

Quality indicators for eye bank

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Purpose: The aim of this study is to identify quality indicators of the eye bank and validate their effectivity. **Methods:** Adverse reaction rate, discard rate, protocol deviation rate, and compliance rate were defined as Quality Indicators of the eye bank. These were identified based on definition of quality that captures two dimensions – “result quality” and “process quality.” The indicators were measured and tracked as part of quality assurance (QA) program of the eye bank. Regular audits were performed to validate alignment of standard operating procedures (SOP) with regulatory and surgeon acceptance standards and alignment of activities performed in the eye bank with the SOP. Prospective study of the indicators was performed by comparing their observed values over the period 2011–2016. **Results:** Adverse reaction rate decreased more than 8-fold (from 0.61% to 0.07%), discard rate decreased and stabilized at 30%, protocol deviation rate decreased from 1.05% to 0.08%, and compliance rate reported by annual quality audits improved from 59% to 96% at the same time. In effect, adverse reaction rate, discard rate, and protocol deviation rate were leading indicators, and compliance rate was the trailing indicator. **Conclusion:** These indicators fulfill an important gap in available literature on QA in eye banking. There are two ways in which these findings can be meaningful. First, eye banks which are new to quality measurement can adopt these indicators. Second, eye banks which are already deeply engaged in quality improvement can test these indicators in their eye bank, thereby incorporating them widely and improving them over time.

Key words: Eye bank, quality assurance, quality indicator

Eye banking has a long and impressive history in the field of ophthalmology, having enabled millions of vision-restoring surgeries. Maintenance of integrated quality assurance (QA) program for eye bank is mandatory. QA is needed for timely availability of corneal tissue to the corneal surgeons, effectiveness and efficiency, safe utilization of tissue and infection control. However, a set of universally accepted indicators of QA in eye banking is not available. There is also a lack of available literature to guide the eye banks and researchers on this topic. Although audits can be done to validate the state of QA performed by an eye bank, it is not in itself a quantitative indicator that eye banks can monitor as part of their quality program. Therefore, this paper identifies quality indicators (QI) for eye bank and validates them through observations tracked over a specific time frame.

Juran^[1] included the following two elements in the meaning of quality:

1. Features of product or service that satisfy customer needs
2. Freedom from deficiencies.

Over time, many definitions have been proposed but the central theme has revolved around the idea that quality is conformance to specifications and customer requirements. In this article, the QI of the eye bank has been conceptually based on the expanded definition proposed by Imai.^[2] He identifies two dimensions of quality – “result quality” and “process quality.” Adopting this viewpoint ensures that focus

of QA includes quality of the processes and the activities that produce the output.

Methods

This study was conducted at the eye bank after approval from the institutional research board. The eye bank is a registered eye bank recognized by the Ministry of Health and Family Welfare, Government of India. A structured QA program was initiated in a phased manner in the eye bank in 2011. The first step was defining quality which led to the documentation of detailed standard operating procedures (SOP), encompassing all critical processes. These standards were implemented and monitored rigorously. QA was made a formal activity and enmeshed with roles and responsibilities of all eye bank staff. For measuring quality, the eye bank defined QI which covered both “result quality” and “process quality” aspects.

Result quality

For eye bank, the primary output is cornea for transplants. Surgeons are treated as end-users from eye bank perspective because it is the surgeon who chooses and finally uses a tissue based on the diagnosis of the patient’s condition. From surgeon viewpoint, the key measure of the quality of tissue is positive impact on surgical outcome. However, if there is an adverse reaction^[3] then doubtlessly the surgery outcome

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has been subpar, and the key end-user expectation has not been satisfied. Adverse reaction postkeratoplasty is accepted as any unexpected or unwanted effect in the recipient caused by the donor tissue. Thus, the rate of incidence of adverse reaction, named adverse reaction rate, was taken as an indicator of quality. Adverse reactions can happen due to causes not attributable to the eye bank. However, this study took a conservative approach and counted any adverse reaction irrespective of the source of error in calculating the rate.

Process quality

To identify QI covering this dimension, a reference model of the eye bank shown in Fig. 1 was prepared and analyzed.^[4] The following observations were made:

1. Tissue is checked at each stage of the process chain for safety and fitness for patient use. The processes are designed to be elimination focused and lead to high wastage or tissue discard on deviation from standards
2. There are multiple technical functions which need to follow established protocols
3. At multiple stages, there is risk of contamination which needs to be managed

Based on the reference model observations, the following QI were identified as measures of process adherence to standards, regulations, and clinical guidelines:

1. Discard rate: Number of donor tissues deemed unsuitable for transplant as a percentage of number of donor tissues recovered or harvested

2. Protocol deviation rate: Number of incidents or deviations from SOPs as a percentage of number of cornea collected.

The three QI, adverse reaction rate, discard rate, and protocol deviation rate, provides advance information as to the efficacy of QA in place, and therefore are called leading indicators. They were recorded and tracked from the beginning of the quality initiative.

To validate the outcome of the QA program, external audits were conducted. These audits used checklists to validate the following two conditions:

1. The alignment of SOPs with regulatory and surgeon acceptance standards. The standards of eye banking in India^[5] issued by the National Program for Control of Blindness, Government of India, was the minimum acceptable threshold in the audits
2. The alignment of activities performed in the eye bank with the documented SOPs.

The eye bank was evaluated against each parameter on the checklist and marked noncompliant if any criterion was not met. Based on this, a consolidated compliance rate was calculated. This is a composite measure of what percent of critical QA activities were being performed appropriately by the eye bank. This metric was taken as the trailing indicator which indicates the achieved state of QA after a specific time.

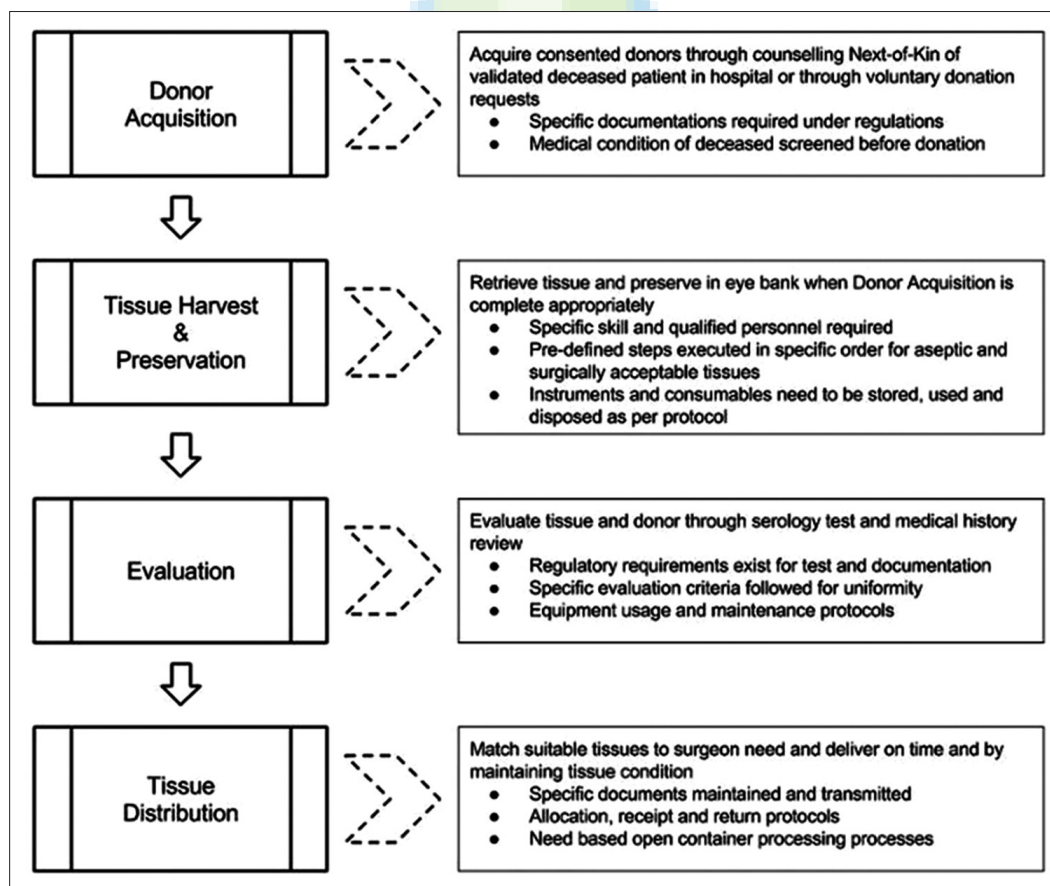


Figure 1: Reference model of the eye bank. Diagram of the workflow of the eye bank shows the main functional blocks and the key considerations that go into devising quality indicators

Table 1: Descriptive details of quality indicators in the eye bank (name and detailed descriptions)

Indicator	Definition	Purpose	Calculation
Adverse reaction rate	Incidence of adverse reaction in patients where the tissue used in keratoplasty was provided by the eye bank	Captures the fulfillment of surgeon's requirement from tissue. Adverse reactions are investigated and "corrective and preventive actions" are initiated based on findings	Number of adverse reaction reported after surgery using tissue supplied by eye bank divided by total number of keratoplasty done using tissue supplied by the eye bank. Expressed as percentage
Discard rate	Relative measure of the number of tissues that were harvested from donors but found not suitable for keratoplasty during evaluation	Captures wastage generated in the system due to key functions of the eye bank, namely, donor acquisition and tissue harvesting	Number of tissues evaluated to be unsuitable for surgery divided by number of tissues harvested from donors. Expressed as a percentage
Protocol deviation rate	Relative deviation from SOP occurring in activities and tasks driving the key eye bank functions	Internal metric to monitor how well the processes adhere to SOP. A high ratio, large spikes in this ratio or swings necessitate action	Number of recorded incidents of deviation from SOP divided by number of tissues harvested. Expressed as a percentage
Compliance rate	What percent of critical quality assurance activities are being performed appropriately by the eye bank	Composite metric which points out adherence to the underlying definition of quality adopted by the eye bank. This number should be close to 100% as quality assurance matures	Number of nonconformances noted in audit divided by total number of criteria used in audit. Expressed as a percentage

SOP: Standard operating procedures

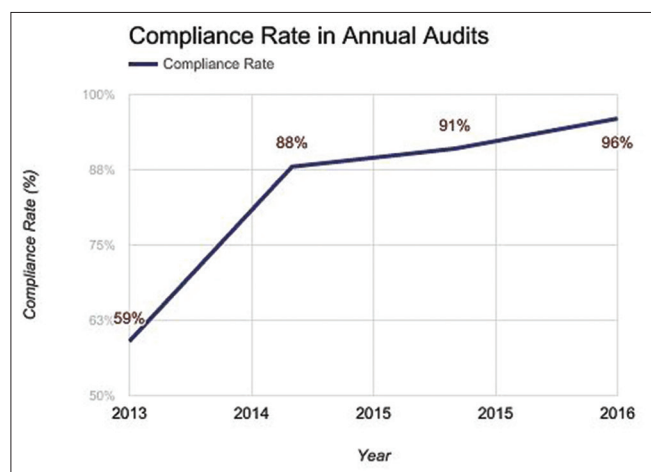


Figure 2: Compliance rate in annual audit plotted against the year of the audit

The regular annual audit cycles started from early 2013. All the four QI were compiled and compared across the period 2011–2016. Table 1 summarizes the four QI defined, recorded, and analyzed.

Results

In the period from 2011 to 2016, the corneal tissue collection of the eye bank increased from 532 to 1469 at cumulative average growth rate (CAGR) of 22.5%. The number of corneas transplanted increased from 326 to 954 at CAGR of 24%. These two data points bear proof that the level of activity at the eye bank expanded enormously in the study period. This provided a challenging testing ground for QA and QI.

Compliance rate

As per Fig. 2, compliance rate moved up from 59% to 96%, thereby showing a large improvement in QA in the study period. There was a big improvement between the first and

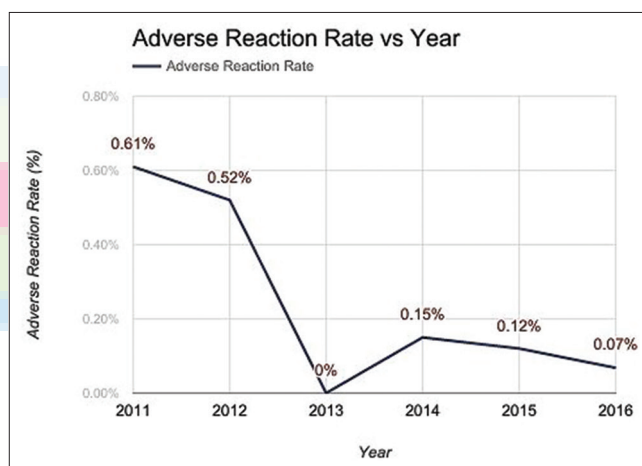


Figure 3: Adverse reaction rate plotted against year. Annual consolidated adverse reaction rate shown against the respective year indicates definite decrease in adverse reactions in proportion to corneas supplied for transplant

second audits followed by stabilization into a continual improvement stage at very high levels.

Adverse reaction rate

Fig. 3 shows that the adverse reaction rate decreased >8 times from 0.61% to 0.07%. This is in alignment with the improvement in compliance rate.

Discard rate

Fig. 4 shows that despite rapid increase in the volume of tissue harvested, the discard rate reduced from about 40% and finally stabilized at a low value of 30%. This shows that year on year donor acquisition processes became better and tissue recovery improved. This indicates the increased effectiveness of QA and aligns with the outcome captured by compliance rate.

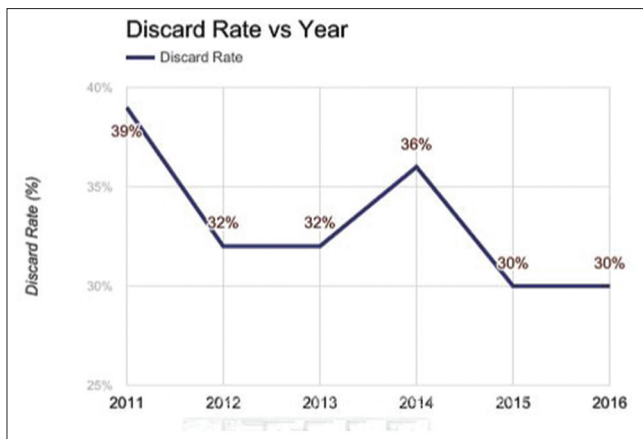


Figure 4: Discard rate plotted against year. Annual consolidated discard rate shown against the respective year indicates the decrease and stabilization in the proportion of harvested tissues that were discarded because of not meeting tissue or donor quality parameters

Protocol deviation rate

Fig. 5 shows that there has been a decline in the reported rate of incidents or deviations from the SOP. The value decreased from above 1% to <0.1%. This is directly indicative of the stabilization of all human performed processes at the eye bank. This indicator too agrees with the overall improvement shown by compliance rate.

Adverse reaction rate, discard rate, and protocol deviation rate provided reliable early indication of the state of QA at the eye bank. Compliance rate based on QA specific audit then provided a direct validation.

Discussion

QA has been recognized as an integral part of eye banking. Following the European directive on setting standards of quality and safety for human tissues, Toniolo *et al.*^[6] outlined the implementation of quality management system using ISO 9001:2000 reference model. Eye bank Association of America has been conducting accreditation of eye banks in the USA based on medical standards published by them.

In India, where the prevalence of corneal blindness is significantly high,^[7] the National Program for Control of Blindness issued standards^[5] for eye banking in 2009. This document puts forth the standards, regulatory requirements, and also a set of SOP for eye banks in India to adopt and implement. The Eye Bank Association of India has signed memorandum of understanding with Quality Council of India for conducting audit of Indian eye banks. The increasing emphasis on quality makes this study on measurement of quality highly relevant.

It was observed that the measuring of these QI necessitated data collection and stringent reporting discipline. Swings, variations, or trends in the lead indicators were methodically analyzed using fishbone analysis technique, and improvement measures were identified. The results of the improvement activities undertaken were in turn captured by the indicators themselves. This created a feedback loop which pushed the quality program toward success. During the course of the

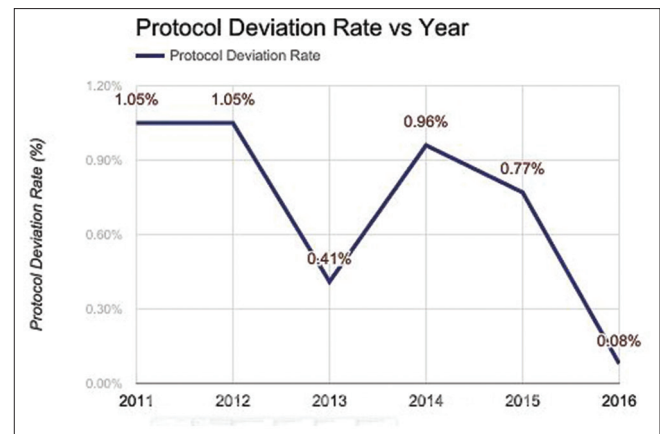


Figure 5: Protocol deviation rate plotted against year. Annual consolidated protocol deviation rate indicates decrease in cases of deviations from established standard operations procedures

study, the number of activities performed at the eye bank increased manifold due to increase in cornea harvesting. However, the output quality was not affected as evidenced by decrease in adverse reactions from tissues supplied.

As the quality of the eye bank matures the relative change in compliance rate from one audit to another will not change or will change by a very small percentage. Thus, once the eye bank attains stability at high-quality levels, a new generation of QI will be needed. Similarly, with introduction of new donor acquisition methods and advanced tissue processing functions (e.g., pre-cut cornea), new measures of quality need to be established.

Arguably, these four QI are results of exploratory thinking.^[8] Higher quantity of data is needed for testing statistical significance of the correlations that were observed during the study. However, since a comprehensive quality audit and subsequent activities are time-consuming, shortening the audit cycle is not practical. This means that generating a larger data set effectively means a longer time commitment to the study – in the range of 15 or more years. One of the aims of this publication is to bridge this time gap by letting other eye banks measure these indicators, and thereby increase the data pool available.

Conclusion

Adverse reaction rate, discard rate, protocol deviation rate, and compliance rate are four QI that reliably represents the state of QA of an eye bank. They cover both the product and process quality dimensions. They fulfill an important gap in available literature on the topic of QA in eye banking. There are two ways in which these findings can be meaningful. First, eye banks which are new to quality measurement can adopt these indicators. Second, eye banks which are already engaged in the quality improvement can test these indicators in their own setting, thereby incorporating them widely. Quality is a journey since the continuous improvement phase keeps moving onward, thus over time these indicators will be improved, and even newer indicators will be added to the list.

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Conflicts of interest

There are no conflicts of interest.

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