

## Cost Savings of Appropriate Screening of Potential Donors

Although a certain amount of recovered donated ocular tissue will, for one reason or another, ultimately be determined to be unsuitable for transplantation, minimizing this loss is important for many reasons. In the present day, the number of exclusions for risk of communicable diseases has been increasing. Hepatitis B, Hepatitis C, Syphilis and HIV have been joined by West Nile, COVID 19, and Zika. The loss of transplantable tissue can lead to the possible delay of a surgery and a patient's expectation for improved vision, disappointment for the donor family; such losses also represent a financial burden to the eye bank. While most eye banks would consider the financial loss as the least important factor in their mission to restore sight, it is nevertheless a necessary consideration for the delivery of corneal tissues for transplantation, teaching and research.

A recent prospective study of corneal recovery in a Medical Examiners population reviewed 189 cases over an 8-month period. Of the 189 cases reviewed, 27 cases were determined to be unsuitable for transplantation due to risk of transmission of communicable disease based on serology testing. In addition, there were 38 case deferred due to high risk behaviors as defined by FDA 21CFR 1271 but not serology reactive. All of these deferrals were for reasons of concern for recipient safety and compliance with FDA guidance and EBAA medical standards.

These 65 potential donors would have possibly led to 130 recovered corneas. The loss of these corneas carries with it a varying level of financial impact for the eye bank. Corneal tissue may be provided for transplantation for the traditional penetrating keratoplasty (PK), Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK) or Descemet's Membrane Endothelial Keratoplasty (DMEK), each with different costs. The fees must reflect additional complexity of the preparation as well as instrumentation and supplies. The service fee, which must include recovery and processing for transplantable tissue, may range anywhere from approximately \$3,000 to \$3,600 for a PK, to approximately \$3,800 to \$4,800 for a DSAEK or DMEK. In this case, we look not specifically at service fee loss, but rather at a non-recoverable resource expenditure. Therefore, of greatest concern financially is that tissue is not recovered if it will later be found unsuitable for transplantation.

In these 65 cases, 58 of them avoided major financial loss to the eye bank as they were deferred during screening and were not recovered. This would prevent approximately \$81,000 in eye bank unrecoverable costs. The seven cases that were recovered but then deemed unsuitable for transplant led to a loss of approximately \$21,000. This

represents a fourth of the amount that would have been lost if appropriate screening had not led to the decision to defer the other high-risk cases.

Balancing the decisions to defer or recover potential donors is an important consideration for financially responsible non-profit eye bank operations. In a cost-recovery operation, unpredictable revenue loss can limit an eye bank's ability to provide the appropriate level of physician- and patient services. Therefore, the training and retention of screeners, technicians, and education staff is paramount to the success of eye banks' mission to restore sight and to control health care costs. As the risk of disease transmission changes and expands, eye banking staff and those involved with potential donor screening must be aware of emerging diseases, the symptoms of these diseases and how to ascertain the information necessary to appropriately screen for the risks involved.

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