

# IMPLEMENTATION OF CLINICAL GUIDELINES FOR REQUESTING FAMILY INFORMED CONSENT TO DECEASED ORGAN DONATION FOR TRANSPLANTATION: POSITIVE EFFECT ON CONSENT RATES

FRANCISCO CABALLERO<sup>1</sup>, JESÚS LEAL<sup>1</sup>, MIREIA PUIG<sup>1</sup>, ANA MANZANO<sup>2</sup>, JOSEP RIS<sup>3</sup>, SALVADOR BENITO<sup>1</sup>

<sup>1</sup> Department of Emergency Medicine and Transplant Coordination, Hospital de la Santa Creu i Sant Pau, Universitat Autònoma de Barcelona, Barcelona, Spain

<sup>2</sup> Center for Health, Technologies and Social Practice, University of Leeds, Leeds, UK  
Hospital de la Santa Creu i Sant Pau, Universitat Autònoma de Barcelona, Barcelona, Spain

<sup>3</sup> Medical Urgent Assistance Management, Hospital de la Santa Creu i Sant Pau. Universitat Autònoma de Barcelona

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**Summary** - This study aimed to analyse the effectiveness of implementation of a clinical guide for requesting family informed consent to deceased organ donation for transplantation at the Hospital de la Santa Creu i Sant Pau (HSCSP). From 1<sup>st</sup> January 2011 to 28<sup>th</sup> February 2013 there were 52 consecutive brain-dead patients at HSCSP. Fifty-two family interviews took place requesting organ donation for transplantation. In all cases experienced hospital transplant coordination staff performed the family interview. Transplant coordinator case reports are comprehensive records of clinical data and the process of requesting donation in every family interview. Quantitative descriptive analysis was used to describe the main features of the data. Free text items were analysed using content analysis focusing on contributing factors to consent/refusal for organ donation. A retrospective case note review (secondary analysis) was carried out for 52 referrals during this audit period. These were also compared with data from the period of 1994-2010 before the clinical guide was implemented. Percentage difference of family refusal before and after clinical guide implementation was used in the statistical analysis of data.

The percentage of family refusals before and after clinical guide implementation was 17.5% (95% confidence interval, 14.7 to 20.3) and 1.9% (95% confidence interval, 0.04 to 10.3), respectively, reaching statistical significance ( $p=0.001$ ). The implementation by experienced transplant coordination staff of a clinical guide for requesting family consent for deceased organ donation significantly increased consent rates.

## Introduction

Currently in Spain, the majority (around 90%) of transplantable organs are recovered from deceased donors,

mainly brain-dead donors (BDD). Despite current presumed consent (opt-out) legislation on organ donation for transplantation (1, 2), in practice, family consent is always requested before organ donation. This is an informed consent in writing and signed by at least one member of the donor's family. Family consent is a key factor in the process of the organ procurement for transplantation (3). Interviews with potential donor families are fundamental and they require careful planning, and a specific methodology. They must be performed by qualified and trained

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*Correspondence:* Francisco Caballero, M.D., Ph.D., Department of Emergency Medicine and Transplant Coordination, Hospital de la Santa Creu i Sant Pau, Avd. Sant Antoni Maria Claret 167, 08025 Barcelona, Spain; e-mail: fcaballero@santpau.cat

<b>BRAIN-DEAD DONOR-DEMOGRAPHICS AND EPIDEMIOLOGICAL DATA</b>	
Gender / Age (year) brain-dead patient:	Nationality :
Admission date:	
Brain death diagnosis (date):	
Causes of brain death (brain haemorrhage, anoxic brain injury, brain ischemia, traumatic brain injury, bacterial meningitis, brain abscess, primary brain tumour, cerebral oedema):	
Length of hospital stay (days):	
Coroner involvement (yes/no):	
<b>FAMILY INTERVIEW DATA</b>	
TCT member performing family interview (name):	
Interview setting (ICUs, HDU, PIC):	
Time of interview (morning, evening or night shift):	
Family representatives present in the interview (number):	
Referral's family-rural or urban origin:	
Family verbally consented to organ donation for transplantation to the physician in charge before the interview with the transplant coordinator (yes/no):	
Patient consented organ donation during lifetime (yes/no):	Donor card (yes/no):
The family respected the wishes of the patient during lifetime (yes/no):	
Donor had not expressed any preference for/against organ donation and it was the family who opted for donating the organs (yes/no):	
Adequate family satisfaction with hospital care (yes/no):	
Family member signing written informed consent to organ donation (immediate family: parent, spouse and progeny; or a second-degree relative: siblings, grandparents, grandchildren and brothers-in-law):	
Family member signing consent (gender/age):	
Start time and date of the interview:	End time and date of the interview:
Length of interview (minutes):	
Cremation or burial:	
Consent to organ donation (yes/no):	
Consent to organ donation (reasons: solidarity, reciprocity, coroner autopsy, patient consented during lifetime, socio-economic factors, religious beliefs, cremation, others):	
Actual organ donor (yes/no):	Organs generated :
Actual donor autopsy (yes-reasons/no):	
Initial family refusal (yes/no):	
Family refusal (reasons):	
Reversed refusal (yes/no):	
Family wishes to be informed (in writing) of organ transplantation follow-up (yes/no):	
Observations:	
<b>INTERVIEW SUMMARY</b>	

TABLE 1 - Family interview-related information. Transplant coordinator case reports (TCCR).

hospital staff from the transplant coordination team (TCT) and must never be improvised. Spanish medical schools do not teach specific skills for requesting organs from deceased patients and this is one of the reasons the transplant coordination department at the hospital de la Santa Creu i Sant Pau (HSCSP) in Barcelona (Spain) developed a family interview guide (FIG) for requesting informed consent to organ donation for transplantation (3). This FIG was de-

veloped in January 2011 by the head of the hospital TCT with more than 20 years' experience in requesting authorization from families for organ donation. The content of this FIG was published in 2012 by our research team in a previous issue of this journal (3). The guide was evaluated with AGREE II (Appraisal of Guidelines Research and Evaluation), a generic tool designed to help users and designers of clinical guidelines to assess their methodological

quality (4). FIG scored 71% in the AGREE II evaluation and it was recommended as a clinical guideline (3).

The aim of this study was to describe and analyse routinely collected local data on the process of requesting informed consent for organ donation after clinical guide implementation with 52 family interviews from 1<sup>st</sup> January 2011 to 28<sup>th</sup> February 2013 at HSCSP. Percentage family refusal before clinical guide implementation during 1994-2010 at HSCSP was also analysed retrospectively. Data for 715 referrals between 1<sup>st</sup> January 1994 and 31<sup>st</sup> December 2010 for requesting organ donation for transplantation were available for analysis. Percentage difference in family refusal before and after clinical guide implementation was used in data analysis.

## Materials and Methods

### Study design

Transplant coordinator case reports (TCCR) are comprehensive records of clinical data and the process of requesting consent to organ donation throughout TCT staff involvement (Table 1). No new data were collected and TCCR were the data source available. The record in every family interview is used and maintained by transplant coordination staff and it consists of both structured data (such as dates, integers and dichotomous items -yes/no-) and unstructured free text (including perception of family satisfaction with hospital care, reasons for consent/refusal, observations and interview summary).

Case reports contain data on the demographic case mix, interview setting, consent-related information, outcome, funeral arrangements for referrals to request the TCT for organ donation. Donor data are recorded by two trained hospital transplant coordinators according to precise rules and definitions, and are subject to local validation (head of TCT) before being pooled in the database.

In total, data for 52 referrals between 1<sup>st</sup> January 2011 and 28<sup>th</sup> February 2013 were available for analysis. A retrospective case note review was carried out. All brain-dead patients referred for requesting authorization from families for organ donation during the audit period were examined. The case mix was measured by age, sex, nationality, length of hospital stay, and critical care status (admission date, reason for brain death and brain death certified date). All interviews were performed by experienced TCT staff.

The interview setting was measured by: interview time and duration, location, professionals doing the interview, total number of interviews and number of family members attending the interview. Consent-related information was measured by whether the patient expressed views favourable to organ donation and if the patient held a donor card.

The referral's family-related information was measured by rural or urban origin, family member signing consent, level of family satisfaction with hospital care, spontaneous family consent to donation prior to referral, initial refusal to consent, reversed refusal, reasons for consent/refusal, family wishes to be informed (in writing) of organ transplantation outcomes. Funeral arrangements were measured by: coroner involvement, burial or cremation and funeral reimbursement.

### Statistical analysis

Outcome was measured by consent/refusal rates to organ donation. Free text items were analysed using content analysis focusing on contributing factors to consent/refusal for organ donation.

Quantitative descriptive analysis was used to describe the main features of the data. Statistical analysis was conducted using Microsoft Excel 2003. Family refusal percentage is the ratio of the number of refusal and total family interviews made to request consent to organ donation. Percentage family refusal before clinical guide implementation during 1994-2010 was also analyzed retrospectively. Data for 715 referrals between 1<sup>st</sup> January 1994 and 31<sup>st</sup> December 2010 for requesting organ donation for transplantation were available for analysis. The percentage difference in family refusal before and after clinical guide implementation (audit period) was used in the statistical analysis of data. Fisher's exact test was used in the analysis of contingency tables. A p value <0.05 was considered statistically significant. Ethical approval was not required.

## Results

From 1<sup>st</sup> January 2011 to 28<sup>th</sup> February 2013 there were 52 consecutive brain-dead patients at HSCSP and 52 family interviews for requesting organ donation for transplantation took place. This represents a 100% identification to referral target.

### Demographics and epidemiological data

The average age of the 52 brain-dead patients was 55.5±23.4 years (interval: 14 months-81 years of age), 18 (34.6%) were male and 34 (65.4%) were female; 90.4% (n=47) of the 52 brain-dead patients had Spanish nationality, and 9.6% (n=5) were foreigners from the following countries: Dominican Republic, Uruguay, Venezuela, Morocco and Romania. 98% of the potential donors with Spanish nationality consented to organ donation and 100% of the potential donors who had nationalities other than the Spanish consented to organ donation. Average length of hospital stay for all referrals was 4±7.2 days (interval: 0.2-41.3 days).

### Causes of brain death

Causes of brain death were: spontaneous intracranial haemorrhage (n=7; 51.9%), subarachnoid haemorrhage (n=1; 1.9%), anoxic brain injury (n=10; 19.2%), brain ischaemia (n=5; 9.6%), traumatic brain injury (n=7; 13.5%), bacterial meningitis (n=1; 1.9%), and bacterial brain abscess (n=1; 1.9%).

Brain death (BD) diagnosis was established in all cases following Spanish law on organ donation and transplantation (1, 2): clinical neurological criteria of BD and confirmatory tests of BD (electroencephalogram and/or transcranial Doppler ultrasonography).

### Coroner cases

The coroner was involved in ten of the 52 referrals (19.2%), seven died due to traumatic brain injury (two were caused by traffic accidents and five were not caused by traffic accident) and three died from anoxic brain injury due to drowning.

### Actual organ donors

Of the 52 referrals 48 (92.3%) were actual donors with attrition due to medical contraindications (n=3; 5.8%) and one family refusal (1.9%). The 48 actual donors generated 163 organs for transplantation: kidney (n=93), liver (n=35), heart (n=9), lung (n=21), pancreas (n=4) and small intestine (n=1). The average number of organs obtained per donor was 3.4. The number of multi-tissue donors was 29 (60.4%), including corneas, osteotendinous tissue, skin and cardiovascular tissue.

### Consent to organ donation

In the present study 51 out of 52 families consented to organ donation for transplantation: 98.1% consent rate. Reasons for donation were: solidarity (n=22; 43.1%); reciprocity (n=16; 31.4%); solidarity and coroner autopsy (n=6; 11.8%); patient consented during lifetime (n=5; 9.8%); and multiple reasons (socio-economic factors, coroner autopsy, religious beliefs, cremation and reciprocity) in two cases (3.9%). In 51 cases families provided written informed consent to organ donation. In 37 cases (72.5%), the consent form was signed by members of the immediate family (parent, spouse and progeny). In 14 cases (27.5%), consent was signed by a second-degree relative (siblings, grandparents, grandchildren and brothers-in-law).

### Family interview data

In all cases experienced TCT staff performed the interview. In four (7.7%) out of the 52 cases, families verbally consented to organ donation for transplantation to the physician in charge. A formal interview took place after these wishes were clearly expressed and written informed consent was granted.

### Time of the interview

In 28 cases (53.8%) the interviews took place in the morning (7am-2pm), 17 families (32.7%) were interviewed during the evening shift (2pm-9pm) and seven interviews (13.5%) took place during the night shift (9pm-7am).

The duration of the interviews ranged between five and 15 minutes in 23 cases (44.2%); between 20-30 minutes in 21 cases (40.4%); between 40-60 minutes in seven cases (13.5%) and in one case (1.9%) the family interview lasted 150 minutes. The overall average duration was 25 minutes (range: 5-150 min). In all cases consent was granted after one interview with the family.

### Interview setting

All family interviews took place in a private office routinely dedicated to communicate with families in the intensive care units (ICU). A total of 47 (90.4%) interviews were in a general ICU, two (3.8%) in high dependency units (HDU) located in the Emergency department and three (5.8%) were in paediatric intensive care (PIC).

### Number of people attending the interview

In 35 interviews (67.3%) the number of family representatives present in the interview was one to three, and in 16 interviews (30.8%) was between four and seven. In one case (1.9%), 16 relatives were present at the interview.

### Family satisfaction with hospital care

In 51 out of 52 cases (98.1%), the families scored an adequate satisfaction with the hospital care during their hospital stay. In one case (1.9%) the family was unsatisfied with the clinical information provided on admission, but not with the information received later on.

### Organ donation wishes

Five (10.4%) actual donors had expressed wishes to donate their organs when deceased and the families respected those wishes. One of these had a donor card, and another patient had been a bone marrow donor. In 43 cases (89.6%), the donors had not expressed any preference for/against organ donation and it was the family who opted for donating the organs.

Period, year	Family interview/ Family refusal (n)	Family refusal (%)	Percentage difference of family refusal, p value**
1994-2010	715 / 125	17.5%	0.001
2011-2013*	52 / 1	1.9%	

\*1<sup>st</sup> of January 2011 and the 28<sup>th</sup> of February 2013

\*\* Fisher's exact test

TABLE 2 - Family refusal percentage of organ donation for transplantation before and after clinical guide implementation at Hospital de la Santa Creu i Sant Pau.

### Cremation or burial

A total of 27 (52%) referrals were cremated and 25 (48%) were buried. There was no correlation between these choices and donation consent rates.

### Actual donor autopsy

In 11 (22.9%) out of the 48 actual donors, after consent for organ donation was granted the consent for an autopsy was requested. The 11 families (100%) consented to the autopsy which took place in the same hospital after organ recovery and before organ transplantation.

### Letter of appreciation

Sixteen (33.3%) of the 48 actual donor families opted to receive written information on the clinical follow-up of the transplant recipients. Approximately four weeks after the consent, a letter of appreciation is sent by a TCT member to donor families. This contains generic information about organs transplanted and their follow-up, while respecting the anonymity of the recipients.

### Family refusals

Four (80%) out of five initial verbal refusals to donate organs were converted into consent after the family interview. The only refusal that was not converted was from a patient who had formally expressed wishes not to donate organs and the family respected those wishes. Percentage of family refusal before and after clinical guide implementation was 17.5% (95% confidence interval, 14.7 to 20.3) and 1.9% (95% confidence interval, 0.04 to 10.3), respectively. This difference in family refusal before and after clinical guide implementation was statistically significant ( $p=0.001$ ) (Table 2).

## Discussion

Currently in Spain, despite a presumed consent (opt-out) system for donation and transplantation of organs from deceased patients, in practice family informed consent to donation is always obtained. This is formalized in writing and signed by at least one member of the donor's family. It is the family of the deceased patient that ultimately agrees freely and consciously whether to donate organs for transplantation (3, 5). In practice, the families of any potential organ donor must be consulted since they are the ones authorised to grant written consent. Solidarity (43.1%) and reciprocity (31.4%) were the main reasons for consenting to organ donation in the present study. 72.5% of the consent forms were signed by members of the immediate family.

In our view it is essential, a few hours before the interview, to obtain accurate information with the family on the

prognosis from the physician in charge of the patient. In addition, it is this physician who must discuss all concerns –mainly clinical concerns– with the family. A TCT member should be present during this information exchange but only as an observer because in some cases families inquire about organ donation at this initial point. Our results suggest that the physicians in charge of potential organ donors should limit their role to calling early and to referral to a professional from the TCT and working in the organ donation process under the direction of this transplant coordinator to perform the family interview and donation request (3).

The application of FIG in HSCSP for 26 months (1<sup>st</sup> January 2011-28<sup>th</sup> February 2013) has proven a success. This is evidenced by comparing the institutional result prior to FIG application during 1994-2010 when the rate of family refusal was 17.5% ( $n=715$ ). Family consent rates before implementation of this clinical guidance during 1994-2010 were 82.5% with 590 out of a total of 715 families agreeing to donate family member's organs for transplantation. This FIG has two main objectives: to increase donation consent rates and to maintain our excellent success rates in an efficient and sustainable manner. To achieve these objectives this guide will be subjected to a continuous improvement process.

One of the key aspects of FIG refers to the professionals responsible for conducting the family interview. Family interviews to request informed consent for organ donation should be held by skilled staff from the hospital TCT with successful expertise in requesting consent. This expertise must be evidenced with average consent and conversion from refusal to consent rates. In our study 80% of initial refusals ( $n=4$ ) were converted to donations. Our experience strongly indicates that the initial involvement of the family with a skilled professional from TCT was closely related to their final decision to donate. It is fundamental to have a transparent, respectful, empathetic and concise attitude towards the potential donor's family consent to organ donation for transplantation. Donation should be explained briefly and then it must be made clear that their deceased relative – naming him/her by their name – “can help others”. In our experience this simple message helps the majority of families to understand donation.

It is not recommended to extend the number and duration of the family interviews to more than one occasion. In this study, 100% of informed consent to donation was obtained after just one interview. As with other studies, we observed a correlation between initial family request for donation and consent to donate (6). In 84.6 % of our cases the interview did not last more than 30 minutes.

Often the position in favour of donation is immediate during the initial request. In exceptional cases the family may take longer than usual to take the final decision. In these

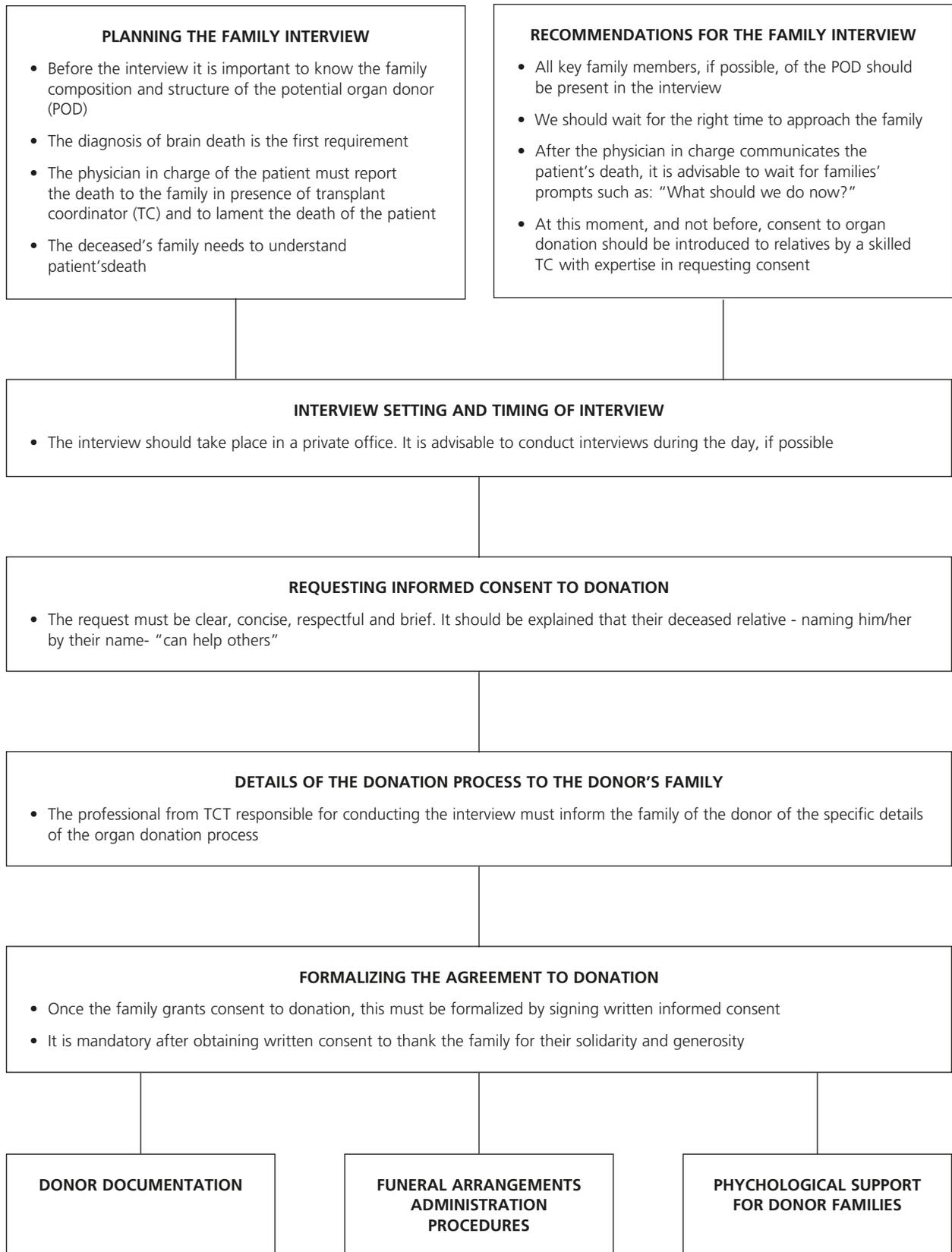


FIGURE 1 - Algorithm of the Family Interview Guide for requesting informed consent to deceased organ donation for transplantation at Hospital de la Santa Creu i Sant Pau.

cases, families must be allowed the necessary time to make their decision without feeling rushed. Often, after the initial interview, families may ask to be left alone to further discuss in private. At this point it is imperative that we leave the family alone and allow them time and space to make their decision, without feeling pressurised. It will need to be explained exactly where they may find us when they have made their decision or if they have any further questions about the donation process. Contact with the family should resume only at their request, not before. Clear communication is imperative to every aspect of the process in requesting authorization from families for organ donation.

The interview setting must always be taken into consideration. All interviews in the study took place in a private office located in the ICU. It is advisable to conduct interviews during the day and, if possible, to avoid interviews during the night to ensure families are able to rest. This would also facilitate logistics with transplantation teams if the donation takes place. In our study, 86.5% of the interviews took place during the morning and/or evening shift. This allowed for the majority of organ recovery to occur during the evening shift and the majority of the organ transplantations to be performed during the evening and/or night shift (between 9pm-12pm).

The solidarity and generosity of the donor families must be always acknowledged. There are, however, two interesting observations from the families' attitudes to donation. The first is that families tend to respect patients' expressed wishes whether they are favourable or unfavourable to donation and contravening patient's wishes only occurs exceptionally. In our study 10.4% of actual donors had expressed favourable views to donation and their families respected those views. The second observation is that the majority of deceased patients had not expressed their views about donation to their relatives (89.6% of our cases) and their families decided to donate their organs for transplantation. Generally, families respect patients' wishes if these are explicit and when these are unknown, their decision is unanimous (n=52; 100%).

There are two significant factors in consent to organ donation. The first factor is the expressed will of the deceased in favour of donation. If the deceased did not express donation views to his/her family, satisfaction with hospital care is a second fundamental factor. The higher levels of perceived hospital care, the higher the rates of consent. If the family experience of medical and institutional treatment during admission is satisfactory, families usually consent to donation. This was the case in 98% of our cases. Other authors have documented other factors (socioeconomic, ethical, ethnicity, etc.) that may influence family consent to donation of organs and tissues for transplantation (6-16). Our data showed no significant difference in donation rates between Spanish nationals and migrants.

In HSCSP, the most frequent reason for families refusing

consent is to support their relative's expressed wish not to donate their organs for transplantation. This was the case in the only family refusal recorded in the period of this present study. Some authors have reported a relationship between interview skills when communicating death (i.e. unclear and insensitive), and family refusals (5). When families initially refuse to donate, it is recommended to ask for their reasons for refusal. Strongly expressed family refusals are unlikely to be reversed. Families' views and wishes must always be respected but it is also important to explain to the families that they can choose to donate and the significance of donation for other patients. There may be two instances when refusals could be reversed. Firstly, when there is no strong opposition to organ donation, and the patient is going to be cremated. Our study, however, showed no correlation between funeral choices and consent rates. Secondly, when the potential organ donor is due to have a coroner autopsy. In one of our cases, the family consent was due to multiple reasons and one of them was the coroner autopsy. In our study, all ten (19.2%) cases dealt with by the coroner consented to organ donation.

Every family and every situation is different. However, a correct planned approach with experienced professionals from the TCT provided a proven record of increased success and positive family experiences (3, 6, 17). Our experience confirms that TCT members are the appropriate staff to request authorization from families for organ donation for transplantation. Continual improvement in family interviews is necessary in all hospital TCTs to increase the number of donors and transplantable organs.

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## Authors' contributions

Francisco Caballero participated in research design, performed the study, and wrote the paper.

Jesús Leal participated in the performance of the research, and in data analysis.

Mireia Puig participated in data analysis.

Ana Manzano participated in research design, and in the writing of the paper.

Josep Ris participated in data analysis.

Salvador Benito participated in data analysis.

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