



## ORIGINAL ARTICLE

# Use of an eligibility checklist on arrival of emergency room as a registry system for corneal donation—A 9-year retrospective cohort study

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**Abstract**

**Aim:** This study aimed to evaluate whether the use of an eligibility checklist uncovered potential corneal donors among deceased outpatients and increased the donation.

**Methods:** In this retrospective cohort study, we applied the eligibility checklist to nearly all outpatients (age  $\geq 18$  y/o) who were transferred to our emergency department and identified as deceased between 2012 and 2020. Whether the use of the checklist contributed to the increase in corneal donation was examined, and the reasons for refusal of the donation were also evaluated. Furthermore, yearly changes in the number of the donation were assessed, with the data obtained before initiation of the checklist in 2010–2011 as references. The primary outcome was the number of corneal donors, with yearly changes in donation numbers assessed using data from 2010 to 2011 as a reference before the checklist was introduced.

**Results:** Among 1776 outpatients to whom the eligibility checklist was applied, 1169 patients were regarded as potential donors. Of them, 126 families gave consent and 80 patients finally donated cornea; medical diseases as a cause of death were less likely to retract donation offer (OR = 0.31 [95% CI: 0.09–0.99]). The number of corneal donors in 2010–2011 corresponded to 1.6% of the deceased outpatients but increased since the checklist was introduced the total number of donors reached 87 (4.3%) during 2012–2020.

**Conclusion:** A routine use of the eligibility checklist at the initial interview will reinforce the awareness of corneal donation among the families of patients and contribute to the increased number of corneal donors.

**KEYWORDS**

checklist, corneal donation, emergency department, opt-in approach, transplantation

## INTRODUCTION

Corneal blindness constitutes a critical burden that causes personal disability, including impaired quality of life and psychological depression, and diminishes social activity.<sup>1,2</sup>

Among the worldwide population, corneal opacities account for approximately 4% of cases with blindness.<sup>3</sup> Although nearly 80% of all corneal blindness is preventable,<sup>4</sup> there exist many patients who have progressive course of corneal disease requiring corneal transplantation.

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Limited availability of corneal tissue constitutes a major problem for the therapeutic strategy of corneal blindness. In Japan, most of the health care providers have fewer opportunities for interviews to obtain information concerning the attitudes toward corneal donation and less time to discuss with the families of deceased patients because of an opt-in approach without legal requirement to check for the willingness of donation.

Since the enforcement of revised organ transplantation act in Japan in 2010, our hospital is struggling for improving transplant medicine, particularly corneal transplantation. We made up an eligibility checklist for screening potential corneal donors in 2012. In this study, we applied this checklist to almost all patients admitted to our emergency department during 2012 to 2020 and attempted to clarify whether this checklist contributed to the increase in the offer of corneal donation in comparison with the results obtained before 2012. Furthermore, we evaluated what factors were associated with the recruitment of corneal donation.

## METHODS

### Study information and patient evaluation

This retrospective cohort study was conducted at St. Marianna University Yokohama Seibu Hospital and used the STRENGTHENING the Reporting of OBSERVATIONAL studies in Epidemiology (STROBE) guidelines. Information from medical records was anonymized prior to final analyses.

The primary outcome measure of this study was the number of corneal donors during the period when the

eligibility checklist (Table 1) was used. The eligibility for corneal donation was evaluated in nearly all outpatients who were aged 18 or over and were identified as deceased in our emergency department between October 2012 and May 2020; the patients hospitalized via our emergency room were not enrolled. The doctors had in-depth interviews with the families of the patients for potential donation of corneal graft (Step 1, Figure 1), using the eligibility checklist. The interviews covered the exclusion of medical/social contraindications to corneal donation (Step 2) and the recognition of awareness and attitudes of patients' families toward corneal donation (Step 3). All medical staff was urged to follow these procedures to minimize the number of the families uninformed of the eligibility for corneal donation. If the families refused corneal donation, factors (e.g., age, gender, and causes of death) that affected their decision were assessed.

In case there is a request from the patient's family to meet with the coordinators, we contact our university's transplant support service (TSS) team,<sup>5</sup> and the TSS team requests out-of-hospital eye bank coordinators to cooperate with our team in managing the procedures, including the preparation of a consent form, the assessment of families' attitudes toward corneal donation, and the arrangement of the extraction and the transplant team (Step 4, Figure 1). If the bereaved refused corneal donation, the factors for the refusal were obtained (e.g., age, gender, causes of death, location of events, do-not-attempt-resuscitation (DNAR) order, brain CT evaluation, transfer to police station, and patients' own willingness of donation).

### Annual number of corneal donors

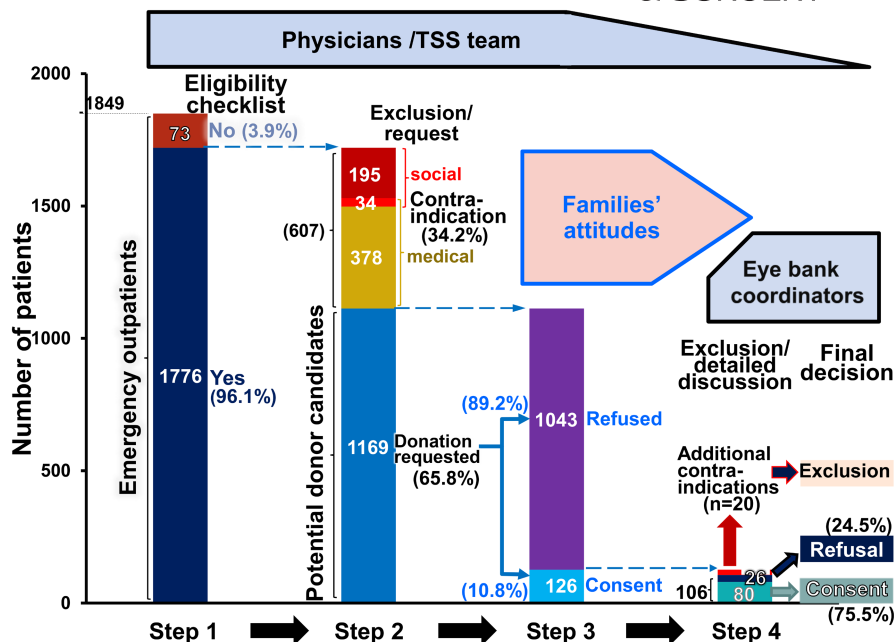
Yearly changes in the number of outpatients deceased between January 2010 and May 2020 were evaluated, and the ratios of those who performed corneal donation versus deceased outpatients were estimated. Furthermore, the ratios of the number of corneal donors in our hospital versus in Japan were calculated. Because the use of the eligibility checklist was started in 2012, the results obtained in 2010–2011 were deemed as references. The number of corneal donors per year at our facility and in Japan was obtained from our hospital database and the report of Japan Eye Bank Association ([www.j-eyebank.or.jp/pdf/2021statistic.pdf](http://www.j-eyebank.or.jp/pdf/2021statistic.pdf)), respectively.

### Data analysis

Results of continuous variables are expressed as the median [interquartile range; IQR]. Categorical variables are presented as the number (%). The Mann–Whitney *U* test or the Kruskal–Wallis test was used for comparison between two groups or among three groups, respectively. The chi-square test or Fisher's exact test was applied for analysis of categorical variables. Yearly number of donors among deceased outpatients was compared with the data acquired prior to the use

**TABLE 1** Eligibility checklist for corneal donation.

A. Eligibility for corneal donation		(1) Yes (2) No
If “no”, fill out the following checklist		
• Medical contraindications	• Social contraindications	
<input type="checkbox"/> Unknown cause of death	<input type="checkbox"/> Cannot deny criminal cases	
<input type="checkbox"/> Drowning	<input type="checkbox"/> Cannot procure cornea within 12h	
<input type="checkbox"/> Corneal opacity/ injury	<input type="checkbox"/> Unidentified body	
<input type="checkbox"/> Hematologic malignancies	<input type="checkbox"/> No next-of-kin	
<input type="checkbox"/> Infection (HBV, HCV, HTLV-1)	<input type="checkbox"/> Families cannot make decision	
<input type="checkbox"/> Severe infection	<input type="checkbox"/> Psychological problems (severe dementia, etc.)	
<input type="checkbox"/> Others ()	<input type="checkbox"/> Others ()	
B. Do doctors provide all available information on corneal transplantation and confirm whether or not corneal donation is offered?		
(1) Yes		
(2) No (describe the reasons)		
C. Willing to donate corneal tissue?	(1) Yes (2) No	



**FIGURE 1** Use of an eligibility checklist and changes in the number of patients at each step. Upon admission to our emergency department, physicians used an eligibility checklist (Step 1) and excluded medical and/or social contraindications (Step 2). The physicians then requested corneal donation to the remaining 1169 patients and obtained consent from 126 families of the patients (Step 3). Both physicians and out-of-hospital eye bank coordinators discussed with the bereaved the donation offer and 26 families retracted it (Step 4). Finally, 80 patients performed corneal donation.

of the eligibility checklist in 2010–2011. Similarly, changes in the ratios of the number of donors in our facility versus total donors in Japan were assessed, using the data obtained in 2010–2011 as references. Odds ratios (OR) for consent or refusal of corneal donation in association with various variables were calculated, using the univariable logistic regression analysis. Statistical analyses were performed using JMP Pro (v.16, SAS Institute Inc., Cary, NC, USA), and the level of significance was set at  $p < 0.05$ .

## RESULTS

### Outpatient evaluation

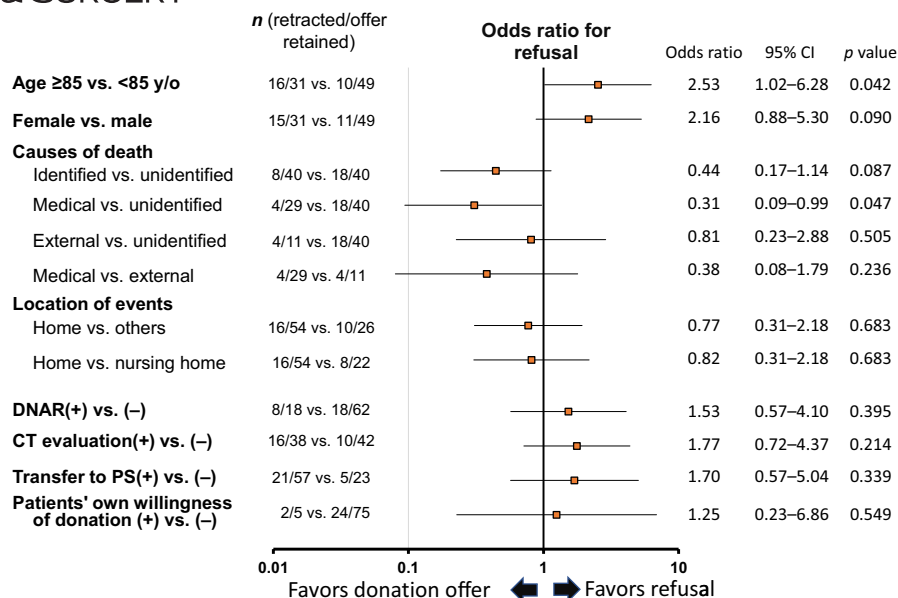
Among the outpatients who had been transported to our emergency department, 1849 patients were identified as deceased by our physicians. Then, they evaluated the eligibility for corneal donation among 96.1% of the patients (1776/1849), using an eligibility checklist (Step 1, Figure 1), and recognized that one-third of the patients (607/1849) were excluded because of medical or social contraindications (Step 2, Figure 1, Table S1). We thus considered 1169 patients as potential candidates for corneal donation (Step 2, Figure 1), corresponding to 65.8% of the emergency outpatients evaluated using the checklist.

We requested 1169 families of the deceased patients for corneal donation, and 126 families (10.8%) expressed interview request (Step 3, Figure 1). When dichotomized by age 85 y/o, the bereaved of the patients aged 85 y/o or older were more likely to give consent for corneal donation than

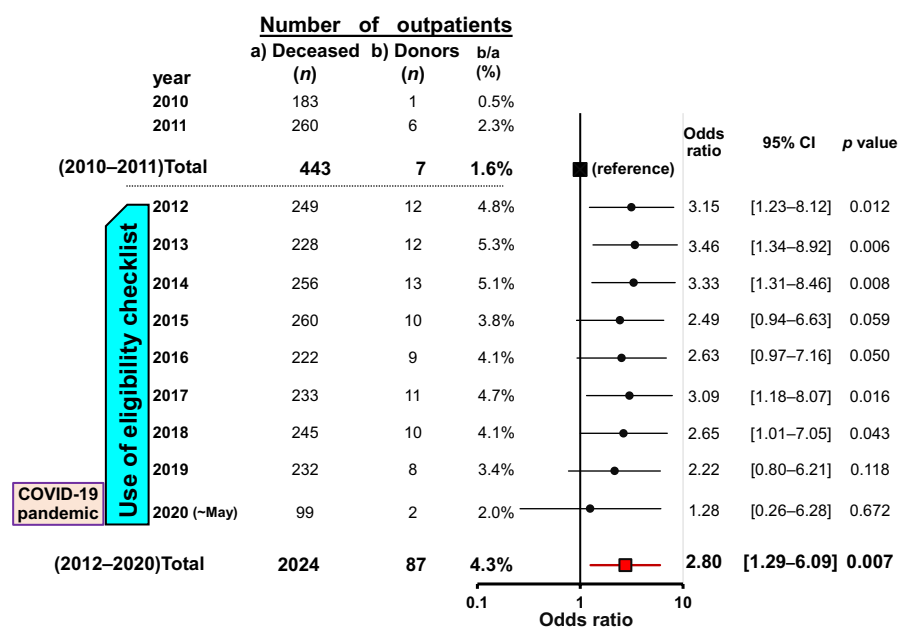
those aged <85 y/o (OR = 1.45 [95% CI: 1.00–2.11],  $p = 0.050$ , Table S2).

We then proceeded to a next evaluation step (Step 4, Figure 1), which resulted in the detection of additional contraindication cases ( $n = 20$ ), including body donation ( $n = 2$ ), autopsy cases ( $n = 5$ ), infection ( $n = 3$ ), and beyond the time limit for corneal procurement ( $n = 3$ ). Among the remaining 106 patients (age; 83.5 [IQR: 75.0–89.8] y/o, male/female; 60/46), 26 families (24.5%) of the patients retracted their consent; 10 families refused the donation because of “lengthy time to harvest cornea.” Ultimately, corneal donation was performed in 80 patients, that is, 6.8% of the potential donor candidates.

Figure 2 characterizes 80 patients who retained the offer of corneal donation and 26 patients who finally withdrew it. The patients who retracted donation offer were older than those in whom corneal donation was performed (87.5 [IQR: 81.3–92.8] vs. 82.5 [IQR: 72.8–87.3] y/o,  $p = 0.009$ ). The patient population aged 85 y/o or older was more likely to withdraw the donation offer than that aged <85 y/o ( $p = 0.042$ ), and females tended to predominate among the patients who retracted the donation offer ( $p = 0.09$ ). The patients with diagnosed (i.e., identified) disorders as a cause of death tended to be more likely to retain donation offer than those with unidentified causes (OR = 0.44 [95% CI: 0.17–1.14],  $p = 0.087$ ), and this trend was particularly conspicuous among the patients with medical causes (vs. unidentified; OR = 0.31 [95% CI: 0.09–0.99],  $p = 0.047$ ). Neither DNAR orders nor transfer to police station for autopsy had significant impact on the option for corneal donation. Although seven patients had their own willingness of donation in their lifetime, two



**FIGURE 2** Factors affecting the retraction of offer of corneal donation at Step 4. DNAR, do-not-attempt-resuscitation; Identified, caused by medical disease or external incidents; PS, police station; unidentified, caused by unidentified disease or incidents.



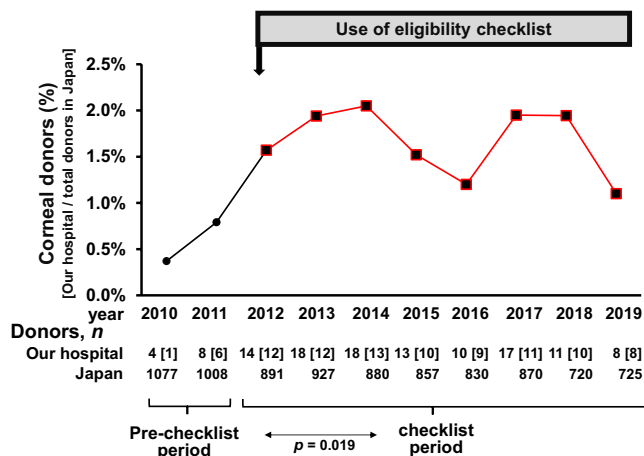
**FIGURE 3** Annual number of corneal donors in our emergency department. The number of deceased outpatients in our emergency department reached 233 [IQR: 225–253] per year during the observational period, and the rate of corneal donors among the outpatients was elevated in 2012 and thereafter. An odds ratio for corneal donors versus non-donors in each year was calculated, with the data in 2010 and 2011 as references.

families of the patients finally refused the implementation of harvesting corneas.

### Annual changes in number of corneal donors

Whether the eligibility checklist contributed to the increase in corneal donation in our hospital was assessed during the period of 2010 to 2020. The mortality observed in our

outpatient emergency department during 2010 and 2011 was 443, among whom seven patients (1.6%) performed corneal donation (Figure 3). Using these data as references, the annual number of corneal donors was evaluated over the period of 2012 to 2020. After the checklist was started, the number of donors increased to 12 cases in 2013 (5.3% of the deceased, OR = 3.46 [95% CI: 1.34–8.92]) and this trend was sustained thereafter, except in 2020. The total number of donors during 2012 to 2020 reached 87 (4.3%), with the OR for donation



**FIGURE 4** Changes in the number of corneal donors in our hospital and total donors in Japan. The proportion of the number of donors in our hospital versus all donors in Japan was significantly elevated in 2012 and thereafter. Repeated measures analysis of variance (ANOVA) was applied to compare the number of donors during the pre-checklist period (2010–2011) with that during 2012–2019. The data in brackets indicate the number of outpatient donors in our hospital.

of 2.80 [95% CI: 1.29–6.09] compared with that prior to the use of the checklist ( $p=0.007$ ).

We further assessed yearly changes in the number of corneal donors in our hospital between 2010 and 2019 and compared our results with the data reported by Japan Eye Bank Association. The corneal donors in our hospital increased since the checklist was started (Figure 4); the number of donors in our hospital corresponded to 0.37%–0.79% of the total corneal donors in Japan in 2010–2011, but tripled in 2013 (1.94%) and was further elevated to 2.1% in 2014.

## DISCUSSION

We have introduced into our emergency care a novel evaluation approach (i.e., an eligibility checklist, Table 1) that could facilitate the enrollment of outpatients as candidates for corneal donation. This system was created to raise physicians' and bereaved families' awareness of corneal donation, to know the attitudes of the bereaved toward corneal donation, and to maximize the baseline number of patients eligible for the donation. Thus, we interviewed almost all the families of patients using this checklist, and the families responded to our queries whether our staff provided information on corneal transplantation, whether the patients were eligible for corneal donation, and whether the families were willing to donate cornea (Figure 1). The awareness of corneal donation is heightened among the bereaved families in our hospital, even compared with that in other hospitals worldwide.<sup>6,7</sup> Because of the benefit acquired from of this study, we are collaborating with the Vision and Health Foundation (Shinjuku, Tokyo) to operate the system in such a way as to confirm the attitudes of the bereaved toward corneal donation, with the

policy of conducting a hospital-wide evaluation using this checklist, not only in the emergency department. This study report is the first to demonstrate the effectiveness of this system. Of note, Sasaki et al.<sup>5</sup> showed that the routine referral of corneal donation to the families of the patients who died of urological or other cancers increased the opportunities for the donation. Hence, our routine referral of corneal donation, using the eligibility checklist, may expand the opportunity to appraise the eligibility.

In the present study, we found that among the population to whom physicians proposed corneal donation, only 10.8% of the families accepted this proposition (Figure 1). This rate is lower than that reported previously in many studies from other countries.<sup>7,8</sup> However, corneal donors increased threefold during the 9-year period compared to the period before using the checklist (Figure 3). The bereaved are required to decide whether cornea should be donated under the circumstance where they can hardly accept the death of the family member. Nevertheless, the fact that 10.8% of the families agree to the donation is noteworthy, and expanding the background population who are given the information on the donation would contribute to the increase in donation.

Strategic approaches to corneal donation among emergency outpatients and comprehensive survey of potential donors may increase the opportunity for the donation. In our hospital, we performed a small number of corneal donations before initiation of the eligibility checklist (i.e., 2010–2011, Figure 4). Since the introduction of this check system and its influence on hospital staff, corneal donations increased more than threefold per year. Because most of the corneal donors in our hospital were outpatients (66.7%–100%), the use of our checklist is likely to be responsible for the increased contribution to corneal donation in Japan. These findings may be relevant to the report showing that a higher interview rate is associated with the increasing number of corneal donors.<sup>9</sup> It appears obvious, therefore, that providing the information constitutes a critical determinant of recruiting corneal donors.<sup>8,10</sup>

Of note, one of the reasons why the bereaved refuse corneal donation is the “lengthy time for harvesting corneas.” This supposition, however, appears misleading because of the time between death confirmation.<sup>11</sup> Our TSS team cooperates as closely as possible with police authorities in autopsy to minimize the additional time for donating corneas and the hospital stay, which could contribute to the increase in corneal donation.

This study shows that 24.5% of the families retracted the offer of corneal donation though they initially gave consent (Step 4, Figure 1). Among them, elderly and females were associated with the retraction of the donation (Figure 2). Inferentially, the bereaved are concerned about “disfigured face” due to removal of eyeballs entailed by corneal procurement.<sup>8</sup> Alternatively, some of the bereaved do not wish any further physical burden on their super-elderly loved one. In contrast, the bereaved were less likely to retract the donation offer when the cause of death was identified, particularly as medical causes. Under the circumstance where the bereaved



have limited time to accept patient's death, the clarification of the cause of death may serve as valuable information in deciding corneal donation. Finally, among 26 patients who had expressed DNAR, 18 patients offered corneas. Hence, DNAR does not necessarily indicate the renunciation of the donation procedure but presenting the patients' families with the option of donation appears important at death confirmation, which may alter the families' attitudes toward donation.

## Limitations

Although we interviewed almost all families of deceased patients, using the checklist, the results were obtained in a single hospital. Furthermore, as a screening process for corneal donation, we check twice for contraindications (Steps 2 and 4, Figure 1) that might be identified during the procedure. This process appears different from that implemented in the nations where TSS or family-support teams actively participate in the management of critical care and donation process from the early step.<sup>12</sup> Alternatively, our dual check procedure may help the bereaved verify their attitudes toward donation, which could avoid family disagreement and minimize the potential risk for legal issues.

Refusal of donation constitutes a critical determinant of successful transplantation medicine. We attempted to clarify what factors affected donation process but used univariable, but not multivariable, regression analysis due to the small number of patients in a single hospital. More extensive studies collaborating with other facilities will detail the factors favoring or disfavoring corneal donation.

Finally, this study was performed between 2010 and 2020, during which the revised organ transplantation act was enforced. Hence, the long-term nature of this study and the dissemination of the knowledge on this law may affect the number of outpatients and social attitudes toward donation. Prospective studies will be required to clarify our current issue.

## CONCLUSION

The present study demonstrates that a routine use of the eligibility checklist at the initial interview raises the awareness of corneal donation among hospital staff and the general public, whereby almost all patients are evaluated. Such a simple tool but closely associated with fundamental communications between hospital staff and the bereaved may contribute to the increase in corneal donors and could alleviate the gap between supplies and needs of donor corneas, particularly in the countries where opt-in consent policies for organ donation prevail.

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## CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

## DATA AVAILABILITY STATEMENT

Data are available on reasonable request. Raw data supporting the findings of this study are available from the corresponding author on reasonable request.

## ETHICS STATEMENT

Approval of the research protocol: The study was approved by the Institutional Review Board and Ethics Committee of St. Marianna University School of Medicine and was conducted in accordance with the Declaration of Helsinki.

Informed consent: The requirement for informed consent was waived because of the retrospective nature of this study (institutional approval No. 2615). The opt-out information was provided in our university website (<https://www.marianna-u.ac.jp/houjin/disclosure/clinical-research/marianna/file/optout/2615.pdf>).

Registry and registration no. of the study /trial: The study was registered at UMIN (UMIN000048919).

Animal studies: N/A.

Consent for publication: N/A.

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## REFERENCES

- Haymes SA, Johnston AW, Heyes AD. Relationship between vision impairment and ability to perform activities of daily living. *Ophthalmic Physiol Opt.* 2002;22:79–91.
- Van der Aa HP, Comijs HC, Penninx BW, van Rens GH, van Nispen RM. Major depression and anxiety disorders in visually impaired older adults. *Invest Ophthalmol Vis Sci.* 2015;56:849–54.
- Pascolini D, Mariotti SP. Global estimates of visual impairment. *Br J Ophthalmol.* 2012;96:614–8.
- Lamm V, Hara H, Mammen A, Dhaliwal D, Cooper DK. Corneal blindness and xenotransplantation. *Xenotransplantation.* 2014;21:99–114.
- Sasaki H, Nakamura H, Ono H, Yoshino S, Sakurai Y, Yoza N, et al. Routine referral by urologists increase opportunities for corneal donation. *Transplant Proc.* 2018;50:2986–91.
- Muraine M. Logistic problems have a tendency to hinder cornea procurement. *Transplantation.* 2002;73:839–40.
- Williams AM, Muir KW. Awareness and attitudes toward corneal donation: challenges and opportunities. *Clin Ophthalmol.* 2018;12:1049–59.

8. Rock D, Wude J, Yoeruek E, Barts-Schmidt KU, Rock T. Evaluation of factors limiting corneal donation. *Transplantation*. 2016;21:701–7.
9. Nebiker M, Frueh BE, Tappeiner C. Impact of changing the recruitment and interview procedures for corneal donation on the consent rate at a university hospital in Switzerland. *Transpl Int*. 2018;31:1052–4.
10. Haddad MF, Khabour OF, Alzoubi KH, Bakkar MM. Public attitudes toward corneal donation in northern Jordan. *Clin Ophthalmol*. 2018;12:1973–80.
11. Abe T, Wakatake H, Kawanishi F, Ota N, Yoshino S, Takita M, et al. Does corneal donation affect the length of hospital stay after death? *Kanto J Jap Assoc Acute Med*. 2017;38:215–9. [in Japanese].
12. Davidson JE, Powers K, Hedayat KM, Tieszen M, Kon AA, Shepard E, et al. Clinical practice guidelines for support of the family in the patient-centered intensive care unit: American College of Critical Care Medicine Task Force 2004–2005. *Crit Care Med*. 2007;35:605–22.

## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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