



## Review article

# Global legislation regulating the donation, procurement and distribution processes of organs and tissues from deceased donors for transplants: A scoping review<sup>☆</sup>

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## ABSTRACT

**Introduction:** Organ transplantation is one of the most successful advances in modern medicine. However, a legal system is necessary for its practice to be free from ethical flaws and to respect donors, recipients, and family members.

**Objective:** To map the global legislation regulating the donation, capture and distribution processes of organs and tissues from deceased donors for transplants.

**Method:** A scoping review according to the Joanna Briggs Institute was conducted in the following databases: Medline, CINAHL, Virtual Health Library, SCOPUS, Web of Science, Science Direct, and EMBASE, as well as gray literature, and reported according to the PRISMA extension for scoping reviews.

**Results:** We identified 3302 records, of which 77 were analyzed which enabled mapping the type of consent adopted and the existence of current legislation for harvesting organs and tissues after circulatory and brain death.

**Conclusion:** *Opt-out* consent predominates in Europe, and there is harvesting after brain and circulatory death. *Opt-out* predominates in the Americas, while *Opt-in* and harvesting of organs and tissues after brain death predominate in Asia and Oceania. The procurement of organs and tissues from deceased donors is practically non-existent in Africa.

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## 1. Introduction

With the consolidation of organ and tissue transplants across the globe, there was a need to develop legislation that would guarantee their allocation to the respective recipients in a way that respected the rights of the donor, recipient and their families. However, each country has its own legislation regarding the organ and tissue harvesting system and adopts different types of rules and consents [1]. This work focuses on deceased donor legislation and will discuss definitions of brain and circulatory death and examples of global organ and tissue donation statistical data on donors in brain death (BD) and circulatory death (CD).

Consent to obtain organs can be done in two ways: *Opt-in* or *Opt-out*. The *Opt-in* system, also called explicit, considers that the individual must express their desire to be an organ and tissue donor before death by means of communication to family members or signing the organ donor register, or by appointing an individual or by testamentary letter, and in accordance with the legislation in force at the location [2,3]. Countries such as Brazil [4] and the United States of America [5] adopt this system.

In contrast, the *Opt-out* system, also called presumed consent, understands that all individuals are presumed donors of organs and tissues and the person who does not have this desire must declare to be excluded from the donor pool before their death [2,3].

However, there are excluded groups as provided in current legislation even in the *Opt-out* system. For example, in England, children under 18, residents in the country for less than 12 months and those diagnosed without mental capacity are considered unfit to donate [6]. In the Netherlands, the Donor Law applies to all people aged 18 or over who are registered in a Dutch municipality. Foreign citizens are invited to register their choice in the Donor Registry three years after moving to the Netherlands [7]. Countries such as Spain, Belgium and England adopt the *Opt-out* system [8]. Denmark, Switzerland, Germany are currently *Opt-in*, but are in the process of changing legislation to adopt the *Opt-out* system [9].

Obtaining organs and tissues from a donor can occur when they have deceased from BD or after CD. Brain death is the irreversible loss of brain stem function that results in the death and decay of all organs and systems [10]. Organ and tissue procurement after CD occur when cardiac and respiratory functions cease [11,12].

There are evidently disparities when comparing data from European countries which have the highest organ and tissue procurement rates; for example, Spain obtained 40.8 effective donors per million population (pmp); Portugal had 29.6 effective donors pmp in 2021, while Brazil and Argentina on the American continent had 13.8 effective donors pmp [13], but the reason for the disproportions has not yet been fully elucidated [14].

When considering that the legal framework constitutes a tool to protect the general security of the population and guarantee citizens' rights against abuses by other people, organizations and the government itself [15], and whether the adopted *Opt-in* or *Opt-out* policy [3] has an impact on actual donations, this knowledge gap may result in fewer bodies and tissues obtained for transplants and the consequent increase in waiting lists.

Therefore, this study is justified in terms of examining aspects of global normative variations in the process of obtaining organs and tissues for transplants and the impact of legislation on donations. The objective was to map current global legislation for donation, procurement and distribution of organs and tissues from deceased donors for transplants.

## 2. Methods

A scoping review (SR) of studies which deal with current global legislation regarding the donation, procurement and distribution of organs and tissues for transplants was conducted. The protocol was previously registered on the Open Science Framework (OSF®) online storage platform, according to DOI registration <https://doi.org/10.17605/OSF.IO/G5XHC>. The review is reported according to the PRISMA extension for scoping reviews [16], and conducted according to the Joanna Briggs Institute (JBI) methodology [17].

**Table 1**

Search strategies in the databases to perform the scoping review study. Campo Grande/MS, Brazil, 2023.

Database	Search strategies
Medline/PubMed	1# (“legislation and jurisprudence” [Subheading]) AND (“Tissue and Organ Procurement/legislation and jurisprudence”[Mesh] OR “Tissue and Organ Procurement/methods”[Mesh] OR “Tissue and Organ Procurement/organization and administration”[Mesh] OR “Tissue and Organ Procurement/supply and distribution”[Mesh])) AND (“Tissue and Organ Harvesting/ethics”[Mesh] OR “Tissue and Organ Harvesting/legislation and jurisprudence”[Mesh]) 2# (“legislation and jurisprudence” [Subheading]) AND “Tissue and Organ Procurement”[Mesh]) AND “Donor Selection”[Mesh]) AND “Tissue Donors”[Mesh]
CINAHL	1# (legislation and jurisprudence) AND (tissue and organ procurement or organ donation)
Biblioteca Virtual da Saúde - BVS	1# (legislation and jurisprudence) AND (Tissue and Organ Procurement) AND (Donor Selection) AND (Tissue Donors)
SCOPUS	1# TITLE-ABS-KEY (legislation AND jurisprudence AND tissue AND organ AND procurement AND donor AND selection AND tissue AND donors.) 2# TITLE-ABS-KEY (legislation AND jurisprudence AND tissue AND organ AND procurement)
Web of Science	1# ((TS=(legislation and jurisprudence)) AND TS=(Tissue and Organ Procurement)) AND TS=(Donor Selection)) AND TS=(Tissue Donors) 2# ((TS=(legislation and jurisprudence))) AND TS=(Tissue Donors) 3# (TS=(legislation and jurisprudence)) AND TS=(Donor Selection)
EMBASE	1# 'transplantation'/exp AND 'jurisprudence'/exp
Science Direct	1# legislation and jurisprudence AND Tissue and Organ Procurement AND Donor Selection AND Tissue Donors 2# legislation and jurisprudence AND Tissue and Organ Procurement

### 2.1. Guiding question

The PCC acronym was used to prepare the guiding question, in which P (population) corresponds to the current standardizing legislation; C (concept) refers to the donation, procurement and distribution process of organs and tissues from deceased donors for transplants; and C (context) represents the global legal system.

Therefore, the guiding question of this review is: What are the current laws in the global scenario for regulating the donation, harvesting and distribution of organs and tissues from deceased donors for transplants?

### 2.2. Eligibility criteria

Complete scientific articles, guides, editorials, government websites and regulatory legal documents were included, published in full and free of charge. There were no language and/or time period restrictions. The reference lists of publications were reviewed so that all reviews relating to the topic of interest were identified. Summaries of event annals, letters to the editor and research protocols were excluded.

### 2.3. Search strategy

The search strategies, as well as the selected crosses are detailed in [Table 1](#). The databases used for the review were: Medline (PubMed), Cumulative Index to Nursing and Allied Health Literature (CINAHL), *Biblioteca Virtual de Saúde (BVS)*, SCOPUS, Web of Science, Science Direct and the Excerpta Medical Database (EMBASE). Government institutions/websites that have data regarding legislation for organ and tissue harvesting were consulted for gray literature.

The following controlled descriptors were used: Legislation and Jurisprudence; Tissue and Organ Procurement; Donor Selection; Tissue Donors. The searches took place in the Periodicals Portal of the Coordination for the Improvement of Higher Education Personnel (CAPES) via CAFE remote access through the proxy of the Federal University of Mato Grosso do Sul. The search took place in January 2022 by two independent researchers simultaneously (A. M. S. and P. T. B.) and was updated in June 2023 due to the time elapsed between the data search and consolidation of results.

### 2.4. Study selection

After implementing the search strategy, the studies were allocated into the Mendeley® software program to count and remove duplicates. The reference selection process occurred in two stages.

First, the references were selected by reading titles and abstracts by two reviewers independently (A. M. S. and P. T. B.). This process was performed using the Rayyan QCRI® application (Qatar Computer Research Institute, Qatar) [18]. Disagreements were resolved through a consensus meeting.

The selected articles were assessed for eligibility by reading the full text. This process was also carried out by two reviewers (A. M. S. and P. T. B.), independently and in duplicate. Any disagreements at this stage were resolved with the support of a third reviewer (A. I. Q. C.).

### 2.5. Data extraction process

Data collection was performed by filling out a structured form in Microsoft Excel® which contained the reference domains for characterizing the study and current legislation on the donation, procurement and distribution of organs and tissues from deceased donors for transplants. A third reviewer checked the collected data entry after consolidating the spreadsheets (A. I. Q. C.).

The following variables were obtained from the selected articles: first author and year of publication; country where the study was conducted; title; current legislation for donation, harvesting and distribution of organs and tissues from deceased donors for transplants, BD, and organ donation/harvesting, cardiopulmonary arrest (CPA) and donation/harvesting of organs for transplants, type of consent adopted for organ harvesting and tissue for transplants.

### 2.6. Summary measures, data analysis and interpretation

The results were synthesized based on a descriptive analysis of the findings found in the studies. The summary of the studies and their characteristics were presented in synoptic tables to enable comparison of the legislation in force in different countries and continents.

The main summary measures used were: current legislation, BD and donation of organs and tissues, CPA and donation of organs and tissues, and the type of consent adopted for donating, harvesting and distributing organs and tissues.

A critical assessment (risk of bias) of the evidence sources was not performed since the main objective of this review was to describe and map in detail a body of scientific knowledge in terms of characteristics and factors [19].

## 3. Results

The search in research databases retrieved 3302 references. Next, 1952 references remained after removing duplicates, and the

analysis of titles and abstracts resulted in 61 selected articles for full reading. Then, 41 studies were selected from the analysis of the 61 full texts. The reference lists of the publications included for full reading were reviewed and 22 full texts were included. In addition, 14 documents were included from the gray literature search. Thus, the final sample consisted of 77 references (Fig. 1).

Data were collected from 55 countries belonging to the American, European, Asian, African and Oceanic Continents. The data specifically referring to countries of the American continent are shown in Table 2.

The sample from the American continent totaled 22 countries [20–50]. Of these, 54.54% adopt the *Opt-out* system, while 45.46% adopt *Opt-in* consent. It is worth noting that although Brazil [26] is *Opt-in* and also adopt family consent.

Regarding legislation for obtaining organs and tissues from deceased donors for transplants, the majority of countries (91.45%), except Nicaragua [40], recognize BD as irreversible and mandatory notification to organ procurement institutions and tissues.

Each country has strict protocol measures for proving BD and requires at least two doctors in the process of confirming BD, at least one of whom is a neurologist, and who are not part of the team organizing the search for organs and tissues.

An individual in the United States must register on a government platform and express their desire to donate after death in order to be a donor [46]. The country enacted a statute in 2006 that prohibits revoking a donor’s consent after death when they have legally registered as a donor during their lifetime in order to avoid problems of refusal after death [48].

Due to low organ and tissue donation rates, and the greater number of transplants carried out with living donors, Mexico (currently *Opt-in*), is in the process of updating its legislation and will adopt the *Opt-out* and family system. From this modification onwards, every individual over 18 years of age will be considered a donor [39].

El Salvador started using organ harvesting from BD individuals only from 2020 [33], and although Honduras has legislation that recognizes BD as irreversible, it has not yet regulated organ and tissue harvesting [36].

Organ and tissue harvesting after CD occurs in a few countries (31.81%). Brazil [25] harvests tissues after controlled and uncontrolled CD. The United States [48] performs organ harvesting after CD in controlled and uncontrolled modes. Although Argentina [22] has legislation that provides for harvesting organs and tissues after CD in controlled and uncontrolled modalities, it is at the beginning of this activity. The province of Nova Scotia (Canada) only performs the controlled modality [41].

Countries such as: Venezuela [50], Uruguay [49], Peru [23], Paraguay [45], Bolivia [24], Colombia [29], Ecuador [34], Chile [27], Puerto Rico [23], Honduras [36], Guatemala [35], El Salvador [33], Panama [44], Nicaragua [40] and Mexico [38] do not have specific legislation for obtaining organs and tissues after CPA, and therefore do not perform this procurement method.

All countries provide for free disposal of tissues and organs for transplants and prohibit their trade in their respective legislation.

Data from countries belonging to Europe are shown below in Table 3.

Europe counted 16 countries [6,51–73]. Of these, the majority (68.75%) adopt the *Opt-out* system, and the minority (31.25%) adopt *Opt-in* consent. Spain, Lithuania, Wales, England, France, Ireland, Italy and the Netherlands also consider family consent [64].

On the other hand, Portugal and Finland only communicate to family members about the presumed desire of the deceased person to be an organ and tissue donor [64]. It is worth mentioning that Denmark [55], Switzerland [71] and Germany [65] are studying to change their systems from *Opt-in* to *Opt-out*.

All countries recognize BD as irreversible with mandatory notification, and harvest organs and tissues for transplants in this way. Except for Belgium, all other countries have strict protocol measures to prove BD. Although BD is recognized as irreversible in Belgium, it has not yet been subject to specific legislation on the subject, and therefore the team is advised to follow recent knowledge [54].

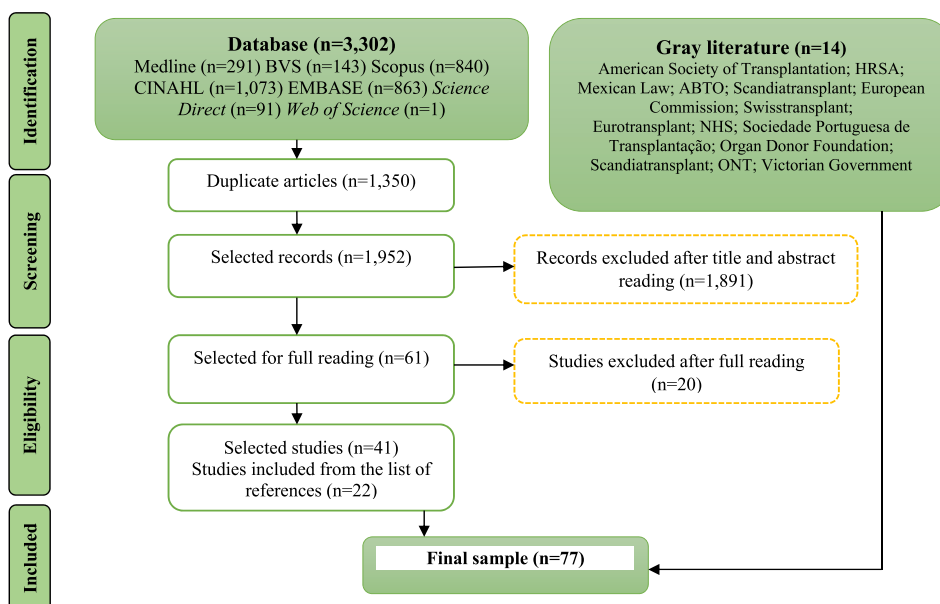


Fig. 1. Flow diagram (PRISMA-SCR), Campo Grande/MS, Brazil, 2023.

**Table 2**

- Characterization of the legislation in force in countries of the American continent for the donation, procurement and distribution processes of organs and tissues for transplants. Campo Grande/MS, Brazil, 2023.

Primary author/Year of publication	Country/Year of implementation of legislation	BD <sup>+</sup> and Donation	CPA and Donation	Type of Consent
Gondolesi (2018)(20) Incucai (2023)(21) Farinelli (2023)(22)	Argentina - 2018	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-in.</i>
García (2017)(23) Congreso Nacional (1996)(24)	Bolivia - 1996	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out.</i>
García (2017)(23) ABTO (2020)(25) ABTO (2023)(26)	Brazil - 2017	Recognizes BD and has specific legislation.	Provided by legislation and tissue harvesting carried out.	<i>Opt-in</i> and family consent.
Zúñiga-Fajuri (2018)(27) Congreso Nacional (2019)(28)	Chile - 2019	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out.</i>
García (2017)(23) Acto (2022)(29)	Colombia - 2016	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out.</i>
García (2017)(23) Asamblea Legislativa de la república de Costa Rica (2014)(30)	Costa Rica - 2014	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-out.</i>
García (2017)(23) Sánchez (2014)(31)	Cuba - 1995	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-in.</i>
García (2017)(23) INCORT (2023)(32)	Dominican Republic - 2004	Recognizes BD and has specific legislation.	Provided by legislation.	<i>Opt-out.</i>
García (2017)(23) Asamblea Legislativa de la República de El Salvador (2020)(33)	El Salvador - 2020	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-in.</i>
Huertas (2020)(34)	Ecuador - 2011	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out.</i>
García (2017)(23) Fundación donare (2020)(35)	Guatemala - 1996	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-in.</i>
García (2017)(23) Republica De Honduras (2014) (36)	Honduras - 2014	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-in.</i>
Contreras (2016)(37) Reyes-Acevedo (2019)(38) Mexican Law (2023)(39)	Mexico - 2023	Recognizes BD and has specific legislation.	Not executed.	<i>Opt-in</i> , but under study to change to <i>Opt-out</i> and family consent.
García López (2014)(40)	Nicaragua - 2013	Does not recognize BD as death of the individual.	Not executed.	<i>Opt-in.</i>
Krmpotic (2020)(41) CBS (2018)(42)	Nova Scotia/Canada - 2019	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-out.</i>
Weiss (2021)(43) García (2017)(23)	Panama - 1998	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out.</i>
Minsa (2016) [44] García (2017)(23)	Paraguay - 2018	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out.</i>
Congreso de la Nación Paraguaya (2018)(45)				
García (2017)(23)	Peru - 2005	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out.</i>
García (2017)(23)	Puerto Rico - 2000	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-in.</i>
Siminoff (2013) [46] American Society of Transplantation (2023) [47]	United States - 2006	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-in.</i>
HRSA (2023)(48) García (2017)(23)	Uruguay - 2020	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out.</i>
INDT (2022)(49) García (2017)(23)	Venezuela - 2011	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out.</i>
Cappa (2022)(50)				

**Abbreviations:**+BD: Brain Death; <sup>+</sup>CPA: Cardiopulmonary arrest.

The majority of countries (81.25%) have legislation for organ harvesting after CPA, as well as technological equipment, and use this method of obtaining organs and tissues. England and Ireland perform harvesting after controlled CD. Spain, France, Italy, Belgium and the Netherlands harvest organs after controlled and uncontrolled CD [63].

On the other hand, Portugal harvests organs and tissues after uncontrolled CD and recognizes the need for changes in legislation which may include obtaining organs and tissues after controlled CD and resources to implement this modality [70]. Belgium and the Netherlands have the particularity of harvesting organs and tissues after euthanasia [54].

**Table 3**

- Characterization of the legislation in force in European countries and the United Kingdom for donating, harvesting and distributing organs and tissues for transplants. Campo Grande/MS, Brazil, 2023.

Primary author/Year of publication	Country/Year of implementation of legislation	BD <sup>+</sup> and Donation	CPA and Donation	Type of Consent
Stadlbauer (2013)(51) Eurotransplant (2016)(52) European Commission (2023) (53)	Austria - 2018	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-out.</i>
Detry (2017)(54) Eurotransplant (2016)(52)	Belgium - 1986	Carried out, but without specific legislation on BD.	Provided by legislation and carried out.	<i>Opt-out.</i>
Jensen (2020)(55) Scandiatransplant (2023)(56)	Denmark - 2019/2023	Recognizes BD and has specific legislation.	Approved in March 2023.	<i>Opt-in</i> , but under study to change to <i>Opt-out</i> .
Hubner (2020)(57) NHS (2022)(6) European Commission (2018) (58)	England - 2019	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-out</i> and family consent.
Miranda (1999)(59) Escudero (2015) [60] ONT (2023) [61] European Commission (2023) [53] Van (2023) [62]	Spain - 2014 and 2021	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-out</i> and family consent.
Lomero (2020)(63) González (2021)(64) Scandiatransplant (2023)(56)	Finland - 2001	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out.</i>
Lomero (2020)(63) González (2021)(64) European Commission (2023) (53)	France - 2016	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-out.</i>
Nashan (2017)(65) Eurotransplant (2016)(52) Schönburg (2020)(66)	Germany - 2019	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-in</i> , but under study to change to <i>Opt-out</i> .
Lomero (2020)(63) González (2021)(64) European Commission (2023) (53)	Ireland - 2012	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-in.</i>
Lomero (2020)(63) González (2021)(64) European Commission (2023) (53)	Italy - 2012/2014	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-out.</i>
Migliņas (2019)(67) European Commission (2023) (53)	Lithuania - 2016	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-in</i> and family consent.
Guzik-Makaruk (2019)(68) Małosa (2020)(69) European Commission (2023) (53)	Poland - 2017	Recognizes BD and has specific legislation.	Provided for in legislation, but rarely performed.	<i>Opt-out.</i>
Lomero (2020)(63) González (2021)(64) Sociedade Portuguesa de Transplantação (2023)(70)	Portugal - 1993/2015	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-out.</i>
Schaub (2019)(71) Swisstransplant (2023)(72)	Switzerland - 2021	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-in</i> , but under study to change to <i>Opt-out</i> .
Lomero (2020)(63) González (2021)(64) Nashan (2017)(65)	The Netherlands - 2020	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-out.</i>
Eurotransplant (2016)(52) Moore (2018)(73) European Commission (2018) (58)	Wales - 2015	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-out</i> and family consent.

**Abbreviations:**+BD: Brain Death; <sup>+</sup>CPA: Cardiopulmonary arrest.

Although Poland regulated organ and tissue procurement after CD in 2017, little is implemented, as it is not well accepted by society [68]. Denmark approved harvesting organs and tissues after CD in March 2023, and is in the process of preparing the team to implement this modality [56]. Germany and Finland do not have specific legislation, therefore they do not capture organs and tissues after CD [63].

Spain, a global reference in transplant numbers, does not have any legislative aspects that are different from other countries in Europe and the West. However, the model success consists of a continuous national multidisciplinary approach which encompasses medical, economic and political aspects [61].

In the 28 member countries of the European Union, the exchange of organs and tissues is planned via the European health

commission through a single waiting list in order to reduce long waiting lists [53]. There is also Eurotransplant [52] composed of 8 countries (Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands and Slovenia) that primarily exchange organs and tissues among themselves, and in the presence of some impeding factor, share them with other member countries of the European Union.

In addition, there is ScandiTransplant [56] made up of Denmark, Finland, Iceland, Norway, Sweden and Estonia, which, in a similar way to Eurotransplant, initially share donated organs and tissues with each other, and in the event of any impediment they make collections available with the European Union. The United Kingdom, although no longer part of the European Union, continues to share harvested organs and tissues.

All countries provide for the free disposal of tissues and organs for transplants and prohibit their trade in their respective legislation. Furthermore, they strive for ethics and organ distribution and follow a strict single waiting list.

The results regarding the data found in the literature referring to countries in the Asian, African and Oceanic continents are shown below in Table 4.

The majority of Asian countries (66.8%) adopt *Opt-in* consent, while 16.6% adopt the *Opt-out* system and 16.6% adopt what they call family consent. The majority of countries (91.7%) recognize BD as irreversible and harvest organs and tissues in this modality. On the other hand, only 41.7% of countries have legislation and technological equipment to harvest organs and tissues after CD.

**Table 4**

- Characterization of the current legislation in Asian, African and Oceania countries for donation, harvesting and distribution of organs and tissues for transplants. Campo Grande/MS, Brazil, 2023.

Primary author/Year of publication	Country/Year of implementation of legislation	BD <sup>+</sup> and Donation	CPA and Donation	Type of Consent
<b>Asia</b>				
Siraj (2022) [74]	Bangladesh - 2018	Recognizes BD and has specific legislation but is rarely performed.	Provided for in legislation, but rarely performed.	<i>Opt-in</i> .
Chapman (2015) [75]	China - 2014	Not regulated in the country.	Provided by legislation and carried out.	<i>Opt-in</i> .
Lobo (2018) [76]	India - 2014	Recognizes BD and has specific legislation.	Provided by legislation and carried out.	<i>Opt-in</i> and family consent.
Yadla (2019) [77]	Iran - 2000	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-in</i> .
Kiani et al. (2018) [78]				
Mahdavi et al. (2008) [79]				
Ashkenazi et al. (2015) [80]	Israel - 2008	Recognizes BD and has specific legislation.	Provided by legislation and in its initial activity stages.	<i>Opt-in</i> .
Berzon (2018) [81]				
Soyama and Eguchi (2016) [82]	Japan - 2010	Notification of brain death is not mandatory.	Does not have specific legislation.	<i>Opt-out</i> .
Gonchigjav et al. (2022) [83]	Mongolia - 2018	Recognizes BD and started activity after changing the law in 2018.	Does not have specific legislation.	Family authorization. Authorization required from 3 family members.
Bile et al. (2010) [84]	Pakistan - 2010	Recognizes BD and has specific legislation, but rarely performed.	Not performed.	<i>Opt-in</i> .
Rizvi et al. (2013) [85]				
Ullah et al. (2023) [86]				
Lee and Kim (2009) [87]	South Korea - 2011	Recognizes BD and has specific legislation.	Does not have specific legislation.	<i>Opt-out</i> .
Min et al. (2015) [88]				
Saeed (2020) [89]	Syria - 2003	Recognizes BD and has specific legislation.	Not performed.	<i>Opt-in</i> .
Wang et al. (2016) [90]	Taiwan - 2014	Established since 1987.	Not performed.	Family authorization.
Haberal (2022) [91]	Turkey - 2001	Recognizes BD and has specific legislation.	Provided for in legislation, but rarely performed.	<i>Opt-in</i> .
<b>Africa</b>				
Lokulo (2022) [92]	Nigeria - 2014	Not regulated in the country.	Not regulated.	<i>Opt-in</i> .
Adejoro (2023) [93]				
Organ Donor Foundation (2023) [94]	South Africa - 2003	Recognizes BD and has specific legislation.	Not regulated.	<i>Opt-in</i> .
Ahmed et al. (2018) [95]	Sudan - not regulated	Not regulated in the country.	Not regulated.	<i>Opt-in</i> .
<b>Oceania</b>				
Victorian Government (2023) [96]	Australia and New Zealand - 2020	Recognizes BD and has specific legislation.	Not regulated for organs, only corneas.	<i>Opt-in</i> .

**Abbreviations:**+BD: Brain Death; +CPA: Cardiopulmonary arrest.

There must be a testamentary letter signed by at least two people for an individual to be an organ or tissue donor in India, and in the absence of the document, authorization is at the family's discretion. The request for organs and tissues from family members only happens after a medical team completes a death certificate [76].

Although there is legislation for obtaining organs and tissues in BD and *Opt-in* consent in Syria, the country only has donation between living donors, since there is no active program for obtaining organs and tissues from deceased donors [89].

It is important to highlight that China does not have legislation, therefore it does not harvest organs and tissues after BD is diagnosed. They used organs from prisoners after the death penalty until 2014. Although there was an announcement not to use these organs and tissues, there was no change in legislation or regulations governing the supply of organs [75].

Another country that deserves to be highlighted is South Korea, which, unlike all the other countries, has a financial incentive system for hospitals that harvest organs and tissues and for family members of donors for funeral assistance in the amount of \$4500.00 dollars [88].

Israel [81] regulated that individuals registered as donors for a minimum period of three years have priority on the transplant waiting list over a non-donor individual in order to encourage donation of organs and tissues. Communication of BD to family members is mandatory, however confirmatory tests are only carried out after authorization from the family member.

Although Japan has undergone changes in legislation, it still does not adopt notification of BD as mandatory and does not have legislation to harvest organs and tissues after CD [82].

Bangladesh has legislation to harvest organs and tissues after BD and CD, however, little is implemented due to religious reasons. The country is mostly composed of Muslims who believe that the human body should not be altered in any way. Furthermore, BD by religious leaders is not considered death, since physical death only happens when the heart stops beating [74]. Thus, corneas are only harvested after CD or when family members authorize a BD test and organ harvesting, or in deceased donors in which no family member appears to claim the body [74].

Pakistan has a similar situation to Bangladesh. Although there is legislation for organ harvesting after BD, it does not happen due to the widely spread Muslim belief in the myth that the post-mortem human body should not suffer physical damage. For individuals who are in favor of donation, a constitution was approved in Pakistan in 2007 which allows people over the age of 18 to write a declaration of donation before their death if they agree to donating their organs and tissues [86].

Turkey also performs few BD donor transplants for religious reasons. Although there is legislation for harvesting organs and tissues after uncontrolled CD, it also does little due to family denials [91].

Iran, an Islamic country, has a well-developed transplant program that operates under the supervision of its Ministry of Health. However, organ and tissue harvesting only occurs in cases of BD, as there is no legislation in the country regarding obtaining after CD [78].

Taiwan [90] and Mongolia [83] deserve to be highlighted, which, unlike other places, consider consent to organ and tissue donation in their countries as pertaining to the family only. Regardless of the wishes of the deceased individual, only the wishes of the family prevail.

On the African continent, Sudan [95] and Nigeria [92] adopt the *Opt-in* system, however they still do not regulate organ and tissue harvesting from donors in BD and after CPA, and therefore only perform transplants from living donors.

In South Africa, if family members choose to donate organs and tissues, it is necessary for the family itself to contact the Organ Donation Foundation via telephone and express their intention to donate the organs and tissues and then the foundation contacts the transplant centers or nearest tissue bank [94].

Although they have legislation that prohibits organ trafficking, countries in the African and Asian continents face the serious problem of organ trafficking and tourism [92].

Australia and New Zealand in Oceania share the same legislation for organ harvesting. Both also exchange organs and tissues obtained in their jurisdiction. Their governments have reimbursed hospitals which carry out organ procurement activities since 2009 as a way of encouraging this practice in order to increase organ and tissue procurement. Furthermore, the legislation was updated in 2020 and allows individuals who intend to be organ and tissue donors to express in writing and register with government institutions their desire to become a donor after BD [96].

#### 4. Discussion

Adequate legislation, ethical frameworks, regulatory oversight and governance are essential for the legal and ethical practice of organ and tissue procurement for transplants in order to meet the needs of recipients, protect donors and ensure the dignity of everyone involved in the process [97]. It is worth noting that each country and its governments adopt different legal and institutional models suited to their purpose as a nation [1].

Legislation must prescribe basic topics such as permission to perform a transplant from a deceased donor with BD and/or a stopped heart, criteria for BD, living donor, form of consent for the donation of organs and tissues, waiting list, prohibition of trade in bodies and sanctions and infractions for non-compliance with the law [98].

In relation to the type of consent on all continents, notably Europe and America, this study identified a tendency to change legislation from the *Opt-in* to the *Opt-out* system. However, a study that evaluated the effect of *Opt-in* versus *Opt-out* consent on the organ procurement rate found similar results in both situations, with the exception of cases in which the patient or family had a formed opinion [9].

In the same direction, one study showed that only the legal change from the *Opt-in* to *Opt-out* system cannot reverse the shortage of organs and tissues. In addition to changing the legal framework, it is necessary to invest in organ perfusion technology to add quality



and increase the number of organs harvested, as well as investing in measures which change social culture, so that the family's choice for donation is the standard [99].

Brazil deserves to be highlighted, which, unlike the global trend of changing consent from *Opt-in* to *Opt-out* due to population pressure, took the opposite path, and through law no. 10,211, of March 23, 2001, changed the provisions of the law no. 9,434, of February 4, 1997 and started to adopt family consent [98].

Considering the global and growing number of people with chronic diseases and organ failure, the World Health Organization together with The Transplantation Society (TTS) have called on their members to take legal and policy measures to increase the procurement of donor organs from deceased persons, and one path is CD, both controlled and uncontrolled [22].

It is important to highlight that harvesting organs and tissues after uncontrolled CD is promising, however few countries carry it out or have specific legislation due to the logistical, financial and ethical-legal challenge, in addition to the lack of confidence in the quality of the organs and tissues obtained [12]. In addition to Belgium and the Netherlands identified in the results of this review, Spain and Canada also allow organ donation after assisted euthanasia within strict legal regimes [62].

Europe stands out from other continents due to the existence of Eurotransplant [52] and Scandiatransplant [56], which together with the 28 members of the European Union [53] work in parallel and exchange organs and tissues in order to improve the use of harvested organs and reduce waiting lists for transplants among its member countries.

Thus, when considering the data made available by the world's global donation and transplant observatory [100] which provides data from the countries best ranked in organ and tissue donation, 25 among the 31 best-ranked countries belong to Europe. On the other hand, the best placed country in the American continent is the United States which occupies second place, followed by Uruguay and Brazil. The best placed country in Asia is Israel, which occupies 30th place.

Organ donation in Asian countries is shaped by socioeconomic, religious and cultural indicators. Therefore, most countries adopt donations from living donors to the detriment of deceased donors [86]. BD donors are practically not used in the Middle East due to the ongoing debate in the medical and religious community about the concept of BD and inadequate public awareness [91]. As a result, countries such as Vietnam, Nepal, Bangladesh, India, among others, face the serious problem of crimes involving trafficking in human organs [74].

The only country in African which has regulations for organ and tissue donations from a deceased donor is South Africa [92]. Most centers try to ensure that there is no financial incentive for the living donor, however tourism and organ purchasing remains a challenge [101].

Conflicting situations can arise when donating bodies for research or educational activities [102]. A study investigating body donation in Europe found that a clear and rigorous legal framework is not yet available in several countries. National regulations were found in only 18 of the 39 countries studied [103].

This problem has been highlighted in Italy due to the recent introduction of the law on the donation of whole bodies, organs and tissues for the purposes of teaching, scientific research and training [104]. Anatomists argue that priority should be given to the removal of organs and tissues for donation to living people waiting on the waiting list for a transplant and only after that should consideration be given to making the body available for teaching, research and training. Furthermore, they argue that donating the body for study does not preclude donating organs for transplantation [105].

A limiting factor of this study is that despite efforts to apply a comprehensive search strategy, there are 194 countries in the world [106], so even when using the gray literature search it was not possible to map them all. However, substantial losses of possible discoveries were mitigated by investigating the characteristics of the continents in databases and gray literature and not restricting time or language. However, it is suggested that future work explore this topic and incorporate data from countries not covered in this review.

However, despite the limitations, the study strictly followed the scientific method for SR. Its result has practical implications to contribute to the knowledge and update of health professionals, public authorities and legislators about the organ and tissue harvesting processes on different continents and the impact of the type of consent model adopted. Furthermore, the legal framework highlighted can guide policymakers in reviewing and updating existing laws and regulations. The discussion about successful strategies/results identified in the study and adopted by continents or countries can be used to support public policies to increase the number of harvests and reduce waiting lists for organs or tissues for transplants.

The need for legislation and ethical principles regarding the donation of organs and tissues for transplants is highlighted, attested by the transparency of the process, and guaranteed by the fulfillment of the donors' intentions.

## 5. Conclusion

Most countries in Europe adopt the *Opt-out* consent system. Germany, Denmark and Switzerland are in the process of changing their laws to the *Opt-out* system. Most countries have established legal criteria for harvesting organs and tissues, both after BD and controlled CD. Organs and tissues are exchanged between European Union member countries via Scandiatransplant and Eurotransplant.

Most countries in the Americas adopt the *Opt-out* system. They perform harvesting after BD and the minority harvest organs after CD. Asia has established *Opt-in* consent; however, it faces difficulties in putting into practice the legislation that provides for harvesting organs and tissues after BD. Furthermore, few countries have legislation that provides for harvesting organs and tissues after CD.

Only South Africa has an established program in Africa for harvesting organs and tissues from deceased donors. Australia and New Zealand deserve to be highlighted in Oceania for having joint legislation and harvesting organs and tissues after *Opt-in* consent from brain-dead donors, since they only harvest corneas after CD.

## Ethical considerations

This is a scoping review study, therefore prior review by an ethics committee was unnecessary.

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## Data availability statement

No data associated with this study has been deposited into a publicly available repository. Data availability in article and referenced in article.

## Additional information

No additional information is available for this paper.

## CRediT authorship contribution statement

**Aline Moraes da Silva:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Patrícia Trindade Benites:** Writing – original draft, Formal analysis, Data curation. **Maria Eduarda Gonçalves Zulin:** Writing – original draft, Data curation. **Marcos Antonio Ferreira Júnior:** Writing – review & editing, Supervision, Formal analysis, Conceptualization. **Andréia Insabralde de Queiroz Cardoso:** Writing – review & editing, Data curation, Conceptualization. **Elenir Rose Jardim Cury:** Writing – review & editing, Supervision.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.heliyon.2024.e26313>.

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