh frozen plasma. The Quality control (QC) failure rates were meeting the quality requirement. The overall donor deferral rate and adverse donor reaction rate were 14% and 0.78% respectively. The component issued in study period was 99.8%. **Conclusion:** Quality improvement enables an organization to attain higher level of performance by creating better standards and removing deficiencies in product, processes or services.

Key words: Quality Indicators, NABH- National Accreditation Board for Hospitals and Healthcare Providers, Quality control, Blood Transfusion Services

INTRODUCTION:

Blood transfusion services (BTS) has become an integral and crucial part of patient health care management in modern medicine. Therefore a well-organized and efficient blood transfusion services would contribute towards better patients care and also towards the development of healthcare system in the country [1].

The quality as well as judicious use of blood and blood products may affect the health care facility and this can be achieved through implementation of quality management systems (QMS). Quality management systems can be monitored with the help of key performance measures known as Quality Indicators (QI's) which can be used for continuous quality improvement [2,3,4].

This ensures maximum therapeutic benefit to the patients receiving the blood components. The desire to achieve near zero-risk blood transfusion has led to implementation of QMS. Most developed countries have established an autonomous external accreditation agency that monitors the mandatory quality control parameters in transfusion services. These accreditation agencies have devised tools for assessing the level of Quality control by Performance Indicators [5]. Regular monitoring of these QIs and taking Corrective action and Preventive action (CAPA) whenever there is a deviation or breach will keep QMS in robust performance of transfusion service. In India such accreditation agency is NABH (National Accreditation Board for Hospitals and Healthcare Providers) or NABL (National Accreditation Board for Testing and Calibration Laboratories) under the Quality Council of India. The basis for accreditation of blood centre by NABH is as per standards drafted by NABH Technical committee. In India, though it is not obligatory, many leading Blood centres attached to corporate hospitals, Medical Colleges, and few stand-alone blood centres have been accredited by NABH. NABH has defined ten QIs as an important tool for quality improvement in the BTS [6]. Establishing and meeting the criteria of such quality indicators in the present day has become a necessity for establishing blood safety from donor's vein to patient's vein [7].

Thus, our study is aimed to evaluate and analyse quality indicators as performance tools of our blood transfusion services

MATERIAL AND METHODS:

A retrospective descriptive observational study was conducted for a period of 4 years from January 2019 to December 2022 in Department of Immunohaematology and Blood Transfusion (IHBT) at tertiary care hospital of North India. All the blood units were collected from voluntary donors either in house or through voluntary blood donation camps.

The records of seven parameters like Transfusion transmitted infections (TTI) rate, adverse transfusion reaction (ATR) rate, wastage rate, component quality control (QC) failures, adverse donor reaction (ADR) rate, donor deferral rate (DDR), components issued were taken. The parameters used in the analysis based on QIs defined by NABH, are depicted in the table below:

Table 1: Parameters used in the analysis (Quality indicators):

Sr. No.	Quality Indicators	
1.	TTI Rate%	$\frac{\text{Combined TTI cases (HIV+HBV+HCV+Syphilis+MP)}}{\text{Total number of donors}} \times 100$
2.	Adverse Transfusion Reaction Rate%	$\frac{\text{No. of adverse transfusion reaction}}{\text{Total no. of blood and components issued}} \times 100$
3.	Wastage Rate% PRBC Platelet FFP	$\frac{\text{No. of blood/ blood components discarded}}{\text{Total no. of blood / blood components issued}} \times 100$
4.	Component QC Failures PRBC Platelet FFP	$\frac{\text{No. of Component QC Failures}}{\text{Total no. of components tested}} \times 100$
5.	Adverse Donor Reaction Rate%	$\frac{\text{No. of donors experiencing adverse reaction}}{\text{Total number of donors}} \times 100$
6.	Donor Deferral Rate %	$\frac{\text{No. of donor deferrals}}{\text{Total number of donations + Total number of deferrals}} \times 100$
7.	% of Components Issued	$\frac{\text{Total components issued}}{\text{Total whole blood + components issued}} \times 100$

RESULTS:

During the 4 year study period, a total of 73379 units of whole blood were collected. There was an increasing trend in collection of whole blood except in year 2020 and 2021, in which collection was less due to Covid Pandemic. The components preparation was 99% in year 2019 and 99.6% in year 2022 [Table 2].

The results of these QIs were calculated yearly for a period of four years, from January 2019 to December 2022 and arranged in an organized manner [Table 3]. Each indicator was also analyzed by using different diagrams and the trends were observed (Fig 1 to 6). It was found that TTI rate was high (1.7%) in Covid pandemic as compared to non Covid period. Majority of the cases were caused by Hepatitis C Virus (HCV), followed by Hepatitis B Virus (HBV) and then by Human Immunodeficiency Virus (HIV) [Fig 1]. Adverse Transfusion Reaction Rate (ATR) decreased from 0.34% to 0.33% (2019 and 2022 respectively) except in the period of Covid pandemic (0.38% & 0.37%) in year 2020 & 2021 respectively [Fig 2].

The wastage rate of whole blood (WB) and Packed RBC (PRBC) was from 0.82% to 1.3%, for Fresh Frozen Plasma (FFP) was from 3.92% to 5.47% and for Random Donor Platelet (RDP) was 7.3% to 16.3% [Fig 3]. Wastage of platelets was maximum followed by FFP and then WB/PRBC. The QC failure of different components was within normal range.

It has been observed that Donor deferral rate increased and Adverse donor reaction rate decreased except in the period of Covid pandemic (year 2020 and 2021). Overall Components issued rate was 99.88% in the present study.

It was observed that TTI Rate, Adverse Transfusion Reaction Rate, Wastage Rate of blood/Blood Components (PRBC& WB, Platelet, FFP) and Adverse Donor Reaction Rate were higher in years 2020 and 2021 as compared to years 2019 and 2022. Donor Deferral Rate was lower in years 2020 and 2021 as compared to years 2019 and 2022.

Table 2: Blood Components Preparation

Years	Total Collection	PRBC (Packed red blood cells) No.(%)	FFP (Fresh frozen plasma) No. (%)	RDP (Random donor platelets) No.(%)
2019	19277	19140 (99)	19000 (98.5)	8112 (42)
2020	15529	15381 (99)	15352 (98.8)	8923 (57)
2021	16415	16375 (99.6)	16375 (99.6)	8487 (52)
2022	22158	22072 (99.6)	22072 (99.6)	7302 (33)

Table 3 : Outcome of Quality Indicator Parameters

Sr. No.	Quality Indicators	2019 n(%)	2020 n (%)	2021 n(%)	2022 n(%)	Overall
1.	TTI Rate	277 (1.4)	282 (1.7)	292 (1.7)	364 (1.6)	1.6%
2.	Adverse Transfusion Reaction Rate	65 (0.34)	57 (0.38)	60 (0.37)	70 (0.33)	0.35%
3.	Wastage Rate PRBC& WB Platelet FFP	314 (0.82) 3856(10.11) 1496 (3.92)	380(1.1) 5612(16.3) 1662(4.82)	491 (1.3) 4689(13.15) 1950 (5.47)	395(0.88) 3261(7.3) 2451(5.47)	1.025% 11.7% 4.92%
4.	QC Failures PRBC Platelet FFP	5/193 (2.6) 5/100 (5) 15/190 (7.9)	4/156 (2.5) 6/90 (6.6) 14/154 (9.1)	2/164 (1.2) 5/85 (5.8) 13/164 (7.9)	4/221 (1.8) 3/73 (4.1) 17/220 (7.7)	2.025% 5.375% 8.2%
5.	Adverse Donor Reaction Rate %	150 (0.75)	144 (0.90)	163 (0.96)	122 (0.54)	0.78%

6.	Donor Deferral Rate %	3372 (15)	1994 (11)	2603 (13)	4534 (17)	14%
7.	% of Components Issued	38013/38050(99.9%)	34364/34439(99.78%)	35616/35660(99.87%)	44731/44747(99.96%)	99.88%

Fig 1: Seropositivity of Viral markers (%)

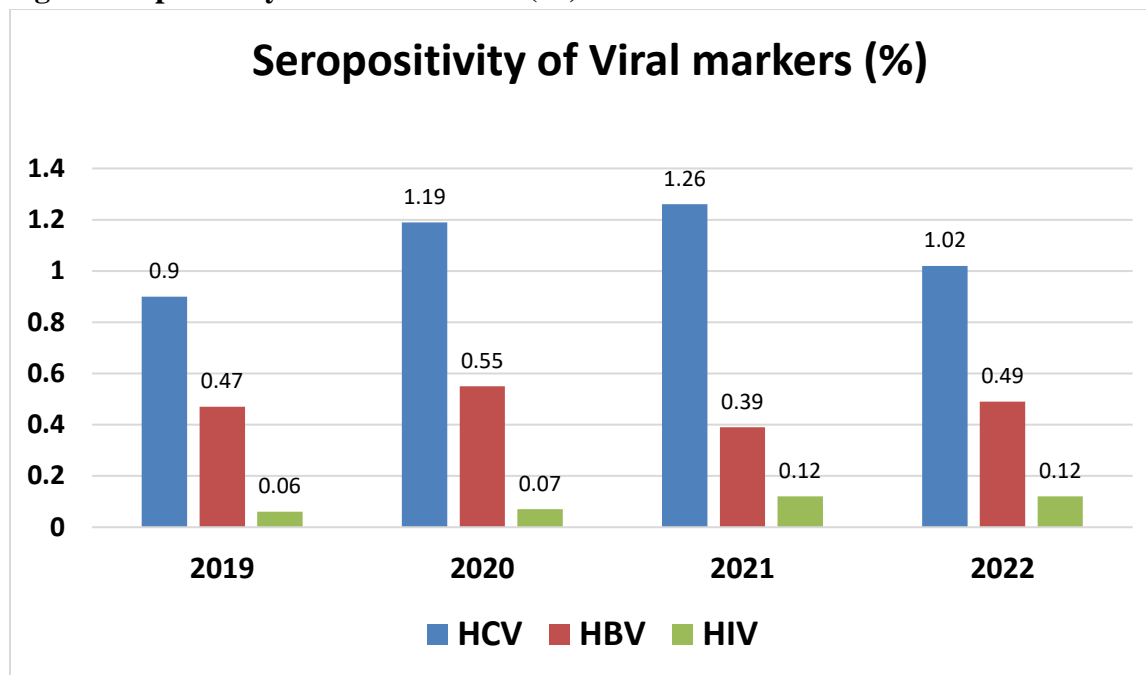


Fig 2: Adverse Transfusion Reaction Rate %

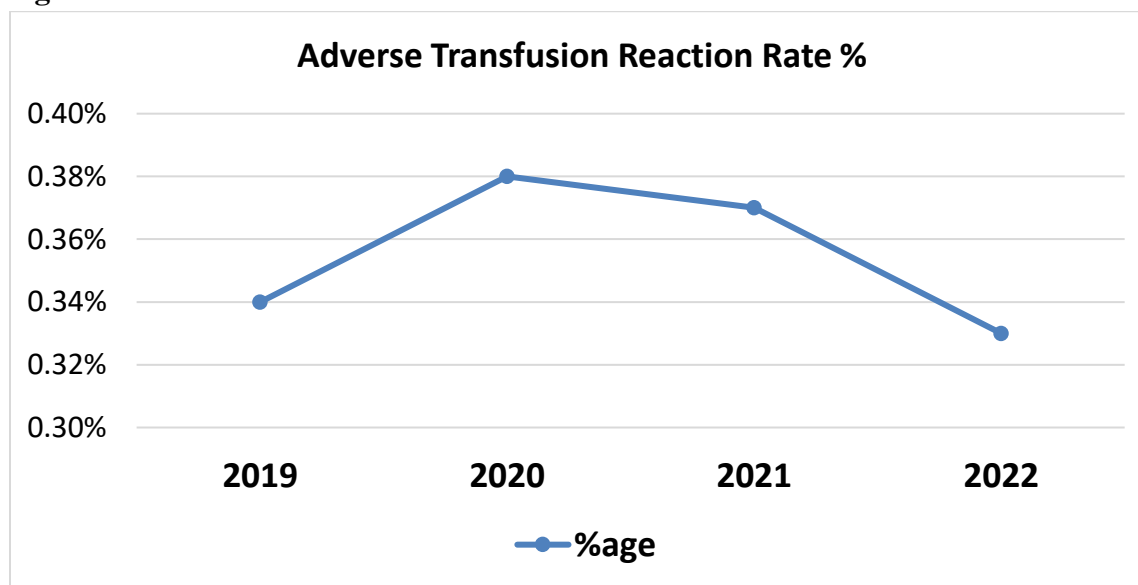


Fig 3: Blood Components Wastage Rate %

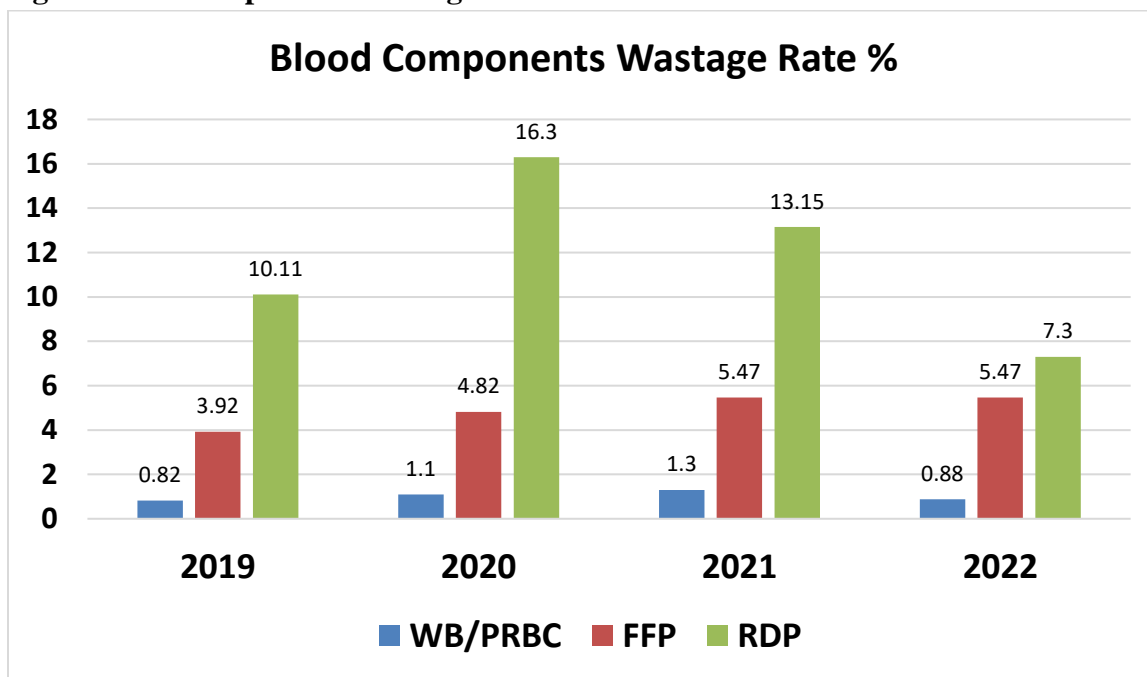


Fig 4: Blood Components Quality Control Failures %

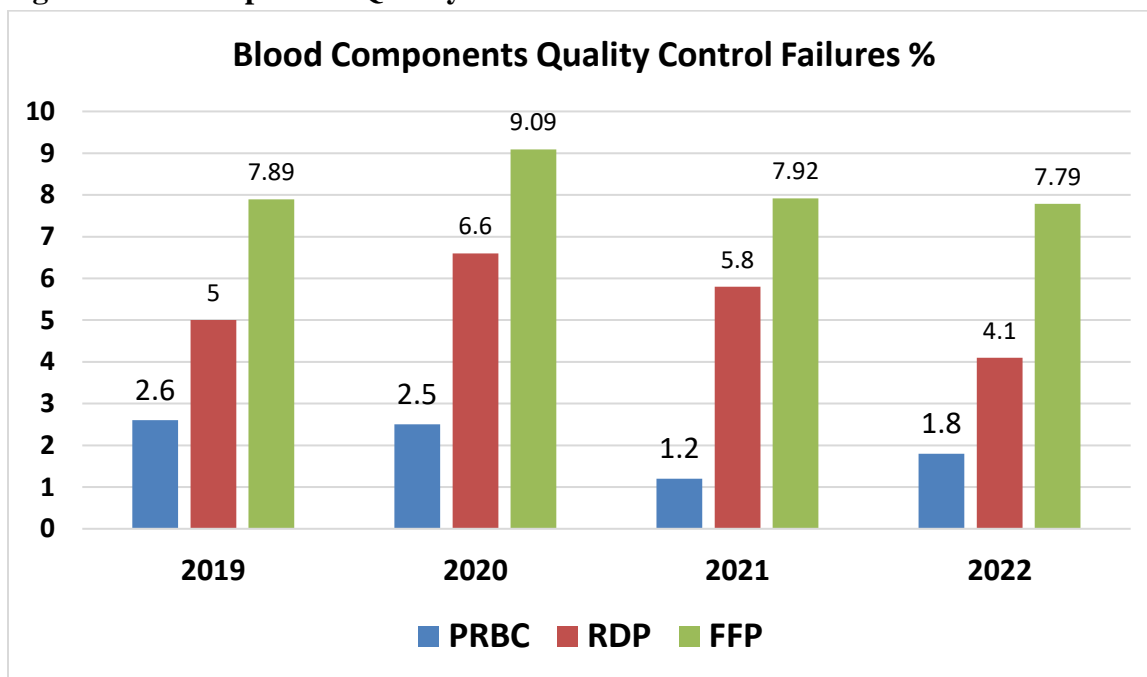
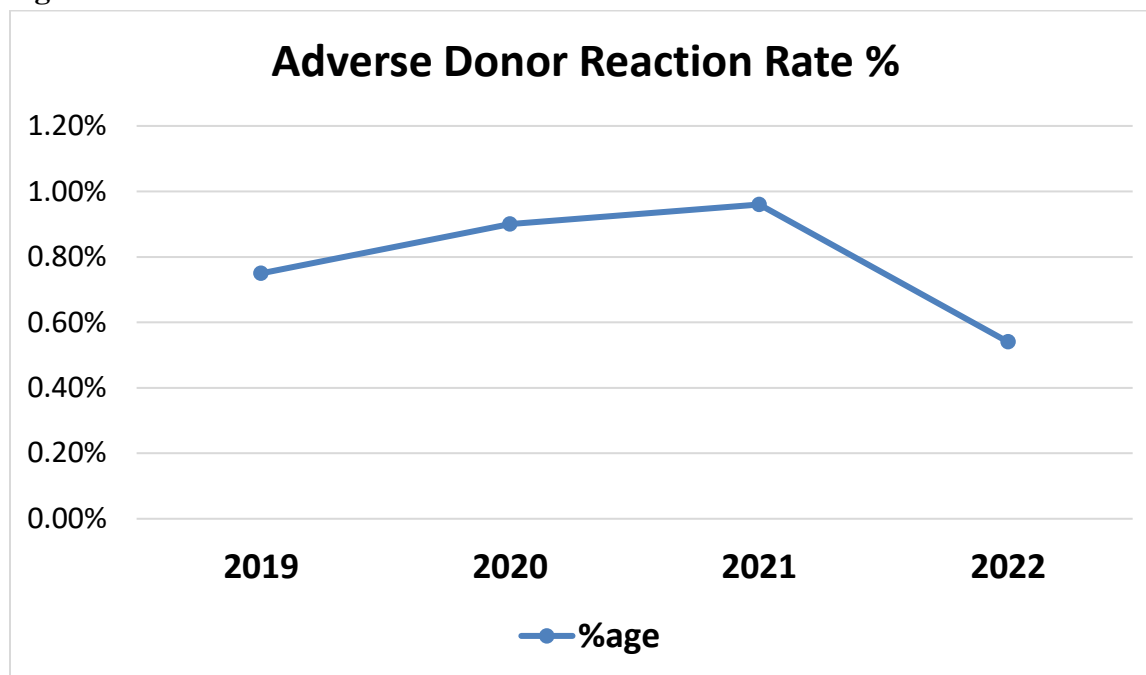
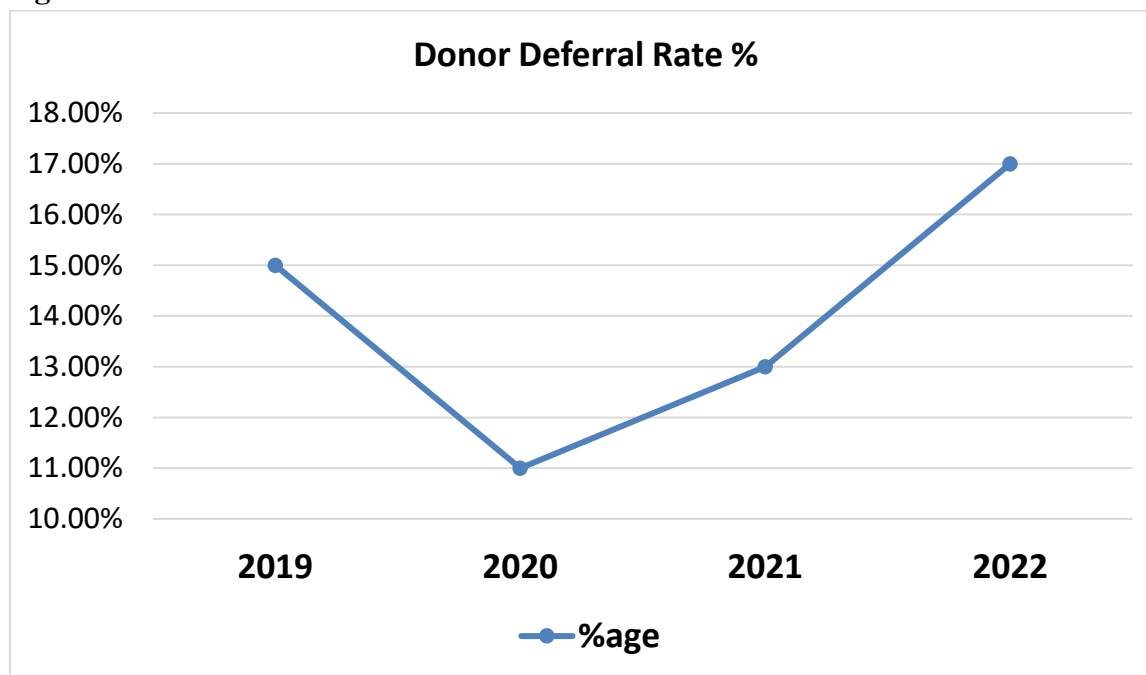


Fig 5: Adverse Donor Reaction Rate %**Fig 6: Donor Deferral Rate %****DISCUSSION:**

The transfusion of blood components is a complex procedure that not only requires a donor and a recipient but also health-care workers working at different levels within the institution.

Quality indicators evaluate the quality of services and its efficiency offered by the blood transfusion services [7]. Therefore, it is very important to have a very stringent quality assurance program in place to ensure a safe and effective transfusion services [8].

Blood transfusion is considered appropriate when it is used after proper analysis of the real needs. Various strategies have been developed to reduce the inappropriate use of blood and blood components. These include guidelines as well as monitoring of transfusion practice, education of clinicians and self audit of blood center by transfusion medicine specialist [3]. Quality Indicator Data is utilized to identifying problems, root cause analysis and implementing corrective action and preventive action to develop a quality improvement strategy [9].

Table 4: Comparison of Quality Indicators In Various Studies:

Sr. No.	Quality Indicators	Varshney et al [7] (2017)	Hariharan A[10] (2019)	Gananraj J[11] (2022)	Present Study
1.	TTI Rate (%)	0.93	0.60	3.39	1.6
2.	Adverse Transfusion Reaction Rate (%)	0.16	0.14	0.11	0.35
3.	Wastage Rate (%) WB& PRBC Platelet FFP	2.05 & 3.19 16.11 1.52	7.26 8.02 7.83	-	1.025 11.7 4.92
4.	QC Failures (%) PRBC Platelet FFP	10.67 8.22 8.63	1.9 10.2 3.3	23.33 21.67 41.11	2.025 5.375 8.2
5.	Adverse Donor Reaction Rate (%)	1.15	0.58	1.71	0.78
6.	Donor Deferral Rate (%)	8.23	8.99	15.19	14
7.	% of Components Issued	98.18	95.6	-	99.8

It was observed that Donor Deferral Rate was lower in years 2020 and 2021 as compared to years 2019 and 2022. This is possibly due to Covid Pandemic in year 2020 and 2021. However TTI Rate, Adverse Transfusion Reaction Rate, Wastage Rate of blood/Blood Components (PRBC& WB, Platelet, FFP) and Adverse Donor Reaction Rate were higher in years 2020 and 2021 as compared to years 2019 and 2022. During the Covid period there was an overall low turnover of donors due to lockdown and mobility restrictions, however those who came forward were highly motivated and determined donors who sometime hid their high risk behaviour and

could not be deferred inspite of counselling and vigilant screening. This led to decreased rate of donor deferral as well as increased rate of TTI,s in this period.

Overall TTI rate in the present study was 1.6%, similar to Mukherjee G et al who found TTI prevalence to be 1.82% [12]. Among the five transfusion transmitted infections tested in our blood centre, HCV was found to be more seroprevalent followed by HBsAg and then HIV. This is in contrast to Varshney et al [7] where HBs Ag was found to be more sero prevalent followed by HIV. A possible cause for a higher TTI rate in this study was thought to be testing with higher sensitivity for screening viral markers and high prevalence of HCV in general population of this region. TTI rate is variable in different studies 0.6%, 0.82% [13, 14] and as shown in table 4. An integrated strategy for blood safety is required for elimination of TTIs and for provision of safe and adequate BTS to the people [15]. This difference in TTI rate may be because of different demographic profile and lack of awareness about high risk activities among blood donors. Proper donor screening, education, self deferral of persons with high risk behavior and counseling of potential donors can help in decreasing rate of TTI.

Another major patient related parameter, i.e. Adverse transfusion reaction rate found in our study was 0.35% and was comparable with the study done by Mukherjee G et al who found ATR prevalence to be 0.30% [12]. Majority of the cases were caused by Febrile Non Hemolytic Transfusion Reactions (FNHTR's) and allergic reactions, similar to study done by Varshney et al [7]. Incidence of ATR is much higher in our study when compared to various studies [16,17] and as shown in Table 4. To increase awareness about transfusion practices guidelines among resident doctors and staff nurses, we organized a CME on "Rational use of Blood for clinicians" in our hospital. Use of newer technologies like leukoreduction, reporting of all adverse events by enrolling in the National Haemovigilance Programme of India and continuous training of medical and paramedical staff will help in reducing the ATR's [18].

The mean wastage rate in our setup was 1.025% for whole blood and PRBC, 11.7% for platelets and 4.92% for fresh frozen plasma and is compared with various studies in table 4. In the present study, the most common discarded units were platelets due to short date of expiry and the most common cause of discarded PRBC/WB was sero positivity which is similar to the studies like Suresh et al and Kaur et al [19,20]. In our centre platelet discard rate decreased in year 2022 due to more utilization of platelets. Wastage of FFP was due to seropositivity, RBC contamination and breakage or leakage while processing of blood. Other causes for wastage of whole blood and PRBC units included low volume, over collection, rupture and hemolysis. Regular audits and analysis for wastage of blood and blood components along with strategy of FIFO (First In First Out) may help to minimize unnecessary wastage of blood components [21]. Implementation of MSBOS (The Maximum Surgical Blood Ordering Schedule) policy may help in further reduction of wastage rate. A maximum surgical blood order schedule was also prepared after

discussion with the operating clinicians and the Hospital Transfusion Committee to avoid unnecessary wastage of blood and components.

QC failure rate found in our study was 2.025% for packed red blood cells, 5.375% for platelets and 8.2% for FFP which is compared to various studies in table 4. QC failure was not observed for whole blood. According to NABH 1% of component is tested for QC out of which 75% should match the acceptable ranges [6]. In our study, we found that the QC failure rates were meeting the quality requirement. Training of technical staff for component separation techniques as well as sensitization of technician on proper stripping of segment before performing QC will help in further reducing QC failure rate.

The adverse donor reaction rate was decreased from 0.75% in 2019 to 0.54% in 2022, the overall rate was 0.78%. The rate was almost similar to Kumar et al [22] 0.93% and comparatively less than various studies [7,11, 23] (table 4). This variation can be attributed to donor demographics or pre-donation and post-donation counseling methodologies. Majority of the adverse donor reactions were vasovagal reactions (90%) similar to Varshney et al. Female donors had higher rate of adverse donor reaction. Measures like adequate sleep, proper meal intake, waiting period in air-conditioned rooms with appropriate fluid intake before and after the donation, donation under supervision of transfusion medicine specialists and adoption of good motivational strategies and counseling methods [24] can help to minimize the donor reactions.

Present study showed an increase in donor deferral rate from 15% in 2019 to 17% in 2022, the overall donor deferral rate was found to be 14% which is comparable to Gananraj J (15.19%). Studies shows different deferral rate of 9.3%, 11.6%, 5.12, 12.4% [7,25,26,27]. The most common cause for deferral found in our study was anaemia followed by medication history. Anaemia is the most common cause of deferral in various studies [25,26,27]. Amendments in donor selection criteria in year 2020 might be the reason for increment of the donor deferral rate. Registration of male donors was more as compared to females; but female donors were deferred more than the male donor population in our study. Better donor awareness strategies can help to reduce the donor deferral. Awareness was done to educate the potential donors about the criteria for donation with emphasis on self-deferral with high-risk behaviour and history of certain diseases.

The component issued in our blood centre was 99.8% in the study period, which is near NABH recommendation of 100%. SOPs and protocols with regards to component separation and component issue will help us to achieve target of 100%

CONCLUSION:

QI data in our study helped us to evaluate problems, identify root cause of problems and formulate strategies for quality improvement. Drawback of national guidelines is lack of benchmark for each quality indicator. Wastage of Blood/blood components can be reduced by

modifying MSBOS and avoiding excessive unnecessary ordering of blood in elective cases. Other measures like regular training of clinicians, nurses and technical staffs in blood centre, regular auditing and following blood centre guidelines etc should be put into practice for further improvement. Quality improvement enables an organization to attain higher level of performance by creating better standards and removing deficiencies in product, processes or services. There is therefore an absolute need to select quality indicators for all the areas involved in the manufacture of blood and blood products and to ensure that these indicators are analyzed for quality transfusion services.

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