

Ilona Kiel-Puślecka<sup>1,2\*</sup>, Mateusz Puślecki<sup>3,4,5</sup>, Marek Dąbrowski<sup>5,6</sup>, Bartłomiej Janyga<sup>2</sup>, Bartłomiej Perek<sup>4</sup>, Agnieszka Zawiejska<sup>7</sup>

<sup>1</sup>Center of Medical Simulation, Poznan University of Medical Sciences, Poznan, Poland

<sup>2</sup>B. Janyga and Partners Law Office, Poznan, Poland

<sup>3</sup>Department of Medical Rescue, Poznan University of Medical Sciences, Poznan, Poland

<sup>4</sup>Department of Cardiac Surgery and Transplantology, Poznan University of Medical Sciences, Poznan, Poland

<sup>5</sup>Polish Society of Medical Simulation, Poland

<sup>6</sup>Department of Medical Education, Chair of Medical Education, Poznan University of Medical Sciences, Poznan, Poland

<sup>7</sup>Department of Medical Simulation, Chair of Medical Education, Poznan University of Medical Sciences, Poznan, Poland

# Current knowledge of legal determinants of postmortal organ donations among lawyers and physicians — a cross-sectional survey and narrative review regarding potential criminal liability in opt-out donation model country

## Corresponding author:

Ilona Kiel-Puślecka,  
Center of Medical Simulation, Poznan  
University of Medical Sciences,  
Poznan, Poland e-mail: ilonakiel@wp.pl

Medical Research Journal 2022;  
Volume 7, Number 1, 54–60  
DOI: 10.5603/MRJ.a2022.0009  
Copyright © 2022 Via Medica  
ISSN 2451-2591  
e-ISSN 2451-4101

## ABSTRACT

**Introduction:** Knowledge of the basic legal acts and regulations concerning postmortal organ donation is a crucial issue in ensuring that the will of the potential donors is respected and that physicians are legally protected from potential consequences. This study aimed to assess the awareness and knowledge of physicians and lawyers about the basic legal determinants and criminal responsibility in an opt-out donation model country.

**Material and methods:** Survey-based study involved 100 participants, including physicians (group P; n = 50) and lawyers (group L; n = 50). An original questionnaire consisted of 21 questions about the knowledge of the legal regulations of organ donation in Poland. Additionally, a narrative review of Polish transplantation legal acts was performed to identify potential criminal responsibility related to postmortal transplantation.

**Results:** In the study group all lawyers and 50% of physicians declare that their routine work does not include donors' death confirmation. 62% of physicians are included directly in donors' qualification. 92% of lawyers and 90% of physicians suggest that access to knowledge in the subject is not easy. The results of substantive knowledge in the field of transplantation law did not differ statistically between the groups, the median total score in 9 questions test was 5 (3:6) in L and the same in P 5 (2:6). The authors identified four aspects of a physician's criminal responsibility in the case of postmortal transplantation.

**Conclusions:** This study has revealed that knowledge of the basic legal acts and regulations of postmortal donation, considered to be of paramount importance in ensuring respect for transplant law, needed to be improved. Therefore, further education in these aspects may result in more sufficient protection of physicians from potential legal consequences.

**Key words:** postmortal donation, legal aspects, criminal liability, organ donation, transplantation

Med Res J 2022; 7 (1): 54–60

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## Introduction

The main criterion for legal postmortal procurement is either the consent or the objection to a donation by a potential donor. It is legally allowed in Poland to take cells, tissues and organs for transplantation from any deceased person who has not declared objection during life (Art. 5 (1) of the Polish Transplantation Act (TA)). This model is an *opt-out* one. However, the above rule does not apply if such harvesting is a part of the autopsy and serves to establish the final diagnosis and cause of death. In Poland, the postmortal donation is allowed if criteria of cerebral death or death as a result of irreversible cardiac arrest (since 2009) are fulfilled [1].

The legal formula of such objection constitutes a kind of declaration of will (*pro futuro*), so it must be free from legal defects, either of the potential donor themselves or of their legal representative, where the declaration of will is “only such a manifestation of will that expresses sufficiently the intention to produce a legal effect in the form of establishing, changing or abolishing the legal relationship” [2]. A declaration of objection to postmortal donation formulated as a *pro futuro* statement remains valid even though the subject who expressed it is dead and when at the time of death loses their personality and legal capacity [3]. The legislator in Art. 6 of the TA provides the following guidelines of such objection (by the requirements of Directive 2004/23/EC of the European Parliament and Council of Europe):

1. it is expressed by an adult or a minor who has reached the age of 16,
2. it may be expressed by a legal representative in a case of a person without full legal capacity,
3. it may be withdrawn at any time.

Additionally, the following forms of objection are accepted:

1. entry in the Central Register of Objections (CRS);
2. a written, signed declaration;
3. an oral statement made in the presence of two witnesses and confirmed by them in writing.

It should be clearly emphasized that the guarantee of respect for human autonomy and one’s right to decide about oneself, concerning the postmortal donation, is the institution (formula) of objection. In addition, the effectiveness of such objection is based on the obligation — imposed on the physician or a person authorized by them — to exhaust information about the existence of such an objection not only in the CRS but also to confirm or exclude it in any other forms defined by law, based on available information or documents. Knowledge of the basic legal acts and regulations concerning postmortal donation is, therefore, the crucial issue in ensuring that the will of the potential donor is respected and that physicians are protected from any legal consequences.

## Material

This study aimed to assess the awareness and level of knowledge among physicians and lawyers regarding the basic legal determinants of postmortal donation and methods of death confirmation for transplantation by Polish law. In addition, the main situations of the physician’s potential criminal responsibility during postmortal transplantation were identified and discussed.

## Methods

### Participants:

One hundred participants, including 50 physicians (group P) and 50 lawyers (group L) were enrolled in this study. A simple comparison of the aforementioned groups disclosed that group P subjects were older and presented longer professional experience when compared to group L. Naturally, working place was different. Of note, the majority of group P individuals worked in university hospitals where post-graduate education is usually mandatory. The details of demographics and data regarding current professional experience are outlined in Table 1.

**Table 1.** Participant’s demographics and professional experience

	Lawyers (n = 50)	Physicians (n = 50)	P-value
Age [years] (Q1)	33 (28; 61)	36 (29; 54)	<b>0.002</b>
Sex (F/M) (Q1)	24 (48%) / 26 (52%)	32 (74%) / 18 (36%)	0.107
Professional experience [years] (Q4)	6 (2; 30)	9 (4; 25)	<b>&lt; 0.001</b>
Place of work [%] (Q3)	Law Office — 100%	University hospital — 58% Emergency Department — 20% Regional hospital — 18% Transplant Medicine Department — 4%	NA

Data are presented as numbers (n) with percentages (%). They were compared by the means of Chi-square test with or without Yates correction. Bolded values are of statistical significance ( $p < 0.05$ ); (Q — question number in supplementary survey — Appendix)

An original questionnaire consisted of 21 questions, the first 4 regarding demographics, 8 — the availability of substantive information on postmortal procurement and the other 9 about the knowledge of the legal regulations of organ donation in Poland, a developed European country that adopted the opt-out model (see App.). To make it easier to analyse the results of the survey, particularly the latter part assessing the level of theoretical knowledge, quantitative analysis was carried out. An adequate answer to each of 9 points was scored with 1 and then they were added. Eventually, the medians of the sums were compared between professional groups (L vs. P). The study protocol was confirmed by Institutional Review Board.

A narrative review of Polish transplantation legal acts was performed to identify potential criminal responsibility associated with the procedures of postmortal transplantation. The main acts included:

1. Act on the Procurement and Transplantation of Cells, Tissues and Organs, 25<sup>th</sup> October 1995 [1],
2. Act on the professions of doctor and dentist, 5<sup>th</sup> December 1996, Journal of Laws, 1997 [4],
3. Polish Criminal Code,
4. Polish Civil Code.

### Statistical analysis

First, the quantitative variables were checked for normality with the use of the Shapiro-Wilk W test. Because the analysed parameters did not meet the criteria of a normal distribution, they were presented as median (minimum; maximum). The categorical variables were expressed as the numbers (n) with percentages (%). For statistical analysis, the Mann-Whitney test or Chi-square

with or without Yates correction was used. The analysis was performed using the Statistica 12 software (Tibco Inc., Tulsa, OK, USA).

## Results

The comparative analysis of the survey findings revealed significant differences in respect of experience in donor qualification and practical/professional involvement in organ transplantation between study participants representing two professions.

All of group L declared their routine work did not include donors' death confirmation. Moreover, they neither were involved themselves nor knew persons directly involved in donors' qualification. Moreover, 100% of group L confirmed that during professional career or university education they had no opportunity to acquire knowledge of postmortal transplant qualifications law. Most of them (92%) suggest that access to information about transplantation is not easy and its presentation in generally available media is rather superficial (Tab. 2). Contrary to group L, a half or more of group P declared that their routine work included postmortal donors' death confirmation and they were involved directly in donors' qualification. Additionally, 64% confirmed that they had an opportunity to acquire knowledge of postmortal transplant medicine during both university education and postgraduate professional career. Notably, they did support the opinion of group L that access in various media in respect of donor qualification and other crucial aspects of transplantation is not adequate and their presentation is too rare and superficial (Tab. 2).

Table 2. Availability of substantive information on postmortal donation

	Group L (n = 50)	Group P (n = 50)	P-value
Routine work includes donors' death confirmation (Y/N) (Q5)	0/50 (100%)	25 (50%)/25 (50%)	< 0.001
Direct involvement in donors' qualification (Y/N) (Q6)	0/50 (100%)	31 (62%)/19 (38%)	< 0.001
Knows persons who are included directly into donors' qualification (Y/N) (Q7)	0/50 (100%)	45 (90%)/5 (10%)	< 0.001
Opportunity to acquire knowledge of transplant qualification during university education and/or professional career (Y/N) (Q8)	0/50 (100%)	32 (64%)/18 (36%)	< 0.001
Access to knowledge on transplantation (Q11)			
I Easy	0	2 (4%)	0.475
II Needs effort	41 (92%)	45 (90%)	0.387
III Difficult	4 (8%)	3 (6%)	1.000
Transplantation issues information in various media (Q12)			
I Adequate	0	4 (8%)	0.126
II Excessively	3 (6%)	3 (6%)	1.000
III Superficially	25 (50%)	18 (36%)	0.160
IV Rarely	22 (44%)	25 (50%)	0.550

Data are presented as numbers (n) with percentages (%). They were compared by the means of Chi-square test with or without Yates correction. Bolded values are of statistical significance ( $p < 0.05$ ); (Q – question number in the supplementary survey — Appendix)

The overall knowledge of transplant law, reflected by the median total score in the particular studied groups, was at most average and did not differ statistically between the groups. However, the more detailed analysis of individual questions confirmed statistically significantly better knowledge of the legal regulations regarding brain death, and the confirmation methods of donation objection in group L postmortal donation law among group P individuals.

A narrative review of Polish transplantation legal acts identified four listed below main aspects of potential criminal responsibility of any physician involved in a complex procedure of postmortal transplantation, when:

- A. the organ is removed as a consequence of a mistake in death determination,
- B. the organ is removed against the will of the person who objected during their lifetime (legal and required conditions),
- C. the transplant is carried out for financial intention,
- D. the physician during the transplant procedure makes a mistake that causes serious injury or leads to the death of the recipient.

## Discussion

### Transplantation Legal Acts in Poland

The first comprehensive regulation of transplantation in Poland was the Act on the Collection and Transplantation of Cells, Tissues and Organs, called the Transplantation Act (TA), issued on 25th October 1995 [1]. The current Act of 1st July 2005, together with its implementing acts, has become a document regulating the admissibility of transplantation *ex mortuo* and *ex vivo*. It resulted in the adaptation of Polish law to the international standards, in particular, European Union directives. This Act has been in force since 1st January 2006 (except the following Art. 22–35 (1, 2 and 11), Art. 36, 37, 38 (3, 11), 39 (6), 41 (6) and (8a), 42 (2, 3 and 5), 45 and 48, which entered into force on 31st December 2006) [1]. A change in the legal status was brought about by the amendment of 17th July 2009. Art. 9a was added to the TA, according to which the collection of cells, tissues and organs for transplantation was permissible after death confirmation as a result of irreversible cardiac arrest (Par. 1). At the same time, the current Art. 9 remained in force, allowing the organ collection for transplantation after permanent irreversible cessation of brain function.

In the amendment dated on 24th February 2017 which entered into force on 27th April 2017, both provisions were repealed. The provisions on the determination of both permanent irreversible cessation of brain function

and as a result of irreversible cardiac arrest have been transferred to Art. 43a of the Act of 5th December 1996 on the professions of doctor and dentist [4]. In the Explanatory Memorandum to the draft amendment act, it was indicated that “the declaration of death is one of the many activities that every physician performs and the most appropriate action to regulate this matter is the Act on the professions of doctor and dentist”. Attention was also drawn to the fact that the previous location of the regulations created a very unfavourable impression that the determination of death as a result of permanent irreversible cessation of brain activity was performed by physicians to collect cells, tissues and organs. It discouraged this procedure not only to society but also to physicians, thus creating a barrier to the development of organ transplantology. Therefore, it was decided not to combine the provisions on the determination of permanent irreversible cessation of brain function and the determination of death as a result of irreversible cardiac arrest with the provisions of the TA [1].

### Knowledge of legal determinants of organ donations in Poland

According to the authors’ knowledge, it is the first such study in Poland and one of the few in the world focused on a detailed assessment of the knowledge and applicable law concerning very sensitive issues of postmortal organ donation.

Unfortunately, the obtained results confirm the poor knowledge of the legal regulations, not only among physicians but also lawyers. While in the case of lawyers, the logical explanation may be the lack of a direct relationship between professional work and death confirmation or donors’ qualification, in the case of the surveyed physicians seems to be weird. Of note, more than half of them declared participation in the donor’s qualification and donation procedures.

The surveyed also declared that they did not have the opportunity to acquire knowledge in the field of transplant qualifications during their professional career or university education. That situation may lead to the reflection that donation activity in a country depends on the knowledge in this area among people directly involved in the postmortal donation. Lack of knowledge and awareness of the possible consequences may contribute to the underestimation of donor availability and qualification for organ procurement.

### Possible criminal liability of the physician in connection with the transplantation *ex mortuo*

In the case of transplantation processes, mainly due to their specificity, problems related to the violation of transplantation law regulations may occur. This applies

**Table 3.** Comparative analysis of answers to questions concerning the knowledge of the postmortal organ donation law

Group	Question	Group L (n = 50)	Group P (n = 50)	P-value
Death determination	Brain death regulation (c/w)* (Q13)	17 (34%)/33 (66%)	0/50 (100%)	0.003
	Confirmation of death criteria for transplantation in Poland (c/w)* (Q14)	19 (38%)/31 (62%)	18 (36%)/32 (64%)	0.865
	Declaration of death (c/w)* (Q15)	35 (70%)/15 (30%)	27 (54%)/23 (46%)	0.168
Legal donation condition	Legal postmortal donation in Poland (c/w)* (Q16)	0/50 (100%)	21 (42%)/29 (58%)	< 0.001
	Forms of donors' objection in Poland (c/w)* (Q17)	38 (76%)/12 (24%)	44 (88%)/6 (12%)	0.303
	Possibility of withdrawing the objection (c/w)* (Q18)	50 (100%)/0	45 (90%)/5 (10%)	0.390
	Objection confirmation (c/w)* (Q19)	26 (52%)/24 (48%)	2 (4%)/48 (96%)	< 0.001
Organ trafficking	Illegal organ procurement (c/w)* (Q20)	34 (68%)/16 (32%)	42 (84%)/8 (16%)	0.230
	Abroad organs transfer (c/w)* (Q21)	50 (100%)/0	48 (96%)/2 (4%)	0.728
Total score [maximum-9]		5 (3; 6)	5 (2; 6)	0.171

\*Letter 'c' means correct answer whereas 'w' wrong answer to the detailed questions defining knowledge of postmortal donation law. Data are presented as numbers (n) with percentages (%). They were compared by the means of Chi-square test with or without Yates correction. Bolded values are of statistical significance ( $p < 0.05$ ); (Q — question number in the supplementary survey — Appendix)

primarily to physicians who are members of the commissions confirming brain death or death as a result of irreversible cardiac arrest, persons responsible for the procedures of harvesting and implantation of cells, tissues and organs, commissions qualifying recipients as well as any persons who come into contact with a potential recipient — i.e.: all personnel involved in rescue and therapeutic processes. The other medical staff (eg., nurses), as well as all non-medical professionals who participate actively in each of the logistical and coordination stages of the transplantation procedure, may also be responsible for the law violation. The sensitivity of transplant medicine issue was emphasized in the preamble of the Convention for the Protection of Human Rights and Dignity of the Human Being in the Context of the Applications of Biology and Medicine — “improper use of biology and medicine can lead to actions that threaten human dignity” [5].

**A. The organ is removed as a consequence of a mistake in death determination**

Opponents of organ donation argue their objection according to possible mistakes regarding the confirmation of brain death [6–8]. Mistakes in assessing brain death are not impossible and have happened despite the high qualifications of physicians and their many years of professional experience. The pressure of enormous responsibility may additionally negatively affect their work.

Correct determination of the moment of death of the donor is regulated in Art. 43 (5, 6) of the professions of doctor and dentist [4]. However, if physicians make a mistake, they may be criminally liable for the consequences of their error, and the basis of liability will be an incorrect statement of the death of a person who is alive, and with critical consequences. It is then necessary to determine whether “the rules of knowledge of medical

practice applicable in this respect and the objective attribution of the effect and the fact of culpability have been violated”. The consequences of an incorrect declaration of death will form the basis for the legal classification of such an act. If, as a result of an error, organs were removed from a still-alive person, a physician may be held liable for manslaughter — according to Art. 155 of the Polish Criminal Code (hereinafter referred to as the Criminal Code — CC). If, after the false brain death confirmation, the removal of organs has not yet occurred, the physician may answer for exposure to the immediate danger of loss of life or serious health detriment — according to Art. 160 of the CC. Usually, in such situations, there is an unintentional fault. If the doctor acts with a possible intention, which means that he or she was aware that the person is alive, and yet he or she confirmed the death and the organs were removed, he or she will be responsible for intentionally causing death — Art. 148 of the CC. An incorrect declaration of death must be analysed in the same way as any other medical error (*lege artis*) [7].

The confirmation process of brain death or the irreversible cardiac arrest preceding the removal of organs is carried out by a commission consisting of two specialist doctors. In any case, “the rules related to responsibility in the performance of team activities may also apply here”. We may have to deal with a situation of complicity in unintentional crimes [8–10].

**B. The organ is removed against the will of the person who objected during his lifetime (legal and required conditions)**

The prohibition of postmortal removal of cells, tissues and organs if the deceased person has objected from during life, following Art. 5 (1) of the TA and similarly, in Art. 17 of the European Bioethical Convention



Protocol, seems to be a minimum legal and ethical condition [5, 11]. The protection of human autonomy is expressed by the introduction of additional, necessary conditions. They should be fulfilled in the absence of donor objection or if there are any doubts about the will of the deceased potential donor. Art. 10 of the TA imposes the need to conduct a mandatory investigation procedure to ensure that no objection has been filed in another form defined in Art. 6 of the TA, next to CRS. Through an interview with family and relatives based on available information or documents, it should be decided, whether there is a possible opposition expressed in the will of the deceased: explicitly or implicitly. It should be emphasized that the preferences and will of the family of the deceased in the assumptions of the TA cannot be decisive in the context of the donation. For violation of the filed objection, the law in Art. 46 (1) TA provides for the following penalties: fine, restriction of liberty and imprisonment of up to 3 years.

Art. 11 of the TA personally obliges the physician who takes cells, tissues and organs from the corpse to ensure that the corpse is given the proper appearance. This provision is not intended to order the performance of beauty treatments, but only to leave the corpse in a state similar to that which the deceased had during their lifetime. Specific organ and tissue donation, such as the collection of a limb or face, will disturb the aesthetics of the corpse, but the idea is to give due respect to the remains and body of a person subjected to “mutilating” procedures. The basis for the implementation of this rule is the provision of Art. 23 of the Civil Code. The consequences of failure to comply with the obligation imposed in Art. 10 of the Act have not been fully specified. This may be compensation under Art. 24 of the CC for violation of personal rights, but also in extreme cases criminal liability provided for in Art. 262 (1) of the CC for desecration of corpses [3, 11].

### C. The transplant is carried out for financial intention

An important group of violations of the law may concern attempts to trade or obtain financial benefits from transplantation procedures. The European Convention on Action against Trafficking in Human Beings prohibits trafficking in organs, guaranteeing respect for human dignity and stresses that the human body and its parts cannot constitute a source of financial benefit for anyone [12]. This also applies to the *ex vivo* transplant donor as well as the closest people — families of *ex mortuo* donors, as well as outsiders. Only the financing of technical aspects related to coordination, transport, storage of organs and the performance of procedures is allowed. Similarly, Art. 3 of the TA provides that “cells, tissues and organs are taken from a donor may not be remunerated or accepted for payment, other financial or personal benefits”, but provides for reimbursement of the costs of collection, storage, processing, sterilization,

distribution and transplantation following Art. 3 (3). The Act provides for penalties for persons violating the prohibition of demanding and accepting fees, disseminating advertisements or intermediating in the paid acquisition or disposal of tissue or organ for transplantation in Art. 43, 44, 45. In addition, TA provides statutory regulations with extensive requirements for health institutions where organ donation and transplantation can be performed. National and international rules, including the penalties provided for, must prevent the transplantation of organs of unknown origin and guarantee the professionalism of the persons responsible and involved in transplantation procedures.

### D. The physician during the transplant procedure makes a mistake which causes serious injury or leads to death of the recipient

Another prerequisite for the criminal liability of the physician is the defective implantation, i.e. the performance of the transplant in violation of the rules of *lege artis*. A postmortal transplantation procedure includes incorrect implantation of cells, tissues or organs in a way that endangers the health or life of the recipient. In this case, the fact of culpability must first be established. Because this procedure is complex and performed by a larger group of specialists, can also deal be unintentional complicity. A physician, like any other medical staff, violating the rules of professional medical art, may answer under Art. 155 of the CC for manslaughter or under Art. 156 or 157 of the CC for inadvertently causing health detriment. If the consequences of such conduct could be prevented or if the effect cannot be attributed, the physician may respond based on Art. 160 of the CC [13, 14].

### Limitation

The study concerns the aspects of transplantation in Polish law and the assessment of knowledge about postmortal donation among physicians and lawyers in Poland. However, in the authors' opinion, the identified aspects of criminal liability in the context of postmortal donation are universal. In all countries with transplant regulations in force, each time a criminal offence will arise in all identified cases.

### Conclusions

Knowledge of the basic legal acts and regulations concerning postmortal donation that is considered to be crucial for donors, recipients and physicians needs to be improved. It is of importance to protecting the latter one from potential legal consequences. Therefore, further education in transplant law of the medical teams involved in the procedure of organ transplantation seems to be mandatory.

**Appendix:** See supplementary survey.

**Conflicts of interest:** None.

**Funding:** None.

**Ethical permissions:** According to the rules of the Local Bioethical Committee of Poznan University of Medical Sciences the Statement of Ethics approval is not required for anonymous surveys therefore no formal ethical approval was required.

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