Resuming eye bank services during the COVID-19 pandemic: Experience and inferences

Manisha Acharya, Saurabh Biswas, Animesh Das, Abhishek Dave, Umang Mathur

Purpose: The aim of this study was to formulate a methodological approach for resuming eye bank services during COVID-19 pandemic. Methods: Eye bank operations were temporarily halted in March after the government-mandated “Lockdown” in response to COVID-19 pandemic. Before restarting eye bank operations in May, we studied sources of exposure, performed risk assessment, instituted additional process validations and redefined the Standard Operating Procedures (SOPs) in consultation with the guidelines published by the Eye bank Association of India and All India Ophthalmological Society. The eye bank staff were rigorously trained before and after operations were restarted. We conducted a survey at the end of July to gauge staff attitude and reaction. Results: Eye banks services resumed on 20th May 2020. Since reopening till the end of July total 41 keratoplasties have been done. 91.75% of all keratoplasties done were therapeutic surgeries and 17% of the surgeries were done using glycerine preserved tissues. No staff had COVID-19 symptoms when the operations restarted and none developed symptoms up to the end of July. All eye bank staff were aware of COVID-19 pandemic and 96% said they felt safe working at the eye bank. 86% of the staff said that they received adequate training and 66% of the staff expressed that they always received proper PPE and kits. Overall, 93% of the staff expressed that the measures taken by the eye bank ensured their safety. Conclusion: Based on our experience we suggest the following activities for planned resumption of eye bank services during the pandemic: Exposure Risk Analysis, Personal Protective Equipment usage training, SOP Revision and staff training on modified SOPs. Criteria based selection of donor sources, participatory planning involving the staff and double-checking at critical process junctions helped us in managing a smooth transition.

Key words: COVID-19 pandemic, eye bank, reopening

Following the outbreak of the SARS-COV-2 pandemic, Government of India formally declared a “lockdown”. After the release of Order No. 40-3/2020-D dated 24.03.2020 by the Ministry of Home Affairs, Government of India, the Eye Bank Association of India in its communication to eye banks suggested halting of eye bank services. Our eye bank took cognizance of the guideline and decided to halt all donor facing activities of the eye bank. On 11.05.2020 the Eye Bank Association of India released “Guidelines for Cornea and Eye Banking During COVID-19 Era Version 1.0” which laid down the conditions for continuing donor-facing operations of eye banks.[1] Even then, reopening the eye bank given the uncertainty surrounding the pandemic and continued spread of SARS-COV-2 infection was a daunting prospect. Three key challenges dominated. Firstly, there was the probability of causing transmission of SARS-COV-19 to recipients and eye banks staff. Secondly, uncertainty existed regarding availability of donors and feasibility of tissue recovery. Thirdly, there was no clarity about volume of surgeries to be expected and probable demand for tissues. The Eye bank Association of India and All India Ophthalmological Society further assisted the process of operating eye banks in the COVID-19 scenario by codifying most of the key aspects of eye banking.[2] We also restarted our operations and resolved to achieve full-scale operations in a stepwise manner. Multiple learnings were gathered during that phase which we believe can be instrumental in formulating a methodological approach in the current and other similar circumstances.

Methods
We designated the month of May as the “Observation and Planning” month in order to prepare for eventual reopening of the eye bank. On priority we onboarded the staff, explained the need to adopt new tools and methods and immediately started training on using Personal Protective Equipment (PPE). In parallel we analyzed the sources of exposure to determine a way forward. The study was approved by the hospital’s Institute Review Board.

Sources of exposure study
We focused on two key groups within the sphere of Eye Bank’s responsibility in the context of COVID-19 situation. These groups were “Eye Bank Staff” and “Recipient and Recipient’s treatment center staff”. Our principal responsibility was to ensure that eye bank activities didn’t transmit SARS-COV-2 to any of these two groups. Then we looked at sources of

Cornea and Refractive Surgery Services, ‘Eye Bank, Dr. Shroff’s Charity Eye Hospital, New Delhi, India, ‘Institute of Cognitive Science, Universität Osnabrück, Neuer Graben, Osnabrück, Germany

Correspondence to: Dr. Manisha Acharya, Medical Director - Eyebank Consultant Cornea and Refractive Surgery Services, Dr. Shroff’s Charity Eye Hospital, 5027, Kedar Nath Lane, Daryaganj, New Delhi - 110 002., Delhi, India. E-mail: manisha28dr@gmail.com

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exposure in terms of internal and external to the locus of these two groups. From our perspective, the key locus of “Eye Bank Staff” is the “Eye Bank” and for “Recipient and Recipient’s treatment center staff” is the “Surgery Center”.

After mapping the sources of exposure, we answered the question: “Does the Eye Bank activity contribute to the exposure?”. In the case of Eye Bank staff, we understood that multiple exposure opportunities are directly created due to the eye bank’s activity. However, in the case of the Recipient and Recipient’s treatment center staff the only connection to the eye bank was through the distributed tissue. Transmission of SARS-CoV-2 virus through tissue in preservative media is a very low probability event and there is no evidence of it having happened.[8] Therefore, we focussed on the “Eye Bank Staff” and devised a set of protocol to minimize the probability of their exposure from internal as well as external source.

Exposure risk categorization

Identifying the Eye Bank staff as the central focal point helped us narrow down our analysis of exposure risk. For this we used the reference model of eye bank operations which identifies the key processes as Donor Acquisition, Tissue Harvest and Preservation, Evaluation, and Tissue Distribution.[4] Donor Acquisition contains two distinct kinds of operating methods- voluntary donation and Hospital Cornea Recovery Program (HCRP). We created four graded exposure risk levels- High, Medium, Low and Nil. Then each eye bank staff was asked to grade risk levels of each component in the aforementioned process chain. We aggregated the responses and created risk categorization of each process in the eye bank operations.

Donor acquisition

Voluntary Donation was flagged as a high-risk activity. The EBAI-AIOS guidelines too suggested against it.[3] We decided to follow the EBAI-AIOS Guideline of conducting HCRP only in “non-COVID-19” classified hospitals. For identification of hospitals, we built a decision matrix and used the matrix to decide which hospitals to operate in. The data points used in our decision matrix were:

a. Name of Hospital
b. Location
c. COVID-19/non-COVID-19 designation Hospital
d. Deaths per month (COVID-19 and Non-COVID-19 separately)
e. COVID-19 positive patient currently admitted
f. Separate Ward for COVID-19
g. Separate Floor for COVID-19
h. Overall Safety rating for operations
i. Decision (Start/Hold).

Tissue distribution

To prepare for any wastage of tissue due to the unpredictable situation, we decided to use longer term storage media (Comisol™) for preservation. Glycerine preserved tissues were earmarked for emergencies, in case of unavailability of media preserved tissues.

Additional quality assurance

A separate tracker for all donor and tissues was introduced, where every tissue was manually tracked from source to usage point and periodically checked. The objective was to build another layer of check for any missed or suspicious cases of COVID-19 positive donor. Any eye bank staff participating in any stage of operations had to update the tracker. The Eye Bank Manager and Medical Director reviewed the tracker daily.

SOP modification

Finally after we identified risks, risk levels and a strategy for donor acquisition and distribution we revised our SOP’s to reflect special steps needed under the new situation. The changes introduced in the SOP are listed in Table 1.

All eye bank staff were trained over videoconferencing and after resumption of operations were given one-on-one training on the changes in SOP.

To measure efficacy and staff response to the measures we conducted a survey at the end of July amongst the eye bank staff. The questions asked and response options are provided in Table 2.

Results

Our eye bank resumed operations on 20th May 2020 after remaining closed from March 22, 2020. No staff had COVID-19 symptoms when the physical eye bank operations restarted and none developed symptoms until the end of July.

No corneas were collected in April and May. In June and July, 12 and 24 corneas respectively were collected from HCRP programs in non-COVID-19 designated hospitals. In April, no keratoplasties were done. In May, June and July, 3, 16 and 22 surgeries, respectively, were done. Of the keratoplasties in May, June and July, 3, 4 and 1, respectively, were done using glycerine preserved corneas. Out of these, 3 keratoplasties in June and 1 keratoplasty in July was done using glycerine preserved tissues supplied by another eye bank. Refer Fig. 1 for summary of data.

From reopening in May till end of July, 91.75% of all keratoplasties done were therapeutic surgeries. From beginning of 2020 i.e., from 1st January, till the closure of the eye bank on 22nd March, 24.82% of the keratoplasties were therapeutic surgeries. Refer Fig. 2 for detailed data.

The eye bank has a total of fifteen staff members including the Eye Bank Manager. Post-reopening in May, June and July, 23%, 41%, 29% of the total available human resource capacity of the eye bank was utilized. This we calculated by dividing the sum of the man-days worked by each employee by the total number of man-days available if all employees worked on all working days. The result of the division was then converted into percentage. We also calculated, for each employee, the percentage of total days of work-from-home as against the total days actually worked and then aggregated the data for the eye bank. In May, June and July, on a monthly basis, 33%, 22% and 30% respectively, of the total days worked was in the work-from-home format.

We summarized the response to the Eye Bank Staff Attitude Survey at eye bank level and also at the level of staff roles. Two roles were distinguished, office staff and field staff. Field staff comprised of Eye Bank Technicians and Eye Donation Counsellors cum Eye Recovery Technicians. There are total seven field-staff. All other staff were designated as office staff. On the days a field-staff is doing work-from-home, she is performing activities over the phone only. If there is a case of eye donation, she informs the relevant field-staff who is operating that day from the eye bank. The field-staff stationed at the eye bank then proceeds with subsequent steps. 100% of eye bank staff across both roles were aware of COVID-19 pandemic. 7% of the staff said they felt unsafe about attending eye bank during the pandemic, 7% said that they felt safe only sometimes, and the rest 86% said they felt safe. About adequacy of training, 86% of the staff said that they received adequate training and the rest were neutral. 66% of the staff expressed that they always received proper PPE and kits, while 34% said they received so only sometimes. 93% of the staff said that the measures taken by the eye bank ensured their safety and the rest were neutral. Amongst field staff, 43% felt safe about attending field duties, 14% felt unsafe and rest 43% sometimes felt safe, sometimes unsafe. All field staff felt safe about attending the night-shift. For details refer to Table 3.

Discussion

Total number of corneas collected and used in keratoplasties registered a dramatic slide as expected due to the closures.
However, as shown in Fig. 1, both collection and utilization are rising since the “Unlockdown” started. As is evident from the fact that keratoplasties done were 91.75% therapeutic, most of the patients who were operated upon needed emergency surgeries. Under the situation, glycerine preserved tissues were used to tide over acute shortage of donors corneas and accounted for 17% of the 41 surgeries done between reopening in May and the end of July. The practicality and conditions of use of glycerine preserved tissues in the COVID-19 pandemic situation has been corroborated by other researchers as well.\(^6,7\)

Overall at this moment, the demand for corneas far exceed the supply, leading to rapid utilization of all corneas which are not rejected due to donor’s medical history or serology tests. This situation is expected to continue till the time major hospitals are amenable to HCRP.

A central theme in our approach was increasing the number of checkpoints so as to achieve a very low probability of unnoticed changes in standard operating procedure (SOP) specific to COVID-19 situation

| Process                  | Changes post COVID-19                                                                 |
|--------------------------|--------------------------------------------------------------------------------------|
| General Regulations      | Daily self-validation form mandatory before entering eye bank\(^6\)                  |
|                          | All eye bank staff mandated to use mask, cap, gowns, visors as a protection measure |
| Donor Acquisition        | New screening COVID-19 template form mandatory. Filled up at medical screening stage and peer reviewed before donor family contact was initiated. |
|                          | Counseling only in Non COVID-19 HCRP centers as per EBAI guidelines                 |
| Tissue Harvest and preservation | Double exposure of povidone-iodine during Recovery process: 10% Betadine for face preparation with duration of contact time to be increased to 4 min from previous 2 minutes. 5% Betadine instillation on cornea and wash after 2 min contact time. Longer term media (Cornisol\(^{1(\text{m})}\)) to be used as the default storage media instead of MK. Additionally visors, double gloves, head cover, long shoe cover along with disposable gowns mandatory (PPE) to be used for Tissue Harvesting and preservation. Cleaning of tissue boxes, bottles with alcohol swab before and after recovery and before keeping it in refrigerator. Keeping the donor records papers under laminar flow hood in UV light for 30 minutes for sterilizing. |
| Evaluation               | A checklist to validate pre-donation screening was introduced. The purpose is to cross check the medical history and COVID-19 screening details from the family members within 48 hours of recovery. |
| Distribution             | Established media transfer protocol to transfer tissues approved for transplant to Glycerine, four hours before expiry in the primary storage media. Corneo-scleral rim left after keratoplasty and DSAEK stromal cap to be preserved in glycerine for potential later use in patch grafts. Each staff handling a tissue is responsible for updating Tissue-Tracking Sheet. Medical Director and Eye Bank Manager to review the data entered daily. |

| Question                              | Question Type | Response Options                           |
|---------------------------------------|---------------|--------------------------------------------|
| Are you aware of COVID-19 pandemic?   | Multiple Choice | Yes, No, Cant Say                          |
| Do you feel safe about attending eye bank? | Multiple Choice | Yes, No, Sometimes Yes/Sometimes No        |
| Do you feel safe about attending field duties? | Multiple Choice | Yes, No, Sometimes Yes/Sometimes No        |
| Do you feel safe about attending night-shift? | Multiple Choice | Yes, No, Sometimes Yes/Sometimes No        |
| Do you think you have received enough training from eye bank? | Multiple Choice | Yes, No, Neither sufficient, nor insufficient |
| Have you received proper PPE and kits? | Multiple Choice | Yes, No, Sometimes, Most of the times      |
| Do you think the measures taken by the eye bank ensures your safety? | Multiple Choice | Yes, No, Sometimes Yes/Sometimes No        |

\[\text{Figure 1: Bar Chart of corneas collected and transplanted from March, 2020 to July, 2020}\]

\[\text{Table 1: Changes in standard operating procedure (SOP) specific to COVID-19 situation}\]

\[\text{Table 2: Survey for assessing eye staff staff attitude on operating in COVID-19 pandemic}\]
exposure slipping through. We captured eye bank staff health data (daily form to be filled before eye bank entry), introduced checklist for double-checking donor medical history and a detailed tissue tracker. All these data captured was reviewed daily by Eye Bank Manager and the Medical Director. This additional layer of validation may seem to increase workload but in reality this was not observed because the volume of activities in the eye bank was lower compared to usual times.

In our experience planning ahead and consulting multiple sources for cues before modifying the SOP proved helpful. However, most of the changes we introduced were based on the EBAI-AIOS guidelines. The measure of double exposure to povidone-iodine during recovery was adopted based on findings of Kampf et al.

We started to plan for resumption of operation even before it was officially allowed. This helped in maintaining staff morale by engaging them meaningfully in the process of reopening. We saw a lot of value in participatory planning by involving the eye bank staff. The checklist used to cross-validate donor medical history was created because the eye bank technicians expressed concern that donor family may have too many things to handle, given death during the pandemic, and may not be able to provide all necessary background medical information.

The confidence of the staff in their level of knowledge about COVID–19 and faith expressed in the measures taken by the eye bank to ensure staff safety was overwhelmingly positive. Most importantly, field staff who are required to attend to donor cornea recoveries in hospital, unanimously felt safe about coming to the eye bank and considered that training given to them was adequate. Of course, they didn’t all feel safe about going for cornea recoveries in the hospitals but this is expected. However, the fact that they were confident about the measures taken by the eye bank, helped them in maintaining a positive outlook and continue field duties.

Based on our experience we can produce the following glide-path for effective reopening of operations under pandemic:
1. Exposure Risk Analysis
2. PPE usage Training (online)
3. SOP Revision
4. Staff training on SOP changes including new documentation (online)
5. Staff training on SOP changes and PPE usage (In-person)

At this point our focus is to continue with the new operating protocol we have set-up and generate enough tissues to continue treating the emergency situations. To increase our collections and reach previous volumes, we will continue to review the hospital selection decision through the aforementioned matrix, and constantly monitor if more hospitals become safe for functioning. In a way, this pandemic has again shown us the benefit of HCRP and helped us in improving our telephone-based death notification system. This wouldn’t be possible without the strong relationships built with our HCRP centers, indicating the success of the strategic hospital relationship management program the eye bank had implemented.

**Conclusion**

We are yet an unknown distance away from business-as-usual, particularly since the emerging usual scenario is still nebular. Our experience demonstrates a methodical approach for dealing with the ambiguity and modifying the operating procedures, to enable functioning during stressful times.

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**Conflicts of interest**

There are no conflicts of interest.

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