EUROPEAN AND COMPARATIVE LAW STUDY REGARDING FAMILY'S LEGAL ROLE IN DECEASED ORGAN PROCUREMENT [*]

Por

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Revista General de Derecho Público Comparado 29 (2021)

ABSTRACT: Several European countries are approving legislative reforms moving to a presumed consent system in order to increase organ donation rates. Nevertheless, irrespective of the consent system in force, family's decisional capacity probably causes a greater impact on such rates. In this contribution we have developed a systematic methodology in order to analyse and compare European organ procurement laws, and we clarify the weight given by each European law to relatives' decisional capacity over individual's preferences (expressed or not while alive) regarding the destination of his or her organs after death. In this sense, the results constitute the first comprehensive and comparative legislative mapping on European transplantation laws.

KEYWORDS: Organ Donation Rates; Presumed Consent; Explicit Consent; Family's Authorization; Registry.

ESTUDIO DE DERECHO COMPARADO EUROPEO ACERCA DEL PAPEL DE LA FAMILIA EN LA OBTENCIÓN DE ÓRGANOS DE FALLECIDOS PARA TRASPLANTE

RESUMEN: Numerosos países europeos están introduciendo reformas normativas a favor de un sistema de consentimiento presunto con el objetivo de incrementar las ratios de donación de

[*] Acknowledgements: this research was conducted as part of the project INEDyTO (Investigation on the Ethics of Organ Donation and Transplantation), funded by the Spanish Government (MINECO FFI2017-88913-P) and the Grant IT-1066-16, funded by the Government of the Basque Country. The authors wish to acknowledge David Rodríguez-Arias and Iván Ortega-Deballon for their final reading of this work and their valuable comments and suggestions.

órganos post mortem. No obstante, independientemente del sistema de consentimiento vigente, el papel decisional de la familia causa probablemente un impacto mayor en dichas ratios. En esta contribución desarrollamos una metodología sistemática para analizar y comparar las normativas europeas, y esclarecemos el peso que las leyes de trasplante de órganos de cada estado europeo otorgan a la decisión de la familia sobre las preferencias del individuo (expresadas o no en vida) acerca del destino de sus órganos tras su fallecimiento. En este sentido, los resultados constituyen el primer mapeo jurídico comparativo de las leyes de trasplante europeas.

PALABRAS CLAVE: Ratios de Donación de Órganos; Consentimiento Presunto; Consentimiento Explícito, Autorización de la Familia; Registro

Fecha recepción: 12/12/2020

Fecha aceptación: 18/02/2021

I. INTRODUCTION

When it comes to organ donation and transplantation, there are several international normative instruments approved so far, such as the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation[1]. Documents issued within the European Union and the Council of Europe gain particular relevance. In this context, most relevant regulations are the *Directive 2010/45/EU, of 7 July 2010, on standards of quality and safety of human organs organs intended for transplantation*[2], the *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and*

[1] In May 2010, the Sixty-third World Health Assembly Resolution WHA63.22 endorsed the WHO Guiding Principles intended to provide an orderly, ethical and acceptable framework for the procurement and transplantation of human cells, tissues and organs for therapeutic purposes. Each jurisdiction determines the means of implementing these guiding principles.

[2] The proposal of this Directive 2010/45/EU, of 7 July 2010, was elaborated together with the Action plan on Organ Donation and Transplantation (COM(2008)818 final) and was approved after the Opinion of the European Economic and Social Committee 2009/C 306/14. As it is well known, this is a mandatory standard for member states. In this sense, in 2017 a Report on the implementation of the Directive 2010/45/EU, elaborated by the European Parliament Commission, the Council, the Economic and Social Committee and the Committee of the Regions, was published. Conclusions reached in that Report were two: on the one hand, that all EU member states and Norway have designated national authorities and have established other inspection mechanisms to assure the quality and safety of the organ donation and transplantation, although cooperation between states, in that sense, should be improved. And, on the other hand, that most of the countries must optimize their monitoring systems on donors and recipients, offering more medical controls.

Tissues of Human Origin[3], and the *Council of Europe Convention against Trafficking in Human Organs*[4]

In these texts, essential principles in the field of organ transplantation are set forth, such as voluntary consent, altruism and the protection of the public health[5].

With regard to deceased organ procurement (DOP) laws, it is arguable that respect for the principle of voluntary consent must materialise through potential donor's last wills or through his or her family's preferences. It is even questionable if the family should make the last decision.

To this respect, the Directive 2010/45/EU only determines that states must verify "the details of the donor's or the donor's family's consent, authorisation or absence of any objection, in accordance with the national rules that apply where donation and procurement take place" (art. 4)[6]. The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, is a lot more resounding when it states in its article 17 that "Organs or tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained. The removal shall not be carried out if the deceased person had objected to it". In that same way, the Convention against Trafficking in Human Organ establishes in article 4 that "each Party shall take the necessary legislative and other measures to establish a criminal offence under its domestic law, when committed intentionally the removal of human organs from living or deceased donors: (a) where the removal is performed without the free, informed and specific consent of the a living or de-

[3] By the 13th of May 2020, this Protocol has been signed by the following states, although it has not been upheld yet by some of them: Bulgaria, Croatia, Estonia, Finland, France, Georgia, Greece, Hungary, Iceland, Italy, Luxembourg, Macedonia, Moldova, Montenegro, The Netherlands, Portugal, Romania, Serbia, Slovenia, Spain, Switzerland and Ukraine.

[4] By the 24th of February 2021, this Convention has been signed by the followings states, although it has not been upheld yet by some of them: Albania, Armenia, Austria, Belgium, Croatia, Czech Republic, France, Greece, Ireland, Italy, Latvia, Luxembourg, Malta, Montenegro, North Macedonia, Norway, Poland, Portugal, Republic of Moldova, Russian Federation, Slovenia, Spain, Switzerland, Turkey, Ukraine and the United Kingdom.

[5] To this respect, see: Moya Guillem, C. "El Convenio contra el Tráfico de Órganos Humanos del Consejo de Europa (2014). Nuevas claves para la interpretación del delito del artículo 156 bis del Código Penal", *Revista General de Derecho Penal*, nº 22, 2014, pp. 1-25.

[6] Besides, this rule considers that "To obtain an accurate, reliable and objective history, the medical team should perform an interview with the living donor or, where necessary and appropriate, with the relatives of the deceased donor, during which the team should properly inform them about the potential risks and consequences of donation and transplantation. Such an interview is particularly important due to the time constraints in the process of deceased donation which reduce the ability to rule out potentially serious transmissible diseases". Thus, it determines that "the medical team shall endeavour to obtain such information from relatives of the deceased donor or other persons. The medical team shall also endeavour to make all parties from whom information is requested aware of the importance of the swift transmission of that information (art. 7).

ceased donor, or, in the case of the deceased donor, without the removal being authorised under its domestic law […]".

In order to shed light on how organ procurement policies are articulated across the European territory, it becomes essential to clarify the level of intervention of the deceased's family in the decision-making process. To this end, it is firstly fundamental to clarify how law grants binding legal force to the decisions both of the individual and the family. More specifically, the role of the family has to be clarified under two circumstances: when the deceased's wills are already known and when the deceased's wills are unknown. In this study we provide an understanding of how individual's autonomy is respected after death.

Ultimately, clarifying this constitutes a key in the understanding of the organ donation rates of European countries. On this basis, this study seeks to facilitate policymakers the task of clarifying and developing more focused organ donation and transplantation policies.

Policies regarding individual consent for deceased organ procurement are commonly divided between opt-in (explicit consent) and opt-out (presumed consent) systems. Opt-in means that individuals must declare their willingness to donate their organs after death in order to be included in the donor pool. Opt-out means that individuals must declare their refusal to donate in order to be excluded from the donor pool. The most common policy for deceased organ procurement (DOP) in Europe is opt-out, while opt-in is the most common elsewhere[7]. The Netherlands, England and Scotland have moved from opt-in to opt-out for DOP in 2020. Switzerland is currently considering it[8], and Denmark[9], Germany[10], and Romania[11] have been discussing it recently.

Becoming an actual deceased donor may depend on several factors. First, procedures for individuals to express a preference while alive, in favour or against DOP, are variable. Depending on each nation's legislation and clinical practices, these procedures may in-

[7] A. Rithalia et al. "A Systematic Review of Presumed Consent Systems for Deceased Organ Donation", *Health Technology Assessment*, Vol. 13, n° 26, Appendix I, pp. 47-53.

[8] Conseil Fédéral, "Don d'organes : le Conseil fédéral est favorable au consentement présumé au sens large", Press Release of the Swiss Government, Bern, 25 November 2020, Available at: https://www.admin.ch/gov/fr/accueil/documentation/communiques.msg-id-81325.html [Accessed March 16th 2021].

[9] Jensen, A. M. B., & Larsen, J. B. "The public debate on organ donation and presumed consent in Denmark: Are the right issues being addressed?" *Scandinavian Journal of Public Health*, Vol. 48, n° 5, 2019, pp. 480-85.

[10] Geir Moulson, "German Parliament votes against new system for organ donors", *Medical Press*, January 16th, 2020. Available at: https://medicalxpress.com/news/2020-01-german-parliament-donors.html [Accessed March 16th, 2021].

[11] Grigoras, I. et al. "Presumed Consent for Organ Donation: Is Romania Prepared for It?" *Transplantation Proceedings*, Vol. 42, n° 1, 2010, pp. 144-46.

clude donor and refusal registries, organ donor cards and other documents, such as living wills, private documents, and oral communications to relatives. In addition, in some countries, the family is allowed or even asked to make a decision when the deceased had not[12]. Some countries even allow relatives to overrule the deceased's explicit decision regarding organ procurement to donate, thus preventing organ donation against the deceased's wishes[13]. When individuals fail to use any of these valid procedures to express their preferences while alive and families fail to play the role they are allowed to play in the specific jurisdiction, the default course of action is then determined by the law: organs can be removed under opt-out policies, they cannot be removed under opt-in policies.

The family thus plays an important, sometimes decisive, role in DOP decision-making. Although many articles have previously explored the role of the family, they often lacked accuracy in their description of what relatives can or cannot do, both *de iure* and *the facto*, in any given situation. For instance, in their analysis of the authority of the next-of-kin in DOP in 54 nations, Rosenblum and colleagues[14] failed short to distinguish what exact role relatives are allowed to play, within a given nation, under 3 possible scenarios: (1) when the deceased had expressed consent; (2) when the deceased had expressed refusal; and (3) when the deceased had not expressed any preference. Furthermore, it was not always clear from their study when the next-of-kin's authority in a given nation was granted *de iure* or *de facto* (i.e. in some situations, families' views about deceased's wishes become particularly decisive in clinical practice, even when they are not legally enshrined such decisional capacity)[15]. In addition, European laws have experienced some changes, so the aim of this study is also to provide up-to-date information regarding this issue.

Consent policies in which relatives play a significant role, *de iure* or *de facto*, are usually qualified as "soft" systems, while the others are qualified as "hard" systems[16]. However, this distinction does not accurately describe what role the family may or may not have in a particular jurisdiction. To foster a better and more fine-grained description of

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[12] A. M. Rosenblum, L. D. Horvat et al., "The authority of next-of-kin in explicit and presumed consent systems for deceased organ donation: an analysis of 54 nations", *Nephrology Dialysis Transplantation,* Vol. 27, nº 6, 2012, pp. 2533 - 2546.

[13] *Ibid*.; D. Shaw, D. Georgieva et al., "Family Over Rules? An Ethical Analysis of Allowing Families to Overrule Donation Intentions", *Transplantation,* Vol. 101, nº 3, 2017, pp. 482 - 487.

[14] A. M. Rosenblum, L. D. Horvat et al., "The authority of next-of-kin", cit. pp. 2533 - 2546.

[15] J. Delgado, A. Molina-Pérez et al., "The Role of the Family in Deceased Organ Procurement: A Guide for Clinicians and Policymakers", *Transplantation*, Vol. 103, nº 5, 2019, pp. e112 - e118.

[16] C. J. Rudge, "Organ donation: opting in or opting out?", *British Journal of General Practice*, Vol. 68, nº 667, 2018, pp. 62 - 63.

organ procurement policies, we have followed a systematic classification of the family's actions and decisions into four incremental levels of involvement[17]:

> Level 0 (no role): the family plays no role whatsoever in the decision-making process, although they may be kept informed about organs removal.
>
> Level 1 (witness): the family is expected or allowed to inform or update the medical team about the last expressed wishes of the deceased, if any, but nothing else.
>
> Level 2 (surrogate): In addition to acting as a witness of the deceased's wishes, if any, the family is allowed to make a decision when the deceased had not, i.e. when the individual failed to express any valid preference while alive. In that case, the family can decide either on behalf of the deceased (according to what they believe he or she would have wished) or according to their own views.
>
> Level 3 (full decisional authority): In addition to acting as a witness and as a surrogate, the family is allowed to overrule the deceased's expressed preferences. This implies that relatives can prevent organ donation against the explicit will of their loved one.

Besides medical and organizational considerations, the decision to remove or not to remove organs thus depends on three factors: (a) the preferences expressed by the deceased, if any, (b) the precise role the family is allowed to play, and (c) the system's default. The combination of these three factors is variable from one country to another, and it may also vary in a given country between regulations and actual practices, or even from one hospital's practices to another.

The first objective of this article is to propose a simple yet accurate and comprehensive framework to analysis consent policies for DOP. This framework builds from the four-level classification of the family's involvement in Delgado et al., 2019. Our overall aim is to develop a systematic and uniform methodology to describe consent policies in any given nation. This methodology can help to address the differences among DOP laws, allowing for more precise, uniform and meaningful international comparisons.

The second objective of this article is to conduct the very first systematic review of DOP consent policies in the European Union 27 member states and in the United Kingdom's four countries, according, specifically, to current laws. In this way, we have focused on the legal provisions regarding the default system, the respect for the individual's decisions, the role that the family is allowed to play *de iure*, and the family´s right to informa-

[17] J. Delgado, A. Molina-Pérez et al., "The Role of the Family", cit., pp. e112 - e118.

tion contemplated in the law. This research may facilitate policy makers the decision-making process in the development, reform, and application of different policies when trying to improve organ donation rates in their country.

As mentioned above, actual practices in a given country may differ from the law in force in the same country[18], the analysis of these differences between the law and the practice is beyond the scope of this research. This study will lead us to verify if the laws analysed comply with the content of the main European legal texts on this field: the *Directive 2010/45/EU, of 7 July 2010, on standards of quality and safety of human organs intended for transplantation,* the *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin,* and the *Council of Europe Convention against Trafficking in Human Organs.*

II. DEFINITIONS

To systematically analyse the laws of EU countries, we first provide a list of definitions to clarify the exact meaning of the terms used.

Opt-in and *opt-out* are consent policies for DOP defined by the default course of action when neither the deceased had expressed any valid preference while alive, nor his or her family has made a decision regarding organ procurement when they have been allowed to: organs are procured by default under opt-out systems, they are not procured by default under opt-in systems[19].

The term *registry* or *register* refers to an official record system intended for collecting DOP preferences of individuals. Those preferences about donation are recorded by the deceased while alive and can be consulted by the medical team after death. Registries can record either individual consent, individual refusal, or both. It is possible in some countries to designate a representative who will deal with the organ procurement issue after individual's death.

The term *family* refers to relatives, next of kin, close friends of the deceased or those people who may discuss with healthcare professionals about DOP[20], as well as the representative, if any, nominated by the individual while alive to deal with the decision after his or her death. In the context of healthcare as well as DOP, the family can be consid-

[18] *Ibid*.

[19] There exists a third consent policy called "mandatory choice" where individuals shall register their preference regarding DOP when applying for an id card or a driver's licence, filing their tax returns, etc. Depending on the default, this policy is equivalent to an opt-in or an opt-out system. To our knowledge, only New Zealand has strictly enacted such policy.

[20] J. Delgado, A. Molina-Pérez et al., "The Role of the Family", cit., pp. e112 - e118.

ered as a "collective actor"[21]. However, this does not mean that the family is a monolithic entity: it is made up of different persons who may have different attitudes and knowledge towards the deceased's preferences with regard to organ procurement[22]. Laws embrace a wide range of terms to refer to the concept of "family" we have handled: among which we have found terms such as "relatives", "close person", "person in a qualifying relationship", "representative", etc. In all these cases, we have made a broad interpretation of the term used by the law. When members of the family are explicitly mentioned, some laws establish a list of relatives by order of priority, others mention the family without further specification.

Unknown preferences. The deceased's preferences can be considered *unknown* under two circumstances:

> (a) when the deceased did not express any preference regarding DOP while alive in any official public registry or private document defined by the law for this purpose (living wills, advanced directives, health register, donor card, etc.). The deceased did not express his or her wills orally either while alive, so neither the medical team nor the family know the deceased's preferences.
>
> (b) when the deceased did not record his or her preferences regarding DOP in an official registry or private document contemplated by the law for this purpose, but did express his or her preferences to the family.

To inform. Family can *inform* when the deceased's wills are unknown. In this case, family intervention is minimal. It implies that the deceased's preferences have not been recorded, but the family can provide information about them to the medical team. In this case, the family does not decide but only reports. For example, this situation arises when the deceased's wishes have not been recorded in an OP registry or private document legally binding, but a relative provides a donor card (not legally binding in that specific country) that the deceased kept at home, which informs about the deceased´s preferences.

Family authorisation and *opposition* refer to the decision expressed by the family regarding organ procurement. Family can authorise or oppose OP when (1) the deceased's preferences are unknown; (2) there exists an explicit consent by the deceased. In case

[21] K. Beier, I. Jordan et al., "Understanding collective agency in bioethics", *Medicine, Health Care and Philosophy*, Vol. 13, nº 3, 2016, pp. 411 - 422.

[22] J. R. Rodriguez, D. L. Cornell et al., "Does family disagreement affect donation decisions by next of kin?", *Progress in Transplantation,* Vol. 18, nº 3, 2008, pp. 179 - 184.

there exists an explicit opposition by the deceased, the family may only authorise, vetoing the deceased's opposition.

(a) To authorise: the family can authorise OP in accordance either to the deceased's wills if they happen to know them, to what they believe the deceased would have wished, or to their own wishes.

(b) To oppose: family can oppose to OP in accordance either to the deceased's wills if they happen to know them, to what they believe the deceased would have wished, or to their own wishes.

In some circumstances, the family authorises or opposes OP *on behalf of* the deceased, that is: (i) when the deceased had designated a specific person (a relative, a friend, etc.) to deal with the issue of OP and make a decision when the time comes —in this case, that person may decide in accordance to his or her own preferences or in accordance to the preferences he/she already knew or assumed from the deceased[23]—, and (ii) when the family is required by law to make a decision in accordance to the deceased's wishes expressed while alive, or in accordance to what they believe the deceased would have wished[24]. Aside from those two cases, the family would not be making a decision on behalf of the deceased.

To update. The deceased's preferences are recorded in an official register or private document defined by the law for this purpose, but the family can indicate that the deceased changed his or her preferences after that recording. The family can only update the deceased's wills when they have been expressed while alive, so it is not possible to update the deceased's wills if they are unknown.

a) When there is evidence of an explicit consent expressed by the deceased, the family can update the deceased's last wishes in a negative way (hence making him a non-donor). In this case, the family is not making a decision on behalf of the deceased but reporting his or her last wishes.

b) When there is evidence of an explicit opposition by the deceased, the family can update the deceased's last wishes in a positive way (hence making him a donor). In this case, the family is not making a decision on behalf of the deceased but reporting his or her last wishes.

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[23] The deceased's will is respected, in this case, as far as decisional capacity is granted to the person designated by the deceased, for the purpose of making a decision, but not because that specific person was going to make a decision respectful with the deceased's wishes.

[24] In case family authorises or oppose on behalf of the deceased, we will mark it with an asterisk in the Table 2.

The difference between "inform" and "update" is that it is possible to update a previous information already available (through a register or any other legally binding instrument to leave an evidence about last wishes), while when there is no previous information available, the family could only inform in case they have relevant information about the deceased's preferences.

Family's right to information. This category indicates if the family has any right to be informed about their loved one's wishes, what is going to happen about his organs, or about their decisional capacity to authorise or oppose OP. This category does not indicate that the family does have any decisional capacity, it only indicates their right to receive information.

III. METHODOLOGY

III.1. Framework of analysis

Based on the analysis and classification of consent policies for DOP developed by Delgado et al.[25], as well as other analyses[26], we have designed a framework (table 1) that includes, for each country:

A. The consent policy (opt-in, opt-out);

B. The possibility for individuals to register their wills regarding OP (the existence of registries to express a consent, a refusal, both, or to designate a representative to deal with the issue);

C. The decisional capacity allowed or required from the family depending on the deceased's wishes (unknown, expressed consent, expressed refusal);

D. The family's right to be informed about organ procurement decisions.

[25] J. Delgado, A. Molina-Pérez et al., "The Role of the Family", cit., pp. e112 - e118.

[26] B. J. Boyarsky, E. C. Hall et al., "Potential limitations of presumed consent legislation", *Transplantation*, Vol. 93, nº 2, 2012, pp. 136 - 140; and A. M. Rosenblum, L. D. Horvat et al., "The authority of next-of-kin", cit. pp. 2533 - 2546.

Table 1: framework of analysis

	Consent policy		Registry		Family's role when the deceased's wishes on DOP are								Family's right to be informed
					Unknown			Expressed consent			Expressed refusal		
Country	opt-in	opt-out	consents	refusals	Inform	Authorise	Oppose	Update	Authorise	Oppose	Update	Authorise	

III.2. Systematic review of laws

Our aim is to provide an analysis of the categories mentioned as they are mentioned by the law for each of the countries configuring the European space (including the United Kingdom's four nations).

III.2.1. *Scope of the study*

This review is limited to the legislation and does not account for actual practices that may differ from the law, even when these practices are backed up by official guidelines. This review includes the laws in force by 2020 in each EU country and in the United Kingdom's four nations —since in the beginning of this research (2018), the United Kingdom was part of the UE. In the case of countries that have passed a law update to be implemented by 2020, we have taken into account those last updates. This has been the case for Scotland, England, and the Netherlands.

Thus, we have conducted a systematic review of laws on deceased organ donation for transplantation in all EU member states and in the United Kingdom: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom's nations—England, Northern Ireland, Scotland, Wales.

This study includes provisions regarding competent adults only (i.e. individuals deemed legally capable to make a decision on organ donation by themselves) and excludes provisions regarding other individuals (children, legally incompetent adults, foreign citizens, etc.).

III.2.2. *Data collection and analysis*

Relevant laws in force in each country were collected from government websites and legal databases. In addition, national transplant organisations, ministries of health, or hospitals were contacted by email to ask for any information or update regarding their

domestic law. After two consultations, we did not receive any answer from: Croatia, France, Hungary, Latvia, Portugal, Romania, and Slovakia. Each country's legislation was first examined and codified independently by two authors, then examined again by the whole group. Any codification differences were discussed and a consensus was reached.

III.2.3. *Review proceedings*

Our responses to fill the table 2 are based on three possible answers: yes/no/blank (no answer at all). Throughout the research, we have noticed that laws respond to a given scenario in an explicit or tacit way, or don't mention the given scenario at all.

> *Explicit response.* The law contemplates a specific situation and gives a clear and explicit response to it. We only use 'yes' or 'no' when the law is clear in solving a cell in the table. 'Yes' and 'no' answers mean that the law is explicitly positive or negative about the question. For example, in Malta the family has the capacity to authorise OP if the deceased wishes are unknown: *"(1) The next of kin of a deceased person who is not a registered donor may be approached by a transplant coordinator or a clinician to declare whether they consent to the donation taking place*" (art. 10). This provision would imply an explicit 'yes' in the cell 'authorise' within the 'unknown' column in the table.
>
> *Tacit response.* The law does mention the given situation, but it does not respond to it in a clear and explicit way. This could happen under two circumstances: when the law hints a response, or when the law mentions the situation but its response is not clear. Two asterisks appear in the table 2 in order to indicate that the law mentions the given situation but that no clear response is given. For example: when the law says that "the deceased's wishes must be respected" (as it happens in Spain), we cannot say that the law explicitly says that the family cannot oppose organ removal. So we can understand a tacit 'no', as it is mandatory by law to respect the deceased's will.
>
> *No answer at all:* The law does not mention the given situation. The cell remains blank.

III.2.4. *Methodological problems and strategies to overcome them*

Throughout the development of the study we have faced some limitations in trying to clarify the exact regulation provided by the law to the questions studied and the given situations. Most of the constraints showed by this study emanate from the interpretation of the laws.

We must start highlighting the vague wording of all European laws with regard to provisions referring to consent policies, registries and the role of the family granted by the law.

When it comes to consent policies, the main constraint found in trying to apply the proposed methodology is that literalism in many laws does not express exactly the default course of action as proposed for opt-in or opt-out consent policies definitions. For example, it is the case of the article 9.2 of the Greek law (2011), or the article 20 (3) of the Cypriot law, among others, which state that in the case the individual has not expressed his preferences, his or her family will make a decision. But, in those cases, the laws do not specify what is the default course of action in case the family does not make any decision (e.g., relatives are not reachable, the individual has no family, etc.). Similar are the cases of countries whose law states that organs will not be procured unless the next of kin authorise the process, but again, it does not specify what would be the course of action in case it is not possible to reach the family, e.g. article 22(2) of the Irish law, or article 21 of the Romanian law. This is also the case in opt-out countries, laws that in many cases limit to consider that organs may be procured from those individuals that have not opposed to OP while alive, but at the same time grant the possibility for the family to oppose or even authorise in a circumstance of unknown deceased's wishes, e.g. sec. 4 of the Sweden law, sec. 6D (2) (d) of the Scottish law, article 13.2 of the Slovenian law, or article 21.3 of the Bulgarian law. In all the cases raising some doubt about the default course of action, we have made an extensive interpretation of the law. So for the first ones, we are considering that deceased's organ procurement is not legal without a previous authorisation of the individual or his or her family, hence, those are opt-in consent systems, and in the case of the last ones, in case family is not approached, it would be legal to proceed with the deceased's organ procurement.

When addressing the provisions regarding registries for recording the wishes of individuals, there are some countries whose law creates a specific registry for individuals to express their preferences regarding DOP, e.g. article 10 of the Dutch law. Nevertheless, there are some other countries which do not create a specific registry but do use another general health register to facilitate this issue for their citizens, e.g. sec. 4 of the Latvian law. The variability of the types and purposes of these registries is the reason that leads us to consider the term "registry" in a broad sense, so, not only we are considering registries created by the organ donation and transplantation laws, but also those registries already created and mentioned by the law in order to register individuals' preferences.

Finally, when addressing the role granted by the law to the family in the organ donation and transplantation process, we have noticed, firstly and probably most importantly, legal loopholes in all European laws when referring to specific given situations (i.e. if the

family could overrule a deceased's expressed consent, opposing to organ donation, or if they could overrule a deceased's expressed refusal, thus authorising organ donation; among others). Secondly, but not less important, we have also noticed a lack of clarity in most European laws when differentiating if the role actually granted to the family refers to the case the deceased's wishes are unknown, or to the case deceased's wishes are already known (both in favour or against organ procurement for transplantation). This is the case, for example, for the Romanian law, when its article 21 mentions that the deceased's organs may be procured if there is an authorisation from the family, but it does not specify if this provision applies when the deceased's wills are unknown, or when the deceased's wills are known, either for or against donation, and regardless of it.

In this sense, ambiguity in the wording of some provisions have constituted a great obstacle when trying to understand the family's level of involvement. For example, the provisions: "deceased's will must be respected" in case the deceased has expressed a consent while alive, or "if the deceased had expressed a refusal while alive, the measure may not be performed", neither of them mention expressly the family (as is the case for Spain (art. 1.a), Belgium (art. 10, §2bis and 4) and Finland (sec. 9), in comparison with other laws which mention specifically that the family has no authority in all those situations, i.e. Estonia (§ 17 [4]) or Malta (art. 10 [1] in fine).

This sort of wording opens the door to two interpretations: on the one hand, the case for the deceased's will to be respected and the family not to play any role in the decision making process, or, on the other hand, the case for the family to have some decisional capacity (update, or even authorise or oppose) regardless the deceased's expressed wishes. A good example is the case of Spain. Although the Spanish law contemplates exactly this provision "the deceased's will must be respected"[27], it is possible for the family to update the deceased's known wishes, so the family does play a role *de iure*, despite that resounding provision of respecting the deceased's known wills.

Although we cannot say that this statement contemplates specifically the family, neither could we say that the family is not indirectly affected by this provision: the law seems quite resounding when claiming that the deceased's wills must be respected, so this could lead us to think that the family is not left out of this provision. But we cannot affirm neither of these questions categorically. In trying to overcome this limitation, we have not made a strict interpretation of the law —so no 'yes' or 'no' appear in the table— but we have marked the cell in order to warn the reader about this circumstance.

[27] Article 9.1.a) of the RD, 2012.

IV. RESULTS

		Registries		Unknown			Consent			Refusal		
Country	Consent systems	Consent	Refusal	Inform	Authorise	Oppose	Update	Authorise	Oppose	Update	Authorise	Family's Right to be informed
AT	OPT OUT		YES									
BE	OPT OUT	YES	YES	**							**	
BG	OPT OUT	**	YES			YES						
CY	OPT IN	YES			YES	YES			NO			YES
CZ	OPT OUT											
DE	OPT IN	YES		YES	YES*	YES*	**	**	**	**	**	YES
DK	OPT IN			**	YES	**			NO			
EE	OPT OUT	YES		YES					NO		NO	
ES	OPT OUT			YES			YES		**	YES	**	YES
FI	OPT OUT			**							**	YES
FR	OPT OUT		YES	YES								YES
GR	OPT IN	YES	YES		YES			NO				
HR	OPT OUT		YES									
HU	OPT OUT		YES									YES
IE	OPT IN				**			**			**	
IT	OPT OUT	YES	YES	**		YES	YES		NO			YES
LT	**	YES	YES		YES	YES						
LU	OPT OUT	YES	YES									
LV	OPT OUT	YES	YES	YES								YES
MT	OPT IN	YES	YES		YES	**					NO	
NI	OPT IN				YES*	YES*						
NL	OPT OUT	YES	YES		YES*	YES*	YES					YES
PL	OPT OUT		YES	**								
PT	OPT OUT		YES									
RO	OPT IN				**			**			**	
SC	OPT OUT	YES	YES		YES	YES*	YES			YES		
SE	OPT OUT			**		YES						YES
SI	**	YES	YES			YES						YES
SK	OPT OUT		YES									
WA	OPT OUT			YES	YES*	YES*						

AT: Austria; BE: Belgium; BG: Bulgaria; CY: Cyprus; CZ: Czech Republic; DE: Germany; DK: Denmark; EE: Estonia; EN: England; FI: Finland; FR: France; GR: Greece; HR: Croatia; HU: Hungary; IE: Ireland; IT: Italy; LT: Lithuania; LU: Luxembourg; LV: Latvia; MT: Malta; NI: Northern Ireland; NL: Netherlands; PL: Poland; PT: Portugal; RO: Romania; SC: Scotland; SE: Sweden; SI: Slovenia; SK: Slovakia; ES: Spain; WA: Wales.

*: The decision must be made on behalf of the deceased.
**: Law mentions something, but not explicitly.

Table 2: comparison of the DOP laws in European countries.

In the appendix "laws by country," we have gathered all the laws and reforms applicable in this research. Consequently, we only refer in this section to the articles or sections of the laws collected there. In this sense, when several laws appear in the appendix and we only refer to an article or section in parentheses, we are referring to the highest ranking one. When we refer to a precept, we are mentioning the norm in force, taking into account the reforms carried out in it at the time of work on this research.

IV.1. Consent systems

Of the 31 nations studied, 21 were opt-out and 8 were opt-in when the study was conducted (Table 2, Fig. 1). Three of these nations, Scotland, England, and the Netherlands, moved to an opt-out system by mid-2020 (see Annex I). Two countries, Lithuania[28] and Slovenia[29], cannot be clearly described as either opt-in or opt-out according to our definitions and analysis.

Countries with an opt-out system by law are: Austria (§5 [1]); Belgium (art. 10.§ 1er.); Bulgaria (art. 19); Czech Republic (§11.1 [a]); Estonia (§15 (1) [2]); England (sec. 3, subsec. 6 [ba]); Finland (sec. 9); France (art. L1232-1); Croatia (art. 17.1); Hungary (§6); Italy (arts. 4.1, 4.4.b of the Law, 1999; and art. 1 of the Ministerial Decree, 2000); Luxembourg (arts. 6, 9 and 10[30]); Latvia (sec. 11 of the Law, 1992; and art. 4 amended by the Law in 2019); Netherlands (art. 10a, 1, 2 y 3); Poland (art. 5.1); Portugal (art. 10.1); Scotland (sec. 6, subsec. 6D); Sweden (sec. 3); Slovakia (§37 [2]); Spain (art. 9.1 of the RD, 2012); and Wales (art. 4 [2]).

For example, the legislation in Spain explicitly mentions that to carry out obtaining organs from deceased donors it is enough if the deceased person had not expressly stated their opposition to the organ procurement being carried out after the death. Consequently, the law recognizes a presumed consent system.

Countries with an opt-in system by law are: Cyprus (art. 20), Germany (§3 [1]); Denmark (sec. 53, subsec. 2); Greece (arts. 9.2 of the Law and sec. 9.6 of the Ministerial Decision, 2018); Ireland (art. 22 [2]); Malta (arts. 6[1] and 10[1]); Northern Ireland (art. 3(6); Romania (art. 21).

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[28] Following the articles 4 and 5 (2) of the law, it is an opt in system, because the person needs to consent, or, if he or she did not express his or her wills, relatives need to consent. However, article 5 (4) states that if the person did not express preferences and did not have relatives, the decision to give the deceased person's tissues or organs for transplantation shall be taken by a consultation of the doctors of a health care institution six hours after the establishment of the fact of death of the above-mentioned person. The consultation of the doctors shall comprise a representative of the medical ethics commission of the health care institution, the doctor who treated the deceased person and the head or any other representative of the administration of the department where the person was treated. Only this last section refers as an opt-out system.

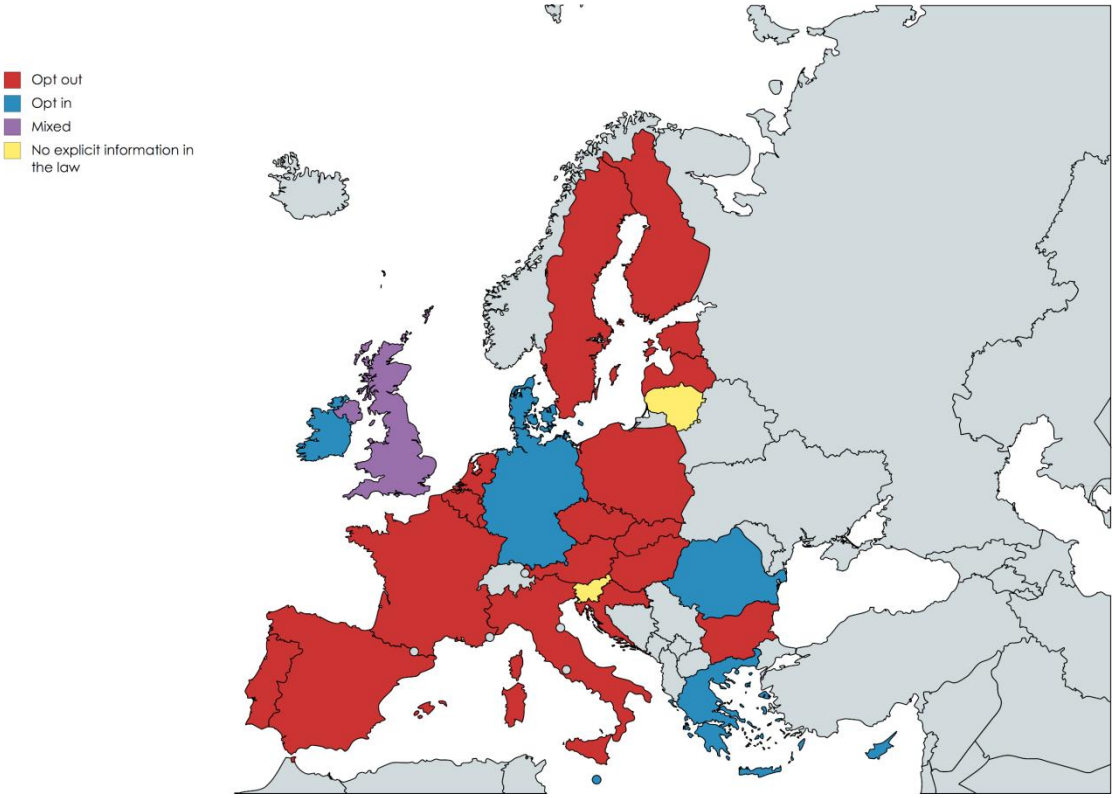
[29] The Law states in article 13.1 that organs may be removed even in the case the deceased had not consented previously (thus, this could indicate an opt-out); nevertheless, in article 13.2. it is stated that procurement will not be carried out in case relatives are opposed, adding that if family is not approached, it may not be possible to proceed with organ procurement (this rather indicates an opt-in system). We have considered this article contradictory.

[30] Although articles 6 and 9 clearly refer to an opt-out system, art 10 refers to a mandatory choice. The law mentions that whenever a passport or an identity card is issued, the person will receive a declaration form with two options to express that he/she is or is not an organ donor after his or her death. The Minister of Health determines the form of this document and gives copies to the competent services. The authorisation or refusal expressed in this document is equivalent to a declaration of authorisation or refusal recorded in writing.

Cyprus and Greece are classified as opt-in according to our definition above, in spite of the fact that they are usually considered as opt-out. In Cyprus, the law states that if the potential donor had not expressed his or her consent or refusal, organs can be removed under the condition that there is an authorisation from one of the following people, in this order: a) spouse, b) adult children, c) parent or guardian, …, i) close friend (Art. 20.3). This implies that organs should not be removed without authorisation from one of these people. Therefore, if no one is able to produce an authorisation, the default course of action is not to remove the organs. This corresponds to an opt-in system.

In Greece, the law 3984/2011 stated that organ removal shall take place if the deceased had not recorded his/her opposition (Art. 9.2). Thereby, the system was opt-out. However, one year later, the law 4075/2012 modified this article by requiring in addition a consent from the family. This requirement still exists in the law 4512/2018. This implies that, when the deceased has failed to express any preference, organs should not be removed without authorisation from the family. Therefore, if no one is able to produce an authorisation in this case, the default course of action is not to procure the organs. Again, this corresponds to an opt-in system.

Fig. 1: Consent systems in EU member states



IV.2. Registries

Registries are explicitly mentioned by the law in 21 countries (Table 2). Among them, 10 laws mention both donor and non-donor registries: Belgium (art. 10, §3); Greece (arts. 9.1 and 9.3 of the Law, 2011; and sec. 9.1 and 4 of the Ministerial Decision, 2018); Italy (art. 7 of the Law 1999, and art. 1 of the Decree, 2000); Lithuania (art. 7); Luxembourg (art. 10); Latvia (sec. 3 and 4 of the Law, 1992; and art. 4 amended by the Law, 2019); Malta (art. 4); The Netherlands (art. 10); Scotland (sec. 2, subsec. 2A [2]); Slovenia (arts. 11 [2] and 43).

For example, the Dutch law explicitly refers to a donor register to recognize the will of the person concerned, both for permission or objection granted by means of the donor form, or by means of the wish to leave the decision on this matter to the next of kin or to a specific person (art. 10).

Other 8 countries mention only non-donor registries: Austria (§6); Bulgaria[31] (art. 39. [1] 2); France (art. L1232-1 of the Law, and Art 2 [Art. R. 1232-4-4.-I] of the Decree, 2016); Croatia (art. 18); Hungary (§ 8 (3) and §9); Poland (arts. 6.1 and 7); Portugal (art. 11); Slovakia (§ 37 [3]). Finally, 3 countries refer only a donor registry: Cyprus (art. 19); Germany (§2 [3]); Estonia (§17 [1] and [2]).

For example, in the case of Bulgaria, the law mentions explicitly an official register in which to enter the names of the persons who have expressed disagreement over the procurement of their organs, tissues and cells after death[32]. By contrast, in countries such as Estonia, the law contemplates an official register (named “health information system”) for the recording of consents on the procurement of cells, tissues and organs for transplantation purposes after death[33].

The laws of 9 countries do not explicitly refer to any organ donor or non-donor register, although such registries and other equivalent procedures may exist in practice: Czech

[31] Article 39 (1) 2 mention about a public registry, but it does not specify whether it is a registry to express the will to become a donor, only mentions expressly that the persons can register their refusal.

[32] Nevertheless, the article 31(1)1 mentions a “public register” it does not clarify which kind of register it is, and if it could be established for the recording also the agreement for that purpose.

[33] The Estonian Law is particularly different from other European DOP Laws. The § 15 (1) 2) clearly establishes an opt-out system when it reads “(1) Cells, tissues or organs may be removed from a deceased donor if: [...] 2) during lifetime, the deceased donor had expressed a wish to donate cells, tissues or organs after his or her death according to the provisions of § 17 of this Act, or if no information is available that the person had objected to it” —law does not grant any decisional capacity to the relatives in § 17 (3), but only the capacity to inform about deceased’s intention—. Nevertheless, the registry regulated by law is only for recording consents, although it seems that in opt-out countries there should be a legal instrument in order to facilitate individuals to express their opposition regarding organ removal for transplantation purposes. Hence, the wording of this act in this sense could pose some kind of incoherence.

Republic, Denmark, England, Finland, Ireland, Northern Ireland, Romania, Sweden, Spain and Wales.

When establishing a relationship between the consent system and the existence of records by law in each country, our results show that 7 laws of opt-out countries do not mention explicitly a registry for refusals (Czech Republic, Estonia, England, Finland, Sweden, Spain and Wales) and 4 countries with an opt-in law do not refer to a registry for consent (Denmark, Ireland, Northern Ireland, and Romania).

IV.3. Role of the family

Regarding the role of the family, the laws of 8 countries do not include any explicit role for the family, nor their right to be informed: Austria, Belgium[34], Czech Republic, Croatia, Luxembourg, Poland[35], Portugal, and Slovakia. The laws of two countries, Finland (sec. 9.a) and Hungary (8 §[5]), include family's right to be informed but fail to mention explicitly any other provision regarding their role[36]. In other 9 countries, the family's right to be informed is also explicitly granted by the law: Cyprus (art. 22.1); Germany (§3 [3]); France (art. L1232-1); Italy (art. 3.2 of the Law, 1999); Latvia (art. 4 amended by the Law, 2019); Netherlands (arts. 20.6 and 20.7); Sweden (sec. 4); Slovenia (art. 13[2]), and Spain (arts. 9.1 and 9.6.b of the RD, 2012), but in these countries the law also grants the relatives some level of participation in the decision-making process, as we will explain.

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[34] In Belgium, in the article 10.§ 1er. the Law states that the doctor who plans to take the sample must inquire about the existence of an opposition expressed by the potential donor. Thus, in table 2, the cell corresponding to "inform" is blank, since it can be yes, but tacitly. In addition, article 10, §2bis and 4 declare that only the deceased can express the consent to be a donor and the organ removal cannot be carried out if the donor has objected. Therefore, we can understand that the family could not authorise, but tacitly.

[35] The Polish Law establishes in article 10 that, before taking cells, tissues or organs from a deceased person, a doctor must seek information on whether an objection has been raised in the form specified in article 6, clause 1, points 1, 2 and 3. Those points refer to objections recorded in the central register of objections, to written declarations of opposition with a personal signature; or to oral statements made in the presence of at least two witnesses, confirmed in writing by them. Under this wording, the law tacitly unveil that relatives could inform the medical team about the deceased's intention, but does not mention it explicitly.

[36] In Finland, the section 9 of the law asserts that "before removal of a deceased person's organs, tissues or cells for the purpose referred to in section 8 (1), the deceased person's opinion, while still alive, must be investigated as far as possible". Regarding the cell about "inform", we consider that this statement tacitly grants the family the possibility to inform the medical team about deceased's opinion, but does not mention it explicitly. It is a tacit yes, but not explicit. In the same section, the law expresses that "if a person had, while still alive, forbidden the removal of his or her organs, tissues and cells, the measure may not be performed". However, it does not explicitly express that the relatives cannot overrule a refusal. It can be considered that, in the case of Finland, family could have some role in the decision-making process, but it is no clear as written in the law. The only clear provision in the Finnish law is that the family has the right to be informed.

When the deceased preferences are unknown, 10 countries recognise a legal role for the family only in this situation in an explicit way. The law in Latvia (sec. 4 of the Law, 1992, art. 4 and 11 amended by the Law in 2019) as well as in France (art. 2 [Art. R. 1232-4-4.-II and III] of the Decree, 2016) only allows relatives to inform when the deceased´s preferences are unknown. Germany[37] (§4.1), England (sec. 3, subsec. 6 [b] and subsec. 6, 6B) and Wales[38] (art. 4[4] and 3[3]) allow the relatives to inform, authorise and oppose organ procurement. Lithuania (art. 5.2 and 5.3) and Northern Ireland[39] (arts. 4, 3 [6] [b] [ii] and 3 [6] [c]) recognise the legal capacity of the relatives to authorise or oppose organ procurement when the deceased wishes are unknown, but not to inform. In Bulgaria (art. 21.3), Sweden[40] (sec. 4), and Slovenia (art. 13 [2]), following the law, the family can only oppose organ donation if the deceased preferences are unknown, but not authorise.

When the deceased has expressed his or her wills when still alive, there are 10 countries which explicitly mention some level of participation of the family, either to allow or to deny it. In the Netherlands, the family can authorise or oppose (art. 10.2, and arts. 11.2 and 11.3 amended by the Law, 2018) DOP when the wishes of the deceased are unknown, and they only can update the deceased wishes when he or she had consented while alive (arts. 20.4 and 20.5 amended by the Law, 2018)[41]. In Scotland, the relatives can also authorise (sec. 7 [1]) or oppose (sec. 6, subsec. 6D [2][d]) if the deceased's wishes are unknown, but they can update either the deceased had consented (sec. 6, 6A [4] [b]) or refused (sec. 6, 6C [4] [b]). In Spain, the legislation states that the family can inform (arts. 9.1 and 9.6 of the RD, 2012) when the deceased preferences are unknown, and update (arts. 9.6 and 9.1.b.1º) when the person had expressed his or her wills, either

[37] For the case of Germany, the law does not clarify if the family does have a role for the case the individual had expressed a preference while alive (see §3 [3]). In case the deceased had not expressed a preference while alive, the family has the right to authorise and oppose on behalf of the deceased (§4 [1] and [3]).

[38] Regarding the cell about inform, we understand that there are 2 situations: informing the opposition, and opposing based on the preferences of the deceased. For this reason, in the box to oppose we also refer to article 4 (4). Regarding authorisation and opposition, these results are based on section 3 section 4.

[39] In the case of Northern Ireland, family can decide on behalf of the deceased in the cases contemplated in articles 4 and 3 (6) (b) (ii).

[40] In Sweden, section 3 [1] mentions that the wishes of the deceased can be investigated in another way, although family could be considered as included in this provision, there is no explicit mention about it.

[41] Family can authorise and oppose on behalf of the deceased on the basis of arts. 10.2, 11.1 and 11.3. of the law. In addition, in case the deceased had not designated a person to take a decision, they can authorise on the basis of the article 11.4 amended in 2018.

in favour or against procurement[42]. The law in Cyprus states that the relatives can authorise (arts. 20.3 and 22.1) or oppose (art. 22.1) DOP when the deceased preferences are unknown, but they cannot oppose when the person had consented while still alive (art. 20.5 amended by the law in 2017). Similarly, in Denmark the family can explicitly authorise when the deceased preferences are unknown (sec. 53, subsec. 3)[43], but not to oppose when he or she had consented (sec. 53, subsec. 2[44]). In the case of Estonia, the relatives can inform (§17 [3]), but they cannot oppose or authorise (§17 [3]) against the wills of the deceased. The law in Greece recognizes the family´s capacity to authorise (sec. 9.6 of the Ministerial Decision, 2018) if the deceased preferences are unknown, and explicitly states that they cannot oppose OP when the deceased had consented while alive (sec. 9.2 of the Ministerial Decision, 2018). In Italy, while the relatives can oppose DOP when the deceased preferences are unknown (art. 23.2 of the Law, 1999)[45], and in the case the deceased had consented while alive, relatives can update the deceased's preferences (art. 23 AEI of the Law, 1999; and art. 3.2 of the Ministerial Decree, 2000) but they cannot oppose (art. 23 AE1 3 of the Law 1999). In Malta, the family can authorise DOP when the preferences of the deceased are unknown (art. 10)[46], and they cannot authorise if the deceased had expressed his or her refusal while still alive (art. 10.1 *in fine*). Finally, in Ireland the law states that the family has to authorise DOP, otherwise, the process would not take place (art. 22 [2]): "Organs shall not be procured in the case of a deceased donor unless consent to the donation has been given by the deceased donor's next of kin". We can not affirm that explicitly the law allows relatives to authorise against the will of the deceased. However, in a tacit interpretation, the article implies that if the family's authorisation is required in any case, the family has the last word. The same

[42] We can understand that the family can not oppose when the deceased had consented or authorise when he or she had refused of article 9.1.a: "the deceased´s opposition or agreement (...) will be respected", but it is not an express statement.

[43] The law mentions that the person can verbally consent, without specifying to whom. Therefore, one possibility would be that he/she did it to his or her family and then they reported (sec. 53, subsec. 2). The section 53, subsection 3 states that the extraction can only be carried out in case of ignorance of the will of the deceased, if the relatives consent. Therefore, if the family does not authorise, the organ procurement will not be carried out. However, it does not expressly state that they can oppose.

[44] This article also contemplates an exemption: when the deceased has left the decision under his or her family's authorisation.

[45] In case the deceased's wishes are unknown, the article 4.5 establishes that organs may be removed in the case of 4.4.b) (i.e. he or she did not express preferences while alive and by default is considered a donor), unless a signed declaration of will against organ removal is presented. We understand that the family will be able to inform in that sense, but tacitly.

[46] The article 10 only refers to the fact that the relatives can authorise the donation and nothing is mentioned about the rejection. Thus it could be considered that it is not allowed, but this possibility is not expressly denied, so the cell in table 2 remains blank, with two asterisks.

situation happens in Romania: the art. 21 mentions that the organs may be removed after the death if there is a written authorisation from the family. However, it does not specify whether the family's authorisation will be required in the event that the deceased had not expressed anything in life or even if there is an expressed will by the deceased.

V. DISCUSSION

The systematic analysis that we have developed in this paper has allowed us to described thoroughly the main aspects of each European Union country´s law on DOP. The methodological tool designed in this paper can be used to assess the law in any country around the world, which can be beneficial to address comparison among countries on the same conceptual basis.

Regarding the model of consent, while several countries have debated the potential benefits of moving from an explicit consent system to a presumed consent in order to reach higher donation rates, our data shows that the consent system in itself is not enough. Following the law, the role that the family plays does not depend on the model of consent, as we have shown. For instance, in Germany (opt in country) and Wales (opt out country) the family has legally the same role, regardless if the law recognizes or not the right to be informed. Ultimately, in these countries, the decision-making process when the deceased has not expressed his or her preferences, rely on the family, so the default system does not apply. These findings are coincident with previous research[47]. However, our review addresses in a more systematic way the law in each country regarding the role of the family, which demonstrates that it is due to the difference between the law and the practice that the model of consent is not determinant to increase donation rates.

In addition, we have noticed that several countries do have a different consent system than that usually attributed to them. That would be the case of Greece and Cyprus.

To our knowledge, this is the first paper which provides a systematization on the existence or not of a registry for donation or refusal in the organ procurement laws of EU countries[48]. Further research is required to address in depth the similarities and differences between these registries. However, for that purpose, to collect data from the law and the practice will be required, since the majority of legislations does not specify details about the registry system.

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[47] A. M. Rosenblum, L. D. Horvat et al., “The authority of next-of-kin”, cit. pp. 2533 - 2546., J. Delgado , A. Molina-Pérez et al., “The Role of the Family”, cit., pp. e112 - e118; J. Boyarsky, E. C. Hall et al., “Potential limitations”, cit., pp. 136 - 140.

[48] A study regarding organ donation registries worldwide was already conducted, see A. M. Rosenblum, A. H. Li et al., “Worldwide variability in deceased organ donation registries”, *Transplant International,* Vol. 25, nº 8, 2012, pp. 801 - 811.

From our results, and according to the four levels of involvement of the family developed in Delgado et al.[49], it is possible to map the legal participation of the family in each country (see table 3).

No role whatsoever: the family is not mentioned explicitly at all in the laws of 8 countries: Austria, Belgium, Czech Republic, Croatia, Luxembourg, Poland, Portugal, and Slovakia. In Finland and Hungary, the law only refers explicitly to the family in regard to their right to be informed. Therefore, the family plays no legal role (Level 0 of involvement) in these 10 countries, all of them with an opt-out system.

Witnessing the deceased's last wishes: at least in 4 countries (Estonia, France, Latvia and Spain), this is the only role explicitly assigned to the family (Level 1 of involvement). The family may be allowed or asked to act as a witness of the deceased's last wishes either to inform the medical team when no record is available (Estonia, France and Latvia) or to update the record when the deceased had consented or refused (Spain).

Surrogate decision-making: the family is allowed to make a decision only when the deceased had not expressed his or her preferences, which means that the only role allowed to the family in these countries' legislation is to act as surrogate decision-maker (Level 2 of involvement). When the individual failed to express any preference while alive, the family is allowed to make a decision in 16 countries, and no country explicitly prohibits it. The decision may be either to authorise organ procurement (Denmark, Greece, Ireland and Malta), to oppose to it (Bulgaria, Italy, Sweden and Slovenia), or both (Cyprus, Germany, England, Lithuania, Northern Ireland, Netherlands, Scotland and Wales). All the countries that allow only family's authorisation have an opt-in system, the countries which allow family's opposition are mainly opt-out countries. In 6 countries, the decision of the family shall be made on behalf of the deceased, i.e. according to what they believe he or she would have preferred. As we mentioned above, the cases of Ireland and Romania could be also interpreted as witnessing deceased's last wishes since the law does not mention explicitly if in their intervention, family could override an expressed preference of the deceased.

Last word: No country explicitly allows the family to overrule the deceased decision to donate, while 4 nations forbid it (Cyprus, Denmark, Estonia and Italy). In the case of Romania and Ireland explicitly consider an authorisation from the family, although it is not clear if that authorisation would be required even when the deceased had expressed any preference. If we made this interpretation those laws would grant full authority for the family (Level 3 of involvement). By contrast, only Greece explicitly deny this decisional capacity for the family.

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[49] J. Delgado , A. Molina-Pérez et al., "The Role of the Family", cit., pp. e112 - e118.

Table 3: role of the family and level of involvement

		Role of the family					
Country	Consent	No role	Witness	Surrogate	Full authority	Level of involvement	
AT	OPT OUT	X				0	No role
BE	OPT OUT	X				0	No role
BG	OPT OUT			X		2	Surrogate
CY	OPT IN			X		2	Surrogate
CZ	OPT OUT	X				0	No role
DE	OPT IN		X	X		2	Surrogate
DK	OPT IN			X		2	Surrogate
EE	OPT OUT		X			1	Witness
EN	OPT OUT		X	X		2	Surrogate
ES	OPT OUT		X			1	Witness
FI	OPT OUT	X				0	No role
FR	OPT OUT		X			1	Witness
GR	OPT IN			X		2	Surrogate
HR	OPT OUT	X				0	No role
HU	OPT OUT	X				0	No role
IE	OPT IN		*	*			*
IT	OPT OUT		X	X		2	Surrogate
LT				X		2	Surrogate
LU	OPT OUT	X				0	No role
LV	OPT OUT		X			1	Witness
MT	OPT IN			X		2	Surrogate
NI	OPT IN			X		2	Surrogate
NL	OPT OUT		X	X		2	Surrogate
PL	OPT OUT	X				0	No role
PT	OPT OUT	X				0	No role
RO	OPT IN		*	*			*
SC	OPT OUT		X	X		2	Surrogate
SE	OPT OUT			X		2	Surrogate
SI				X		2	Surrogate
SK	OPT OUT	X				0	No role
WA	OPT OUT		X	X		2	Surrogate

AT: Austria; BE: Belgium; BG: Bulgaria; CY: Cyprus; CZ: Czech Republic; DE: Germany; DK: Denmark; EE: Estonia; EN: England; FI: Finland; FR: France; GR: Greece; HR: Croatia; HU: Hungary; IE: Ireland; IT: Italy; LT: Lithuania; LU: Luxembourg; LV: Latvia; MT: Malta; NI: Northern Ireland; NL: Netherlands; PL: Poland; PT: Portugal; RO: Romania; SC: Scotland; SE: Sweden; SI: Slovenia; SK: Slovakia; SP: Spain; WA: Wales.
*: We notice that article 22(2) of the Irish law and article 21 of the Romanian law could have different interpretations.

VI. LIMITATIONS

The development of this study has posed two main limitations. The first one is related to the conceptual framework established for the analysis of DOP laws. In order to get a rigorous level of uniformity, we have designed a conceptual framework in which every legislation could fit. This conceptual framework stems from previous readings of the laws —which has led us to understand how, in general, laws regulate the DOP process— and also from the considerations of previous definitions given to the concepts managed in the literature[50]. This conceptual framework we propose is intended to fit for our pretended analysis of the DOP laws, but it is important to highlight that it does not aspire to constitute the only framework for the study of DOP laws. Some other definitions could also fit for this kind of study (i.e. considering "registry" as only for those registries that are created by DOP laws). So, it is good to remark that sticking to this conceptual framework could cause some interpretative problems in the understanding of the laws depending on the objective of the research. This conceptual framework has shown useful for the fulfilment of our objective, which was to clarify the role the family is allowed to play legally in the DOP process, and thus, the level of intervention granted for them legally.

The second limitation found is related to the extent of our research. This research has focused exclusively on following what is written in the law in each of the European countries. However, it is important to take into account that there are significant differences between law and practice worldwide[51]. We believe that the comparison between what is written in the law and what happens in practice is necessary, but this question is beyond the scope of this investigation due to the complexity of an analysis based only on organ donation laws. Further research focused on the comparison between the law and the practice is needed in order to clarify how deceased's and family's rights configured in the law are respected in practice. Our research would constitute a good starting point for this aim.

[50] See Ibíd.

[51] F. Bilgel. "The impact of presumed consent laws and institutions on deceased organ donation", *European Journal of Health Economics,* Vol. 13, nº 1, 2012, pp. 29 - 38; A. M. Rosenblum, L. D. Horvat et al., "The authority of next-of-kin", cit. pp. 2533 - 2546; Ibíd.

VII. CONCLUSIONS

Family's decisional capacity may have a great impact on organ donation rates. In order to comprehend the importance of this factor it is firstly necessary to address family's role granted by the law. In this contribution, we provide a systematic review of every DOP law within the European area regarding the level of participation of the family according to the lack or not of the previous will of the deceased.

We have shown that not every country legally articulates a donor register, either for expressing a consent when there is an opt-in system, or for expressing a refusal when there is an opt-out system. In those countries whose law does not mention a register there may be other ways to express a will regarding DOP, however the will expressed through those means will not have binding legal force.

Family's decisional capacity has a great impact, not only when deceased's wishes are unknown but also in the case there are previous expressed wills. Despite the impact the intervention of the family may have on organ donation rates, 8 countries within the European area do not explicit in their laws the role granted for the family, neither even their right to be informed about the process. Meanwhile, there is another group of countries which do legally specify only some level of intervention for the family, but not in all possible scenarios regarding the previous expressed will (or the lack of it) of the deceased. This aspect may be of a great importance in order to grant legal force to the actual decisional capacity conceded in the practice for the family in those countries. The same could be mentioned in the case any country grants in the practice the possibility for the family to overrule an expressed will of the deceased, since no country explicitly allows that possibility in the law.

The Directive 2010/45/EU determines that the exchange of organs constitutes an important way to increase the number of available organs for transplantation, and thus, to get a better compatibility between the donor and the recipient. It should be possible to move available organs smoothly across borders, and without unnecessary delays. But, for that purpose, common safety and quality standards are needed for the procurement, transportation and use of organs. Such standards would facilitate the exchange or organs, thus, benefiting every year to thousands of European patients in need for this kind of therapy.

Nevertheless, as we have shown in our study, after ten years of this Directive being in force, European laws governing deceased organ procurement show conflicts that are of the greatest importance.

Some of the laws of the countries analysed may not comply with the standard set in the article 17 of the *Additional Protocol to the Convention on Human Rights and*

Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, since they are (or may be) legally allowing the procurement of organs from the deceased that had opposed to it. Among the countries that have signed this Additional Protocol, this could be the case for Finland, Romania or Spain. Only Estonia complies strictly with this article 17. Among the rest of the countries, only Malta pronounces clearly in the same sense, depriving the family of any authority in case the deceased had expressed an opposition while alive. In a similar sense, it is important to take into account what the *Council of Europe Convention against Trafficking in Human Organs* establishes in its article 4.1.a, when condemning deceased organ procurement when carried out without the proper authorisation.

The development of a systematic methodology to classify legal data on the consent model and the role of the family in the organ donation process is crucial when comparing different countries laws. We hope that our methodology can be used by other researchers for comparative reviews in other countries, or states within the same country. We also expect that our systematic classification of the role *de iure* each country grants to the family can facilitate establishing correlations and drawing conclusions about trends in legislative changes in Europe. In addition, we encourage other researchers to apply our conceptual framework to compare OP laws in countries worldwide.

APPENDIX: LAWS BY COUNTRY

Nation	Laws and availability	Year
Austria	Organtransplantationsgesetz - OTPG sowie Änderung des Bundesgesetzes über Krankenanstalten und Kuranstalten, des Arzneimittelgesetzes, des Gewebesicherheitsgesetzes und des Bundesgesetzes über die Gesundheit Österreich GmbH. Available at: https://www.ris.bka.gv.at/Dokumente/BgblAuth/BGBLA_2012_I_108/BGBLA_2012_I_108.html	2012
Belgium	Loi du 13 juin 1986 sur le prélèvement et la transplantation d'organes http://www.ejustice.just.fgov.be/eli/loi/1986/06/13/1987009088/justel	1986
	3 JUILLET 2012. - Loi modifiant la loi du 13 juin 1986 sur le prélèvement et la transplantation d'organes et la loi du 19 décembre 2008 relative à l'obtention et à l'utilisation de matériel corporel humain destiné à des applications médicales humaines ou à des fins de recherche scientifique. Availability: http://www.ejustice.just.fgov.be/mopdf/2012/08/24_2.pdf#Page37, p. 50695.	2012
	21 MARS 2018. - Loi modifiant la loi du 13 juin 1986 sur le prélèvement et la transplantation d'organes en ce qui concerne les possibilités de s'enregistrer comme donneur d'organes postmortem, p. 70079. Legislation only available in French and Dutch. All updates and	2018

	changes can be found at: http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=1986061337&table_name=loi	
Bulgaria	ЗАКОН ЗА ТРАНСПЛАНТАЦИЯ НА ОРГАНИ, ТЪКАНИ И КЛЕТКИ В сила от 01.01.2004 г. Обн. ДВ. бр.83 от 19 Септември 2003г., изм. ДВ. бр.88 от 4 Ноември 2005г., изм. ДВ. бр.71 от 1 Септември 2006г., изм. ДВ. бр.36 от 15 Май 2009г., изм. ДВ.бр.41 от 2 Юни 2009г., изм. ДВ. бр.98 от 14 Декември 2010г., изм. ДВ. бр.9 от 28 Януари 2011г. Last updated 2019. https://www.mh.government.bg/media/filer_public/37/96/379681ed-5e58-43c2-b6a7-460eb3df9b07/zakon-za-transplantaciya-na-organi-takani-i-kletki_28-01-2011.pdf	2004, last updated 2019
Czech Republic	ZÁKON ze dne 30. května 2002 o darování, odběrech a transplantacích tkání a orgánů a o změně některých zákonů (transplantační zákon) Only in Czech. Available at: https://www.global-regulation.com/law/czech-republic/507382/transplantan-zkon.html	2002
Croatia	ZAKON O PRESAĐIVANJU LJUDSKIH ORGANA U SVRHU LIJEČENJA. Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3071.html	2012
Cyprus	127(I)/2012. Ο ΠΕΡΙ ΑΦΑΙΡΕΣΕΩΝ ΚΑΙ ΜΕΤΑΜΟΣΧΕΥΣΕΩΝ ΤΩΝ ΟΡΓΑΝΩΝ ΑΝΘΡΩΠΙΝΗΣ ΠΡΟΕΛΕΥΣΕΩΣ ΝΟΜΟΣ ΤΟΥ 2012. Available at: https://www.moh.gov.cy/moh/moh.nsf/222C730B732366FEC2257BD5003A2F59/$file/ΝΟΜΟΣ%20127(I)2012_ΠΕΡΙ%20ΑΦΑΙΡΕΣΕΩΝ%20ΚΑΙ%20ΜΕΤΑΜΟΣΧΕΥΣΕΩΝ%20ΤΩΝ%20ΟΡΓΑΝΩΝ%20ΑΝΘΡΩΠΙΝΗΣ%20ΠΡΟΕΛΕΥΣΗΣ.pdf	2012
	102(I)/2014 ΝΟΜΟΣ ΠΟΥ ΤΡΟΠΟΠΟΙΕΙ ΤΟΝ ΠΕΡΙ ΑΦΑΙΡΕΣΕΩΝ ΚΑΙ ΜΕΤΑΜΟΣΧΕΥΣΕΩΝ ΤΩΝ ΟΡΓΑΝΩΝ ΑΝΘΡΩΠΙΝΗΣ ΠΡΟΕΛΕΥΣΕΩΣ ΝΟΜΟ ΤΟΥ 2012 Available at: https://www.moh.gov.cy/moh/moh.nsf/222C730B732366FEC2257BD5003A2F59/$file/ΝΟΜΟΣ%20102(I)2014_ΠΕΡΙ%20ΑΦΑΙΡΕΣΕΩΝ%20ΚΑΙ%20ΜΕΤΑΜΟΣΧΕΥΣΕΩΝ%20ΤΩΝ%20ΟΡΓΑΝΩΝ%20ΑΝΘΡΩΠΙΝΗΣ%20ΠΡΟΕΛΕΥΣΗΣ%20(ΤΡΟΠΟΠΟΙΗΤΙΚΟΣ).pdf	2014
	160(I)/2017 ΝΟΜΟΣ ΠΟΥ ΤΡΟΠΟΠΟΙΕΙ ΤΟΥΣ ΠΕΡΙ ΑΦΑΙΡΕΣΕΩΝ ΚΑΙ ΜΕΤΑΜΟΣΧΕΥΣΕΩΝ ΤΩΝ ΟΡΓΑΝΩΝ ΑΝΘΡΩΠΙΝΗΣ ΠΡΟΕΛΕΥΣΕΩΣ ΝΟΜΟΥΣ ΤΟΥ 2012 ΚΑΙ 201 Available at: https://www.moh.gov.cy/moh/moh.nsf/222C730B732366FEC2257BD5003A2F59/$file/Ο%20Περί%20Αφαιρέσεων%20και%20Μεταμοσχεύσεων%20των%20Οργάνων%20Ανθρώπινης%20Προελεύσεως%20Νόμος%20του%202017.pdf	2017
Denmark	Bekendtgørelse af sundhedsloven https://www.retsinformation.dk/eli/lta/2018/1286	2018

	Lov om ændring af sundhedsloven og lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter https://www.retsinformation.dk/eli/lta/2018/1732	2018
England	Human Tissue Act http://www.legislation.gov.uk/ukpga/2004/30/pdfs/ukpga_20040030_en.pdf Last reform: Deemed Consent Act 2019: http://www.legislation.gov.uk/ukpga/2019/7	2004 2019
Estonia	Procurement, Handling and Transplantation of Cells, Tissues and Organs Act https://www.riigiteataja.ee/en/eli/ee/Riigikogu/act/502042019004/consolide	2015 (updated in 2017, 2018, 2019)
Finland	No. 101/2001. Act on the Medical Use of Human Organs, Tissues and Cells (Amendments up to 277/2013 included). Issued in Helsinki on 2 February 2001 https://www.finlex.fi/en/laki/kaannokset/2001/en20010101_20130277.pdf	2013
France	Code de la santé publique https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665	updated
	Décret n° 2016-1118 du 11 août 2016 relatif aux modalités d'expression du refus de prélèvement d'organes après le décès https://www.legifrance.gouv.fr/affichTexteArticle.do;jsessionid=5832366938CF26062A6B7E35D24F973B.tplgfr24s_3?cidTexte=JORFTEXT000033027728&idArticle=LEGIARTI000033038802&dateTexte=20160814	2016
Germany	Gesetz über die Spende, Entnahme und Übertragung von Organen und Geweben (Transplantationsgesetz - TPG) "Transplantationsgesetz in der Fassung der Bekanntmachung vom 4. September 2007 (BGBl. I S. 2206), das zuletzt durch Artikel 16 des Gesetzes vom 19. Mai 2020 (BGBl. I S. 1018) geändert worden ist" https://www.gesetze-im-internet.de/tpg/BJNR263100997.html#BJNR263100997BJNG000202310	2007, last updated 2020.
Greece	ΝΟΜΟΣ ΥΠ΄ ΑΡΙΘΜ. 3984 ΦΕΚ Α΄150/27.6.2011 Δωρεά και μεταμόσχευση οργάνων και άλλες διατάξεις. https://www.kodiko.gr/nomologia/document_navigation/123599/nomos-3984-2011	2011
	Υπουργική Απόφαση Γ2γ/ΓΠ/76110/18 - ΦΕΚ 4695/Β/19-10-2018 Καθορισμός και εξειδίκευση του τρόπου και των τεχνικών λεπτομερειών σχετικά με την εκδήλωση θετικής ή αρνητικής δήλωσης κάθε εν ζωή ατόμου ως προς την προσφορά οργάνων του για μεταμόσχευση	2018

	https://www.e-nomothesia.gr/kat-ygeia/upourgike-apophase-g2ggp-7611018.html	
Hungary	18/1998. (XII. 27.) EüM rendelet az egészségügyről szóló 1997. évi CLIV. törvénynek a szerv- és szövetátültetésre, valamint -tárolásra és egyes kórszövettani vizsgálatokra vonatkozó rendelkezései végrehajtásáról. https://net.jogtar.hu/jogszabaly?docid=99800018.EU	1998
Ireland	STATUTORY INSTRUMENTS. S.I. No. 325 of 2012. EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) REGULATIONS 2012. http://www.irishstatutebook.ie/eli/2012/si/325/made/en/pdf	2012
Italy	REGIO DECRETO 18 giugno 1931, n. 773 Approvazione del testo unico delle leggi di pubblica sicurezza. (031U0773) *(GU n.146 del 26-6-1931 - Suppl. Ordinario n. 146)* *https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:regio.decreto:1931-06-18;773!vig=*	1931
	Legge 01 aprile 1999, n. 91. Disposizioni in materia di prelievi e di trapianti di organi e di tessuti. (G.U. Serie Generale, n. 87 del 15 aprile 1999) http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=19372	1999
	Ministero della Sanità. Decreto 08 aprile 2000. Disposizioni in materia di prelievi e di trapianti di organi e di tessuti, attuativo delle prescrizioni relative alla dichiarazione di volonta' dei cittadini sulla donazione di organi a scopo di trapianto. (G.U. Serie Generale, n. 89 del 15 aprile 2000) http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=17738	2000
Latvia	LATVIJAS REPUBLIKAS LIKUMS. Par miruša cilvēka ķermeņa aizsardzību un cilvēka audu un orgānu izmantošanu medicīnā. https://likumi.lv/ta/en/en/id/62843-on-the-protection-of-the-body-of-deceased-human-beings-and-the-use-of-human-tissues-and-organs-in-medicine	1992
	Grozījumi likumā "Par miruša cilvēka ķermeņa aizsardzību un cilvēka audu un orgānu izmantošanu medicīnā" *https://likumi.lv/ta/id/307176*	2019
Lithuania	REPUBLIC OF LITHUANIA LAW ON DONATION AND TRANSPLANTATION OF HUMAN TISSUES, CELLS AND ORGANS. 19 November 1996. Nº I-1626. Vilnius (As last amended on 12 May 2016 – No XII-2344) https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/19d1d990225011e6acbed8d454428fb7?jfwid=191fum8213#part_3528cab269d44fbdb4f71ca91f31a9b4	1996, last updated in 2016
Luxembourg	Loi du 25 novembre 1982 réglant le prélèvement de substances d'origine humaine. http://legilux.public.lu/eli/etat/leg/loi/1982/11/25/n2/jo	1982

	Loi du 25 juin 2015 modifiant la loi du 25 novembre 1982 réglant le prélèvement de substances d'origine humaine. http://legilux.public.lu/eli/etat/leg/loi/2015/06/25/n1/jo	2015
Malta	CHAPTER 558 HUMAN ORGANS, TISSUES AND CELL DONATION ACT. To provide for human organs, tissues and cell donation and transplantation in Malta and to provide for matters ancillary or consequential thereto. 16th December,2016. ACT XXVIII of 2016. http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=12519&l=1	2016
Netherlands	Wet van 24 mei 1996, houdende regelen omtrent het ter beschikking stellen van organen (Wet op de orgaandonatie) https://wetten.overheid.nl/BWBR0008066/2019-04-02 Updates to be in force in 2020 available at: https://zoek.officielebekendmakingen.nl/stb-2018-95.html	1996 last updated 2018.
Northern Ireland	Human Tissue Act 2004. CHAPTER 30. http://www.legislation.gov.uk/ukpga/2004/30/pdfs/ukpga_20040030_en.pdf	2004
Poland	USTAWA z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów. Dz. U. 2019 poz. 1405 OBWIESZCZENIE MARSZAŁKA SEJMU RZECZYPOSPOLITEJ POLSKIEJ z dnia 14 czerwca 2019 r. w sprawie ogłoszenia jednolitego tekstu ustawy o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20190001405/T/D20191405L.pdf	2005
Portugal	Lei nº 12/93, de 22 de Abril COLHEITA E TRANSPLANTE DE ÓRGÃOS (versão actualizada 2015 (DL nº 168/2015, de 21/08). http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=236&tabela=leis&so_miolo=	1993, last updated 2015
Romania	Parlamentul Romaniei. Lege nr. 104/2003 din 27/03/2003 Publicat in Monitorul Oficial, Partea I nr. 222 din 03/04/2003 privind manipularea cadavrelor umane si prelevarea organelor si tesuturilor de la cadavre in vederea transplantului https://www.transplant.ro/(X(1)S(2sm04mntp340iz5ghvshhyf3))/Lege/Lege-2003-104.pdf	2003
Scotland	Human Tissue (Scotland) Act 2006 https://www.legislation.gov.uk/asp/2006/4/pdfs/asp_20060004_en.pdf Last updated 2019: http://www.legislation.gov.uk/asp/2019/11/enacted?view=extent	2006, last updated 2019
Slovakia	576 ZÁKON z 21. októbra 2004 o zdravotnej starostlivosti, službách súvisiacich s poskytovaním zdravotnej starostlivosti a o zmene a doplnení niektorých zákonov DRUHÁ HLAVÁ ODOBERANIE, UCHOVÁVANIE A PRENOS ORGÁNOV, TKANÍV A BUNIEK http://www.ncot.sk	2004

Slovenia	Zakon o pridobivanju in presaditvi delov človeškega telesa zaradi zdravljenja (Uradni list RS, št. 56/15) https://www.uradni-list.si/glasilo-uradni-list-rs/vsebina/2015-01-2357?sop=2015-01-2357	2015
Spain	Ley 30/1979, de 27 de octubre, sobre extracción y trasplante de órganos https://www.boe.es/buscar/pdf/1979/BOE-A-1979-26445-consolidado.pdf	1979
	Real Decreto 1723/2012, de 28 de diciembre, por el que se regulan las actividades de obtención, utilización clínica y coordinación territorial de los órganos humanos destinados al trasplante y se establecen requisitos de calidad y seguridad. https://www.boe.es/buscar/doc.php?id=BOE-A-2012-15715	2012
Sweden	Lag (1995:831) om transplantation m.m. https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-1995831-om-transplantation-mm_sfs-1995-831	1995
Wales	Human Transplantation (Wales) Act 2013 http://www.legislation.gov.uk/anaw/2013/5/pdfs/anaw_20130005_en.pdf	2013