

Original research

Impact of quality assurance on utilization of corneal tissues in a community Eye Bank

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Abstract

Purpose: To determine the linkage between Quality Assurance Program (QAP) and increase in utilization of donor corneas at a community Eye Bank.

Methods: A donor cornea is defined as utilized when it is used for cornea transplant. Two metrics, utilization rate (UR) and non-utilization rate (NUR), were defined. The Eye Bank implemented QAP from 2011. As a part of QAP, detailed gap analysis of tissue utilization was performed. Four major categories causing non-utilization of recovered corneas were identified. These categories were poor “Tissue Quality”, “Seropositive” donor blood sample, “Medical History” of donor, and donor “Blood Sample Issues.” The years 2008–2011 were labelled the pre-intervention period, and the years 2012–2017 were labelled the post-intervention period. Annual UR and annual NUR for the four categories of non-utilization from the pre and the post-intervention periods were statistically compared.

Results: In the pre-intervention period, the Eye Bank recovered 1425 donor corneas in total and transplanted 762. In the post-intervention period, the Eye Bank recovered 6661 corneas in total and transplanted 4393. The UR improved from 53.47% (762/1425) in the pre-intervention period to 65.95% (4393/6661) in the post-intervention period ($P < 0.001$). NUR in “Tissue Quality” category decreased from 34.32% to 29.7% from the pre to the post-intervention period ($P < 0.001$). NUR in “Blood Sample Issues” category reduced from 3.23% to 0.32% from the pre to the post-intervention period ($P < 0.001$). NUR in “Medical History” category decreased from 5.68% to 0.33% from the pre to the post-intervention period ($P < 0.001$).

Conclusions: The study indicates that QAP improves UR of recovered corneas. In countries with a shortage of donor corneas, increasing utilization of recovered corneas can lead to an increase in corneal transplants. Implementation of QAP at the Eye Bank can be a means of achieving this outcome.

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Keywords: Eye bank; Cornea transplant; Utilization rate; Non-utilization rate; Quality assurance; Reasons of non-utilization

Introduction

Corneal blindness is a major public health problem in India. The burden of corneal blindness, bilateral and unilateral combined, was estimated to be 6.8 million in 2001 and

projected to rise to 10.6 million by 2020.¹ Successful cornea transplants using human donated cornea is a treatment modality and can reduce the burden of corneal blindness. However, globally on average, only one cornea is available for seventy needed.² In India too, the lack of availability of donated cornea is a public health challenge.

In India, 52,750 corneas were collected in 2015 out of which 22,860 corneas were transplanted, indicating that only 43% of the recovered corneas were used.³ In contrast, in the same year, the Eye Bank Association of America reported that 128,675 corneas were recovered in the USA, and 79,304, or

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62%, were transplanted.⁴ This indicates that there is a huge potential to increase the rate of utilization of donated corneas in India.

Most importantly, given the shortage of donor corneas, a determined focus on increasing the utilization of the donated corneas is needed. Eye Banks play a pivotal role in ensuring this outcome. They are the node through which donors are accessed, corneas are recovered, tested, processed, and finally provided to surgeons for actual transplantation. In this paper, we demonstrate that Quality Assurance Program (QAP) at the Eye Bank is a viable and practical means of increasing utilization of donated corneas and thereby in addressing this public health issue.

Methods

This retrospective, cross-sectional study was conducted at the Dr. Shroff Charity Eye Hospital Eye Bank, which is a registered Eye Bank recognized by the Ministry of Health and Family Welfare, Government of India. Appropriate permissions were sought from the Institute's Review Board and tenets of the Declaration of Helsinki were adhered to. The Eye Bank performs only in-situ recovery of donor cornea.

Utilization efficiency of recovered corneas is measured by utilization rate (UR) defined as the number of corneas used for transplantation as percentage of the number of corneas recovered. This metric has been used by the Eye Bank for performance measurement since 2010. The number of corneas used for transplantation and number of corneas not transplanted add up to the total number of corneas recovered from donors. Thus, exact complement of UR is defined as the percentage of the number of corneas discarded without being transplanted as the percentage of the number of corneas recovered. In this study, we shall call it the non-utilization rate (NUR).

The Eye Bank formalized and started a QAP in 2011. As a part of the QAP, the Eye Bank undertook three major steps. First, it updated the clinical guidelines and formally adopted documented standard operating procedures (SOPs). Second, it implemented quality indicators (QI) to track outcomes of QAP.⁵ Third, regular monitoring of all activities of the Eye Bank was diligently done using detailed data of the operations.

Gap analysis of operating performance was part of regular monitoring process. Gap analysis on the corneas not utilized for transplant based on data from 2008 to 2010 revealed that there were four major reasons behind non-utilization of the donor corneas. These reasons are listed below in order of their contribution to the volume of unused corneas:

1. Tissue Quality: As determined by slit-lamp and specular microscope evaluation of the recovered cornea.
2. Seropositive: Determined from serology test conducted in-house on donor blood sample. Tests were done for Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus, and Syphilis.
3. Medical History: Existing medical conditions of donor which negate usage of donated corneas on human recipient.

4. Blood Sample Issues: Causes because of which serology test on donor blood sample could not be performed. These included cases where no sample was collected, sample was inadequate, sample coagulated, sample was not stored or transported correctly, etc. The Eye Bank did not use corneas for which it could not perform serology test on the donor blood sample in its own laboratory.

The Eye Bank defined NUR for a specific reason as number of corneas not transplanted due to that specific reason as percentage of the total number of corneas recovered.

Because of the nature of the QAP, the researchers expected that tissues that could not be transplanted due to the last two reasons mentioned above i.e. pre-existing medical conditions and blood sample-related problems, will rapidly subside thereby reducing NUR and concurrently increasing the UR.

The major steps of QAP were implemented during the year 2011. Retrospectively, data from the post-intervention period, January 2012 to December 2017, was compared with data from the pre-intervention period i.e. January 2008 to December 2011. The year during which the QAP was implemented, i.e. 2011, was included in the pre-intervention period.

The data was entered in MS EXCEL spreadsheet and statistically analysed using SPSS. The annual UR, NUR, and specific NUR for each of the four reasons from the pre and post-intervention periods were analysed. In order to compare two proportions (i.e. across the two time periods selected), the term “fold” which is similar to odds ratio, has been used. It is defined as follows: if p_1 increases to p_2 , it is called a (p_2/p_1) -fold increase; if p_1 reduces to p_2 , it is called a (p_1/p_2) -fold decrease. Thus, fold-change is always higher than or equal to one. Direction of change is indicated by the term increase or decrease. Z-test for equality of proportions, F test, and Levene's test for equality of variance were used for testing statistical significance.

Results

During the pre-intervention four-year period (2008–2011), the Eye Bank collected 1425 donor corneas in total and transplanted 762 of them. During the post-intervention six-year period, it collected 6661 corneas in total and transplanted 4393 of them. Compound annual growth rate of cornea collection was estimated to be 26.44% during the period 2008–2017.

Table 1 presents the key parameters evaluated, number of corneas collected and transplanted, and the annual UR and NUR, respectively, from 2008 to 2017.

Table 2 presents summary of statistical analysis done on overall UR and NUR. The UR increased 1.23-fold from 53.47% (762/1425) in the pre-intervention period to 65.95% (4393/6661) in the post-intervention period, and correspondingly, the NUR decreased 1.37-fold from 46.53% in the pre-intervention period to 34.05% in the post-intervention period. The difference in UR (as well as in NUR) between the two periods was found to be statistically significant ($P < 0.001$, z-test for equality of proportions). Variances of the

Table 1
Procurement and transplantation of corneal tissues (2008–2017).

Year	Pre-intervention period					Post-intervention period						
	2008	2009	2010	2011	Total	2012	2013	2014	2015	2016	2017	Total
Cornea recovered (No.)	202	296	395	532	1425	575	736	1044	1169	1469	1668	6661
Cornea transplanted (No.)	131	139	166	326	762	393	497	663	813	954	1073	4393
NUR (%)	35.15	53.04	57.97	38.72	46.53	31.65	32.47	36.49	30.45	35.06	35.67	34.05
UR (%)	64.85	46.96	42.03	61.28	53.47	68.35	67.53	63.51	69.55	64.94	64.33	65.95

NUR: Non-utilization rate; UR: Utilization rate.

Table 2
Analysis of utilization rate (UR) and non-utilization rate (NUR) across periods.

Year	Pre-intervention period	Post-intervention period	Fold change (from pre-intervention to post-intervention)	P-value of change between the pre and post-intervention periods
Average UR (%)	53.47	65.95	1.23-fold increase	P-value = 0.000, z-test for equality of proportions
Variance in annual UR	0.0121	0.0006	19.71-fold decrease	P-value = 0.000, z-test for equality of proportions
Average NUR (%)	46.53	34.05	1.37-fold decrease	P-value = 0.003 under F test; P-value = 0.000 under Levene's test for equality of variance

UR: Utilization rate; NUR: Non-utilization rate.

annual UR in the pre and post-intervention years were estimated to be 0.0121 and 0.0006, respectively, indicating a 19.71-fold decrease in the post-intervention period. Reduction in variance was statistically significant ($P = 0.003$ under F test; $P < 0.001$ under Levene's test for equality of variance). This shows that fluctuations in the annual URs grossly stabilized in the post-intervention years.

Table 3 summarizes the pre and post-intervention NUR of the cornea due to the four reasons explained earlier. Due to issues related to blood sample (“Blood Sample Issue”), NUR reduced from 3.23% in the pre-intervention period to 0.32% in the post-intervention period. This was a 10.24-fold decrease and statistically significant ($P < 0.001$, z-test for equality of proportions). Due to unfavourable “Medical History” of the donor, NUR decreased 17.21-fold from 5.68% in the pre-intervention period to 0.33% in the post-intervention period ($P < 0.001$, z-test for equality of proportions). Due to poor tissue quality (“Tissue Quality”), NUR decreased 1.16-fold from 34.32% to 29.7%. This difference was also statistically significant ($P < 0.001$, z-test for equality of proportions). The data revealed a minor increase in the NUR due to seropositivity (1.12 fold from 3.3% to 3.71%), which was not statistically significant ($P = 0.453$, z-test for equality of proportions). It needs to be mentioned here that reduction in the NUR due to seropositivity of donors was not an objective of the QAP as the Eye Bank has little or no control over it.

Table 4 reports the variances of the annual NUR due to each individual reason separately in the pre- and post-intervention period, corresponding fold-increase or decreasing, and P-values for test of significance of the change. The variations of the annual NUR due to individual reasons significantly dropped in the post-intervention period, except for seropositivity, implying that QAP has succeeded in

eliminating the systemic variations for non-utilization of corneal tissue due to three causes-blood sample issues, medical history of the donors, and poor quality of tissue. We note that the change in variance of the annual NUR due to issues related to blood sample was significant under F-test ($P = 0.009$), but not under Levene's test for equality of variance ($P = 0.082$).

Fig. 1 shows the trends of annual NUR due to the four causes separately. The reduction in the NUR and their stabilization are evident from Fig. 1. Fig. 1 also indicates that poor quality of tissue is the first major cause of non-utilization and the determining factor for the overall NUR. Poor quality of tissue contributed to 74% and 87% of the total number of non-utilizations in the pre and post-intervention period, respectively. Unfavourable medical history of donors was the second major cause of non-utilization in the pre-intervention period, contributing to 12% of the total non-utilization. Non-utilization due to this cause has been enormously checked in the post-intervention period, and it now accounts for only 1% of the total non-utilization. The second major cause of non-utilization in the post-intervention years is attributed to seropositivity of donor. Seropositivity of donors accounted for 11% of the total non-utilization in the post-intervention period (as against 7% in the pre-intervention years).

Fig. 2 shows the changing pattern of the causes for non-utilization of cornea from the pre to the post-intervention period. This change of pattern is statistically significant ($P < 0.001$, Chi-square test).

Discussion

QAP is often undertaken solely in response to customer (in this case surgeon) or regulatory demands. However, our study shows that the better operational discipline that QAP forces on

Table 3
Summary of non-utilization of cornea due to various reasons.

Reasons for non-utilization	Year	Pre-intervention period						Post-intervention period						Fold change in the total NUR (pre-intervention to post-intervention)	P-value (comparing total percentages in the pre and post-intervention period)
		2008	2009	2010	2011	Total	2012	2013	2014	2015	2016	2017	Total		
Blood Sample Issue	Number	12	10	8	16	46	7	6	3	1	4	0	21	10.24-fold decrease	0.000
	Percent	(5.94%)	(3.38%)	(2.03%)	(3.01%)	(3.23%)	(1.22%)	(0.82%)	(0.29%)	(0.09%)	(0.27%)	(0%)	(0.32%)		
Medical History	Number	37	14	2	28	81	10	2	6	0	4	0	22	17.21-fold decrease	0.000
	Percent	(18.32%)	(4.73%)	(0.51%)	(5.26%)	(5.68%)	(1.74%)	(0.27%)	(0.57%)	(0%)	(0.27%)	(0%)	(0.33%)		
Seropositive	Number	2	4	16	25	47	32	49	46	36	60	24	247	1.12-fold increase	0.453
	Percent	(0.99%)	(1.35%)	(4.05%)	(4.7%)	(3.3%)	(5.57%)	(6.66%)	(4.41%)	(3.08%)	(4.08%)	(1.44%)	(3.71%)		
Tissue Quality	Number	20	129	203	137	489	133	182	326	319	447	571	1978	1.16-fold decrease	0.001
	Percent	(9.9%)	(43.58%)	(51.39%)	(25.75%)	(34.32%)	(23.13%)	(24.73%)	(31.23%)	(27.29%)	(30.43%)	(34.23%)	(29.7%)		
Total number unutilized	Number	71	157	229	206	663	182	239	381	356	515	595	2268	1.37-fold decrease	0.000
	Percent	(35.15%)	(53.04%)	(57.97%)	(38.72%)	(46.53%)	(31.65%)	(32.47%)	(36.49%)	(30.45%)	(35.06%)	(35.67%)	(34.05%)		
Total number of corneas recovered		202	296	395	532	1425	575	736	1044	1169	1469	1668	6661		

NUR: Non-utilization rate.

an Eye Bank ecosystem, the more ancillary benefits it has. The most important of these benefits is the increase in utilization of donated cornea. We took the additional step of implementing QI to track the outcome of our QAP. A high degree of scrutiny about wastage of precious donated tissues was therefore automatically introduced in the performance-monitoring discipline. The gap analysis which identified the key reasons of cornea wastage and helped us in identifying the linkage between QAP and UR was a result of the QAP initiative itself.

Root cause analysis of the reasons for non-utilization of donated corneas identified the following underlying factors:

1. Condition of the donor: Existing donor conditions which adversely impact transplant suitability.
2. Lack of standardization: Knowledge and competency of staff in key operational areas like donor selection, procedures for cornea recovery, preservation, evaluation, and transportation had intra-staff variations.
3. Uncorrected human errors: There was lack of monitoring of human errors and absence of effectively implemented corrective measures. Together, this led to repetition of errors.

QAP has built-in antidote to rectifying some of these lapses because of the following:

1. QAP necessities formalizing all medical guidelines of the Eye Bank functioning in the SOP document. The SOP is reviewed and updated at a frequency defined therein. The SOP contains the list of contraindications which are existing medical conditions that make the donor tissue unsuitable for transplant. This leads to better selection of donors before recovery of corneas whenever possible.
2. QAP puts in place a formal staff competency management program under the supervision of the medical director to ensure alignment between SOP and actual operating performance. This raises the technical know-how and execution skill of the staff.

Additionally, the QI implementation ensured that the Eye Bank maintained detailed data and regularly reported and analyzed key performance metrics.

Noticeably, the year when quality improvement initiatives were launched, i.e. in 2011, the UR increased to 61.28% from 42.03% in 2010. However, 2011 is a transition year during which the QAP was still being stabilized and so the year was included in the pre-intervention period.

The Eye Bank expected that QAP will directly lead to a reduction of unused corneas in the categories “Medical History” and “Blood Sample Issue”. The results of this study confirmed the same. We also saw a decrease in the non-utilization in the “Tissue Quality” reasons category. In fact, as shown in Figs. 1 and 2, “Tissue Quality” reason contributes a major share in the total tissues not utilized. Therefore, any reduction in NUR for “Tissue Quality” has a sizeable impact on overall NUR. In our understanding, improved technician skill, quicker response by the tissue recovery technicians, and

Table 4
Comparing variances of the annual non-utilization rates (NUR) due to different causes.

Causes of non-utilization	Variance of annual NUR		Fold change	P-values	
	Pre-intervention years	Post-intervention years		F-test	Levene's Test
Blood Sample Issue	0.00028	0.00002	12.49-fold decrease	0.009	0.082
Medical History	0.00594	0.00004	138.71-fold decrease	0.000	0.017
Seropositive	0.00035	0.00034	1.04-fold decrease	0.449	0.659
Tissue Quality	0.03476	0.00181	19.17-fold decrease	0.004	0.006
Grand Total	0.01222	0.00062	19.71-fold decrease	0.003	0.000

NUR: Non-utilization rate.

accumulation of subject matter expertise contributed towards this result. However, we note that attribution of the improvement in tissue quality to human resource-driven factors like quality of the recovery done by the technician requires a different study. The category “Seropositive” was understood to be not targeted because of the lack of direct Eye Bank control on factors influencing it.

Another fact we wanted to note is the reduction in year to year variation in annual UR and the NUR across the reason categories (Tables 2 and 4, respectively). The lower standard deviations indicate that the overall performance became more reliable, which is a positive connotation of improved quality.

Arguably, there are costs associated with implementing and maintaining QAP. Additional time is required for documentation, reporting, analysis, and training. Time spent in oversight of operations also increases. We unequivocally note that the benefits, specifically, increased utilization of tissues and increased patient safety, more than offset any additional cost.

Around 34% of recovered corneal tissues were not utilized even during the post-intervention period. This indicates scope for further improvement. However, the overheads (effort and cost) of implementing mechanisms for further increasing the UR may be more than the benefits. Also, very high UR may be indicative of too stringent donor selection. The Eye Bank does not want to sacrifice the opportunity of securing more corneas for transplant in the interest of implementing a heavy-handed efficiency improvement regimen.

According to Williams et al.⁶ and Ranjan et al.,⁷ lack of awareness is a principal deterrent to increasing availability of corneas. The act of eye donation is believed to be important for generating awareness. Thus, the medical director and medical director designee of the Eye Bank provided case to case exemption to the donor selection criteria specified in the SOP. In these cases, the policy of informed consent was followed wherein families were told that cornea being recovered may be unsuitable for transplant and may be used for research

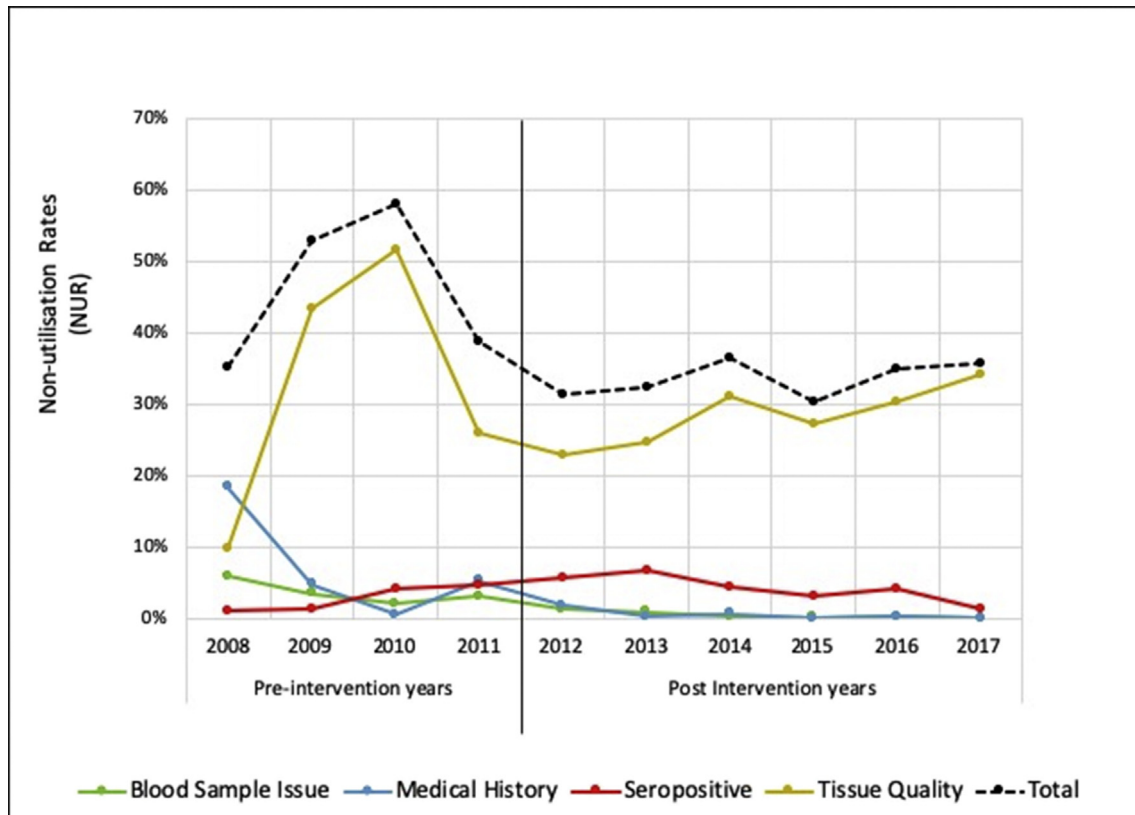


Fig. 1. Cause-wise non-utilization rates (NUR) of corneal tissue.

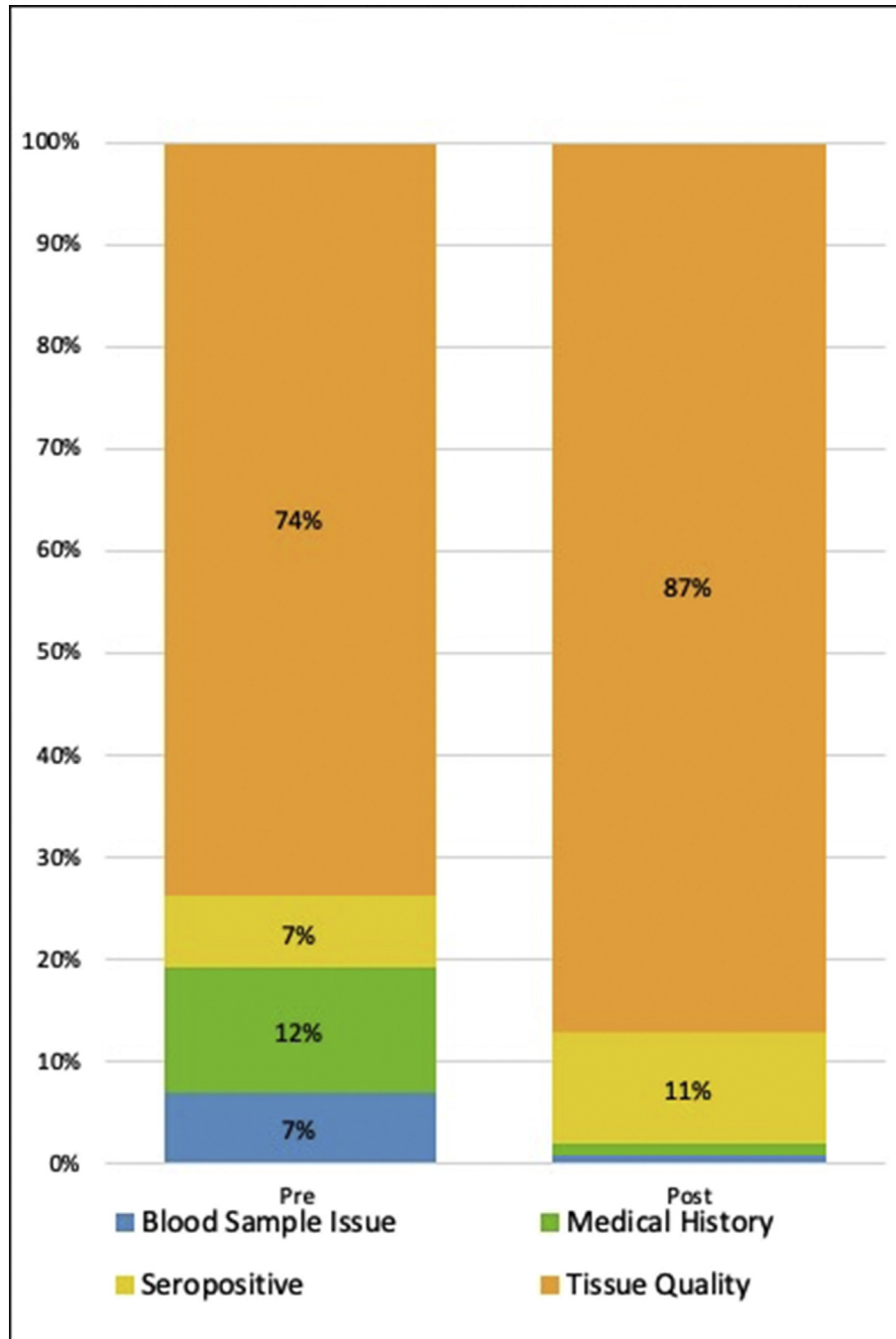


Fig. 2. Contribution of individual causes in the overall non-utilization of corneal tissue.

and training purposes. However, we want to emphasize that though an Eye Bank may trade-off UR for social promotion of the act of eye donation, such trade-offs need to be done sparingly and strategically. We should not forget that the solution to cornea blindness problem lies in recovering corneas that are fit to be transplanted.

We conclude that an increase in UR is an important direct impact of QAP. Over time, QAP ensures that eye banks improve their efficiency automatically. Moreover, better UR of recovered corneas is a good insurance against negative public opinion emanating from non-usage of donated corneas.

Therefore, QAP is not just a necessity for compliance with regulations and with the clinical needs of surgeons. In the longer term, by being a mechanism which increases the number of transplantable corneas available, QAP is also of strategic importance for upscaling the response to cornea blindness as a public health issue.

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