

Impact of telephone consent and potential for eye donation in the UK: the Newcastle Eye Centre study

DSJ Ting¹, J Potts¹, M Jones², T Lawther¹,
 WJ Armitage^{2,3} and FC Figueiredo¹

Abstract

Aims To examine the impact of telephone consent introduced in 2007 on the eye donation rate and to report the changing trend and potential for improvement in eye donation in Newcastle upon Tyne, UK.

Methods Relevant data were retrospectively collected from the local eye retrieval database for two separate years, namely, 2006 (before the introduction of telephone consent) and 2010. All the hospitals within Newcastle were included in the study.

Results From 2006 to 2010, there was a 3.5-fold increase in eye donation from 32 (of 2479 deaths) to 111 donors per year (of 2213 deaths) in Newcastle ($P < 0.001$). Consent was obtained via face-to-face interview in all 32 (100%) and 59 (53.2%) donors in 2006 and 2010, respectively. Introduction of telephone consent increased the donation rate by an additional 88.1% (from 59 to 111 donors) in 2010 ($P < 0.001$). In addition, there was a significant increase in medical notes of the deceased being reviewed from 27.1% (671/2479 cases) in 2006 to 62.4% (1382/2213 cases) in 2010 ($P < 0.001$). Acceptance rate of eye donation was 45.7% (32/70) in 2006 and 49.6% (111/224) in 2010 ($P = 0.575$). Acceptance rate was positively associated with registration on organ donor register ($P < 0.001$) and telephone consent ($P < 0.001$), but not with age ($P = 0.883$), gender ($P = 0.234$), or location of death ($P = 0.984$) of the potential donors. **Conclusion** There has been a substantial improvement in eye donation rate in Newcastle over the recent years. Introduction of telephone consent and high-quality eye donation service serve as effective measures for increasing eye donation.

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Introduction

Shortage of donor corneas remains a problem in corneal transplantation worldwide, including the UK (http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report).¹ Gaum *et al*² estimated that 5000 corneas per year are required for transplantation in the UK; however, only ~3500 per year of corneal transplants were performed over the last decade, highlighting the continual significant shortage and need for improvement in eye donation.²

Organ and tissue donation is an extremely complex subject.^{3,4} Various factors have been implicated to influence the donation rate, including the presence of presumed consent system, level of public awareness and education, number of transplant programs or organisations available in the community, donor factors, next-of-kin factors, religious view, and others.^{4–10} Although presumed consent is not currently available in the UK (except Wales), it has been shown that presumed consent practice alone is not sufficient to resolve the shortage of organ and tissue donation.¹¹ Geissler *et al*¹² suggested that improved eye donation coordination network could enhance eye donation rate, including comprehensive review of all hospital deaths and use of a well-defined protocol. This highlights the importance of the availability and quality of eye donation and eye retrieval services (ie, coordination networking and clear protocol) in a particular region.

One of the major hurdles in tissue donation is the inability to meet the relatives of the deceased in person to obtain consent for donation. Muraine *et al*¹³ reported that 45% of the potential eye donors were lost purely due to the inability to meet the relatives of the deceased in person. To circumvent this particular problem, telephone consent has been introduced in several countries with reportedly great success.^{14,15}

¹Newcastle Eye Centre, Royal Victoria Infirmary, Newcastle University, Newcastle Upon Tyne, UK

²National Health Service Blood and Transplant, Bristol, UK

³School of Clinical Sciences, University of Bristol, Bristol, UK

Correspondence: DSJ Ting, Newcastle Eye Centre, Royal Victoria Infirmary, Newcastle University, Queen Victoria Road, Newcastle Upon Tyne NE1 4LP, UK
 Tel: +44 (0)19 1233 6161; Fax: +44 (0)19 1282 6269.
 E-mail: ting.darren@gmail.com

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In 2007, the Newcastle Eye Retrieval Scheme (NERS), which serves as 1 of the 10 eye retrieval schemes funded by the National Health Service Blood and Transplant (NHSBT) in the UK, introduced telephone consent with the aim of circumventing barriers of face-to-face consenting and consequently improving the eye donation rate in the North East of England, including Newcastle upon Tyne. The objectives of our study were threefold: first, to investigate the impact of introduction of telephone consent on eye donation in Newcastle; second, to describe the changing trend of eye donation from 2006 to 2010 in Newcastle; and finally, to identify potential areas for improvement in eye donation in Newcastle.

Materials and methods

Data pertaining to eye donors' demographic factors, eye donation sites, contraindications for eye donation, consent method, registered intent for donation, and types of donation in January–December 2006 and January–December 2010 were retrospectively collected from the local eye retrieval database (Newcastle Eye Centre, Royal Victoria Infirmary, Newcastle, UK). All the hospitals within Newcastle, including Royal Victoria Infirmary, Freeman Hospital, and Newcastle General Hospital, were included in our study. Our study did not require any ethical approval, but was conducted according to the principle of Declaration of Helsinki.

Process of eye donation and retrieval

All deaths were identified by two full-time eye donation specialist nurses (JP and TL) based in Newcastle Eye Centre. They were professionally trained by the NHSBT to approach and obtain consent for eye donation from relatives, and retrieve eyes from donors. During weekdays, they collected the details of all deceased individuals from the bereavement offices and mortuaries on a daily basis. Cases that anticipated death-to-enucleation interval exceeded the 24-h limit, termed as 'time constraint', were excluded as part of the NHSBT national eye retrieval protocol. Medical records of the remaining potentially suitable deceased were subsequently reviewed and those identified with medical contraindications were also excluded. Medical contraindications included central nervous system disorder, immunosuppression, infection, haematological malignancy, intrinsic eye disease, recent blood transfusion with >50% haemodilution, and previous transplantation.¹⁶ Families of suitable cases were subsequently approached and consented if willing to donate.

In 2006 (before the introduction of telephone consent), families of all suitable cases were only approached via face-to-face interview as per protocol at the time.

In 2010, families were approached via face-to-face interview initially. However, if face-to-face interview was not possible, telephone approach and consent would then be attempted through a standardised and validated procedure as per NHSBT protocol and in accordance with the Human Tissue Act (2004). Following consent, eyes were retrieved with minimal delay, collected and sent for processing in Manchester Eye Bank, which is part of the national Corneal Transplant Service of NHSBT.

Terminology

Acceptance rate refers to the number of families of medically suitable deceased patients agreeing to eye donation, divided by the number of families who were asked to donate. Missing records refers to the medical notes of the deceased that were not reviewed and recorded in the eye retrieval database.

Statistical analysis

The study period was divided into January–December 2006 (period 1) and January–December 2010 (period 2) for descriptive and analytical purposes in view of the introduction of telephone consent in 2007. Unpaired *t*-test was used to examine the difference between the means of two groups. Chi-squared test or Fisher's exact test (if any variable is ≤ 5) was used to examine the difference in the observed frequency of categorical variables. The level of significance was set at 5%.

Results

From 2006 to 2010, there was a significant increase in eye donation from 32 (out of 2479 death) to 111 donors (out of 2213 death) in Newcastle ($P < 0.001$). This was equivalent to a 3.5-fold increase in eye donation. The donors' demographic factors, sites of donation, registration on organ donor register (ODR), consent method, and types of donation in 2006 and 2010 are described in Table 1. There was a non-statistically significant increase in mean age from 67 (SD 19) years in 2006 to 73 (SD 15) years in 2010 ($P = 0.067$). Male preponderance was observed in both 2006 (66%) and 2010 (53%; $P = 0.211$).

Process of eye donation and acceptance rate

The schematic breakdown of the process of eye donation within Newcastle in 2006 and 2010 is depicted in Figure 1. In 2006, a total of 2479 deaths were recorded, with 671 (27%) cases being reviewed for suitability for eye donation. Of the 1808 non-reviewed cases, 572 (32%) and 1236 (68%) cases were due to time constraint and non-time constraint reasons, respectively (Table 2). Of the 671

Table 1 Demographic factors, donation sites, registered intent, and consent details of all eye donors in Newcastle in 2006 and 2010

	2006, n = 32 (%)	2010, n = 111 (%)	P-value
Age (years)	66.5 ± 19.0	72.7 ± 15.4	0.07
Gender			0.2
Male	21 (65.6)	59 (53.2)	
Female	11 (34.4)	52 (46.8)	
Department			<u>0.04^a</u>
A&E/MAU	0 (0.0)	14 (12.6)	
ICU/HDU/CCU	4 (12.5)	40 (36.0)	
General ward	16 (50.0)	57 (51.4)	
Unknown	12 (37.5)	0 (0.0)	
On organ donation register			0.7 ^a
Yes	9 (28.1)	38 (34.2)	
No	21 (65.6)	73 (65.8)	
Unknown	2 (6.3)	0 (0.0)	
Consent method			—
Face-to-face	32 (100.0)	59 (53.2)	
Telephone	0 (0.0)	52 (46.8)	
Consent for			<u>0.005</u>
Clinical only	5 (15.6)	6 (5.4)	
Research only	2 (6.3)	0 (0.0)	
Clinical and research	25 (78.1)	105 (94.6)	
Types of donation			0.09
Cornea only	23 (71.9)	96 (86.5)	
Cornea+tissue	5 (15.6)	5 (4.5)	
Cornea+organ	1 (3.1)	3 (2.7)	
Cornea+tissue+organ	3 (9.4)	7 (6.3)	

Abbreviations: A&E, Accident & Emergency; CCU, coronary care unit; HDU, high dependency unit; ICU, intensive care unit; MAU, medical assessment unit. Statistically significant results were underlined. ^aUnknown group was not included in the statistical analysis.

reviewed cases, 72 (11%) had no medical contraindication for eye donation. Relatives of the deceased were approached in 70 (97%) of the 72 suitable cases, with 2 (3%) remaining cases where the eye donation nurse could not meet the relatives. Consent was obtained in 32 cases, yielding an acceptance rate of 46%. ODR status was checked and documented in 33 (47%) of the approached cases, which 9 (27%) cases were on the registration (ODR-Yes) and 24 (73%) cases were not on the registration (ODR-No).

In comparison with 2006, 1382 (62%) out of 2213 death cases were reviewed in 2010, yielding an increase of 130% ($P < 0.001$). Of the 831 non-reviewed cases, 580 (70%) and 251 (30%) cases were due to time constraint and non-time constraint reasons, respectively (Table 2). Among the 1382 reviewed cases, 253 (18%) cases were suitable with no

medical contraindication for eye donation ($P < 0.001$). Relatives of the deceased were approached in 224 (89%) of the 253 suitable cases, which was less than the rate in 2006 ($P = 0.024$). The relatives of the deceased were not approached in the remaining 29 (11%) cases due to the inability to contact the relatives (24, 9%), inability to meet the relatives (2, 1%), and there being no relative to contact (3, 1%). Relatives were approached via face-to-face interview and telephone consent in 148 (66%) and 76 (34%) cases, respectively. Of all the approached cases 111 consented for donation, yielding an acceptance rate of 50%, which was similar to 2006 ($P = 0.575$). Although there was no significant increase in the acceptance rate from 2006 to 2010, there was a difference in the acceptance rate between face-to-face interview (40%, 59 out of 148) and telephone consent (68%, 52 out of 76) in 2010 ($P < 0.001$). In addition, the use of telephone consent increased the overall eye donation from 59 (ie, face-to-face interview only) to 111 donors, giving an additional 88% increase in donation rate ($P < 0.001$).

In comparison with 2006, the ODR status was checked and documented in 201 (90%) of 224 cases in 2010 ($P < 0.001$). These included 127 face-to-face interview cases and 74 telephone consent cases. Within the face-to-face interview group, 28 (22%) cases were ODR-Yes and 99 (78%) cases were ODR-No. Consent for donation was obtained in 23 (82%) ODR-Yes and 36 (36%) ODR-No cases. The proportion of ODR-Yes (17, 23%) and ODR-No (57, 77%) within the telephone consent group is similar to the face-to-face interview group ($P = 0.879$). Consent for donation was obtained in 15 (88%) ODR-Yes and 37 (65%) ODR-No cases.

A total of 599 (89%) and 1129 (82%) reviewed cases were excluded due to medical contraindications in 2006 and 2010, respectively ($P < 0.001$; Table 3). Central nervous system disorder, immunosuppression, and malignancy were the top three medical contraindications for eye donation in both 2006 and 2010.

Characteristics of donors and non-donors

In 2006 and 2010, there were a total of 143 donors and 151 non-donors. Non-donors refer to donors who were medically suitable for eye donation, but the family refused consent. The demographic factors, location of death, registration on ODR, and consent method of donors and non-donors are detailed in Table 4. The likelihood of eye donation was positively associated with registration on ODR ($P < 0.001$) and telephone consent ($P < 0.001$). The acceptance rate of eye donation was not influenced by the age ($P = 0.883$), gender ($P = 0.234$), and location of death ($P = 0.984$) of the potential donors.

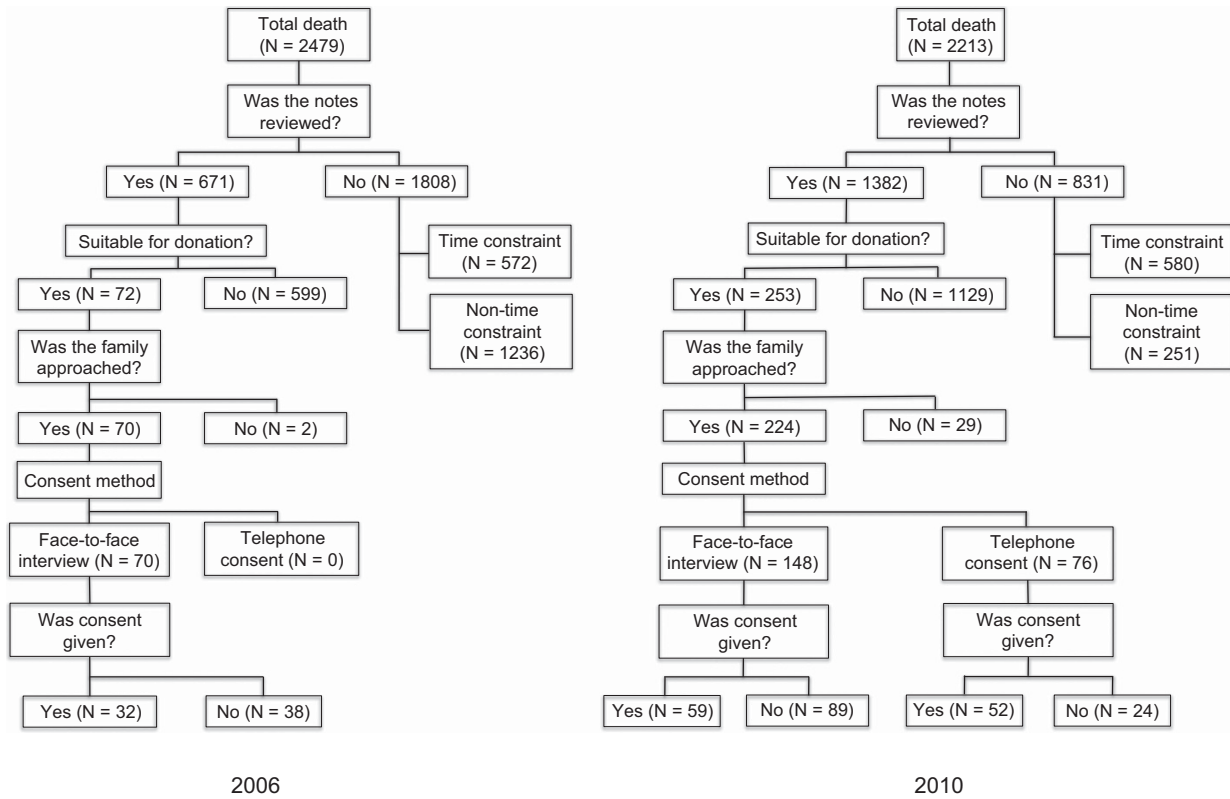


Figure 1 The schematic breakdown of the process of eye donation in Newcastle in 2006 and 2010.

Table 2 Breakdown of reasons for cases not being reviewed for suitability for eye donation in Newcastle in 2006 and 2010

Reasons for cases not being reviewed	2006, n = 1808 (%)	2010, n = 831 (%)
Time constraint (weekend)	422 (23.3)	443 (53.3)
Time constraint (weekday)	150 (8.3)	137 (16.5)
No referral appointment	1 (0.1)	—
Unable to review notes	76 (4.2)	—
Missing records	1159 (64.1)	251 (30.2)

Discussion

To the best of our knowledge, this study represents the first detailed report examining the impact of telephone consent and describing the changing trend and potential for eye donation in the UK. We analysed the donors’ demographic factors, acceptance rate, impact of telephone consent, entire eye donation pathway, and most importantly, potential areas for improvement in eye donation in Newcastle.

Eye donation and potential for improvement

We observed a 3.5-fold increase in eye donation from 2006 (32 donors) to 2010 (111 donors) in Newcastle ($P < 0.001$).

Table 3 Breakdown of medical contraindications for eye donation in Newcastle in 2006 and 2010

Medical contraindications	2006, n = 599 (%)	2010, n = 1129 (%)
CNS disorder	213 (35.6)	360 (31.9)
Immunosuppression	67 (11.2)	220 (19.4)
Malignancy	40 (6.7)	125 (11.1)
Previous blood transfusion	27 (4.5)	4 (0.3)
Intrinsic eye disease	17 (2.8)	47 (4.2)
Previous transplantation	12 (2.0)	13 (1.2)
Infection	6 (1.0)	34 (3.0)
Others	217 (36.2)	326 (28.9)

Abbreviation: CNS, central nervous system.

Our data suggested that the increase in eye donation was predominantly attributed to three main factors, including more extensive screening of the medical notes of the deceased ($P < 0.001$), increase in suitability for eye donation in those reviewed cases ($P < 0.001$), and the introduction of telephone consent ($P < 0.001$).

There were several reasons for the lack of screening of the medical notes in 2006. The current NERS was first established in 2004 and the two eye donation specialist nurses (JP, TL) were appointed in 2005. Therefore, this

Table 4 Characteristics of all donors and non-donors in Newcastle in 2006 and 2010

	Donors, n = 143 (%)	Non-donors, n = 151 (%)	P-value
Age (years)	71.5 ± 16.4	71.2 ± 14.2	0.9
Gender			0.2
Male	80 (55.9)	74 (49.0)	
Female	63 (44.1)	77 (51.0)	
Department			0.98 ^a
A&E/MAU	14 (9.8)	18 (11.9)	
ICU/HDU/CCU	44 (30.8)	48 (31.8)	
General ward	73 (51.0)	84 (55.6)	
Unknown	12 (8.4)	1 (0.7)	
On ODR			<0.001 ^a
Yes	47 (32.9)	7 (4.6)	
No	94 (65.7)	86 (57.0)	
Unknown	2 (1.4)	58 (48.4)	
Consent method			<0.001
Face-to-face	91 (63.6)	127 (84.1)	
Telephone	52 (36.4)	24 (15.9)	

Abbreviations: A&E, Accident & Emergency; MAU, medical assessment unit; ICU, intensive care unit; HDU, high dependency unit; CCU, coronary care unit; ODR, organ donor register. Statistically significant results were underlined.^aUnknown group was not included in the statistical analysis.

scheme was still a relatively new initiative by 2006 (study period 1), with the setting up of the eye retrieval service and the NERS staff connections within the hospitals and facilities still in its infancy. Promotion and raising awareness of eye donation was featured highly on the agenda of this new initiative initially. As the experience increased, it was found that intensive screening of all the medical notes provided additional beneficial impact on eye donation. This was reflected by a significant increase in notes being reviewed from 27% of all death cases in 2006 to 62% of all death cases in 2010 ($P < 0.001$). Furthermore, communication and collaboration with the bereavement officers, mortuary staff, and transplant coordinators continued to strengthen as the experience increased. The increasing experience of the eye donation specialist nurses, the better communications among the health professionals in relation to eye donation, and more appropriate allocation of the resources (eg, focussing more on screening of medical notes) have led to a considerable increase in eye donation rate in 2010. Although there had been an increase in suitability of the reviewed cases, we believe this could be an anomalous observation because the exclusion criteria for eye donation did not change during the study period.

Our data in 2010 demonstrated that there was potential for further improvement in the eye donation rate in Newcastle. It was shown that 580 (26%) cases were

excluded due to time constraint, which commonly occurred outside normal working hours, including weekends, when there was no dedicated eye donation service. Therefore, potentially suitable donors were approached and referred to the National Referral Center (NHSBT) by the staff in wards, emergency department, and intensive care units. Furthermore, 251 (16%) of the medical notes were not reviewed and recorded on the eye retrieval database. This may be attributed to staff being on leave or having to carry out several activities simultaneously (eg, performing medical notes review, consenting for eye donation, and performing eye retrieval). In addition relatives were not approached in 29 (11%) suitable cases, with inability to contact the family being the main reason (24 cases). This issue could potentially be addressed with the help of the ward staff in obtaining the best contact telephone number (preferably mobile) of the relatives.

On the basis of the suitability for eye donation (18%) and the acceptance rate (50%) in 2010, these 860 non-reviewed/non-approached cases could potentially translate into an additional 77 eye donors. We aim to increase the eye donation rate by promoting the awareness and education of hospital staff regarding the need and potential benefits of eye donation and the existence of the local eye donation referral pathway. Future pilot studies may also help to elucidate the cost-effectiveness of increasing the total number of eye donation specialist nurses in improving the eye donation rate in our region.

Impact of telephone consent and the acceptance rate

Introduction of telephone consent was considered a significant initiative in an attempt to improve the eye donation rate in Newcastle. Our data in 2010 demonstrated that the introduction of telephone consent had increased the overall donation rate by 88%, almost doubling the overall donation rate in Newcastle. This underlines the positive impact of the introduction of telephone consent, which serves as the only means of contacting the families in many cases when there is a 24-h death-to-enucleation time constraint set out by the national eye retrieval protocol. Without telephone consent, 52 (47%) out of the 111 donors would have been excluded in 2010 in Newcastle. Similarly, Rodríguez-Villar *et al*¹⁴ and Gain *et al*¹⁵ demonstrated that telephone consent could potentially increase the overall eye donation rate by 37% and 90%, respectively.

Our study observed a similar acceptance rate in 2006 (46%) and 2010 (50%; $P = 0.575$). This is similar to the rate reported by Tandon *et al* (42%), but lower than that reported by Gain *et al* (67%) and Muraine *et al* (72%).^{9,15,17} Studies have shown that the face-to-face acceptance rate

could range between 42 and 82%,^{9,15,17} which is usually higher than the telephone consent acceptance rate.^{14,15} It is however interesting to note that the acceptance rate of telephone consent was higher (68%) than the conventional face-to-face interview method (40%) in our study, which is contrasted with the literature. One possible explanation was that the relatives of the deceased were provided with more time and flexibility to make the decision in their own familiarised environment during telephone consent. The face-to-face interview was usually carried out when the relatives of the deceased came to the hospital to collect the death certificate. Quite often they had not received any prior information regarding the eye donation, which could lead to an unexpected prolonged dialogue of this potentially distressing matter. Some of them might also feel pressurised to make the decision on the spot during the face-to-face interview. Rodrigue *et al*¹⁸ reported that families who felt to have sufficient time for discussion have a higher acceptance rate (59.8%) than those who felt pressurised (26.8%).

Besides telephone consent, the other factor that positively influenced the likelihood of eye donation was the registration on ODR ($P < 0.001$). Webb *et al*¹⁹ reported that 55% of the next of kin would consent for donation purely based on ODR registration alone and the rate increased to 87% if additional previous discussion of donation was held. Another study conducted in Australia similarly reported the positive association between consent for donation and registration on ODR or having knowledge on the deceased's wishes about organ donation.²⁰

We observed a significant increase in checking and documenting the ODR status from 2006 (47%) to 2010 (90%). The lack of data on the ODR status in 2006 could be attributed to several potential reasons. First, checking the ODR status was not part of the eye donation protocol previously. Second, some ODR status were checked but not documented in the database since consent for donation was refused (most of the cases with unknown ODR status were in the refused to consent group). Third, there might be insufficient awareness of the importance of ODR in influencing the success rate of consent for donation. With the growing evidence of the significance of ODR status and the change of eye donation protocol recently, it is now recommended that the ODR status be checked for all potential donors. In addition, age, gender, and location of death had no influence on the acceptance rate of eye donation in our study. Further investigation will be required to examine the actual reason for the refusal of eye donation and the potential benefits of more public awareness and education in order to enhance the acceptance rate in the future.

To result in a 'successful corneal transplantation', it requires a smooth transition of multiple steps during the

donation-transplantation pathway, starting from identifying the suitable donors, approaching the relatives of the donors, obtaining consent for eye donation, timely eye retrieval, processing of the donated corneas in the eye bank, excluding the unsuitable corneas after careful examination, and ultimately transplanting the donated corneas. Our current study focuses primarily on the impact of the telephone consent and the changing trend of eye donation in the Newcastle area. Examination of the suitability and the utilisation rate of the donated corneas is beyond the remit of this study; however, these aspects will be addressed in our following study, which focuses on the changing trend of eye retrieval pathway and the utilisation of the donated corneas in Newcastle area over the last decade.

In summary, our study highlights the changing trend and potential for improvement in the eye donation in Newcastle. Telephone consent and rigorous review of all the potential donors' medical notes serve as effective methods in improving eye donation rate.

Summary

What was known before

- Shortage of donor corneas remains a problem in corneal transplantation worldwide.
- Studies outside the UK demonstrated the effectiveness of telephone consent in increasing eye donation rate.

What this study adds

- Our study represents the first report describing the impact of telephone consent and the changing trend and potential for eye donation in the UK.
 - We observed a 3.5-fold increase in eye donation in Newcastle upon Tyne, UK.
 - Telephone consent provided an additional 88% increase in eye donation rate.
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Conflict of interest

The authors declare no conflict of interest.

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