Guest Editorial

How safe is safe, and where are we in the journey toward safest of safe?

It is nice to have yet another issue of IJO, the official publication of AIOS out in print with a bevy of interesting articles packed with new information. This issue of the journal carries a paper investigating serology results in cornea donors, comparing the reports from donors who died in hospital whose corneas were retrieved under the Hospital Cornea Recovery Program (HCRP) with those recovered from voluntary home deaths. The article has raised the specter of donor transmission of dreaded diseases.

Irrespective of the outcomes of comparison of the two pools of donors, the paper unquestionably reaffirms what we know already – there is a silent presence of sinister diseases which patients, relatives, or caregivers are not aware of and the condition is unveiled only by routine serological screening of asymptomatic individuals. In short, it is a sober reminder that serological testing of eye donors is mandatory and we hope that there are no longer any eye banks in the country not following National Programme for Control of Blindness guidelines. The Eye Bank Association of India has played a key role in assisting in the process of dissemination of information to all stakeholders, further substantiated and reinforced by the requirement as per the Transplantation of Human Organs and Tissues Act checklist for legal registration.

Another aspect the paper uncovers is that in this particular patient population, there was a difference in seroprevalence of blood- and tissue-borne infections between HCRP and voluntary home donors with a higher likelihood among those who were admitted and died in hospital. Consequently, it highlights that the well-placed enthusiastic emphasis on hospital recovery motivated by better efficiency and utilization rates must be tempered by the ground reality that these cases may harbor higher than the expected transmission risks. Hence, more vigilance is required in screening the blood samples, using reliable testing methods, and extra care must be exercised in interpreting the findings before clearing the tissue as safe for transplantation.

In the study reported in this issue, enzyme immunoassay (EIA)-based rapid diagnostic test (RDT) kits have been used for the HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) serologies. The manuscript states that test results (of the specified rapid EIA-based government-approved kits) were double checked by ELISA, but the names and manufacturers of the ELISA kits used for verification are not mentioned. For HIV and HCV, RDTs are considered to have acceptable sensitivity and specificity. These tests are included in national guidelines for HIV testing (NACO, 2015);[1] and for HCV antibody testing, some RDTs are also WHO prequalified.[2] However, many RDTs are unable to detect low levels of HBV surface antigen, particularly in asymptomatic individuals.[2] In view of time constraints, good quality rapid tests would be a particularly useful option for screening cadaveric corneal donors.

An issue which needs to be considered while screening cadaveric (postmortem) samples is that a very small percentage of false-positive and even more rarely, false-negative results, have been reported on comparison with premortem samples.[3] It is probably better to err on the side of caution, and corneas from all serologically positive donors, including the false-positive ones, should not be transplanted, treating this as acceptable wastage in the interest of preventing transmission of infection. This is of relevance, because in the rare case of an adverse event of the recipient ever acquiring one of the blood- and tissue-borne diseases after corneal transplantation, the decision to use the tissue despite a positive result can be questionable.

In an attempt to eliminate false-negative results, in many developed countries, screening by nucleic acid tests (NAT) is also recommended. However, given the known prevalence of HIV, and the low-to-intermediate endemicity of HBV and HCV in India[2, 4] the probability of donors being in the window period (negative serology with a positive NAT) at the time of screening is quite negligible, and these expensive tests are unlikely to provide any real benefit in terms of additional "yield" of infected donors.

Of course, the local and regional variations will impact the practical implications, but a strong emphasis of reliance on serological tests to support the mandatory screening for medical history, social and behavioral risk factors, and physical examination of the donor to ensure full safety of recipients demands a relook at the quality of testing techniques and the reliability of their interpretation. A shift to processing of blood samples by professional facilities with reporting by experts, a transition many eye banks in India have already made, rather than simply depending on underqualified eye bank technicians, may have to be considered.

Finally, some food for thought, are we to believe that safety standards[5-10] should be equivalent globally? Ethical concerns would recommend so, but economic and technical constraints may play an unseemly role in searching for a safe-enough acceptable alternative. The point of the matter is, what some perceive as increasing costs and complexities in eye banking, others may view as a valid price to pay to ensure safety and eliminate risks. As the country has progressed from gloveless, drapeless eye surgeries to near state-of-the-art protective measures, so must the eye banking and corneal transplantation community rise to the occasion by driving for change in mindsets that quality does come for a price and we must find ways to make it affordably available.

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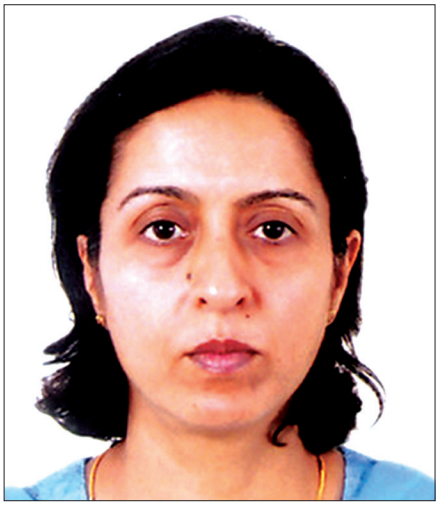

Prof. Radhika Tandon currently heads the clinical unit providing Cornea and External Disease, Cataract and Refractive Surgery, Ocular Oncology and Low Vision Services at the Dr. Rajendra Prasad Centre for Ophthalmic Sciences, AIIMS, New Delhi. She is also the Co-chairperson of the National Eye Bank, Chairperson of Low Vision Services and Chairperson of the Medical Board Ophthalmology. Her extramural positions include Chairperson Visual Disabilities Sub-committee of Ministry of Social Justice and Empowerment, Ophthalmology Expert for Medical Council of India, Technical Expert for Directorate for Health Research, Member of Advisory Board for National Program for Control of Blindness, Task Force member for Department of Biotechnology and Indian Council for Medical Research, Member of Apex Technical Committee for National Organ and Tissue Transplant Organization, and elected President of Eye Bank Association of India. Endowed with a sharp, analytical mind and high intellectual capabilities, coupled with a brilliant academic record, Professor Tandon is a graduate and post graduate from AIIMS, and is devoted to an academic career balancing patient care, teaching and research with numerous publications to her credit. She is well known as co-editor of the renowned textbook Parsons' Diseases of the Eye. Her work on standardization of eye banking in India has resulted in a paradigm change.