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Editorial

United States Cornea Graft Registry: Vision for the Future

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The cornea is one of the most commonly transplanted tissues in the United States.[1] During the last 3 decades, the Eye Bank Association of America (EBAA) through its member eye banks has provided > 1 645 013 corneas, both domestically and internationally.[2] Over the past decade, there has been a 20% increase in keratoplasty procedures with consequent growing demand for donor tissue every year.[2] Coinciding with this growth has been a shift from full-thickness penetrating keratoplasty toward endothelial keratoplasty for treatment of endothelial disorders, resulting in better patient outcomes.

A cornea graft registry has an enormous value. Australia was the first country to develop a successful cornea graft registry in May 1985.[3] Registry data have been published annually and are a valued source of information regarding graft survival and comparison of keratoplasty techniques. Likewise, the United Kingdom and Sweden have cornea graft registries that have also contributed to the knowledge of both donor and patient characteristics associated with keratoplasty outcomes. A US cornea graft registry would potentially provide a nationally representative sample that would benefit society and the profession by comparing outcomes associated with various keratoplasty techniques. It would also help individual surgeons by allowing them to confidentially analyze their data and compare their own outcomes with national benchmarks. The eye banks would have the option to access the complete ocular history of the donor at the time of harvesting tissue, which can improve donor screening and eligibility determination. Integrating recipient and donor information would facilitate eye bank follow-up and reduce administrative burden. International Classification of Diseases 10th Revision coding and EBAA diagnosis coding would be more easily and accurately obtained. Currently, the EBAA requests surgeons to report outcomes voluntarily, limited to adverse event reporting, to close the loop on the entire tissue supply chain using the Online Adverse Reaction Reporting System (OARRS). The real-time data integration in a graft registry could trigger eye banks' OARRS investigations without depending on surgeons to initiate adverse event reporting. This would enhance our ability to monitor the quality of donor tissue, increasing oversight of the reporting process and comprehensiveness of resultant data. Eye banks would also receive clinical statistics on how their tissue performed postkeratoplasty and could compare it with national standards, further improving eye bank functions such as processing for endothelial keratoplasty. Artificial intelligence or multilevel statistical models could be applied to a robust registry data set to analyze recipient and donor characteristics that facilitate successful graft outcomes.

With > 50 000 corneal tissues distributed annually in the United States alone, the EBAA has rich data on donor demographics, donor referral trends, and tissue information, reported by its member eye banks by requirement.[4] However, the EBAA does not operate a central donor or recipient database, which would warehouse more granular donor data (e.g., medical history or tissue quality) or basic recipient data representing each US recipient. A highly cited report published by the EBAA outlines key eye donation findings from data reported by US eye banks every year.[2] The EBAA's OARRS dataset consists of adverse events reported by surgeons. However, this separate, independent data set is also incomplete and is dependent on reporting by eye banks after investigation of the surgeon's initial voluntary report. The determination of whether an investigated event is reportable to the EBAA is made by an eye bank's Medical Director, a process that further influences the data ultimately included in OARRS.[5] Although OARRS expands on the EBAA members' individual databases, the manual entry and voluntary reporting of this information can compromise the robustness and utility of the dataset. The bulk of donor data resides within each eye bank's 52 independent databases. Therefore, without a central donor or recipient database, EBAA data systems are not designed to serve as a national cornea graft registry.

The development of a cornea graft registry in the United States has been further hampered by the lack of resources required to manually collect the necessary data from the thousands of US surgeons performing corneal transplantation. In addition to being cumbersome, the manual extraction and movement of data risk undue exposure. This presents as a risk to patient and donor confidentiality and thus contributes to the impedance among stakeholders to pool the existing data. However, in the era of electronic health records (EHRs) and big data, the ability to use actual patient data to create a national cornea graft registry represents an exciting opportunity. The American Academy of Ophthalmology's Intelligent Research in Sight (IRIS®) registry is an electronic data warehouse. With an enormous amount of data, the IRIS registry helps monitor national trends and quality metrics and

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serves as the basis for various public health interventions. The IRIS interface has built-in tools that allow ophthalmologists to compare their outcomes with peers and identify opportunities for improvement.[6] Lack of donor tissue information is currently limiting IRIS from being used as a cornea graft registry. The Intelligent Research in Sight registry is designed to receive data from other structured query language (SQL) and HTML databases, like those operated by US eye banks.

The IRIS registry's ability to automatically collect data from EHRs offers a solution with a proven secure infrastructure that is already in place. As of May 16, 2022, IRIS was contracted with 14 381 ophthalmologists, 12 346 of whom had EHR integration (Lum F, American Academy of Ophthalmology, personal communication, 2022). With 2 separate large datasets comprising nearly all prerequisite data elements, the creation of the first cornea graft registry in the United States appears to be more feasible than ever with the integration of the 2 sets of data into 1. The clinical data required for a cornea graft registry can be automatically obtained via IRIS by modifying the EHR mapping protocols for practices that are already participating. Donor data can be obtained by mapping IRIS to eye bank databases. Although the system will not capture all grafts performed in the United States, based on the penetration of the IRIS registry, it is anticipated to capture $>$ 80% of them once fully implemented. Furthermore, other registries like the Site Outcome Research Collaborative registry, which are currently capturing data from academic institutions, may complement the IRIS database to capture additional grafts.[7]

There are other significant challenges to establishing a US Cornea Graft Registry. It must be designed with data fields that can be mapped to existing eye bank and clinical databases, so data may be pushed from these databases into the US Cornea Graft Registry database. Certain data fields in the US Cornea Graft Registry will have to be designed to push data back to eye bank and clinical databases. The system must be able to contain data from bar codes and QR codes on tissue labels and in patient records. There are approximately 5 to 7 eye bank database providers in the United States serving 100% of US eye banks. As of 2016, there are 176 electronic medical record/EHR database providers in the United States.[8] Mapping these data systems to a US Cornea Graft Registry will be a massive undertaking. In the near future, cell culture and other biosynthetic therapies may enter into the same ophthalmic space currently occupied by keratoplasty and will require the same monitoring. Finally, the US Cornea Graft Registry must be sustainable financially, not simply for startup, but as an ongoing Registry for years to come; federally supported Registries such as in Australia, Sweden, and United Kingdom have this advantage, while in the United States this would be unlikely. A sustaining source(s) of revenue to support the ongoing activities of the US Cornea Graft Registry would need to be identified. Registration fees paid by members, a percentage of tissue fees paid by Medicare and other payors, project grants from foundations and corporations, and tax-deductible charitable contributions can provide a steady stream of revenue for the registry.

With the rise in the number of big datasets, it is high time that the true potential of individual sets of data is materialized by integrating them together. Integration of EBAA's dataset and IRIS registry offers an opportunity to create the first cornea graft registry in the United States. A cornea graft registry would have the potential to ignite new research, give surgeons and eye banks a more accurate analysis of their performance, support the development of superior evidence-based practice, and guide health policies to the benefit of transplant recipients.

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References

1. Milliman. Milliman Research Report 2020 US Organ and Tissue Transplants: Cost Estimates, Discussion, and Emerging Issues. https://www.milliman.com/-/media/milliman/pdfs/articles/2020-us-organ-tissue-transplants.ashx; 2020. Accessed January 24, 2022.
2. Eye Bank Association of America. 2020 Eye Banking Statistical Report. https://restoresight.org/wp-content/uploads/2021/03/2020_Statistical_Report-Final.pdf; 2021. Accessed January 24, 2022.
3. Williams KA, Sawyer M, Alfrich SJ, et al. First report of the Australian Corneal Graft Registry. *Aust N Z J Ophthalmol*. 1987;15:291−302.
4. Eye Bank Association of America. Medical Standards. https://restoresight.org/wp-content/uploads/2020/07/Med-Standards-June-20-2020_7_23.pdf; 2020. Accessed January 24, 2022.
5. Eye Bank Association of America. Guidance Document for Investigating and Reporting Adverse Reactions to the EBAA. https://restoresight.org/wp-content/uploads/2017/08/OARRS-Guidance_07_2017.pdf; 2017. Accessed January 24, 2022.
6. Chiang MF, Sommer A, Rich WL, et al. The 2016 American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight) Database: Characteristics and Methods. *Ophthalmology*. 2018;125:1143−1148.
7. Bommakanti NK, Zhou Y, Ehrlich JR, et al. Application of the Sight Outcomes Research Collaborative Ophthalmology Data Repository for triaging patients with glaucoma and clinic appointments during pandemics such as COVID-19. *JAMA Ophthalmol*. 2020;138:974−980.
8. Office of the National Coordinator for Health Information Technology (ONC). Hospital Health IT Developers. https://www.healthit.gov/data/quickstats/hospital-health-it-developers. Accessed January 24, 2022.