

XV
Corso Nazionale



RESPONSABILI SCIENTIFICI:
Massimiliano Corneli
Silvia Conforti

13 Maggio
2023



FABRIANO

Tracking the Gift of Sight

Importanza dei dati a lungo termine dei trapianti di cornea. ipotesi di un database nazionale

Francesco Aiello MD, PhD, FEBO, FEBOS-CR
Università di Roma «Tor Vergata»
Direttore: Prof. Carlo Nucci



XV Corso Nazionale  SIBO
Società Italiana Banche degli Occhi

13 Maggio
2023

FABRIANO

Conflict of interest

- *None to disclose*

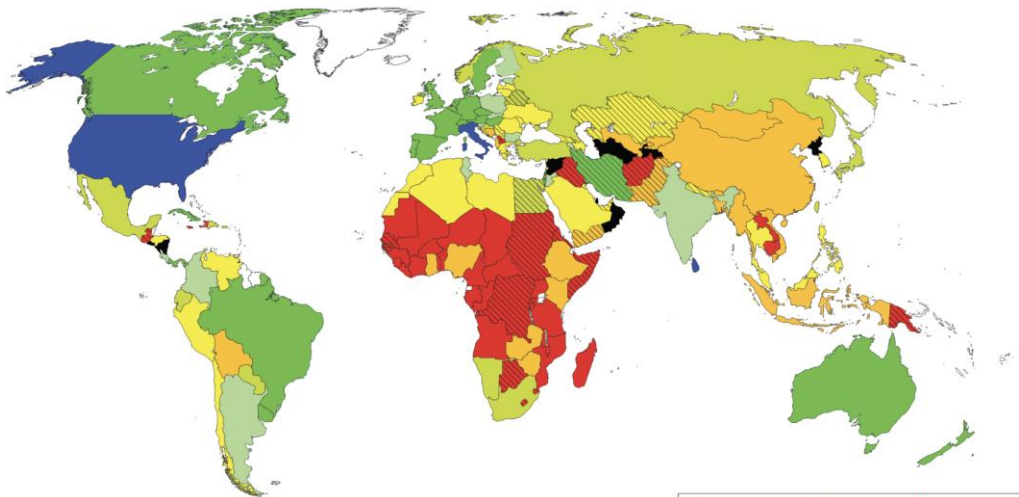




Eye Banking and Tissue Donation

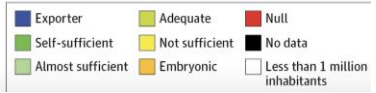
- First Eye Bank funded in New York, US, in 1944 by Dr Paton
- Dr. Paton designed a plan to “*systematically obtain, preserve and redistribute eye tissue to doctors who were performing cornea transplant operations.*”





Global Survey of Corneal Transplantation and Eye Banking

Philippe Gain, MD, PhD^{1,2}; Rémy Jullienne, MD¹; Zhiguo He, PhD²; [et al](#)



- 742 Eye Banks identified;
- 184 576 corneal transplants performed;
- **12.7 million** people awaiting a corneal transplantation;
- At least **53.3%** of the world's population had practically no access to corneal transplantation.

Ethical aspects

*2018 “Provide de-identified donor and recipient transplant data to available recognised jurisdictional data tracking registries (which contribute to a **global tracking**) inclusive of import/export data.”*



GLOBAL ALLIANCE
OF EYE BANK ASSOCIATIONS

Barcelona Principles

An Agreement on the use of human donated tissue for ocular transplantation, research, and future technologies[©].

Corneal Graft Registries

- 16 corneal graft registries (6 regional, 8 national registries, and 1 multinational)
- Different aims (e.g., donor, recipient, transplant)
- Different features (e.g., procedure; F-Up; funding; procedure(s) captured; data collection).

TABLE 1. Characteristics of the Corneal Graft Registries Included in the Current Review (n = 16 Registries)

Name	Scope	Country (Region, City)	Inception Date	Corneal Grafting Procedures Captured	Duration of Follow-Up	Number of Related Publications Found
Australian Corneal Graft Registry (ACGR)	National	Australia	1985	PKP, ALK, DSEK, DMEK, LSCT, and scleral graft	Indefinite	21
BELIEVe (Cohorte Bisontine pour l'Estimation de la survie des greffons cornéens au Long terme à partir des données de suivi Internes du CHRU de Besançon—Évaluation Épidémiologique clinique)	Regional	France (Bourgogne-Franche-Comté, Besançon)	1983	PKP, ALK, DSEK, and DMEK	5 years	1
Cologne DMEK prospective database	Regional	Germany (North Rhine-Westphalia, Cologne)	2011	DMEK	3 years	3
CORneal Transplant Epidemiological Study (CORTES)	Regional	Italy (Veneto)	2001	PKP, ALK, and DSEK	6 years	4
European Cornea and Cell Transplant Registry (ECCTR)	Multinational	Belgium, Czech Republic, Denmark, France, Finland, Italy, Latvia, the Netherlands, Republic of Ireland, Spain, Switzerland, and United Kingdom	2016	PKP, ALK, DSEK, and DMEK	2 years	2
Indianapolis Prospective Transplant Registry	Regional	United States (Indiana, Indianapolis)	1988	PKP, DSEK, and DMEK	5 years	3
Irish National Corneal Transplant Registry	National	Republic of Ireland	2012	PKP, ALK, DSEK, DMEK, and K-Pro	Unknown	1
National Eye Bank Corneal Transplant Registry	National	India	2012	PKP, ALK, and DSEK	Unknown	1
Netherlands Organ Transplantation Registry	National	the Netherlands	1994	PKP, ALK, DSEK, and DMEK	Indefinite	10
New Zealand Corneal Transplant Registry	National	New Zealand	1991	PKP, ALK, and DSEK	2 years	4
Ontario Corneal Recipient Registry	Regional	Canada (Ontario)	1985	PKP	Unknown	3
Registre des greffés cornéens du Centre Hospitalier National d'Ophthalmologie des XV-XX	Regional	France (Île-de-France, Paris)	1992	PKP, ALK, and DSEK	Indefinite	7
Registre des greffés cornéens du CHU de Québec-Université Laval	Regional	Canada (Québec, Québec)	2020	PKP, ALK, DSEK, and DMEK	5 years	0
Singapore Corneal Transplant Registry	National	Singapore	1991	PKP, ALK, DSEK, and DMEK	Indefinite	22
Swedish Corneal Transplant Registry	National	Sweden*	1996	PKP, ALK, DSEK, and DMEK	2 years	14
United Kingdom Transplant Registry (UKTR)	National	United Kingdom	1999	PKP, ALK, DSEK, and DMEK	5 years	20

*Two Danish medical centers and 1 surgeon performing keratoplasties in Iceland also participate in the Swedish Corneal Transplant Registry. K-Pro, Boston Keratoprosthesis; LSCT, limbal stem cell transplant.

Benefits of Registries



Depict more accurately the **“real world” data** (high external validity)



Provide insight into the **efficiency, safety, and quality** of medical care dispensed



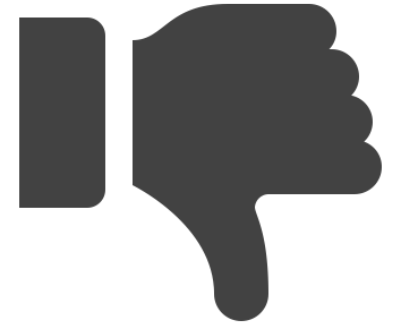
Allow to monitor the **outcomes of new surgical techniques** (including surgeons' learning curves)



Allow to capture and study **rare conditions or complications and to detect late-onset** adverse events

Downsides of Registries

- **High heterogeneity** between surgeons regarding surgical approach, postoperative medical care, and measurement techniques. (Low internal validity)
- **Variable precision** and comprehensiveness of the recorded follow-up information (Very high risk of bias)
- **Lack of standardized measure**
- **High costs**



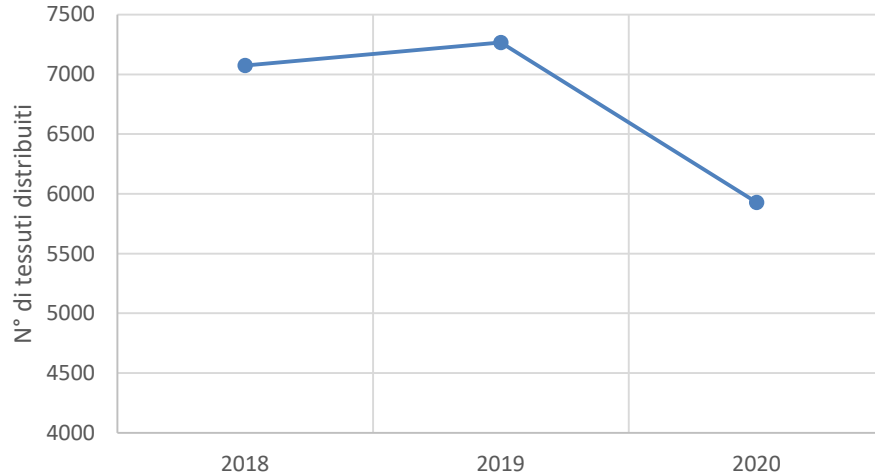
Which Data to Gather?

Impact of the COVID-19 Pandemic on Corneal Transplantation: A Report From the Italian Association of Eye Banks

March 2022

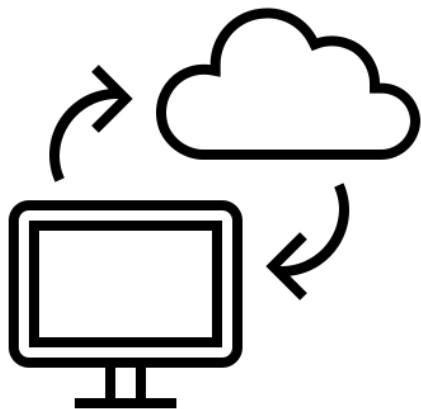


Rita Mencucci^{1*}, Michela Cennamo¹, Diego Ponzin², Federico Genzano Besso³, Giulio Pocobelli⁴, Matilde Buzzi¹, Carlo Nucci⁴ and Francesco Aiello⁴ on behalf of Italian Society Eye Bank Group (SIBO)



Basic principles

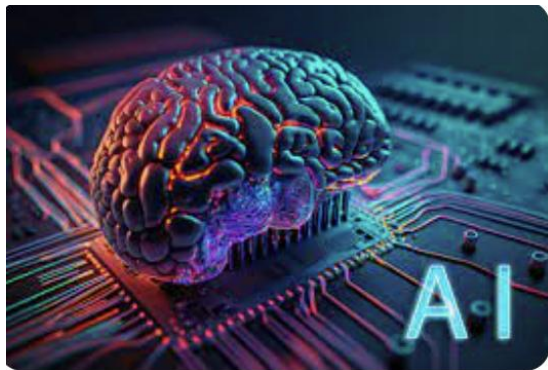
- Obtaining **ALL** relevant data of **ALL** corneal graft procedures performed within the territory covered by the registry is **paramount**.
- The data acquisition process must **NOT** be cumbersome
- How long the follow-up should be
- Centralize the data gathering process



How can it be done?

IT-based system, which allows:

- **Direct** Data Collection;
- **Centralized** Data Collection;
- **Standardized** Data Collection;
- **Quality-checked** Data Collection.



The European Cornea and Cell Transplantation Registry



About the ECCTR Project

Cornea transplantations Worldwide, the cornea is the most frequently transplanted intact tissue with over 180,000 transplants performed annually.

In Europe, an estimated 30,000 cornea transplantations are performed annually. Corneal disease is the second cause of blindness worldwide. Corneal transplantation remains the main method for rehabilitation once vision is affected, pain reduction is needed or the integrity of the eye is at risk.

Who We Are

The European Cornea and Cell Transplantation Registry (ECCTR) is a European Consortium that aims to build an EU web-based registry in the field of cornea and to assess and verify the safety quality and efficacy of corneal transplantation.

The **aim of the project** is to build a common assessment methodology and establish an EU web-based registry and network for academics, health professionals and authorities to assess and verify the safety quality and efficacy of corneal transplantation in ophthalmology.

Take Home Messages

Corneal graft registries are invaluable tool to **evaluate** the quality of **medical care**

Increase our **understanding** of certain **diseases** and **prognostic factors**

inform strategic and economical health decisions.

Take Home Messages

Issues: **lack of internal validity, high risk of bias, lack of standardization** of the information provided.

The application of **centralized, IT-based data collection strategies** might help in setting-up a reliable, standardized, and at low-risk of bias register.

The ultimate goal is the **creation of a large, multinational Eye Bank Register**, for better collection, analysis and planning of the Eye Bank Activity.



francesco.aiello@uniroma2.it

