

Integrated Procurement Model: A new approach to Tissue and Organ Procurement

Un modello integrato per l'identificazione dei potenziali donatori: un nuovo approccio nei trapianti di organi e tessuti.

Angelo Oliva¹ Francesco Zaghini² Marco Martelloni¹ Jacopo Fiorini³ Laura Masci¹ Priscilla Pelei⁴

Silvana Di Florio⁵ Rosaria Gattellaro⁵ Francesca Leonardis⁶ Girolano De Andreis⁵ & Alessandro Sili⁷

ABSTRACT

- 1 Specialized nurse in organ donation, Department of Nursing Professions, Tor Vergata General Hospital, Italy
- 2 RN, MSN, PhD, Research Nurse, Tor Vergata University Hospital, Rome
- 3 RN, MSN, Vascular Access specialist, PhD student, Tor Vergata University Hospital, Rome;
- 4 RN, Department of Biomedicine and Prevention, Faculty of Medicine, University Tor Vergata of Rome, Italy
- 5 RN, MSN, Tor Vergata University Hospital, Rome
- 6 Intensive Care Unit Director, MD, Tor Vergata General Hospital, Italy
- 7 Nurse Manager, PhD, Tor Vergata University Hospital, Rome

Corresponding author:

Dr Francesco Zaghini
Policlinico di Tor Vergata
Viale Oxford, 81
00133 - Roma
francesco.zaghini@pvtonline.it
Tel. +39 06 2090 8175
Orcid
ID 0000-0002-3327-5751

INTRODUCTION: Literature has shown that the process of procurement of organs and tissues is fundamental in determining the number of donations. Starting from these assumptions, an integrated procurement model of organs and tissues has been designed and tested, where nurse specialists in organ donation coordinate the team and the entire process.

AIM: To evaluate the effectiveness of the Integrated Procurement Models in terms of identifying potential donors and the number of donations.

METHODS: A retrospective observational study was conducted before and after the introduction of the new procurement model in a large University Hospital in Rome. The data of potential donors identified, the number of donations made and the efficiency indicators of the donation process were compared.

RESULTS: 692 potential donors were identified. The introduction of the integrated model increased the number of actual donors (from 31 to 51), brain death assessments (from 69 to 99), and the efficiency indicators of the donation process (from 0.25 to 0.29). From the comparison between the activities before and after the introduction of the integrated procurement model, statistically significant differences emerged regarding the number of donors ($\bar{X}_2 = 9.85$; $p < 0.002$) and the amount of corneal tissue extracted ($\bar{X}_2 = 34, 01$; $p < 0.001$).

CONCLUSION: The adoption of the standardized Integrated Procurement Model would increase the number of potential donors and actual donations, thanks also to the key role assumed by the nurse specializing in organ donation as team and process coordinator.

KEYWORDS: Specialist nurse, tissue organ and procurement, tissue donors, transplant

RIASSUNTO

INTRODUZIONE: La letteratura ha evidenziato che il processo di Procurement di organi e tessuti è fondamentale per determinare il numero di donazioni. Partendo da questi presupposti è stato ideato implementato e testato un modello integrato di Procurement di organi e tessuti, in cui infermieri specialisti della donazione di organi coordinano l'equipe e l'intero processo.

SCOPO: Valutare l'efficacia del Modelli integrato di Procurement in termini di individuazione di potenziali donatori e numero di donazioni.

Materiali e metodi: È stato condotto uno studio osservazionale retrospettivo prima e dopo l'introduzione del nuovo modello di Procurement in un grande Policlinico Universitario Romano. Sono stati confrontati i dati dei potenziali donatori individuati, il numero di donazioni effettuate e gli indicatori di efficienza del processo di donazione.

RISULTATI: Sono stati identificati 692 potenziali donatori. L'introduzione del PIM ha aumentato il numero di donatori effettivi (da 31 a 51), gli accertamenti di morte encefali (da 69 a 99), gli indicatori di efficienza del processo di donazione (da 0,25 a 0,29). Dal confronto fra le attività prima e dopo l'introduzione del modello integrato di Procurement, sono emerse differenze statisticamente significative relativamente al numero di donatori ($\bar{X}_2=9,85$; $p<0,002$) e alla quantità di tessuto corneale prelevato ($\bar{X}_2=34,01$; $p<0,001$).

CONCLUSIONI: L'adozione del modello integrato e standardizzato di Procurement permetterebbe di aumentare i possibili donatori e le reali donazioni, grazie anche al ruolo chiave assunto dall'infermiere specialista della donazione di organi come coordinatore dell'equipe e del processo.

PAROLE CHIAVE: Infermiere specialista, procurement, donazione di organi e tessuto, trapianto.

INTRODUCTION

In Italy the number of transplants performed represents about 40% of the national requirement (Cardillo, 2019). The gap between the number of patients awaiting transplantation and the organs/tissues available is a serious problem that prevents an effective and efficient response to the needs of patients and the health system. The Italian National Transplant Centre, at 31 December 2018, verified 8,713 potential recipients on the waiting list as against 3,719 transplants performed (Cardillo, 2019), and 8765 corneal tissues donated, compared to 5945 transplants (Cardillo, 2019). For sclero-corneal tissue, there is no waiting list, as there is for solid organs.

The reasons for the difference between the numbers of donations and of transplant requests, can be found in the process of identifying potential donors of organs and tissues within the health care system (Hoste, Vanhaecht, et al., 2016). This process, known as Procurement, is considered a key point by the whole scientific community (Hoste, Ferdinande, et al., 2016).

Although literature has highlighted the need to standardize the procurement process of organs (National Institute for Health and Clinical Excellence, 2011), health care professionals act differently in different geographical areas (Martelloni et al., 2018). A few hospitals have tried to standardize the procurement process in accordance with one of two methodological approaches: the "Spanish" method (Domínguez-Gil et al., 2017; Sarlo et al., 2016; Silva et al., 2016) adopted in countries in the Mediterranean area (including Italy), and the "Anglo-Saxon" method (Garside, Garside, Fletcher, & Finlayson, 2012; Nolin, Mårdh, Karlström, & Walther, 2017; Summers et al., 2014) mainly used in northern Europe and the United States. Both approaches agree on the management of the potential patient donor and his or her family by a multidisciplinary team, whose integration makes it possible to improve the quality of care provided (Hoste, Vanhaecht, et al., 2016; Roussel, Gorham, Wilson, & Mangi, 2013). A few studies have had as their main objective to verify the real effectiveness of these two procurement processes in terms of increasing the number of donations. Indeed, studies have identified common factors which imply a fragmentation of the procurement process, reducing its real power (Hoste, Ferdinande, et al., 2016; Hoste, Vanhaecht, et al., 2016). In particular, fundamental activities for the procurement process have been highlighted as being done differently, such as: the criteria used to determine brain death; compliance (or not) with the guidelines for donor identification; organ donation being considered (or not) as an integral part of the end of life path by health professionals; a relationship being established (or not) with the families of potential donors (Hoste, Vanhaecht, et al., 2016). By contrast, a standardized procurement process, in line with scientific evidence and shared and promoted by the entire multidisciplinary team, would guarantee the identification of a greater number of potential donors and consequently of donations (Hoste, Vanhaecht, et al., 2016). Furthermore, it emerges from the literature that

entrusting the coordination of the multidisciplinary team to a single healthcare professional who is responsible for identifying and supporting each step of the donation, improves the effectiveness of the procurement process and the quality and safety of the donated organs (Hoste, Ferdinande, et al., 2016). A single study (Garside et al., 2012) investigated the effectiveness of the introduction of a specialized nurse in organ donation (SN: OD), highlighting that it significantly increased the rate of potential donors of organs.

Based on these premises, a standardized procurement pathway for organs and tissues was designed, implemented and tested, which the authors called the Integrated Procurement Model (IPM), in which the SN: OD plays a key role. The main objective of this study was to understand the real effectiveness and efficiency of the IPM in terms of increasing the number of potential donors and consequently the number of donations.

Before the introduction of the IPM, the hospital where the study took place, working to the Spanish model, had not been provided with nursing staff dedicated to the procurement process, and there was no structured coordination of the process. The organ and tissue collection activities consisted exclusively of monitoring admissions in intensive care through company databases, without any targeted, constant or procedural visits. Activities in other operating units, such as first aid and mortuary, were not monitored for the purpose of donating corneal tissue, and no operative procedure was used in the wards for reporting any donors.

METHODS

In order to verify the objective of this research, the new standardized organizational process, IPM, was implemented, which involves three dedicated SNs:ODs who manage and coordinate the procurement process in collaboration with a multidisciplinary team, providing an integrated epidemiological and clinical approach, able to improve efficiency and maximize the identification of potential donors. The multidisciplinary group consists of an anaesthesiologist, an emergency room nurse, an intensive care nurse, a ward nurse and a surgeon.

From the epidemiological point of view, possible brain damage patients and potential living donors are evaluated and monitored daily through an analysis of:

- a) theoretical donor potential of the hospital through a series of processes aimed at a knowledge of the operational context and brain injuries;
- b) deaths;
- c) admissions of potential donors;
- d) Neurosurgical and Orthopaedic Operation Lists;
- e) all hospitalizations for brain injuries and orthopaedic diseases.

From the clinical point of view, in addition to a continuous interface with the anaesthesiologists and emergency doctors (24/24), the data deriving from:

- a) clinical monitoring of potential donors;
- b) daily visits to the wards (Emergency Room, Intensive Care, Stroke Unit, Neurosurgery and Neurology) and mortuary;
- c) ISTAT (national statistical institute) modules;
- d) hospital discharge records.

Furthermore, the IPM provides a specific procedure for the reporting of potential scleral-corneal tissue donors by hospital wards, using a dedicated fax, 24 hours a day, managed by the SN: OD.

After the introduction of the IPM, in the regional procurement reference centre at a University Hospital, a retrospective descriptive correlational study was conducted on the clinical documentation of potential donors, with the aim of verifying its effectiveness.

Procedure

The data were collected within two specific periods of time, both lasting 2 years, before and after starting the IPM. Since the IPM was implemented as from 1 January 2017, the two-year periods January 2015 / December 2016 and January 2017 / December 2018 were the ones considered.

The study was conducted according to the World Medical Association Declaration of Helsinki (2013) and approved by the Ethics Committee of the university hospital. Researchers verbally informed participants' tutors about the purpose and procedures of the study, anonymous collection of data, and voluntary nature of participation. Informed consent was obtained for each participant enrolled.

In order to verify the hypotheses of the study, data derived from the clinical documentation of potential donors with a diagnosis of brain injury were collected. In particular, the data were collected of potential donors with Cranial Trauma, Cerebral Haemorrhage, Stroke (ischemic or haemorrhagic), Coma or brain injury with a Glasgow Coma Scale (GCS) ≤ 8 , without distinction of sex, basic pathologies, comorbidities and age. Data from potential donors not affected by brain injury, or who had a GCS of >8 were excluded from the study despite stroke, coma or brain injury.

The study collected and compared data deriving from the health and administrative documentation of potential donors, already in possession of the healthcare facility and of the Transplant Nursing Coordination where the study took place. Data were collected from the registry of cerebral nerves, the regional organ and tissue donation management system (GEDON), the regional system of Computerized First Aid and Emergency Management (GIPSE), the Corporate Management of Acceptance, Resignation and Transfers (ADT), and the Hospital IT Service (SIO).

Instrument

To measure the effectiveness of the IPM in comparison with the previous approach, the "procurement indicators and efficiency of the donation process" (PROC 1; PROC 2) were studied, in order to gain: a) an assessment of the identification process, diagnosis and ascertaining of brain

death; b) an assessment of the overall efficiency of the donation process; and c) an evaluation of the ability to identify potential donors, of each approach (Procaccio, Gianelli Castiglione, Manyalich, & Nanni Costa, 2012). In particular, the indicators are:

- PROC 1: Evaluation index of the activities, which is obtained from the ratio between the number of actual donors and the number of deaths with brain lesions (0-15%, inadequate = I; 16-25%, good = B; $> 25\%$ excellent = E).
- PROC 2: Evaluation index of the activities, which is derived from the ratio between the number of brain death assessments and the number of deaths with brain lesions (0-20%, inadequate = I; 21-40% good = B; $> 40\%$, excellent = E).

Data analysis

The data were analysed through descriptive statistics with distribution and dispersion indices and through inferential statistics tests. In particular, the analyses were conducted comparing the data of the two years preceding the implementation of the standardized Integrated Procurement process with those of the following two years, through descriptive statistics (central tendency, variability) and inferential statistics (X2 test for independent samples). The results were considered statistically significant with a $p < 0.05$. The SPSS statistical software vers. 22.0 was used.

RESULTS

The final sample is composed of the clinical documentation of 692 potential donors, who from January 2015 to December 2018, were hospitalized in the identified care settings of the reference hospital. 59.97% are men (N = 415), most were aged between 61 and 80 (43.50%; N = 301). The main medical diagnosis of the admitted patient in intensive care is cerebral haemorrhage (42.77%; N = 296; Table 1).

Table 1. Descriptive statistics of the sample (N=390)

Variabile	N	%
Gender		
Male	415	59.97
Female	277	40.03
Age (years)		
< 15	---	---
15-40	104	15.03
41-60	224	32.37
61-80	301	43.50
> 80	63	9.10
Medical diagnosis		
Cerebral haemorrhage	296	42.77
Head Trauma	151	21.82
Cerebral Ischemia	108	15.61
Neofornation	96	13.87
Other	41	5.93
Death in days from admission to intensive care unit		
≤ 3	171	24.70
4-7	183	26.45
8-15	155	22.40
>15	183	26.45

Table 2. Index of the Procurement process before and after IPM

Indicators	2015/2016	2017/2018
Patients with cerebral lesions	306	386
Dead patients with cerebral lesions	122	175
Brain death assessments in ICU	69	99
Actual donations	31	51
PROC1	0.25	0.29
PROC2	0.57	0.57

Procurement process

Table 2 shows data relating to hospitalizations, deaths, brain death assessments and actual donations, divided into the two-year periods of reference, of potential donors hospitalized at the facility where the study was conducted. The quality indicators of the donation process are also reported, PROC 1 and PROC 2. Finally, a comparison was made between the activities in the two-year periods, before and after setting up the new procurement process (Table 3).

In particular, statistically significant differences emerged regarding the number of donors ($X^2 = 9.85$; $p < 0.002$) and the amount of corneal tissue taken ($X^2 = 34.01$; $p < 0.001$) between the two periods considered, before and after the introduction of the IPM.

DISCUSSION

The aim of this study was to verify the effectiveness of the new procurement process for organs and tissues (IPM) developed in the reference centre of a University Hospital. Results of the study highlighted a substantial increase in the number of donations in proportion to the number of brain deaths determined in the hospital. A comparison of the relative frequencies of the data shows that the IPM and the introduction of the SN: OD have had a positive impact on the activities carried out by the centre and on the number of donations that patients awaiting transplants have benefited from.

In particular, comparing the effectiveness results of the donation process (PROC1 and PROC2) before and after

the implementation of the IPM, it can be said that the results achieved have been significant, especially comparing these same data with the average data recorded at the level of the reference Region (Centro Regionale Trapianti Lazio, 2018). Furthermore, there is a statistically significant positive difference between the number of donations and sclero-corneal tissue extracted after the introduction of IPM. This important improvement is even more evident when comparing the data with those of the regional averages. In fact, prior to the introduction of the IPM, 2015-2016, the average collection of scleral-corneal tissues of the regional centre was 34.46, while in the study hospital it was 24; whereas in the two-year period 2017-2018, after the introduction of the IPM, the regional average ($M = 35.87$) remained substantially unchanged (Centro Regionale Trapianti Lazio, 2018) while in the study hospital there was a strong growth in the number of extractions ($N = 64$). Unfortunately, in the case of these data it is not possible to make a comparison with national and international statistics because they are not available; not only are there no lists in which to find data, but above all, the corneas may not be directly implanted, but preserved by the sampling centre and implanted after months.

The IPM implementation and the introduction of SN: OD as coordinator and key figure of the multidisciplinary team and of the procurement process of organs and tissues, allowed early identification of potential donors and increased actual donations. Compared to the Garside study (2012), our study showed, with statistically significant results, how this model optimizes the process and improves caring outcomes. Furthermore, the introduction of the SN: OD, in addition to favouring the identification and care of possible donors, provides a point of reference and support for the potential donor's family, establishing a therapeutic relationship, raising awareness of the issue of organ donation, and caring in the context of death (Garside et al., 2012; Hoste, Ferdinande, et al., 2016; Silva et al., 2016). Future studies should evaluate how the SN: OD is perceived by the donor's family, in relation to death and organ donation.

These results, while representing an important contribution for the scientific community, must be considered in the light of some limitations. First, the results refer to a single-centre study, therefore bias due to internal processes and to the dynamics of the health aspect under scrutiny cannot be excluded. Secondly, the trend of the activities is influenced by important factors outside the organ dona-

Table 3. Comparison of the results of the Activities carried out before and after IPM

Activities	2015-16		2017-2018		X2	p
	N	Fr	N	fr		
Reported donors	69	0.57	99	0.57	0.01	n.s.
Provided donors	31	0.26	52	0.30	0.66	n.s.
Actual donors	26	0.22	46	0.26	0.97	n.s.
Corneal tissue donors	24	0.20	64	0.37	9.85	0.002
Corneal tissue extracted	48	0.39	128	0.73	34.01	<0.001

tion path, above all, the epidemiology of brain deaths. Finally, the sample was a convenience sample and therefore the generalization of the results obtained may not be guaranteed.

CONCLUSION

This study offers the scientific community a new organizational model for the procurement of organs and tissues that has proved effective, efficient and productive for potential donors and health care organizations. The adoption of the IPM within healthcare companies would optimize and standardize the procurement process of organs and tissues and increase possible donors and actual donations, not least through the key role of the SN: OD and lay the starting points for future research. These results enhance the nursing role within the multidisciplinary team of the organ and tissue donation process, from the identification, selection and maintenance procedures of donors, to the allocation, sampling and transplantation (Centro Nazionale Trapianti - CNT, 2018).

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Conflict of interests

No conflict of interests has been declared by the authors.

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