



Organ procurement requiring the authorization of the judicial authority. An epidemiological investigation in the Veneto region (Italy)

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ABSTRACT

Background: When death occurs through a mechanism requiring a forensic investigation, consent for organ harvesting must be sought from the Judicial Authority (JA).

Aim: To perform a retrospective study of potential organ donors in the Veneto region over a six-year period (2012–2017), analysing any differences between cases in which the JA approved or denied organ harvesting.

Material and methods: Both non-heart beating (NHB) and heart beating (HB) donors were included. For HB cases, personal and clinical data were collected. To evaluate the correlation between the JA response and the circumstantial and clinical data a logistic multivariate analysis was performed, estimating the adjusted odds ratios (adjORs).

Results: Between 2012 and 2017, 17,662 organ and/or tissue donors were included, of which 16,418 were NHB donors and 1,244 HB-donors. Among the 1,244 HB-donors, JA authorization was asked in 200 cases (16.1%), approved in 154 cases (77.0%), limited in 7 cases (3.5%) and denied in 39 cases (19.5%). The JA denied the authorization for organ harvesting in 53.3% of cases with hospitalizations of less than 1 day and in 9.4% of cases with hospitalization exceeding one week [adjOR(95%CI) = 10.67 (1.92–59.22)]. The performance of an autopsy was linked to a higher chance of denied outcome from the JA [adjOR(95%CI): 3.45 (1.42–8.39)].

Conclusions: Improvements in the communication between organ procurement organizations and the JA through efficient protocols furnishing detailed information on the cause of death might lead to a better procurement process with an increase in the number of transplanted organs.

1. Introduction

During the 21st century, the progress in scientific and medical research made organ transplantation an efficient life-saving therapy, which is however limited by the insufficient availability of organs.

In Italy, organ and tissue procurement for therapeutic transplantation is included in the essential care levels [1] and Italy ranks at the top in terms of donor rate in Europe (28.9 per million inhabitants) [2]. Despite that, in 2017 Italy registered 1,437 cadaver donors (with the possibility of 3,624 transplants) against a waiting list of 8,874 persons [3]. Currently two European directives make it possible to exchange

organs and tissues between Member States [4,5].

Two main factors cause the loss of organs potentially adequate for transplantation. The first one is the refusal to donate by those entitled (in 2017, 28.7% in Italy, 16% in the Veneto region [3]) since in Italy the concept of tacit approval is not in place, unlike in other Countries [6,7]. The second one is the denial of consent for organ donation by the Judicial Authority (JA).

When donation is possible, but death has occurred through a mechanism that requires a forensic investigation, consent must be sought from the JA (e.g., Medical examiner, Coroner, Public Prosecutor or equivalents). In Italy, the Guidelines developed by the Italian

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transplant centre (NIT) advise that when the death of the potential donor was traumatic in nature or occurred under suspicious circumstances being even hypothetically connected to a crime (e.g., unexpected or sudden death, suicide, accident, work-related death, death in custody, etc.), at the beginning of the death assessment procedure, the transplant coordinator of the hospital must ask to the JA the authorization for organ-tissue harvesting.

The JA has the duty to verify that the organ procurement does not interfere with the justice requirements, and to communicate its decision (consent or refusal) not later than 6 h (i.e., the time needed for the death assessment).

Obviously, there is an inherent conflict between the needs of the JA and the Organ Procurement Organisations (in Italy, national – NIT and regional – CRT, transplantation centres), both requiring rapid access to the body. The JA must preserve physical evidence in order to reconstruct the cause of death and its eventual causal relationship with the suspected crime, whereas the Organ Procurement Agency must rapidly proceed with the organ retrieval [8,9].

Even if numerous studies have been conducted to explore the competing requirements between saving lives through donation and preserving evidence for forensic and medico-legal purposes, proposing different potential solutions [7,10–13], to date, Italy lacks studies on this matter. For this reason, the aim of this retrospective study is to analyse the differences between the cases in which the JA *approved or denied the removal of organs* in order:

1. to identify any potential critical issues in the process of organ procurement;
2. to estimate the number of organs lost due to a denied harvesting authorization;
3. to purpose a standardized procedure useful to reduce the loss of organs potentially adequate for transplantation.

2. Material and methods

A retrospective study regarding organ harvesting was conducted in the Veneto region between 2012 and 2017. The donors were classified as “heart beating” (HB) when the death was assessed according to neurological criteria, and both organs and tissues could be removed, and as “non-heart beating” (NHB) when the death was assessed according to cardiological criteria and only tissues could be harvested.

All the potential donors’ data, which were reported to the Veneto Regional Coordination Centre (CRT), between 01.01.2012 and 31.12.2017, were collected and subsequently donors were divided into two groups: HB donors and NHB donors.

Concerning the potential donors in which it was necessary to ask the authorization to the JA, they were subdivided into three categories, based on the results of the JA response: *approved*, *limited* (limitation on the number of organs and/or tissues that could be removed from the donor) or *denied*.

Subsequently, potential organ donors (HB cases) were considered for further analysis. By examining the computer archive *Donor Manager* and the medical records, personal (age and gender) and clinical data (duration of hospitalization, blood and chemistry panels, radiological imaging) were collected.

Based on clinical and circumstantial data (i.e., medical reports, judicial reports, medico-legal reports, etc.), deaths were defined as “*related to a crime*” when at least one person was included in the list of suspects (e.g., road or work-accidents, professional liability cases, homicides, drug-related deaths, etc.) or as “*not related to a crime*” when the JA did not open a file (e.g., suicides, accidental traumas, natural deaths, etc.). The cause of death was classified as “head trauma” (i.e., cause of death related to a traumatic brain injury) or as “any other cause of death” (e.g., spontaneous cerebral haemorrhage, myocardial infarction, mechanical asphyxia, drug related death, thoracic or abdominal trauma, etc.). Lastly, as for “forensic autopsy” cases were divided into two

groups: autopsy or not performed.

Data were analyzed using the chi-square and the t-Student’s tests where appropriate. To evaluate the correlation between the JA response and the collected circumstantial and clinical data a logistic multivariate analysis was performed, estimating the adjusted odds ratios (adjORs) with the corresponding 95% confidence intervals (CI). A denied authorization from the JA was considered as dependent variable Y and cases with a *limited* outcome were incorporated into the *denied* category, since they were a small number, and they represent a condition that decreases the number of organs potentially available for transplantation. A p-value less than 0.05 was considered statistically significant. Statistical analyses were performed using the IBM SPSS version 27.0 (IBM Corp. Armonk, NY).

Finally, real donors (from which organs were actually removed) were quantified, along with the number of organs removed from each individual. The average number of harvested organs per donor was calculated and used to estimate the number of organs lost due to a denied harvesting authorization.

3. Results

Between 2012 and 2017, 17,662 potential organ and/or tissue donors were reported to the CRT, of which 16,418 were NHB donors and 1,244 HB-donors. Of the 16,418 NHB donors reported, the authorization to the JA was requested in 994 cases (6.1%), *approved* in 715 cases (71.9%), *limited* in 143 (14.4%) and *denied* in 136 (13.7%). Regarding the HB donors, the authorization was asked to the JA in 200 cases (16.1%), *approved* in 154 cases (77.0%), *limited* in 7 (3.5%) and *denied* in 39 (19.5%) (Fig. 1). For the HB donor’s group, 7 cases with *limited* outcome were incorporated into the *denied* category, for a total of 46 cases (23.0%).

Regarding the cases with limited permission, the tissues and organs for which the JA had forbidden the sampling were respectively the skin, the heart and the lungs.

Out of the 200 HB donors, male individuals were the majority (76.0%), but the distribution between male and female based on the outcome of the authorization showed no statistically significant differences. The average age was 48.8 ± 21.6 years old in *approved* cases and 46.6 ± 21.6 in *denied* cases without any significant differences. The manner / circumstances of the death led the JA to open a file in 122 cases (61.0%); in 27.9% of these cases the authorization was denied, with a significant difference between deaths related to a crime and those not related to crime (27.9% vs 15.4%, $p = 0.041$). The cause of death was a traumatic brain injury in 169 cases (84.5%); in the 24.9% of these cases the authorization was denied. The JA denied the authorization for organ harvesting in 53.3% of cases with hospitalizations of less than 1 day respect to the 9.4% of cases with duration of the donor’s hospitalization exceeding one week [adjOR(95%CI) = 10.67 (1.92–59.22)].

A forensic autopsy was performed in a minority of cases (31 cases, 15.5%), both in the group with authorization *approved* (16 out of 154, 10.4%) and *denied* (15 out of 46, 32.6%). Specifically, the completion of an autopsy was linked to a higher chance of *denied* outcome [adjOR(95% CI): 3.45 (1.42–8.39)] (Table 1).

Blood and chemistry panels and radiological imaging (X rays and/or CT) were performed in all cases.

Surgical procedures during hospitalization were carried out in approximately half of the cases (96 out of 200, 48.0%): in 79 cases with *approved* authorization and in 17 cases with *denied* authorization.

Out of the 154 cases with and *approved* authorization, 143 were real donors (92.9%) (Fig. 1), for a total of 536 removed organs, with an average of 3.48 (536/154) organ per donor and a maximum of 7 organs per single donor. Taking into account the average number of organs harvested per donor and the number of cases with a *denied* authorization (39; Fig. 1), a total of 135 organs were potentially lost as a consequence of the JA refusal (Table 2).

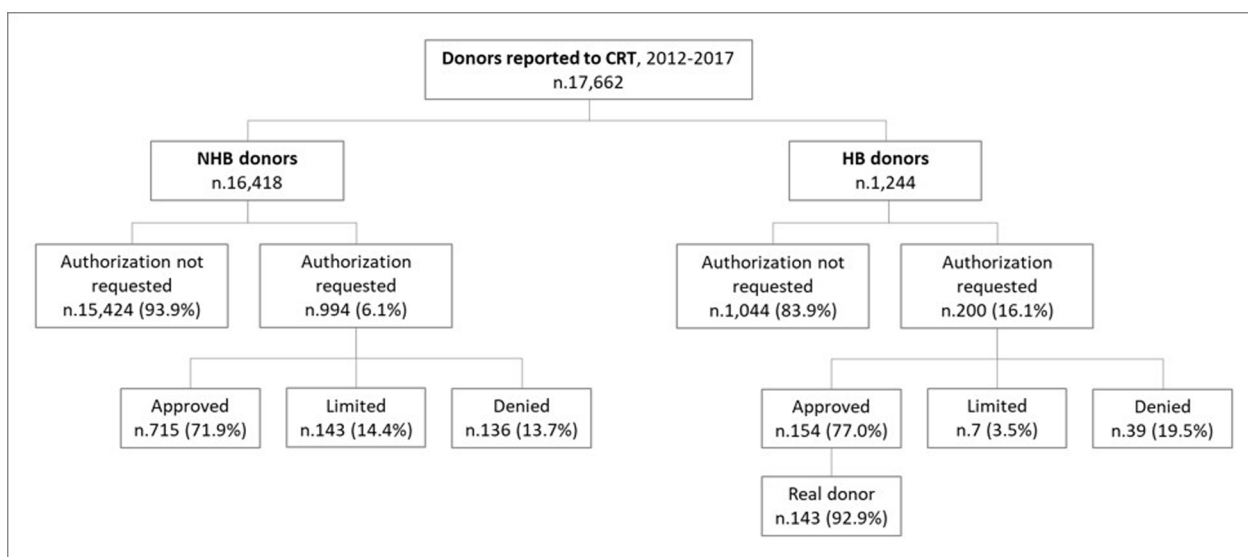


Fig. 1. Flow-chart. Case histories and result of the authorization.

Table 1

Collected clinical and circumstantial data and univariate/multivariate statistical analyses correlated to the outcome of the JA authorization (HB donors).

Donor's characteristics	Total number	Outcome authorization				Univariate analysis		Logistic analysis (Y: "Denied outcome")	
		Approved		Denied		p	OR (95% CI)	adj p	adjOR (95% CI)
		200	154	46					
	n	n	(%)	n	(%)				
<i>Gender</i>									
male	152	119	(78.3)	33	(21.7)	ref			ref
female	48	35	(72.9)	13	(27.1)	0.441	1.34 (0.64–2.82)	0.748	1.14 (0.49–2.67)
Average age ± SD	48.3 ± 21.6	48.8 ± 21.6		46.6 ± 21.6		0.532		0.429	0.99 (0.97–1.01)
<i>Deaths related (or not) to a crime</i>									
Related to a crime	122	88	(72.1)	34	(27.9)	0.041	2.13 (1.02–4.42)	0.081	2.07 (0.91–4.70)
Not related to a crime	78	66	(84.6)	12	(15.4)	ref			ref
<i>Cause of death</i>									
Head trauma	169	127	(75.1)	42	(24.9)	0.146	2.23 (0.74–6.75)	0.292	1.88 (0.58–6.10)
Any other cause of death	31	27	(87.1)	4	(12.9)	ref			ref
<i>Duration of hospitalization</i>									
≤1 day	15	7	(46.7)	8	(53.3)	0.003	11.05 (2.32–52.72)	0.007	10.67 (1.92–59.22)
2–7 days	153	118	(77.1)	35	(22.9)	0.086	2.87 (0.82–9.98)	0.079	3.14 (0.87–11.27)
>1 week	32	29	(90.6)	3	(9.4)	ref			ref
<i>Forensic autopsy</i>									
yes	31	16	(51.6)	15	(48.4)	0.001	4.17 (1.87–9.33)	0.006	3.45 (1.42–8.39)
no	169	138	(81.7)	31	(18.3)	ref			ref

4. Discussion

An efficient collaboration between the organizations managing transplantations and the JA is a key-point, which has already been addressed several times in both clinical and forensic literature in order to improve the procedures of organ procurement [8–9,14].

In Italy, to date, there are no epidemiological studies on this subject. For this reason, we have carried out a retrospective investigation in the Veneto region, where the percentage of *denied* authorization from the JA is around 13.7% regarding only-tissue donors and 19.5% for organ donors. These percentages are higher than those observed in other European countries (Spain 3.46% [10], France 4% [7]) (Table 3).

Consequently, as seen in other surveys [7,10–13], in our study the

number of organs potentially lost due to a *denied* authorization from the JA was quite relevant (135 organs in 5 years). Moreover, as reported in previous literature, in those cases in which the JA denied the authorization, the potential donors were younger (mean age = 46.6 years) than those receiving JA approval (mean age = 48.8 years), implying a potential loss of organs with a better residual function.

The main reason behind the denial of the JA is the possible interference of organ withdrawal with the post-mortem forensic assessment. In this regard, in order to evaluate any potential differences between the cases with an *approved* or *adverse* outcome (*limited* and *denied*), several clinical and circumstantial data, regarding the 200 potential organ donors for which the JA decision was requested, were taken into consideration. The multivariate statistical analysis showed a significant

Table 2

Total number of organs harvested from donors with *approved* outcome and number of organs per donor.

N. of organs	Donors	Organs per donor
0	11	0
1	11	11
2	18	36
3	43	129
4	38	152
5	3	15
6	17	102
7	13	91
Total	154	536

Average number of organs harvested per donor: **3.48**
 N. of organs potentially retrievable from the 39 donors if the authorization were approved: **135.7**

correlation between the outcome of the JA evaluation and the duration of the hospitalization and the execution of a forensic autopsy.

First of all, a longer period of hospitalization was statistically related to a greater degree of approvals (i.e., 90.6% cases approved when the hospitalization was >1 week versus 74.4% in the other cases). A potential reason behind this finding could be that the longer hospitalization period may favour a more in-depth investigation of the health conditions of the donor (performed by the clinicians) and a more precise reconstruction of the traumatic event which led to the hospitalization (performed by the police).

Finally, the execution of an autopsy was quite more frequent when the JA denied the authorization for organ harvesting [adjOR(95%CI) = 3.45 (1.42–8.39)]; however, also within this group (i.e., denied authorization), forensic autopsy was carried out only in a minority of cases (15 cases; 32.6%).

More surprisingly, in 42 cases in which the cause of death was a traumatic brain injury, the JA denied the authorization. This is quite

Table 3

European and non-European studies on the subject.

European and non-European studies					
	France ⁷	Spain (4 province) ¹⁰	Australia ¹¹	United Kingdom ¹²	United States ¹³
Study period	2012	1998–2006	2009–2013	2014–2015	2000–2001
Cases of interest to the J.A. (% n)	7–10%	38.5% (433)	177	43%	56%
Authorization denied (% n)	4% (30/year)	3.46% (15)	2	7%	7%
Authorization limited (% n)	/	/	8	9%	23%
Lost organs (n)	100/year	42	/	77	1451
Causes of the denial	lack of information necessity of autopsy death in criminal context	risk of tampering with evidence		suspicious death necessity of autopsy	lack of information risk of tampering with justice
Previous/in use measures	2004: recommendation letter to J.A. (Minister for justice) 2013: national recommendation (Society of Forensic Medicine)	annual meeting for guidelines topics addressed in the J.A.'s training course	real-time communication J.A.-transplant team routine CT post mortem	2013: strategies for transplants, collaboration with coroner local guidelines	1994, 2003: ad hoc legislation (some states) other states: local regulations and protocols
Indicated/proposed improvement	external examination before removal forensic pathologist participant protocols and local contacts photo pre- and post-removal	external examination before removal forensic pathologist participant protocols per coroners photo before removal		shared guidelines (health system-coroner) monitoring new guidelines (to verify benefit)	improve cooperation
Other notes	organ removal does not interfere with J.A. necessity and autopsy removal does not tamper evidence	individual J.A. choice geographic variability	organ removal does not interfere with J.A. necessity and autopsy removal does not tamper evidence removal does not interfere with the determination of cause of death	statistic analysis (outcome of authorization - circumstantial data) individual J.A. choice geographic variability	“denied” decreased where guidelines are in place individual J.A. choice removal does not interfere with the determination of cause of death

amazing because in these cases the most relevant anatomical district to explore at forensic autopsy is the head (skull and brain), a region that is not manipulated during the organ harvesting phases. Moreover, as reported in the results section of this manuscript, in all of these cases, radiological imaging and blood tests were performed during hospitalization, furnishing potentially useful information also on the dynamics of the traumatic cranial injuries. Additionally, in cases of head trauma, during the death ascertainment, and before organ removal, a forensic external examination along with an eventual radiological investigation could be performed for detecting any skin lesions, fractures/dislocations or injuries of the thoraco-abdominal organs [15,16]. In that way, the “status quo ante” organ harvesting would be documented, and the judicial autopsy could be focused on the head (skull and brain) not manipulated during the harvesting phases. Numerous international studies have underlined the feasibility of an autopsy after organ removal [7,9,11,14], pointing out that the removal of organs does not interfere with the identification of the cause of death, and the trial progression [11]. Furthermore, although the percentage of denials was higher in those cases in which death was related to a crime (34 case), in 12 cases the authorization was denied even if the JA did not open a file for crime investigation.

We believe that the above-discussed main findings of this study could be at least partially explained by the peculiarities of the Italian legislation regarding the death assessment in heart beating (HB) subjects, which foresees that:

- the death ascertainment must last 6 h;
- the request to the JA for authorization can be performed only after the beginning of death ascertainment;
- the JA must communicate its eventual authorization by the end of the investigation.

This very limited period of time (i.e., 6 h) in which the JA must take and communicate its decision represents one of the most significant obstacles in the procurement process of organs. In fact, according to

previous studies on this matter, the communication between the physicians of the organ procurement organization and the public prosecutor is one of the main weaknesses of the process [7,10–13].

Previous studies, conducted in countries with coronial and non-coronial systems [7,10–13], came to similar conclusions on the main strategies useful for reducing the rates of JA denials:

- to uniform protocols and guidelines shared between the parties involved;
- to define specific roles and accountabilities;
- to create a 24 h availability of both organ procurement organizations and JA members;
- to perform a forensic external examination prior to organ harvesting;
- to perform the harvesting at the presence of a medical examiner/forensic expert.

5. Conclusions

The study here presented shows that in the Veneto region, and more generally, in Italy, there is still a lack of homogeneity in the decision-making process, with cases in which the denied outcome of the JA for organ harvesting is not properly justified by the clinical and circumstantial data of the case under investigation, and the denial seems more related to a lack of time to decide, than to a specific need for preserving forensic evidence.

As well-known, the denial for organ harvesting from a single deceased may preclude the access to a life-saving therapy for more than one person on the waiting list, up to 7 potential recipients (i.e., average 3–4, as estimated in this study). Therefore, there is a need to develop an effective and shared protocol between the parties involved in order to reduce as much as possible the loss of organs potentially adequate for therapeutic transplantation. The above protocol should be precise and simple, with all clinical and circumstantial data essential to the JA; it should also allow the latter to request additional data regarding sampling operations and/or examinations deemed necessary for the right to proceed. In addition to the optimization of the procedures currently in place, a greater training of the personnel involved is deemed opportune in order to provide to the JA detailed information of the donor's ante-mortem status and the most probable cause of death.

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The authors declare that they have no known competing financial

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