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Quality indicators in continuous quality improvement at a blood centre in a rural tertiary care centre in India

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Abstract
Context: The quality of services provided by a transfusion service can be gauged by assessing the performance of its Quality indicators (QIs).
Aims: The study aimed to assess the impact of adopting CQI at ADGBB by assessing the various Qis
Settings and Design: The present observational study is undertaken at a Blood Centre associated with a tertiary health care centre in Rural Gujarat, India. The study was conducted over eight years (2008-2016).
Methods and Material: Various QIs encompassing the different areas of the Blood Centre service were monitored monthly, with the addition of new QIs, as and when required. Outliers were dealt with with corrective and preventive actions.
Statistical analysis used: Indicators monitoring the donation process, blood collection process, product quality, transfusion process, and inventory usage were studied.
Results: Positive quality indicators like voluntary donation rate, completeness of donor consent forms have shown an increasing trend over the years. At the same time, negative indicators like double prick rates, rapid testing, sample rejection rates have shown a decreasing trend. However, indicators like C: T ratio and rate of blood transfusion reactions have been constant throughout the years, and well within manageable levels, with minor fluctuations. Indicators like quality control of components, TAT outliers, wastage of components have shown negative trends which have required active interventions, which in turn have shown improvements over the next years.
Conclusions: Regular and keen monitoring of QIs and timely intervention by key personnel can ensure great outcomes and improved CQI.

Keywords: Quality indicators, continuous quality improvement, PDSA cycles

Introduction
The concept of Continuous Quality Improvement (CQI) was introduced by Shewhart and propagated by Deming, post-World War II [1]. The Plan-Do-Study-Act (PDSA) cycle of CQI allow one to see when a process is working predictably and when it is not [2, 3].
This study presents the CQI journey of AD Gorwala Blood Centre (ADGBB) since 2008, through monitoring of key Quality Indicators and demonstrates that quality can be achieved even in resource-constrained settings, with focussed attention.

Subjects and Methods
This observational study was carried out at a NABH accredited Blood Centre of a rural teaching hospital in Gujarat from 2008 to 2016.
Various QIs were identified from different phases of the transfusion service and monitored monthly by the Head and Quality and Technical Managers of ADGBB.[7, 8, 9] New indicators were added in-between. Outliers and root cause analysis were discussed and corrective action taken and preventive actions proposed.
Data was collected retrospectively from the information system of the Blood Centre/hospital.

Statistical Analysis
Data of 50295 blood units collected and 58,898 patients are presented.
The identified quality indicators are mentioned in Table 1 [7, 8, 9].

Table 1: Formulae for the Quality Indicators

Sr. No	Indicator	Formula for the Calculations	Sample size
		A. Indicators monitoring the donation process	
1.	Rate of voluntary donation	$\frac{Number\ of\ Volutary\ donations}{TotalNumberofdonations} x100$	All Donations
2.	Deferral rate of donor	$\frac{Numberofdonorsdeferred}{TotalNumberofdonations} x100$	All Donations
3.	Completeness of Donor consent form	$\frac{Numberofcompletedonorconsentforms}{TotalNumberofdonorconsentforms} x100$	All donation
		B. Indicators monitoring the blood collection process	
4.	Sterility check (Empty blood bag)	$\frac{Total\ Number\ of\ blood\ bags\ sent\ for\ sterility}{Number\ of\ bags\ positive\ for\ sterility}$ x 100	1% of the total donation or 4, whichever is more
5.	Sterility check (Phlebotomy site)	$\frac{Total\ Number\ phleobotomy\ sites\ take\ for\ sterility}{Number\ of\ samples\ positive\ for\ sterility}$ x 100	1% of the total donation or 4, whichever is more
6.	Phlebotomy exceeding prescribed time	$\frac{Numberofphlebotomies\ exceeding\ prescribed\ time}{Total\ Number\ of\ donations} x100$	All donations
7.	Double prick rate	$\frac{Numberofdoublepricks}{TotalNumberofdonations} x100$	All Donations
		C. Indicators monitoring product quality	
8.	Rapid Testing	$\frac{Numberofdonorstestedbyrapiddiagnostictests(RDTs)}{TotalNumberofdonations} x100$	All donations
9.	Internal quality control of components	$\frac{Numberofunitoutliers}{TotalNumberofunitstakenforQualitycontrol} x100$	1% of the total donations or 4, whichever is more
		D. Indicators monitoring the transfusion process	
10.	Specimen rejection process	$\frac{Numberofpatients'specimensrejected}{TotalNumberofpatientspecimensreceived} x100$	All specimens received
11.	Crossmatch: Transfusion ratio	$\frac{Numberofcrossmatchesdone}{Numberoftransfusions} (asaratio)$	All components issued
12.	Turn Around Time (TAT)	$\frac{Numberofcomponentoutliers(outsideTAT)}{TotalNumberofthecomponentsissued} x100$	All components issued
13.	Percentage of blood transfusion reaction	$\frac{Numberoftransfusionreaction}{TotalNumberofissuedcomponents} x100$	All components issued
		E. Indicators monitoring inventory wastage	
14.	Wastages of components	$\frac{Numberofcomponentswasted}{TotalNumberofcomponentsprepareed} x100$	All components prepared
15.	Percentage of transfusion-transmitted infection (TTI)	$\frac{CummulativenumberofPositiveTTICases}{TotalNumberofdonations} x100$	All donations

Results

A. Indicators monitoring the donation process (Table 2)

Increase in voluntary donations from 87.1% (2008) to 100% (2013) is noted. The completeness of donor consent forms has increased from 97.5% (2008) to 100% (2016).

B. Indicators monitoring the blood collection process (Table 2)

Blood bag sterility check by a culture of swabs from bag surface indicate 100% sterility from manufacturer's end throughout.

Phlebotomy site sterility check was established by pre-and post-disinfection swabs for culture. 2.3% (01) and 4.8% (02) swabs were positive in 2012 and 2013 respectively.

Collection time of donor units is monitored to exclude units that have exceeded 10 minutes, for preparing platelet concentrates. Till 2014, the cut-off was taken at 08 minutes.

C. Indicators monitoring product quality (Table 2)

Utilization of rapid diagnostic tests (RDTs) for TTI testing is less preferred compared to ELISA (which shortens the window period of disease due to higher sensitivity). A decrease in the rate of RDTs was observed.

For internal quality, 1% of total collections are tested weekly. Blood components were checked for various parameters (acceptable compliance= 75%).

D. Indicators monitoring the transfusion process (Table 2)

Patient sample rejection addresses pre-analytical discrepancies in grouping and pre-transfusion compatibility testing, through stringent sample acceptance.

Crossmatch: Transfusion ratio (acceptable range=2:1) gives an estimate of blood used against that demanded.

Turnaround time (TAT) for components issued is calculated from confirmation of the request, till the product reaches the ward. TAT outliers were identified and rectified from 2013.

The percentage of blood transfusion reactions has decreased, however, a rise (from 0.05 to 0.35%) was noted in 2015.

E. Indicators monitoring inventory wastage (Table 2)

Wastages of Red Cell Concentrate (RCC) and Fresh Frozen Plasma (FFP) has declined, however, since 2013 an upward trend, peaking in 2015 for platelet concentrate discards is seen. TTI testing includes testing donated blood for HIV, Hepatitis B, and C, Syphilis, and Malaria. Since a seropositive donor unit has to be discarded, it amounts to wastage.

Table 2: Frequency Distribution of the Various Quality Indicators

Year	Total Donations	Donation Process					Blood Collection Process				Product Quality					Transfusion Process				Inventory Wastage			
		Donor Deferral		Voluntary Donations		Completeness of Donor Consent Form	Empty Bag Sterility Check	Sterility check (Phlebotomy Site)	Phlebotomy exceeding prescribed time	Double prick rate	Rapid Testing Done (%)	Components meeting the Quality Criteria (%)				Patient Sample Rejection	C: T Ratio	TAT outliers	BTRs	Component wastage			TTI Positivity Rate
		n	%	n	&							RCC	FFP	PC	CP					RCC	FFP	PC	
2008	4363	--	--	3800	87.10%	97.50%	--	--	--	0.90%	--	84.1	73.3	84.3	72.2	--	--	--	0.30%	--	--	--	1.15%
2009	5460	452	8.28%	4848	88.80%	97.50%	--	--	--	1.20%	--	56.15	53.4	92.6	48.1	--	--	--	0.24%	--	--	--	0.38%
2010	6321	491	7.77%	5721	90.50%	98.10%	--	--	--	1%	--	69.7	58.3	96.5	90.3	--	--	--	0.10%	--	--	--	0.65%
2011	6506	423	6.50%	6454	99.20%	98.20%	--	--	--	1.20%	--	69.7	53	96.4	54.7	--	--	--	0.06%	2.48%	8.00%	4.59%	1.21%
2012	6374	383	6.01%	6342	99.50%	98.10%	100%	2.30%	0.06%	0.90%	12.38%	59.3	60.9	97.8	56	2.30%	--	--	0.07%	1.48%	3.98%	9.92%	1.16%
2013	7746	612	7.90%	7746	100%	99%	100%	4.80%	0.24%	0.42%	15.28%	94.91	88.6	100	63.3	3.00%	1.5:1	2.19%	0.06%	3.00%	3.00%	14%	0.99%
2014	7103	1108	15.60%	7103	100%	99.50%	100%	0%	0.48%	0.43%	12.32%	94.85	91.3	100	85	0.72%	1.9:1	3.33%	0.04%	1.00%	1.00%	17%	0.68%
2015	6422	912	14.20%	6422	100%	99.50%	100%	0%	0.01%	0.22%	5.36%	98.65	89.7	100	82.7	1.01%	1.7:1	1.98%	0.37%	1.87%	1.76%	20%	0.58%
2016	6462	452	8.28%	6462	100%	100%	100%	0%	0%	0.22%	5.70%	95	93.3	84.3	72.2	1%	1.5:1	3.40%	0.22%	2.26%	2.20%	13%	0.71%

Discussion

This study demonstrates CQI through monthly PDSA by monitoring key QIs, and annual management review. The performance of various QIs and the interventions made are discussed.

A. Indicators monitoring the donation process

1. Rate of voluntary donation (VBD)

VBD ensures blood safety as opposed to directed donations[11]. The VBD rate improved from 87% (2008) to 100% (2013) by inculcating good practices, donor motivation programmes, maintaining adequate stock, use of a mobile van in emergency hours, counseling relatives of transfused patients to donate, post-transfusion.

2. Donor deferral rate

Change in the methodology of haemoglobin screening from Copper Sulfate to Hemocue (a point of care photometry-based hemoglobinometer), more stringent implementation of donor selection, and better documentation of deferrals led to a rise in 2014 and 2015. An average 7% donor deferral rate per annum is noted. History of restricted medications and anaemia were the commonest causes of deferral in males and females, respectively.

3. Completeness of donor consent form

A duly filled-up donor questionnaire with informed consent validates the donor's informed willingness to donate and provides an opportunity for self-deferral. Ensuring the completeness of these forms cannot be overemphasized.

B. Indicators monitoring the blood collection process

1. Sterility Check of Empty Blood Bag

Empty blood bags from each batch were sent for post-manufacturing sterility check with 0% positivity.

2. Sterility Check of Phlebotomy Site

Implementing a three swabs technique (alcohol-betadine-alcohol) resulting in 100% compliance after 2014.

3. Collection time of blood exceeding prescribed limit

Collection time of more than 10 minutes is associated with poorer platelet yield. This QI was introduced to prevent the preparation of platelet concentrates from such units.

4. Double prick rate

The double prick rate has stabilized at 0.2%, from 1.2% (2008), indicating the benefits of a robust system of induction training, evaluation, and retraining for all residents and recruits.

C. Indicators monitoring product quality

1. Rapid Testing

The target for rapid testing rate was less than 10%. Keen monitoring has ensured levels of around 5% for the past two years.

2. Quality control of components

The quality of RCC is evaluated in the context of haematocrit and volume. Initial issues related to volume collected (which affects the volume of all components) were due to the practice of using weighing scales instead of blood collection monitors at camps.

Volume outliers of RCC and FFP in 2016 are ascribed to high attrition of technical staff since plasma expression was performed manually.

Until 2012, various components did not meet the QC requirements even after various interventions. Another blood bag centrifuge was purchased. Subsequent results are in an acceptable range including the high outlier rate for platelet counts, volume, and red cell contamination.

The significantly high level of outliers for FFP initially was reduced by managing the inventory of FFPs better, ensuring complete freezing (in the absence of a blast freezer) by limiting the number of FFPs prepared. Only 25% of separated plasma was frozen in the only available -80°C mechanical freezer. Completely frozen plasma within two hours was used as FFP, the rest was stored as plasma.

Being a small volume product (10-20 ml), minor variations in volume also lead to outliers for cryoprecipitate. Additionally, Factor VIII and Fibrinogen are labile factors at 37 °C. The procedure of thawing a segment and submitting for QC was corrected by submitting a frozen segment for coagulation assay, which is thawed only before testing. Higher outliers noted for Factor VIII are obtained during a single cycle of cryoprecipitate are ascribed to attrition of staff.

D. Indicators monitoring the transfusion process

1. Sample rejection process

Patient samples for grouping and compatibility testing are rejected if they are haemolysed, have inadequate quantity, or have improper labels. The rejection rates have come down after rounds of training and sensitization.

2. Crossmatch: Transfusion ratio

The C: T ratio is a measure of the efficiency of blood ordering practice and has stayed in the acceptable range due to active monitoring in the Hospital Blood Transfusion Committee.

3. Turnaround time of blood components

Concrete benchmarks for TAT currently are not available. The Blood Centre has supplied 96.5% of products within the committed time. Reasons for outliers include non-availability of components, incompatible units, delayed demand after booking of components, and multiple requests at the same time.

4. Blood Transfusion Reaction

The steep rise in 2015 is ascribed to the poor quality of blood transfusion sets used for transfusion. As a corrective action, all BT sets were recalled and the problem was resolved.

E. Indicators monitoring inventory wastage

1. Wastage of components

The expiry of mother bags, post-preparation of paediatric units, was the commonest cause for discard of RCC. To reduce wastage, paediatric bags are prepared through a closed system (using a sterile connecting device).

The main reason for FFP wastage was leakage due to cracks in bags, related to frequent handling of frozen units for physical stock taking and disorderly storage. This was corrected by weekly stocktaking along with storage in specially prepared baskets.

The high wastage of platelet concentrates over the years is due to difficulties in managing inventory because of fluctuating demands for cardiac and cancer patients and the unpredictable prevalence of Dengue. More stringent

inventory management and use of single donor platelets have led to a decreased wastage in 2016.

2. Percentage of TTI

TTI is the most dreaded complication of transfusion, as they cause lifelong morbidity and increased incidence of mortality that can be directly linked to the transfusion event. TTI percentage was is a measure of effective donor screening, and wastage owing to seropositivity. TTI prevalence has been close to 1%. The average and overall trend are on the decline since 2008 due to deferral at donor screening.

Conclusion

Monitoring QIs helps identify opportunities for improvement and adverse trends. CQI involves repeated PDSA cycles and taking corrective action if the service falls below an agreed-upon standard; but, also setting newer and higher standards (newer QIs), once the original targets are achieved. A robust CQI program can help in achieving benchmarks in transfusion services, even in a resource-constrained setting.

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