

## Original Investigation

## Global Survey of Corneal Transplantation and Eye Banking

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**IMPORTANCE** Corneal transplantation restores visual function when visual impairment caused by a corneal disease becomes too severe. It is considered the world's most frequent type of transplantation, but, to our knowledge, there are no exhaustive data allowing measurement of supply and demand, although such data are essential in defining local, national, and global strategies to fight corneal blindness.

**OBJECTIVE** To describe the worldwide situation of corneal transplantation supply and demand.

**DESIGN, SETTING, AND PARTICIPANTS** Data were collected between August 2012 and August 2013 from a systematic review of published literature in parallel with national and international reports on corneal transplantation and eye banking. In a second step, eye bank staff and/or corneal surgeons were interviewed on their local activities. Interviews were performed during international ophthalmology or eye-banking congresses or by telephone or email. Countries' national supply/demand status was classified using a 7-grade system. Data were collected from 148 countries.

**MAIN OUTCOMES AND MEASURES** Corneal transplantation and corneal procurements per capita in each country.

**RESULTS** In 2012, we identified 184 576 corneal transplants performed in 116 countries. These were procured from 283 530 corneas and stored in 742 eye banks. The top indications were Fuchs dystrophy (39% of all corneal transplants performed), a primary corneal edema mostly affecting elderly individuals; keratoconus (27%), a corneal disease that slowly deforms the cornea in young people; and sequelae of infectious keratitis (20%). The United States, with  $199.10^{-6}$  corneal transplants per capita, had the highest transplantation rate, followed by Lebanon ( $122.10^{-6}$ ) and Canada ( $117.10^{-6}$ ), while the median of the 116 transplanting countries was  $19.10^{-6}$ . Corneas were procured in only 82 countries. Only the United States and Sri Lanka exported large numbers of donor corneas. About 53% of the world's population had no access to corneal transplantation.

**CONCLUSIONS AND RELEVANCE** Our survey globally quantified the considerable shortage of corneal graft tissue, with only 1 cornea available for 70 needed. Efforts to encourage cornea donation must continue in all countries, but it is also essential to develop alternative and/or complementary solutions, such as corneal bioengineering.

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Corneal transplantation (CT) is the most frequently performed type of transplant worldwide. It restores visual function when impairment caused by corneal damage is deemed too severe to provide acceptable quality of life in the country where it is performed. Corneal blindness is the third leading cause of blindness worldwide after cataract and glaucoma,<sup>1</sup> with 10 million people having bilateral corneal blindness.<sup>2</sup>

Organ and tissue transplantation is a complex process with many legal, ethical, religious, and cultural barriers. However, the cornea presents several characteristics that make storage and transplantation easier than other tissue and organs, and eye banks (EB), responsible for storage, quality, and safety controls, are instrumental in CT success worldwide.

From a surgical viewpoint, conventional CT is also called penetrating keratoplasty. It is the dominant technique worldwide and involves replacing the full corneal thickness. In the past 10 years, lamellar grafts have developed quickly through progress in concepts and instrumentation.<sup>3</sup> Posterior lamellar graft (endothelial keratoplasty) has grown exponentially in developed countries and is indicated for one-third of all CTs. There is currently no practical alternative to CT for most cases worldwide.

To our knowledge, the only available data about CT come from the annual statistical reports of the Eye Bank Association of America, the European Eye Bank Association, and the Eye Bank Association of Australia and New Zealand, representing less than 15% of the world's population. Given that defining comprehensive strategies to fight corneal blindness requires precise knowledge of global supply of and demand for corneal graft tissue, and that cornea donation can also be an indicator for the donation of organs and other tissues, we designed the most exhaustive possible global study and report its findings here. These provide previously unavailable evidence of the global imbalance in donor cornea supply and demand.

## Methods

### Data Collection Protocol

We conducted a global, transversal, and descriptive epidemiological study between August 2012 and August 2013. Forty-two countries with a population of less than 1 million at the time of the survey (34 of which likely had no corneal procurement or CT activity) were excluded. According to United Nations demographic statistics, this left 157 countries, ie, 99.8% of the world's population.<sup>4</sup> The survey was based on a standard questionnaire in 2 parts: CT and EB (Box). It was conducted in 2 steps for each country. In step 1, available data were collected through a systematic, periodical, and extensive review of scientific literature published between January 1, 2005 and December 31, 2013, using the PubMed/Medline database and Google Scholar. This long period was necessary to gather the maximum amount of data, especially for countries with rare reports, and, for others, to analyze whether significant changes occurred over time. Whenever multiple data were available, only the latest were considered. The following broad search terms were used: "corneal transplantation," "corneal graft," "keratoplasty," "corneal blindness," "corneal storage," and "eye banking." We then contacted local and national ophthalmology associations and or-

### At a Glance

- A survey covering more than 95% of the world's population collected data about supply and demand of corneal transplantation.
- Per year, approximately 185 000 corneal transplants were performed in 116 countries, and 284 000 corneas were procured in 82 countries.
- With an estimated 12.7 million people waiting for a corneal transplantation, 1 in 70 of the needs are covered worldwide.
- With 199.10<sup>-6</sup> transplants per capita, the United States had the highest rate (median rate of 19.10<sup>-6</sup> in the 116 grafting countries).
- Fifty-five percent of all corneas were procured in the United States and India.

gan and tissue organizations by telephone or email. We collated their latest reports on CT and EB. Similar statistics from 2010 and 2011 were also obtained from the websites of health ministries and organ and tissue organizations. Lastly, the latest international reports on CT and EB by the Eye Bank Association of America, the European Eye Bank Association, and the Eye Bank Association of Australia and New Zealand were used.

In step 2, we conducted interviews using the standard questionnaire in the Box. To increase the accuracy of the answers for each country, 1 or more respondents were needed to validate the interview results, unless national reports were available. The minimum number of participants for this task (1, 2, or 3) was determined by country population size and the number of active ophthalmologists.<sup>5</sup> The respondents (ophthalmologists and eye bank staff) were selected according to their field of interest (CT and/or EB) and, when possible, were key opinion leaders identified from our own expertise (G.T. and P.G. have, respectively, 17 and 27 years' practice in EB and CT), the literature, and congress abstract books. The interviews were conducted in various forms by 5 investigators (R.J., M.A., Z.H., G.T., and P.G.). We first conducted face-to-face interviews at 11 international congresses that covered clinical ophthalmology, ophthalmic research, and eye banking (eTable 1 in the Supplement). Priority for the face-to-face interviews was given to people working in countries where data were not yet available. Following these interviews, the respondents were encouraged to cross-check and report back additional data on returning to work. In parallel, specialists were contacted by telephone and email. Mailing lists were obtained from board members of national and international ophthalmic and eye-banking associations. They were asked to answer the standard questionnaire and liaise with colleagues to cross-check data and/or obtain additional data. The telephone and email interviews were done in English, French, Spanish, Chinese, or Arabic.

### Accuracy of Data

Data were checked for consistency and accuracy. Numbers that appeared abnormally large or small were cross-checked with additional contacts. For each country, the data sets obtained through steps 1 and 2 were compared and collated. Published data and national reports took precedence over individual interviews. In the latter case, where interviewees' answers differed, data were submitted to a third party to settle any significant discrepancy. We used a 4-level score for data reliability: 4 for evidence-based data,

published statistics, or articles; 3 for at least 2 concordant data obtained from CT and EB professionals, or, in some rare cases, data from 1 person with leader status (for instance, one of a country's few corneal surgeons); 2 for data obtained only from 1 professional; and 1 for uncontrolled data (for instance, deduced from neighboring countries with a similar profile).

### Statistical Analysis

The results discussed below are based on countries' 2011-2013 activity and correspond mainly to 2012. Countries were classified in homogeneous groups in terms of balanced supply and demand. These groups were formed to represent pragmatically each national situation. We first calculated procurement and transplantation rates per million inhabitants in each country and classified each rate using 6 categories (eTable 2 in the Supplement). We assigned the same weight to both rates, so as not to artificially favor importing countries over those with comparable CT activity using nationally procured donor tissue. We therefore added the 2 scores to obtain a total score between 0 and 10. A bonus point was given to countries that were significant exporters of donor corneas. Finally, based on the total scores, a 7-group classification (eTable 2 in the Supplement) was selected after it was deemed to best reflect the classification of the 10 test countries of which we had expert knowledge. A world map was then generated using a 7-color code.

Data distribution normality was tested using both the Lilliefors variant of the Kolmogorov-Smirnov test and the Shapiro-Wilk normality test, with  $P < .05$  as the cutoff for non-normality. Data were expressed as median (interquartile range [IQR]) for nonnormal distribution. All statistical analysis was done with IBM SPSS Statistics version 20.0 (IBM Corporation).

## Results

Of the 157 countries surveyed, data were collected from 148, representing 95% of the world's population. No data were obtained from the other 9 countries (Central America: 2, Asia: 3, Middle East: 4). Eighty-two national and international statistical reports on CT or EB and 136 relevant published articles were analyzed and collated. Some 281 specialists took part in the survey, and the minimum number of respondents was met in 93% of responding countries. The survey comprised 123 face-to-face interviews and 158 telephone and/or email interviews.

### Accuracy of Data

For the 148 countries with data, data-reliability score distribution was similar for CT and EB. For CT, data were collected in 28% of cases from official published documents, 55% from 2 concordant professionals, 8% from only 1 professional, and 9% were estimated. For EB, the percentages were respectively 25%, 55%, 15%, and 5%. Considering only the 2 most reliable sources (scores 4 and 3 for 114 countries), these data were representative of 91% of the 184 576 transplants and of 97% of the 283 530 procured corneas that we identified.

### Patients on Waiting Lists

The waiting-list data provided by 134 countries, covering 91% of the world's population, showed that approximately

## Box. The Questionnaire Used for All Interviews

### Part 1: corneal transplantation activity

1. Total No. of keratoplasties per year
2. Five leading indications in decreasing order among the 8 following causes: keratoconus, bullous keratopathy (pseudophakic/aphakic), regrant, Fuchs endothelial dystrophy, postinfectious scars, posttraumatic scars, other corneal dystrophies, other causes
3. Estimated total cases of corneal blindness (unilateral or bilateral, with visual acuity  $<6/18$ , excluding other causes of blindness)
4. Mean waiting time for surgery, mo
5. Surgical technique: penetrating keratoplasty vs lamellar keratoplasty (anterior or posterior), %
6. Corneal graft availability: national vs imported corneal grafts, %
7. Countries from which corneal grafts are imported

### Part 2: eye-banking activity

1. No. of corneas procured per year
2. No. of corneas exported per year
3. Types of procurement technique: corneo-scleral rim/enucleation
4. Maximal procurement time allowed after death
5. Types of storage technique: cold storage/organ culture/refrigerated eye balls
6. Procurer status: medical/paramedical/technician
7. Availability of eye bank pre-cut corneas for lamellar keratoplasty
8. Donor status, %: multi organ donor (heart beating) vs cadaveric donor (nonheart beating)
9. No. of eye banks
10. Organ or tissue law regulations (opt in/opt out register/opt out family)

12.7 million people were awaiting a transplantation, including 2 million in China and 7 million in India. Estimated waiting time was only analyzed for the 50 countries we deemed to be in the "exporter," "self-sufficient," "almost self-sufficient," or "adequate" categories (eTable 2 in the Supplement). The median was 6.5 months (IQR, 1- 24 months). For the other countries with an imbalance, most patients never received a graft, thus preventing a calculation of waiting time.

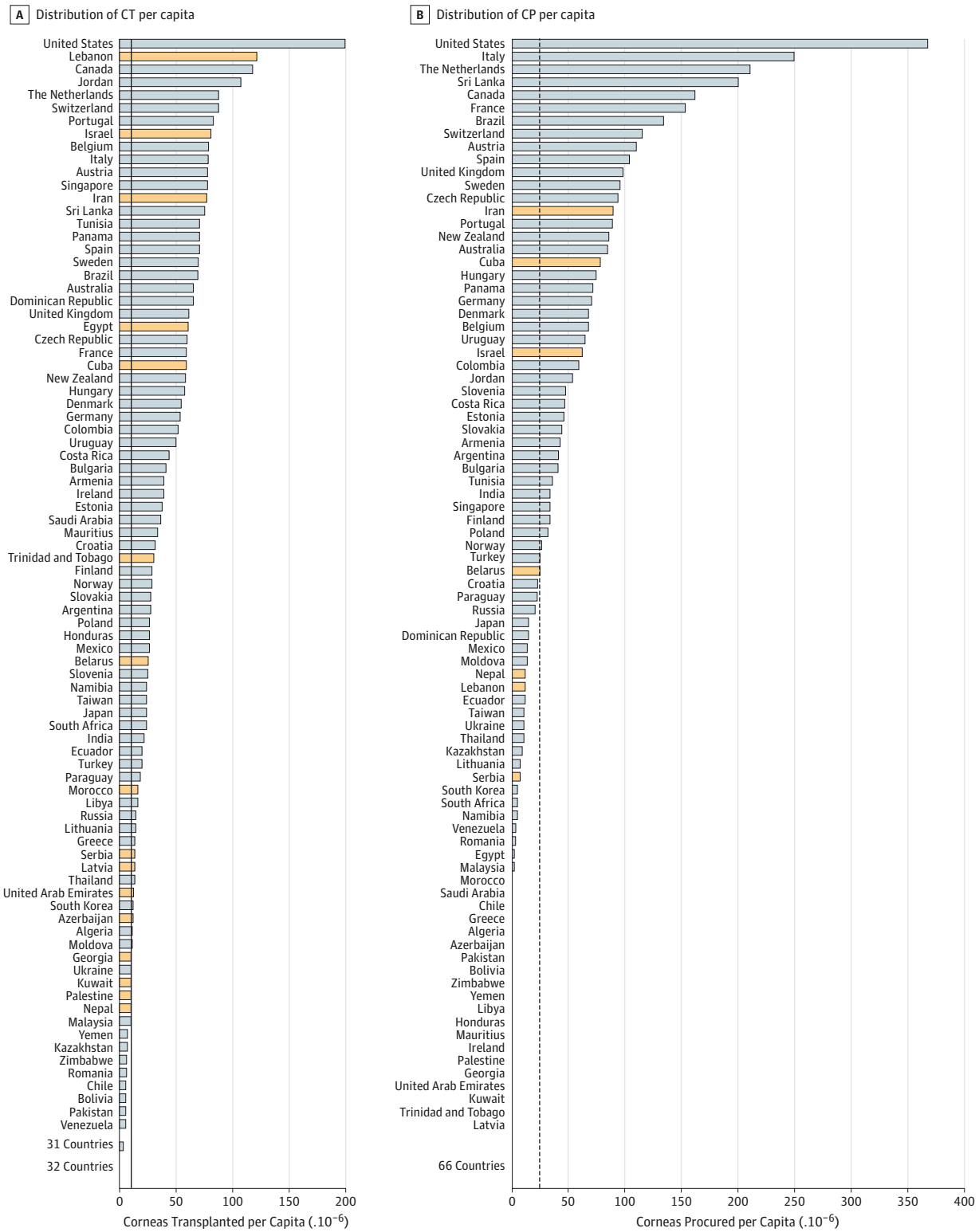
### Transplantation

We identified 184 576 CTs performed in 116 countries. The other 41 countries represented 423 million inhabitants for whom no data could be collected ( $n = 9$ , but activity was doubtless negligible) or no CTs were performed ( $n = 32$ ). Fifty-five percent of CTs were performed in the United States, India, and Brazil (63 596 [ $199.10^{-6}$  CTs per capita], 25 000 [ $22.10^{-6}$ ], and 14 000 [ $70.10^{-6}$ ], respectively). Of the 116 countries, 40 (35%) performed 1 to 100 CTs, 52 (45%) performed 101 to 1000 CTs, 21 (18%) performed 1001 to 10 000 CTs, and only 3 (2%) performed more than 10 000. The rate of CTs per capita is shown in Figure 1A. For the 116 countries, the CT median rate was  $19.10^{-6}$  CTs per capita (IQR, 4-55), but for all 148 countries the median rate was  $10.10^{-6}$  (IQR,  $0.4.10^{-6}$ - $39.0.10^{-6}$ ).

### Cornea Imports

Of the 116 grafting countries, 107 indicated the origin of corneal tissue. Eighty-nine percent (164 510 of 184 576) of

Figure 1. Rate of Corneal Transplantation (CT) and Corneal Procurement (CP) per Capita in the World



A, Distribution of CT per capita. Only countries with more than  $5.10^{-6}$  CTs per capita are shown. The vertical line shows the median ( $10.10^{-6}$ ) of all countries ( $N = 148$ ). Lists of the 31 countries below  $5.10^{-6}$  and of the 32 performing no CTs are available in the eResults of the Supplement. B, Distribution of CP per capita. The same countries as in A are represented. The continuous vertical line, almost

merged with the y-axis, shows the median ( $0.92.10^{-6}$ ) of all countries ( $N = 148$ ). The dotted vertical line shows the median ( $25.2.10^{-6}$ ) of the 82 cornea-procuring countries. In A and B, yellow bars show countries for which we deemed the data of questionable robustness.

transplants were performed with nationally procured corneas. Thirty-seven countries, representing 142 325 transplants (77% of the total), used only nationally procured corneas; 27 countries, representing 2183 transplants (1.2%), used only imported corneas; and 43 countries, representing 40 068 (21.7%) used nationally procured and imported corneas.

### Type of Keratoplasty

Data for 95 countries of 116 (82%), representing 173 637 grafts (94%), were available. Keratoplasties were defined as either penetrating keratoplasty or lamellar grafts, with no distinction between anterior and endothelial grafts. The median rate of penetrating keratoplasty was 90% (IQR, 58%-100%). Thirty-one countries (33%) reported no lamellar graft. In absolute values, lamellar grafts represented 29.7% of all CTs performed worldwide. Indications for keratoplasties are presented in the [Supplement](#) (eFigure and eResults).

### Cornea Procurement and Eye Banking

We identified 283 530 corneas procured in 82 countries in 2012. Fifty-five percent were procured in the United States and India (116 990 [366.10<sup>-6</sup> corneas per capita] and 40 000 [35.10<sup>-6</sup>], respectively).

In total, 742 eye banks were identified: more than 5 banks in 16 countries (19%), 2 to 5 banks in 30 countries (35%), and 1 bank in 28 countries (34%). India had the most banks (238), followed by the United States (84) and China (75). Eight countries (10%) reported corneal procurement (1122 corneas) and transplantation without official eye-banking bodies.

The collected data allowed calculation of the total number of corneas received by all EBs in a given country, but not by individual EBs. The median number of corneas received annually by each EB was 168 (IQR, 58-377), but ranged from 1 to 7000.

Overall, for the 82 countries, the median rate of corneal procurement per capita was 25.10<sup>-6</sup> (IQR, 5.10<sup>-6</sup>-71.10<sup>-6</sup>) (Figure 1B). In proportion to the population of all countries studied (N = 148), this rate was 0.95.10<sup>-6</sup> (IQR, 0-34.10<sup>-6</sup>) overall.

Based on population, the United States was the most active country for cornea donations with 366.10<sup>-6</sup> per capita, followed by Sri Lanka with 150.10<sup>-6</sup> per capita.

### Cornea Exports

Nine countries exported a total of 23 247 corneas (8% of all procured corneas). This figure is consistent with the 19 392 grafts reportedly done with imported tissues. Of these 9 countries, 85%, 9%, and 3% of supply came from the United States, Sri Lanka, and Italy, respectively, ie, an effort of 63.10<sup>-6</sup> corneas per capita for the United States (total: 19 546 corneas), 75.10<sup>-6</sup> corneas per capita for Sri Lanka (2000 corneas), and 10.10<sup>-6</sup> corneas per capita for Italy (600 corneas). The other exporting countries are presented in the eResults of the [Supplement](#).

### Laws Regulating Cornea Donation

According to the answers from 77 of the 82 cornea-procuring countries, 35 (45%) used an opt-in system (donors must give explicit consent), and 42 (55%) used an opt-out system (anyone who has not refused is a donor). The corneal procurement rate was significantly higher with the opt-out than with

**Table 1. Cornea Donation by Majority Religion in the 82 Cornea-Procuring Countries**

Majority Religion (No. of Countries)	Total No. of Procured Corneas (% of Global Effort)	Inhabitants in These Countries, Millions	Median Rate of Procurement per Capita .10 <sup>-6</sup> (Range)
Judaism (1)	500 (0.2)	8.0	62.5
Atheism (2) <sup>a</sup>	1189 (0.4)	59.0	49.5 (5.1-93.9)
Christianity (52)	218 497 (77.1)	1852.8	43.9 (0.5-366.7)
Hinduism (2) <sup>b</sup>	40 350 (14.2)	1176.0	23.6 (12.5-34.8)
Buddhism (7)	7293 (2.6)	376.5	11.7 (0.7-200.0)
Chinese traditional (1)	5000 (1.8)	1360.0	3.7
Islam (17)	10 573 (3.7)	936.2	0 (0-89.7)
Total (82)	283 402 (100)	5768.5	25.2 (0-366.7)

<sup>a</sup> Czech Republic and South Korea.

<sup>b</sup> India and Mauritius.

the opt-in system, with 38.9.10<sup>-6</sup> (IQR, 0.0-248.6.10<sup>-6</sup>) corneal procurements per capita vs 5.4.10<sup>-6</sup> (IQR, 0.2.10<sup>-6</sup>-366.7.10<sup>-6</sup>) ( $P = .008$ ).

### Religion and Donation

Corneal donation was significantly related to the majority religion in countries (nonparametric Kruskal-Wallis test,  $P = .003$ ) ([Table 1](#)).

### Supply and Demand

Based on our combined criteria, including number of transplants per capita and number of procurement per capita, we produced a world map of the balance between supply and demand of CT, highlighting dramatic inequality ([Figure 2](#)). At least 53.3% of the world's population had practically no access to CT, while 35.7% had satisfactory access ([Table 2](#)).

## Discussion

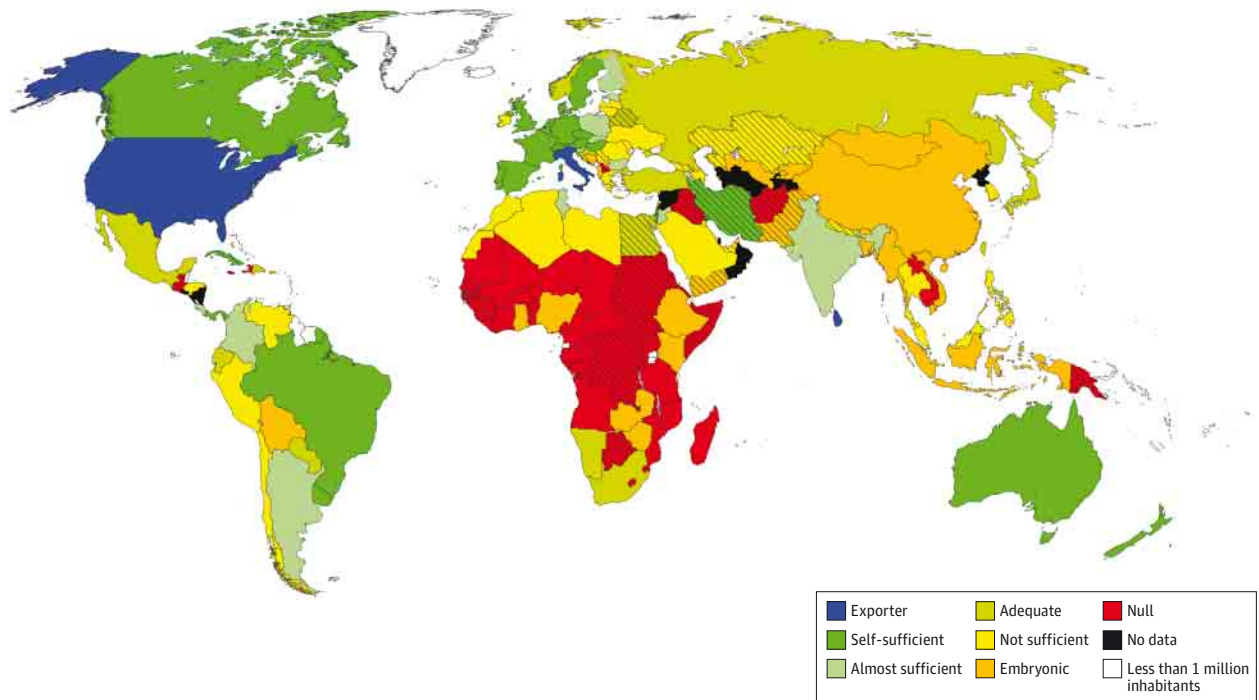
Our survey provides a global measurement, country by country, of the imbalance between corneal blindness and access to transplantation. The methods, combining documentary analysis and interviews with relevant professionals, enabled 95% coverage of the world's population. We reasonably consider that the remaining 5% would not have significantly affected the results. The survey found that one-third of humans have satisfactory access to CT, while more than half have no access. There is an overall mismatch between the number of people benefiting from and those waiting for CT, with a ratio of approximately 1:70.

The major strength of our study was comprehensive data from 95% of the world's population. Because of the absence of official statistics in most countries, we sought information from redundant sources among EB and CT professionals. By strictly grading source quality, we estimate that we obtained reliable data for more than 95% of procured and grafted corneas.

The main weakness of this data set was the absence of independent controls of the individual statements. We tried to minimize this bias by interviewing, in most cases, at least 2 people from different institutions. However, as a precaution



Figure 2. World Map Showing the Supply and Demand of Corneal Transplantation of 148 Countries



The term “embryonic” indicates that an activity does exist, revealing that there is a will to perform corneal graft and at least a small facility to store corneas, but that the number of grafts performed is extremely limited to a few cases. Hatched bars indicate countries for which we deemed the data of questionable

robustness. The boundaries shown on this map do not imply any opinion by the authors regarding the legal status of any country or territory or its authorities or regarding the delimitation of frontiers or boundaries.

Table 2. Balance Between Supply and Demand in the 157 Countries With More Than 1 Million Inhabitants

Categories of Corneal Transplantation/ Corneal Procurement Balance <sup>a</sup>	No.	Inhabitants, Millions	Surveyed Population, %
Embryonic <sup>b</sup>	22	2458.5	36.1
Almost sufficient	14	1322.0	19.4
Self-sufficient	22	709.1	11.3
Adequate	15	674.5	9.9
Not sufficient	28	586.7	8.6
Null	44	585.7	8.6
Exporters	3	399.0	5.9
No data available	9	76.4	1.1
Total	157	6811.9	100

<sup>a</sup>Categories are listed in descending order of the number of people affected.

<sup>b</sup>The term “embryonic” indicates that an activity does exist, revealing that there is a will to perform corneal graft and at least a small facility to store corneas, but that the number of grafts performed is extremely limited to a few cases.

when necessary, we indicated our persistent doubts in the figures (yellow bars and hatched bars). Furthermore, we did not cross-check documents not written in English, German, Chinese, French, or Arabic.

In addition, in an unplanned occurrence, for each country with a deficit, we were unable to explore whether a cornea shortage was the only constraint. Other factors to con-

sider are the number and training of ophthalmologists and the infrastructure required to store and inspect transplant tissues and to perform surgery.

We estimated global CT demand at 12.7 million. This number is conservative, given that the data were based partly on local waiting lists from eye hospitals, and in some cases only bilateral blindness was reported. Populations in remote rural areas with poor access to eye care were probably underestimated in these statistics, while being at an even higher risk of traumatic and infectious corneal scars<sup>6</sup> (see the eDiscussion in the Supplement for further analysis of the indications worldwide). Our data are consistent with the corneal blindness qualitative estimate given by Oliva et al<sup>7</sup> in 2012. Beyond this global perspective of corneal blindness, our survey evaluated each country based on its own epidemiology. Indeed, corneal blindness varies worldwide<sup>8-10</sup> because of several factors: country’s health and economic status, demographics, and environmental and geographic conditions.

We identified about 185 000 CTs in 2012, the highest number ever reported. Previous articles gave global estimates of annual CT activity ranging from 100 000 to 150 000,<sup>7</sup> but these data were extrapolated from the European Eye Bank Association and Eye Bank Association of America annual reports.

The CT rate per capita varies considerably. Only the United States, with 199.10<sup>-6</sup> CTs per capita, stands out, even from countries with similar living standards and demographics (Netherlands 88.10<sup>-6</sup>, United Kingdom 61.10<sup>-6</sup>, and France

59.10<sup>-6</sup>). This rate probably reflects the United States' ability to offer corneal transplants at earlier stages of corneal diseases. The country is also the leading developer of surgical techniques for endothelial lamellar grafts that minimize surgical risk and enable patients to be operated on earlier than with penetrating keratoplasty.

In developed countries with high-quality health care facilities and an efficient eye-banking framework, annual rates of keratoplasty per capita were comparable: 77.7, 59.2, 54.0, 65.8, 78.3, and 61.3.10<sup>-6</sup> for Singapore, France, Germany, Australia, Italy, and the United Kingdom, respectively. This gives a predictable range of 55 to 75.10<sup>-6</sup> CTs per capita annually for an affluent country. This figure may be useful for planning the optimum activity of each bank in a national network.

Special attention should be paid to successful developing countries, and their strategies must be analyzed and shared. One example is Brazil, where 14 000 CTs were performed annually, using only nationally procured corneas and with a 6-month average wait. Population awareness and donation commitment have been promoted by national advertising campaigns to positive effect, as illustrated in a recent article on the causes of nonfulfillment of corneal donation,<sup>11</sup> where the family-refusal rate was only 2%. Another example is Sri Lanka, famous for its people's prodonation dynamism, where 50% of collected corneas were exported. To tap Sri Lanka's uniquely high donation rate, Singapore has opened a new state-of-the-art eye bank in Colombo.<sup>12</sup> Lastly, in several countries (Tunisia, Lebanon, and Egypt), CT rates were significantly higher

than their main regional neighbors, possibly because of a high share of medical tourism. Most CTs there are done with corneas imported from the United States.

We identified about 284 000 procured corneas. The 100 000 nontransplanted corneas (35%) reflect how tissues are selected by EBs (see the eDiscussion in the Supplement for further analysis of the graft section in EBs).

The United States and Sri Lanka, the only countries where exporting corneas is an objective in itself, account for 94% of all exported corneas worldwide.

As already described for organs and other tissues,<sup>13</sup> religious beliefs seem to influence cornea donation, although we did not analyze confounding socioeconomic and cultural factors. Lastly, as with organ donation,<sup>14</sup> an opt-out system promotes donation.

## Conclusions

In summary, we quantified globally and precisely the severe imbalance between CT supply and demand. This study can provide indicators for the future because global population growth (mainly in India, China, and Africa) will likely further aggravate this imbalance if new concepts for treating corneal-blinding disorders, of which CT is only the final event, do not emerge quickly enough. As highlighted by Moffatt et al,<sup>15</sup> new milestones in CT will be achieved through laboratory research, thanks to alternative solutions such as corneal bioengineering.

### ARTICLE INFORMATION

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**Study concept and design:** Gain.

**Acquisition, analysis, or interpretation of data:** All authors.

**Drafting of the manuscript:** Gain, Jullienne, He, Thuret.

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