

# FAMILY INTERVIEW GUIDE FOR REQUESTING ORGAN DONATION FOR TRANSPLANTATION AND EVALUATION USING THE APPRAISAL OF GUIDELINES RESEARCH AND EVALUATION (AGREE II) INSTRUMENT

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**Summary** - Brain-dead donors (BDD) are the single largest source of transplantable organs. Families' informed consent to donate family members' organs is always requested and is a determining factor in the success of organ transplantation. The interview between the transplant coordinator (TC) and the family of possible organ donors requires specific planning and methodology. The transplant coordination department at the Hospital de la Santa Creu i Sant Pau (HSCSP) of Barcelona (Spain) has developed a Family Interview Guide (FIG) for requesting informed consent to organ donation for transplantation from BDD. For the internal evaluation of the guidelines presented in this paper, the AGREE II (Appraisal of Guidelines Research & Evaluation) instrument was used. We present our FIG to request organ donation and its assessment with the AGREE II instrument by four medical specialists.

The FIG describes the process and content of the conversations surrounding the donation request. FIG was implemented in 2011 and consists of the following 13 sections: planning, recommendations, professionals conducting the interview, requestor's attitude towards families, interview setting, timing of the interview, duration of the interview, requesting informed consent, details of the donation process to the donor's family, formalizing the agreement, donor documentation, funeral arrangements administration procedures and psychological support for donor families. The main purpose of this guide is to increase organ donation rates. From January 2011 to August 2012, 40 consecutive family interviews from 40 BDD were conducted using FIG. For the evaluation of this FIG the AGREE II instrument was used. This is a generic tool designed primarily to assist designers and users of clinical guidelines in the assessment of their methodological quality. The rate of family consent to organ donation for transplantation in the HSCSP after implementation of this FIG in 40 consecutive family interviews was 100%. The assessment of this clinical guideline with the AGREE II instrument scored 71%. The application of our guideline in face-to-face interviews with the families of potential brain-dead organ donors was a success. The evaluation of our guide with the AGREE II instrument recommended its use in general clinical practice.

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## Introduction

Currently, about 90% of transplanted organs in Spain originate from deceased patients, mainly from BDD. Family informed consent to donation is a determining factor in the process of obtaining organs for transplantation.

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.<sup>1,2</sup> 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 grants freely and consciously whether to donate organs for transplantation. The family refusal rate (FRR) ranged from 25% in 1993 to 15.2% in 2006.<sup>3</sup> Currently, family refusal rate targets are around 10% in most large and medium size Spanish hospitals.<sup>4</sup>

Interviews with relatives of potential organ donors require planning and a specific methodology.<sup>5,6</sup> Communication with families of deceased patients focuses on the process of organ donation for transplantation but it necessarily involves prior notification of the death of their loved one.<sup>7</sup> The family interview is a process consisting of many steps that can never be improvised by the professionals who must

perform it. Our FIG describes the process and content of the conversations surrounding the donation request. The FIG was implemented in January 2011 and consists of the following sections (see Figure 1): planning, recommendations, professionals conducting the interview, requestor's attitude towards families, interview setting, timing of the interview, duration of the interview, requesting informed consent, details of the donation process to the donor's family, formalizing the agreement, donor documentation, funeral arrangements administration procedures and psychological support for donor families.

Clinical practice guidelines (CPG) represent the most effective method of standardisation to achieve expected outcomes and therefore they should also be formally evaluated for their continuous improvement. The AGREE II instrument for the evaluation of CPG is a tool designed primarily to assist in evaluating the methodological quality of CPG.<sup>8,9</sup>

The aim of this paper is to describe our experience of developing and implementing the FIG in HSCSP for requesting informed consent to organ donation for transplantation from BDD and the results of internal evaluation of the guide using the AGREE II instrument. To our knowledge, there are no reports describing a FIG to request organ donation and its assessment with the AGREE II instrument.

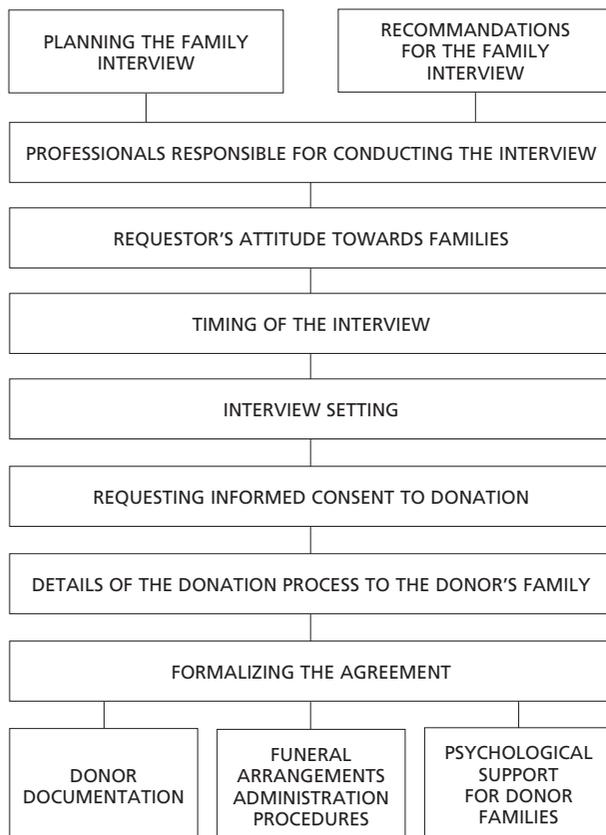


FIGURE 1 - Algorithm of the Family Interview Guide at HSCSP for requesting informed consent to organ donation for transplantation.

## Family interview guide

### Objective

The aim of the guide is to provide practical clinical guidance to all hospital staff of the Transplant Coordination Team (TCT) of HSCSP and other hospitals in order to effectively conduct requests for informed consent to organ donation for transplantation with the deceased patient's family to increase donation rates. All organ donors at HSCSP are BDD, patients who have been declared dead using neurological criteria (irreversible loss of all brain function but maintained on ventilators) according to Spanish legislation on organ donation and transplantation.<sup>1,2</sup>

### Justification of the guide

Spanish medical schools currently have no specific academic training on requesting consent for organ donation and this is one of the reasons the development of this guide is justified. A team of senior staff in the TCT of the HSCSP developed and implemented a practical clinical application of family interview to request consent for organ donation based on their ongoing experience in conducting more than 700 consecutive interviews during 17 years (1994-2010). This guide also aims to be particularly useful to all physicians who have joined HSCSP recently working on duty in the TCT since 2009 and to other transplant coordinators and professionals from other hospitals.

## Scope

The guide is intended for implementation by the team of clinical staff (physicians and nurses) of TCT and the medical team on duty at the HSCSP who can carry out planned family requests for informed consent to organ donation for transplantation. Interviews are conducted face-to-face with relatives of all potential heart-beating brain-dead organ donors in the absence of absolute contraindications for organ donation.

## Development of the guide

The guide was initially developed by the head of TCT at HSCSP and it was consequently reviewed by the TCT clinical staff (physicians and nurses) and has been operational in HSCSP since January 2011.

## Benefits of the guide

Following implementation of the FIG, refusal rate was 0% in 40 consecutive family interviews during the period from 1<sup>st</sup> January 2011 up to 31<sup>st</sup> August 2012. However, this guide is not a “magic bullet” that will improve organ donation rates.

## Monitoring of the guide and the process of family interviews

The guide will be reviewed and updated annually by TCT staff at HSCSP. In addition the guide will be subjected to a continuous improvement process following Deming’s PDCA cycle.<sup>10</sup> The family interview is a systemic process that should be evaluated with quality management processes. Seven goals for improvement are identified in this process:

1. Ongoing identification of activities to increase family consent rates for donation.
2. Use of quality tools for evaluation of processes.
3. Improvement in the training of all staff involved in the family interview process.
4. To establish quantitative and qualitative tools for process evaluation.
5. Standardisation of the family interview process aimed at decreasing variability in minimum requirements.
6. Recording and auditing of the results.
7. Ongoing recording of suggestions to improve and implement the continuous improvement cycle.

These activities are intended to achieve two objectives: first, to increase donation consent rates in family interviews and secondly, to sustain the results effectively and efficiently over time.

## Contents of the family interview guide

### Planning the family interview

The interview with the family of potential BDD to request informed consent for organ donation should be

planned properly. 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.

The interview should take place when several requirements are in place:

1. The medical and legal diagnosis of brain death is the first requirement.
2. The physician in charge of the patient must report the death to the family. It is best to use the term ‘death’ and not the term ‘brain death’ to avoid confusion in the family.
3. It is advisable that the transplant coordinator is present when the physician communicates the patient’s death to his/her family because in some cases families enquire about organ donation at this initial point.
4. The deceased’s family needs to understand the patient’s death.
5. Before the interview it is important to confirm that immediate relatives of the donor will attend. It is important to know the family composition and structure of the potential organ donor.

### Recommendations for the family interview

1. If possible, immediate relatives of the potential organ donor should be present at the interview.
2. The request for consent to donation must never be rushed. We should wait for the right time to approach the family.
3. After the physician in charge communicates the patient’s death, it is advisable to wait for families’ prompts such as: “What should we do now?”
4. At this moment, and not before, consent to organ donation for transplantation should be introduced to relatives by a professional from TCT. It should be explained that their deceased relative – naming him/her by their name – “can help others”. An emphasis on the social and health benefits for patients on the waiting list for organ transplantation is recommended. Death is hard, not donation. And there is no transplantation without donation.

### Professionals responsible for conducting the interview

Family interviews to request informed consent for organ donation should be held by skilled staff from the hospital TCT with expertise in requesting consent. Our experience strongly indicates that the involvement of the family with a professional from TCT is very important.

### Requestor’s attitude towards families

It is fundamental to have a serious, respectful and empathetic attitude towards the potential donor’s family and to lament

the death of the patient. We need to communicate properly with them, allowing time for understanding and clarification. We must respect their silences and moments of grief.

### Interview setting

The interview should take place in a private office. In HSCSP, the office generally used by physicians to communicate with relatives of patients admitted in different intensive care units (ICUs) is also used for requesting donation consent. It would be preferable to have a dedicated space ("family room") which is not adjacent to the ICU to communicate with the families of potential donors.

### Timing of the interview

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.

### Duration of the interview

It is not recommended to extend the duration of family interviews. Often the position in favour of the donation is immediate during the initial request. In exceptional cases the family may take longer than usual to take the final decision. In these 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.

### Requesting informed consent to donation

It is advisable to ask for consent to donation for transplantation in generic terms. The request must be clear, concise, respectful and brief. If the answer is in favour of donation, it can be assumed that donation is for all viable organs for transplantation. In our experience, in almost all cases if the response is favourable to donation, there are no specific restrictions. In the rare event of a family explicitly expressing that they only want to donate specific organs and/or tissues, these wishes must always be respected.

### Details of the donation process to the donor's family

The professional from TCT responsible for conducting the interview must inform the donor's family of the specific details of the donation process. Each specific question must be dealt with adequately and appropriate answers should follow, with special attention to the stages and times of the donation process (i.e. when recovery will take place,

approximate duration of organ recovery process, etc.). In addition, permission is sought to write to relatives a thank you letter approximately one month after the donation and organ transplantation process. This letter of appreciation contains generic information about organs transplanted and their follow-up, while respecting the anonymity of the recipients. In situations where the coroner has a legal duty to investigate the patient's death, families must be made aware that, in addition to their consent, the coroner is responsible for the final decision as to whether a donation goes ahead.

### Formalizing the agreement

Once the family grants consent to donation, this must be formalized by signing written informed consent in an official document generally provided by the relevant national procurement organisation. This must be signed by at least one family member. It is mandatory after obtaining written consent to thank the family for their solidarity and generosity.

### Donor documentation

Once written consent is obtained, all statutory paperwork and other administration requirements must be completed before starting organ recovery.

### Funeral arrangements administration procedures

Hospital funeral arrangement procedures and all necessary documentation to be completed must be explained to the donor's family. They must be informed that once organ recovery is performed, the deceased patient will be transferred to their nominated funeral director's premises. Burial or cremation can subsequently be organised according to their wishes. It is important not to commit ourselves to times or areas which are beyond our control and responsibility.

### Psychological support for donor families

The TC or any other professionals requiring consent must not provide bereavement counselling to donor families. They should, however, refer them to internal or external specialised bereavement services if there is a need. Currently, HSCSP offers a programme of specialized medical care and psychological support for donor families.

### AGREE II instrument

The AGREE instrument was originally published in 2003 by an international group of researchers and developers of clinical guidelines, the AGREE Collaboration (Appraisal of Guidelines Research & Evaluation).<sup>8,9</sup> The aim of this partnership was to develop a tool to assess the quality of practice guidelines. The AGREE II instrument was pub-

lished in 2009 and it was developed to examine the issue of quality variability in guidelines. It is a tool to assess methodological rigour and transparency in guidance development and it aims to assess guidelines quality, providing a methodological strategy for guide development and

establishing what type of information and how it should be included in guidelines. It consists of 23 key items organised in six domains of quality, followed by two overall assessment items. Each domain comprises a single dimension of the quality of the guide:

DOMAIN 1. SCOPE AND PURPOSE	Item 1	Item 2	Item 3						Total
Evaluator 1	7	7	7						21
Evaluator 2	6	6	7						19
Evaluator 3	6	6	7						19
Evaluator 4	6	7	7						20
Total	25	26	28						79
DOMAIN 2. STAKEHOLDER INVOLVEMENT	Item 4	Item 5	Item 6						Total
Evaluator 1	4	6	7						17
Evaluator 2	6	7	7						20
Evaluator 3	5	3	6						14
Evaluator 4	5	4	6						15
Total	20	20	26						66
DOMAIN 3. RIGOUR OF DEVELOPMENT	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	Total
Evaluator 1	1	1	1	2	4	3	3	1	16
Evaluator 2	4	5	5	5	5	7	5	7	43
Evaluator 3	4	4	4	4	5	3	4	6	34
Evaluator 4	4	3	4	5	6	4	6	6	38
Total	13	13	14	16	20	17	18	20	131
DOMAIN 4. CLARITY AND PRESENTATION	Item 15	Item 16	Item 17						Total
Evaluator 1	5	5	6						16
Evaluator 2	7	7	7						21
Evaluator 3	5	6	7						18
Evaluator 4	7	7	7						21
Total	24	25	27						76
DOMAIN 5. APPLICABILITY	Item 18	Item 19	Item 20	Item 21					Total
Evaluator 1	6	7	6	3					22
Evaluator 2	5	7	5	6					23
Evaluator 3	5	6	6	6					23
Evaluator 4	5	7	4						16
Total	21	27	21	21					90
DOMAIN 6. EDITORIAL INDEPENDENCE	Item 22	Item 23							Total
Evaluator 1									
Evaluator 2									
Evaluator 3									
Evaluator 4									
Total									

Results Evaluator x domains (%)	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Domain 6	Total
Evaluator 1	100	77.8	16.7	44.4	37.5	NA	56.3
Evaluator 2	88.9	94.4	72.9	100	39.6	NA	83.3
Evaluator 3	84.2	57.9	54.2	88.9	39.5	NA	69
Evaluator 4	94.4	66.7	62.5	100	37.5	NA	75.4
Total							71

\* We excluded the entire domain 6 (Not Applicable, NA) since the Guide had not been published.

Table 1 - Evaluation of the Family Interview Guide with the AGREE II instrument.

Domain 1. Scope and purpose (items 1-3)  
Domain 2. Stakeholder involvement (items 4-7)  
Domain 3. Rigour of development (items 8-14)  
Domain 4. Clarity and presentation (items 15-18)  
Domain 5. Applicability (items 19-21)  
Domain 6. Editorial independence (items 22-23)  
All items are scored on a seven-point scale (e.g. 1=strongly disagree, 7=strongly agree).

Domain scores can be calculated by summing all the scores of the individual items in a domain. The standardised score for each domain is obtained by applying the following formula:

$$\frac{(\text{obtained score} - \text{minimum possible score})}{(\text{maximum possible score} - \text{minimum possible score})} \times 100 = \dots\%$$

#### Guide evaluators using the AGREE II instrument

The internal evaluation of FIG with the AGREE II instrument was performed by four medical specialists outside the organ procurement and transplantation teams. Selection criteria were: seniority, clinical speciality (critical care, internal medicine or surgeons), experience of the donation-transplantation process and knowledge of quality assurance processes. Evaluators' specialities were: two internal medicine consultants, one critical care consultant and one surgeon. Experience in transplantation ranged from four to eight years and knowledge of quality assurance processes was assessed based on years of practice, ranging from four to 15 years.

## Results

From January 2011 to August 2012, 40 consecutive family interviews from 40 BDD were conducted using FIG at HSCSP and the rate of informed consent to organ donation for transplantation was 100%. The results of the internal evaluation of FIG with the AGREE II performed by four evaluators was:  $(92-21):(147-21) \times 100 = 56.3\%$ ,  $(126-21):(147-21) \times 100 = 83.3\%$ ,  $(108-21):(147-21) \times 100 = 69\%$ , and  $(116-21):(147-21) \times 100 = 75.4\%$ , respectively. In the assessment of FIG with the AGREE II instrument the overall score (all evaluators) was  $(71+105+87+95):(126 \times 4) \times 100 = 71\%$  (see Table 1). Domain 6 was excluded in the assessment as not applicable since the guide had not yet been published.

## Discussion

Clinical guidelines for family interviews to request organ donation for transplantation are little documented in the literature. For this reason and in response to this clinical need in acute care, our group developed the FIG based

on our experience over the past two decades and framed within our social environment which is pro-organ donation for transplantation.

Since January 2011, HSCSP implemented guidelines for family interviews for requesting consent to organ donation from BDD. Before the implementation of this guide (1994-2010) HSCSP's refusal rates ranged from 7.2 to 22% (unpublished data). In our experience, the implementation of the guidelines during a period of 20 months (January 2011-August 2012) was a success. Since implementation of our guide, the rate of consent to donation of organs for transplantation from relatives of heart-beating brain-dead organ donors has been 100% based on 40 consecutive family interviews. The highly supportive attitude towards donation from all the families interviewed must be acknowledged. Without family consent and without a Public Health Service and efficient transplant system (hospital transplant coordinators and transplant teams) the binomial donation-transplantation – which begins and ends in society – could never be achieved.

Implementation of the FIG at HSCSP is an ongoing success and significant contextual factors for the process of organ donation to requesting consent are identified. In our experience there are three significant factors in consent to organ donation. The first factor is the express will of the deceased in favour of donation. If the deceased did not express donation views to his/her family, two other factors are often crucial: the educational level of the family and the institutional treatment received by patients and their family in hospital.<sup>11</sup> The higher the educational level of the family and better hospital treatment received, the higher the rates of consent. If the family experience of medical and institutional treatment during admission is satisfactory, families usually consent to donation. Other authors have documented other factors (socioeconomic, ethical, etc.) that may influence family consent to donation of organs and tissues for transplantation.<sup>12-24</sup> Public education and training courses on organ donation and transplantation in schools performed by transplant coordinators and other professionals involved in transplantation are needed to modify attitudes to organ donation prior to a donation opportunity.<sup>13,14,16</sup>

Our results suggest that the physicians in charge of potential organ donors should limit their role to calling early a professional from the TCT staff and working in the organ donation process under the direction of this TC to perform the family interview and donation request. Our data strongly indicate that the involvement of the family with a professional from the TCT staff for organ donation request is very important and may be a factor influencing family consent to donation. 89% of interviews presented in this study were conducted by the same dedicated and widely experienced TC in HSCSP. In 96% of the cases a single

family interview took place. These initial interviews usually last about 10-15 minutes in more than 50% of cases and less than 30 minutes in 85.7% of the interviews.

The overall internal assessment of the FIG with the AGREE II instrument by four doctors scored 71% and it recommends the use of the guide in other hospitals. Continuous improvement of planning and conducting family interviews is recommended in order to obtain informed consent and to carry out a successful organ donation and transplantation process. In our experience there is great benefit in introducing FIG considering the current shortage of organs for transplantation worldwide.

## Acknowledgements

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The authors declare that they have no conflict of interest.

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