Application of Spanish quality instruments about organ donation and tranplants validated in pilot hospitals in Santa Catarina

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ABSTRACT

Introduction: The need of increasing the number of notifications of potential and actual donors is a worldwide problem. There is still much loss of donors, which can be avoided. **Objective:** To use instruments adapted from the Model of Quality Management of the Spanish National Organization of Transplants in pilot hospitals in Brazil. **Methods:** This was a quantitative research developed in three large hospitals in Santa Catarina, The option by the three institutions is related to the number of Intensive Care Unit (ICU) beds and the number of potential donors notifications Central Catchment Notification and Distribution of Organs and Tissues of State (CNCDO-SC). Data collection was performed in medical records from deceased patients in the units of critical patients using two validated instruments, period of three months, in two steps as directed by ONT. **Results:** In one of the hospitals, there was a higher percentage of losses due to maintenance problems (17.6%), family refusal (64.3%) and escapes (16.7%), and there also was a lower real effectuation index (29.4%). In 70.3%, losses due to maintenance were associated with irreversible cardiac arrest and hemodynamic instability. Family refusal was associated in 48.4% with the fact that the family was against donation and ample desire to keep the body integrate. **Conclusion:** Information obtained allows the manager to administer these data and therefore to implement actions of improvement, increasing the number of donator of organs and tissues.

Keywords: nursing audit; quality of health care; transplantation.

INTRODUCTION

The shortage of organs for transplantation is an issue that affects both developed and developing nations.[1-9] Despite the recent progresses in organ transplantation, opportunities for improvement in the area still abound. The need to change the current state of affairs has been the subject of many studies on missed potential donors.[3-9]

The topics of organ donation and transplantation are often combined in the literature. Some authors have described the factors associated with missed potential donors.[10-24] These studies revealed the distrust with which the population sees the organ donation process and the lack of training and involvement of health care workers with the process, in addition to myriad religious and cultural factors.

Significant effort has been made by political, social, governmental and non-governmental organizations to increase the number of donors and transplantation procedures in Brazil.[2,4,21,24] Nonetheless, the number of missed potential donors has increased at the same rate as the number of notifications to organ procurement organizations (OPO) and organ donations.[25,26]

Although the legislation on the topic is clear and efficient, the means to aggregate the number of cases of brain death (BD) in Brazil or abroad are yet to be described.[5,8,9,21,27] The notification potential could be derived from the

number of cases of BD reported by health care institutions.

Several countries have engaged in intensive care unit (ICU) audits to verify the number of brain deaths occurred in their hospitals, the number of unreported cases of BD, and the causes for potential donor misses.[4,5,27-30] These audits have allowed insight into the following indicators: the number of brain deaths occurred in each institution; the percent rate of cases of diagnosed brain death not reported to an OPO; and the main causes for the nonfulfillment of organ donations.[4-6,27-31]

In Spain, a specific method has been used to define the theoretical organ donation capacity of each type of hospital, detect the potential donors missed during the organ donation process, and analyze the causes of unfulfilled donations and the hospital-related factors impacting the organ donation process.[31,32] The country moved from a rate of 14.3 notifications of potential donors per million population (pmp) in 1989 to become an international reference with 36.2 notifications pmp in 2011.[31,32]

The change was associated to a series of strategies, but the instruments included in the National Transplant Organization (ONT) Quality Management Model played a key role in the improvements. Based on patient chart data, these instruments help estimate the potential number of cases of BD for each hospital considering the facility's characteristics and analyze the data on missed potential donors, unreported donors, the reasons for donor misses, and accurate and inaccurate medical contraindications.[31,32]

Once factual information on the donation process is made available, action plans and strategies may be devised to deal with the identified issues. Additionally, the number of organ donations may increase as the actual number of potential donors is defined.

The purpose of this study was to run a pilot project to implement an adapted version of the ONT Quality Management Model tools at three hospitals in Brazil. The significant and trustworthy information collected from patient charts may help the authorities improve the number of organ donations and transplants in Brazil.

Material and methods

This methodological study is a spinoff of a doctoral thesis in which organ donation quality management instruments were translated, adapted, and validated. This study was developed based on the recommendations published in the literature for instrument validation.[33,34] The ONT authorized the translation of the instruments.

This paper refers particularly to one of the steps in the validation process: the pre-test phase. The instruments were designed by the ONT with the following objectives in mind: identify the number of cases of BD for each type of hospital; detect missed potential donors and analyze the causes for the misses in order to list points for improvement in the organ donation process; and discover the hospital-related factors impacting the process. The ONT produced a guide on how to use the instruments.

The instruments were used in the pre-test phase in two stages, as described in the guidebook. Instrument I (Annex A) was used in the first stage of patient chart analysis, also known as internal assessment stage. In this stage, the analysis was carried out every three months by the transplant coordinators at each of the institutions. Instrument II (Annex B) was used during the second stage in the analysis of a sample of patient charts, referred to as external assessment. In this stage, a hospital transplant coordinator from a different institution carried out the analysis. The institutions participating in the second stage had been performing the tasks pertaining to the first stage for a year. Annex C was used as a reference to fill out the two instruments.

The study was carried out in three large teaching hospitals in the State of Santa Catarina. The three institutions were chosen for the size of their neurosurgery services, which combined account for a mean of 54.0 notifications (pmp) per year to the local OPO and 61% of the organ

donations performed in the State. Institution 1, located in the metropolitan area of Florianópolis, contained 240 beds and a general intensive care unit with 12 beds; institution 2, located in northern Santa Catarina, had 259 beds and two ICUs - one for neurosurgery with seven beds and a general ICU with eight beds; and institution 3, located in the Itajaí River Valley, had 220 beds and two ICUs - one for coronary disease patients with eight beds and a general ICU with another eight beds.

The 119 charts of the patients deceased at the ICUs of these institutions between January 1 and March 31, 2011 were ordered through the Medical Record Service (SAME).

In the first stage of the study, the collected patient charts were used to fill out instrument I containing the following variables: (a) cause of death; (b) whether BD was detected by the transplant coordinator; (c) whether the medical contraindications for the procurement of organs for donation were accurate, and if not, why; (d) the cause of contraindication in the cases of accurate and inaccurate medical contraindication; (e) whether the organ removal procedure was started and, if not, (f) the reason why the organs were not removed; (g) whether the family was interviewed.

The second stage was carried out from March 1, 2011 to June 31, 2012 at only one of the three hospitals. A total of 259 patient charts were analyzed. This hospital was chosen for its numbers of ICU deaths, patients diagnosed with BD, and potential donors identified in internal assessments.

Instrument II was used in this stage. The following issues were considered: (a) did the patient chart mention it was a case of BD identified by the transplant coordinator? (b) Was it really a case of BD? (c) Why was the potential donor missed? d) Was the cause of death determined? e) Was it an acceptable, inevitable, or uncorrectable miss? Or was it an inadequate, evitable, or correctable miss? Or could it not be determined as any of these? (f) Was the family interviewed? (e) Why was the decision made against organ donation? While filling out instrument II, the transplant coordinator compared the information on the guidebook to the data recorded in the patient charts to find whether the cases of missed organ donors should be deemed adequate or inadequate. The researcher, two nurses, and a physician reviewed the patient charts. They were given a copy of the guidebook one month before reviewing the patient charts.[31] The guidebook contains a step-by-step description of how data should be collected and the instruments populated. The guide was adapted to the Brazilian context by the researcher and two medical doctors. Patient chart analysis was carried out only after the guidebook had been presented to the reviewers and all their questions had been addressed. The reviewers took a mean of 20 minutes to look into one patient chart.

The patient charts were categorized as follows: possible donor, when the patient had clinical signs of BD and tests indicative of BD; when the protocol for BD was not started as advised in the guidebook, the patient was categorized as a missed organ donor; potential donors run through the BD protocol and reported to the local OPO who for some reason ended up not having their organs procured were categorized as missed potential donors; confirmed donors were included in the BD protocol, cleared for organ donation, and had their organs removed.

The study was approved by the Research Ethics Committee and given permit no. 0964°/10, only after it had been approved and cleared by the three included institutions.

Data analysis was performed on Microsoft Excel® and presented in the form of tables and charts. The qualitative variables submitted to descriptive analysis were presented in the form of relative (percent) and absolute (n) frequencies.

Results

The three institutions combined yielded a total of 378 patient charts. At institution I, 36 patient charts covering a period of three months were reviewed; at institution 2, 24 charts from a period of three months were analyzed; and at institution 3, 318 patient charts covering a period

of 15 months were reviewed. The three hospitals combined had 117 patient charts meeting the criteria for BD.

Table 1 shows the number of cases of BD at each institution and the number of reported and unreported brain deaths.

Patient chart analysis revealed that the two main causes of BD were head trauma resulting from accidents (48.8%) and hemorrhagic stroke (35%) (Table 2).

Chart 1 shows the data for each hospital and the percent rate of patient charts meeting the criteria for BD at each hospital, donors lost during maintenance, family refusals to organ donation, and missed possible donors.

The non-removal of organs from potential donors lost during maintenance was caused by irreversible cardiac arrest, septic shock, or hemodynamic instability in 92.5% of the cases (Table 3).

Families vetoed organ donations when they were against it for no specific reason, when the donor was against donating organs, or when the family wanted the body of the deceased to remain whole and untouched. Next-of-kin refusals accounted for 72.8% of the misses (Table 3).

Non-identification of BD by the transplant coordinator (26.7%), deaths during maintenance (45.8%), and family refusals (27,5%) were the main causes of preventable potential donor misses. Preventable misses were defined by the reviewers based on the parameters set out in the guidebook for the development of a Quality Management System and the application of instrument II (Annex B), specifically designed with this purpose.

Discussion

One of the main obstacles to the detection of potential donors is the computation of the number of brain deaths occurred in each health care center or, in other words, the actual capacity each institution has of producing possible donors.[4-6,27-30]

In Brazil, the number of potential donors is estimated based on the population of a given area of interest, a wide range of hospital indicators, and the number of brain deaths at ICUs, which account for 10% to 15% of the total number of deaths observed in intensive care settings.[12,19,20]

Yet, these estimations do not reflect the actual number of brain deaths occurred in these institutions, and do not allow the development of indicators for the ongoing improvement of the organ donation and transplantation processes. Improvements should be based on the analysis of data and the ensuing insights applied to the solution of actual problems.[31,32]

Brazil and a number of other countries do not have proper quality management tools to measure and assess organ donation and transplantation processes.[4,28-31]

The only data available in Brazil are the indicators described in Ordinances 1262 and 2600 relative to the number of patients diagnosed with brain death (potential donors) reported to the country's national OPO, the CNCDO, and the number of eligible donors diagnosed with BD. This information only tells the number of donors the hospitals reported to the CNCDO.[26,27]

The results published in this study show the number of possible donors and the potential number of cases of BD for each institution, in

Table 1 Number of ICU patients meeting the criteria for brain death (BD), number of cases reported to the local organ procurement organization (CDCDO), and number of patients not diagnosed with BD at the three care centers for the studied period.

Patient charts	Institution 1 (three months) n (%)	Institution 2 (three months) n (%)	Institution 3 (15 months) n (%)
Patients meeting the criteria for BD	10 (100)	10 (100)	97 (100)
Patients started on the BD protocol reported to the CNCDO	9 (90)	9 (90)	81 (83.3)
Patients not diagnosed with BD	1 (10)	1 (10)	16 (16.7)

Table 2 Causes of death cited in the patient charts

Cause of death	n (%)
Head trauma	57 (48.8)
Ischemic stroke	8 (6.8)
Hemorrhagic stroke	41 (35.0)
Tumor	6 (5.1)
Anoxia	4 (3.4)
Other	1 (0.9)
Total	117 (100)

addition to the number of potential donors lost during maintenance or missed due to family refusals or logistical issues.

These data allow the identification of the institutions failing to start the BD protocol and those with greater numbers of misses. The accurate nature of the information collected with the instrument also allows the determination of actual confirmed donation rates.

Based on such information, the CNCDO and the National Transplant System (SNT) may design strategies to increase the number of donors and, consequently, of performed transplants. The data may also be used to define which institutions should be given priority in the form of training programs to ICU personnel on how to identify patients with BD, BD protocols, maintenance of patients diagnosed with BD, and interviewing patient family members.

In 2009, an estimated 35.8 pmp possible donors were missed in Brazil, *versus* 36.4 pmp in 2010, 32.1 pmp in 2011, 27.9 pmp in 2012, and 33.3 pmp in 2013.[25] However, the reliability of these estimations is questionable, once the number of cases of BD per institution has not been defined. Nonetheless, the number of notifications and organ donations has changed significantly over the years, with some Brazilian States performing better than others.

Santa Catarina moved from a confirmed donation rate of 16.7 pmp in 2008 to 27.2 pmp in 2013; São Paulo leaped from 12 pmp to 19.4 pmp; Ceará, from 10.2 pmp to 22.2 pmp; and Rio Grande do Norte from 4.3 pmp to 13.9 pmp.[25] The number of confirmed donations grew by 62% in Santa Catarina and 60% in São Paulo, while the States of Ceará and Rio Grande do Norte saw increases in organ donations of 100% and 200%, respectively.[26] These figures reflect the growth of confirmed organ donations in Brazil, which moved from 7.2 pmp in 2008 to 13.2 pmp in 2013, a 75% increase.[25]

The numbers convey satisfactory information when analyzed separately. Despite the greater number of confirmed organ donations, the ratio between notifications to organ procurement organizations and confirmed donations reveals that the number of missed organ donors has not decreased. According to the Brazilian Organ Transplant Association (ABTO), 40.75 pmp cases of unreported organ donors were observed in 2004, *versus* 27.9 pmp in 2012 and 23.5 pmp in 2013.[25] The number of unreported donors decreased, and consequently the number of notifications to OPOs improved. Though this is important information, it fails to explain the causes of underreporting and the factors connected to missing potential donors. The identification of the factors leading to missed potential donors, particularly the ones related to the maintenance of patients diagnosed with BD, plays a pivotal role in successful transplantation.[35]

The instruments described in this study allowed the included health care institutions to develop indicators and design strategies to increase the number of confirmed organ donations and reduce the time patients have to wait for an organ. As the waiting list is cut shorter, the level of anxiety experienced by transplant candidates is also mitigated.[24] The number of patients waiting for an organ is generally greater than the number of organ donors, particularly in the case of individuals waiting for a kidney transplant.[36]

It is quite true that this does not happen only in Brazil. The United Kingdom, the United States, Germany, and Poland are also seeking to increase the ranks of confirmed donors. Frequent audits look for opportunities to improve the organ donation and transplant systems in these nations.[5,6,27-30] The development of strategies to improve these processes and increase the number of organ donations is a global issue.[4-6,27-30]

In Spain, the implementation of these instruments in centers categorized as sources of potential organ donors allowed closer monitoring and measuring of the indicators related to the

Chart 1 Organ donation process data from the three included institutions

Percent rates relative to the number of patients diagnosed with brain death	Institutions			Excellence
	Institution 1	Institution 2	Institution 3	
Rate of cases of brain death potential from neurosurgery	41.66	27.8	30.5	54.5
Misses (possible cases of unreported brain death)	10	10	16.7	0
Problems with maintenance	12.5	11	17.6	< 3
Refusal to donate organs	28.6	50	64.3	10
Logistical problems	0	0	0	< 1
Confirmed organ donations	75	44.4	29.4	> 65

Level of excellence or gold standard: values recommended for each step of the process in the European Community.[31,32]

Table 3 Reasons for missing organ donors diagnosed with brain death

Missed patients	Reason	n (%)
Brain death not identified	Hemodynamic instability	8 (44.4)
	Inaccurate medical contraindication	4 (22.2)
	Accurate medical contraindication	3 (16.7)
	No specific reason	3 (16.7)
	Total	18 (100)
Potential organ donor lost during maintenance	Irreversible cardiac arrest	10 (37)
	Hemodynamic instability	9 (33.3)
	Septic shock	6 (22.2)
	Other	2 (7.5)
	Total	27 (100)
Potential organ donor missed due to refusal to donate	Family was against organ donation for no specific reason	9 (27.2)
	Patient formally refused to become an organ donor	8 (24.4)
	Family wished to keep the body of the deceased whole	7 (21.2)
	Problems with the health care team	5 (15.2)
	Religion	3 (9.0)
	Other	1 (3.0)
	Total	33 (100)

organ donation process in every hospital and autonomous community. Every step in the process was developed and the priorities defined for each health care institution, which ultimately led to a rate of 36.2 organ donations pmp in 2011.[31,32,37]

The method described in this study can be implemented in Brazil. The data collected from the charts depicting the facts occurred and recorded at the time of patient death were proven reliable. The information and the data collected revealed the facts transpired from the time patients were categorized as possible donors to the moment they became potential and then confirmed donors. Such data may certainly help improve the quality of the organ donation and transplantation processes.

Conclusion

This study allowed the identification of the causes of death cited in the reviewed patient charts. The numbers of possible, potential, and confirmed donors were verified. Opportunities for improvement were assessed and the priorities and action plans needed to reduce the number of missed organ donors and enhance the overall effectiveness of the process were defined.

The instruments used in this study can be applied with ease at any Brazilian hospital. The results achieved with the method used in the study should serve as a warning to health care authorities over the need to implement these instruments in care

centers with high numbers of brain deaths to thus increase the number of confirmed organ donors and minimize the number of missed potential donors.

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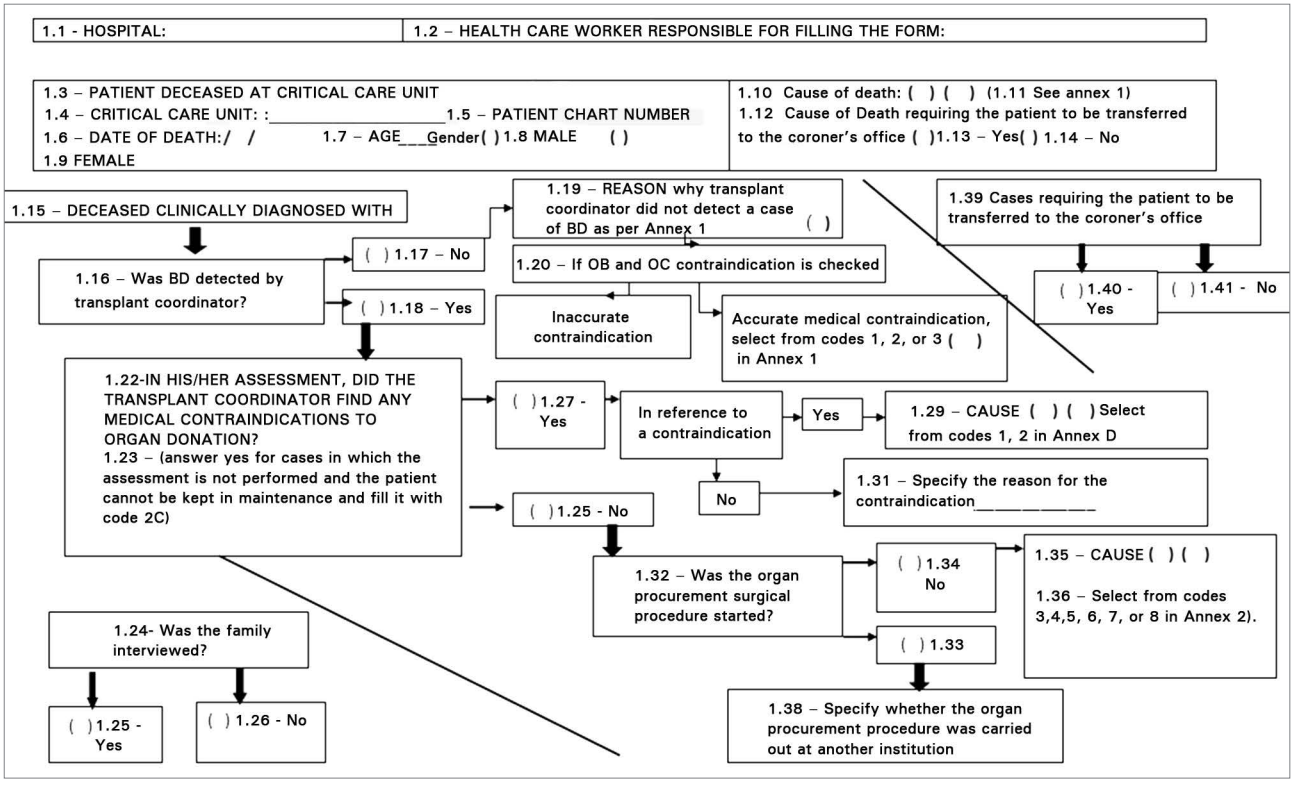
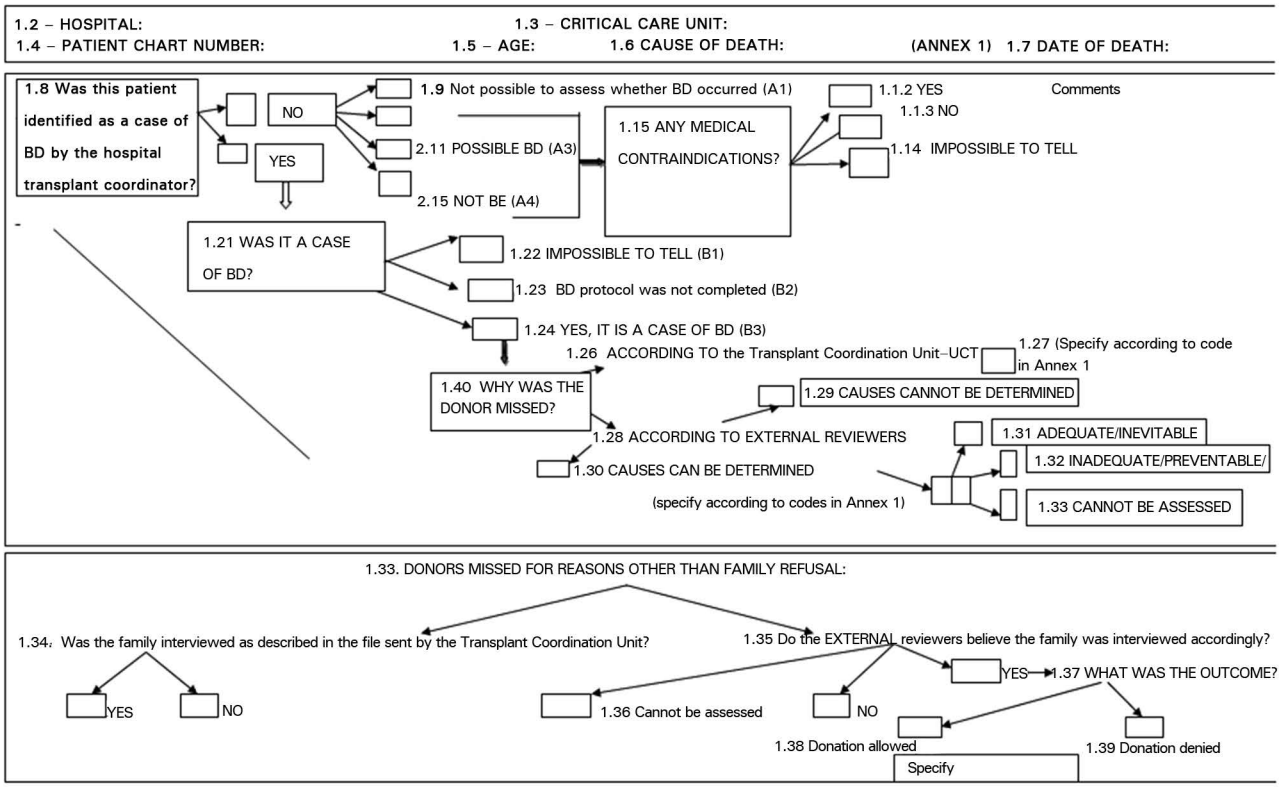
Annex A. Internal assessment instrument (possible brain death).



Annex B. Instrument II – External assessment – Collection of individual data from possible cases of brain death not converted into organ donors.



Annex C. Questions related to annexes A and B

1	A	2.2 – Head trauma – traffic accident
1	B	2.3 – Head trauma – murder
1	C	2.4 – Head trauma – occupational accident
1	D	2.5 – Head trauma – other
2	A	2.6 – Stroke – ischemic
2	B	2.7 – Stroke – hemorrhagic
3		2.8 – Anoxia
4		2.9 – Tumor
5		2.10 – Other: Please specify:_____
2.11 – Annex 2: Reasons for donation failure		
2.12 – The hospital organ and tissue donation committee did not identify the possible donor		
0	A	2.13 – No specific reason
0	B	2.14 – Possible donor was not actively sought
0	C	2.15 – Inaccurate medical contraindication: SPECIFY
0	D	2.16 – Other reason: SPECIFY
2.17 – When not advised of an accurate medical contraindication or maintenance problems, select one of the codes presented in item 1, 2, OR 3 in this Annex.		
2.16 – Medical contraindication		
1	A	2.17 – Active systemic bacterial infection, in which the pathogen has been identified, adequate treatment is started but response is not good.
1	B	2.18 – Untreated TB infection
1	C	2.19 – Active viral infection: SPECIFY
2.19.1- If HBC/HCV is present and the donor is discarded for lack of an adequate recipient, use code 5 and, in the last point, account for it as a missed donor. (organ removal not started) not accounted for as a medical contraindication.		

1	D	2.20 – Systemic disease – collagenosis/vasculitis
1	E	2.21 – Systemic disease – Advanced arteriosclerosis
1	G	2.22 – Malignant tumor
1	G	2.23 – Drug use or other risk factors
1	H	2.24 – Inevitable MULTIPLE ORGAN failure/sepsis
1	I	2.25 – Other medical contraindication: SPECIFY
2.26 – Other medical contraindications		
2	A	2.27 – Impossible to establish cause of death
2	B	2.28 – Impossible to consider personal history
2	C	2.29 – Impossible to assess donor due to hemodynamic instability/cardiorespiratory arrest
2.30 – Maintenance problems		
3	A	2.31 – Systemic infection in which the pathogen has not been identified and/or proper antibiotic therapy was not offered
3	B	2.32 – Irreversible cardiorespiratory arrest
3	C	2.33 – MULTIPLE ORGAN failure (preventable) due to maintenance failure
3	D	2.34 – Other maintenance problem: SPECIFY
2.35 – Organizational issues/delays		
4	A	2.36 – Family not located
4	B	2.37 – Delayed release by the coroner
4	C	2.38 – Internal logistics
4	D	2.39 – External logistics
5		2.40 – Lack of an adequate recipient
2.42 – Family refusal		
7	A	2.43 – The deceased had formally refused to donate organs
7	B	2.44 – Family refused to allow donation for no specific reason
7	C	2.45 – Doubts over brain death
7	D	2.46 – Doubts over the integrity of the body
7	E	2.47 – Social claim
7	F	2.48 – Problems with health care workers
7	G	2.49 – Religion
7	H	2.50 – Others: SPECIFY
2.51 – Incomplete diagnosis of brain death		
8	A	2.52 – Routine diagnostic method not available
8	B	2.53 – Special circumstances requiring unavailable diagnostic method
8	C	2.54 – Testes are inconclusive