



## Consent Systems for Deceased Organ Donation

*A comparative review of opt-in, opt-out, mandated-choice and reciprocity frameworks across sixty countries*

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### ABSTRACT

Few questions in transplant policy generate more debate than the legal architecture of consent for deceased organ donation. Opt-in (informed consent), opt-out (presumed consent), mandated choice, and reciprocity-based systems each carry distinct ethical commitments and operational implications. This article reviews the principal consent systems in use across more than sixty countries, integrating evidence from the Global Observatory on Donation and Transplantation for 2023 and 2024 with the contemporary peer-reviewed literature. The synthesis confirms a now-familiar conclusion: consent law in isolation is a weak predictor of national donation rates. The variance between countries operating the same legal regime — Spain (53.9 donors per million population [pmp]) versus Bulgaria (2.4 pmp) under opt-out, or the United States (49.7 pmp) versus Japan (1.1 pmp) under opt-in — substantially exceeds the variance attributable to the consent model itself. Hospital-embedded transplant coordination, family communication practices, intensive-care infrastructure, and cultural acceptance of brain death emerge as the proximate determinants. The article concludes with implications for countries considering legislative reform and for low- and middle-income countries where the choice of consent model is largely irrelevant in the absence of foundational infrastructure.

01 · INTRODUCTION

## The legal architecture of consent

Globally, transplant activity reached a new record in 2024, with 173,727 solid organ transplants performed across 92 reporting Member States — yet still meeting no more than 10% of estimated need.<sup>[1]</sup> Within this aggregate, the supply of deceased donor organs depends on a chain of clinical, organizational and legal events that begins long before the bedside conversation: legislation establishing the default position on donation, registries that capture individual preferences, intensive-care pathways that identify potential donors, and the trained personnel who approach grieving families. The legal architecture of consent — the focus of this article — sits at the start of that chain.

Three broad consent models are in widespread use. Opt-in (informed consent) requires affirmative registration of a wish to donate and is the default in most of North America, the Asia-Pacific, and parts of Northern Europe. Opt-out (presumed consent) treats every adult as a willing donor unless they have actively recorded an objection, and is the default across most of Western and Eastern Europe and much of Latin America. Hybrid mechanisms — mandated or required choice, reciprocity-based prioritization, and regulated paid living donation — operate in particular countries to address perceived limitations of the binary models. The remainder of this article examines each system, the evidence on its effects, and the structural factors that consistently outperform legal categorization as predictors of donation outcomes.

02 · A TYPOLOGY OF CONSENT SYSTEMS

## Six legal frameworks in use

### 2.1 *Opt-in (informed consent)*

Under an opt-in regime, organs may be retrieved only where the deceased made an explicit pre-mortem expression of willingness to donate, typically via a national registry, donor card, or driver-license flag. In the absence of registration, the next-of-kin are usually invited to consent on the deceased's behalf. Major opt-in countries include Germany, Denmark, the Republic of Ireland, Australia, New Zealand, the United States, Japan, the Republic of Korea, India, and most of sub-Saharan Africa.<sup>[2,3]</sup> The model is grounded in a strong

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reading of bodily autonomy: in the absence of demonstrable willingness, no inference of consent is drawn.

Opt-in countries display strikingly different outcomes. The United States achieved 49.7 donors per million population in 2024 and registers approximately 58% of adults through Department of Motor Vehicles integration.<sup>[1,4,5]</sup> Germany — also opt-in — recorded only 11.7 pmp despite an adult registration rate of approximately 36% and a family consent rate near 75%.<sup>[1,6,7]</sup> The contrast underscores that opt-in does not entail low performance per se; rather, it shifts the explanatory burden onto registry penetration and donor-identification infrastructure.

## 2.2 *Hard opt-out (presumed consent)*

Hard opt-out, sometimes termed strict presumed consent, treats the absence of a registered objection as legally sufficient authorisation for retrieval. Family consultation is not legally required, although in practice most countries involve relatives. Countries operating hard opt-out regimes include Austria, the Czech Republic, Belarus, Poland, Latvia, Slovakia, and — for the deceased donor pathway — Portugal.<sup>[8]</sup> Croatia, Hungary and several other Central European countries are sometimes also classified as hard opt-out, but in practice they consult the next-of-kin and treat sustained family objection as decisive, placing them functionally on the soft opt-out side of the line.

Hard opt-out is associated with a wider performance band than is sometimes recognized. The Czech Republic (34.3 pmp) <sup>[9]</sup>sits near the top of European performers, while Slovakia (12.5 pmp in 2023) and Belarus (25.5 pmp) occupy the middle and Bulgaria (2.4 pmp in 2024) occupies the bottom. This dispersion — among countries sharing a near-identical legal default — represents one of the strongest pieces of evidence that consent law alone is not the operative variable.

## 2.3 *Soft opt-out (presumed consent)*

Soft opt-out preserves the legal default of consent but treats family objection as decisive in clinical practice. This model is in use in Spain, France, Italy, Belgium, the Netherlands, Slovenia, Sweden, Norway, Finland, England, Wales, and Scotland, among others. In each of these countries, families are routinely consulted and donation is rarely if ever pursued in the face of a sustained family objection.<sup>[8,10]</sup> The soft variant therefore functions, in practice, as a default-setting

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mechanism that shapes how families are approached rather than as a unilateral authorisation.

## *2.4 Mandated and required choice*

Mandated choice obliges adults — typically at the point of acquiring or renewing a state-issued document — to record an affirmative preference: yes, no, or in some variants a deferral to family. The clearest implementation is in New Zealand, where applicants for a driver license are required to answer the question of donation willingness, and a status of 'donor' or 'not a donor' is recorded on the license.<sup>[15,16]</sup> Although several authors describe the New Zealand approach as 'mandatory choice', the choice is technically tied to licensing rather than universal: those who never apply for a license remain unrecorded. Even so, New Zealand's 51% adult registration rate is the highest of any high-income country not relying on Department of Motor Vehicles integration.

True universal mandated choice — under which all adults are required to register a preference irrespective of any other administrative event — has been proposed in several countries but is not currently implemented at national scale anywhere. The United States' Department of Motor Vehicles registration is sometimes characterized as 'first-person authorisation' rather than mandated choice, because the prompt to register is universal among license applicants but the choice itself is voluntary.<sup>[4]</sup>

## *2.5 Reciprocity-based systems*

Reciprocity links registration as a donor to preferential access to transplantation in the event of future need. The mechanism can sit on either of two underlying defaults: opt-in or opt-out. Israel layers a reciprocity provision over an opt-in default — its 2008 Organ Transplant Act, in force from January 2010, awards priority points on the waiting list to candidates who have signed donor cards, who have made non-directed living donations, or whose first-degree relatives have donated.<sup>[17,18]</sup> The policy was popularized under the slogan don't give, don't get. Card registration rose sharply post-implementation, and Israel reported 10.4 pmp in 2024.<sup>[1]</sup> Singapore takes the opposite path, layering reciprocity over an opt-out default under the Human Organ Transplant Act (HOTA, 1987; amended 2004 and 2008): citizens who opt out lose waiting-list priority for two years after withdrawing their objection.<sup>[34,35]</sup> In both forms, reciprocity functions as an overlay on a chosen default rather than a stand-alone consent system.

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Reciprocity raises distinctive ethical questions. Critics argue that priority allocation introduces a non-medical criterion into organ distribution and risks distinguishing between citizens on grounds beyond clinical need.<sup>[18,19]</sup> Defenders respond that reciprocity addresses an entrenched free-rider problem — those who would receive but not give — and that a moderate priority advantage is ethically distinct from monetary incentives. The Israeli and Singaporean experience together suggests that reciprocity can shift registration behavior without converting organ allocation into a market.

## *2.6 Regulated payment for living donors*

Iran is the only country worldwide that operates a state-regulated, compensated living-unrelated kidney donor program, established in 1988 under the auspices of the Ministry of Health. Compensation is fixed by the state and supplemented by a charitable component; the model eliminated the national kidney waiting list within roughly a decade.<sup>[20,21]</sup> A separate deceased donor pathway has operated since the 2000 Brain Death Act, which permits retrieval following brain-death determination with donor card or family consent. Iran reported 13.0 pmp in 2023 and continues to rely heavily on living donors.<sup>[22,23]</sup>

The Iranian model lies outside mainstream international transplant ethics, which since the 2008 Declaration of Istanbul on Organ Trafficking and Transplant Tourism has reaffirmed the prohibition of organ commerce.<sup>[24]</sup> It is included here for completeness as a distinct architecture of consent and exchange, not as a recommended model.

## 03 · EMPIRICAL EVIDENCE

# Does the consent system matter?

## *3.1 The headline finding*

Across multiple recent reviews, opt-out countries on average exhibit modestly higher deceased donation rates than opt-in countries, but the effect attributable to legislation is small relative to between-country variance and is sensitive to model specification.<sup>[2,3,25]</sup> Drawing on data from 35 countries over 13 years, Molina-Pérez and colleagues conclude that although opt-out systems are associated with higher rates, the policy effect is not robust to controlling for transplant infrastructure and that 'no conclusive evidence' supports opt-out as a causal mechanism.<sup>[25]</sup> Etheredge reaches a similar conclusion in a global review,

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<sup>[2]</sup> and Bramhall, in his case against presumed consent, points out that Spain operated under presumed consent for a full decade before its institutional reforms produced any meaningful increase in donation — direct evidence that the legal default is not the operative mechanism.<sup>[26]</sup>

The data integrated for this article reinforce the point (Table 1). Among soft opt-out countries, Spain achieves 53.9 pmp while Bulgaria achieves 2.4 pmp — a 22-fold gap.<sup>[1]</sup> Among opt-in countries, the United States achieves 49.7 pmp while Japan achieves 1.1 pmp — a 45-fold gap.<sup>[1]</sup> The within-category dispersion exceeds the between-category mean difference by an order of magnitude, which is the empirical signature of a confounded explanatory variable.

## 3.2 The 'consent paradox'

The within-system variance is more telling than the cross-system difference. Hard opt-out Czech Republic (34.3 pmp) and hard opt-out Bulgaria (2.4 pmp) operate under near-identical legal defaults; opt-in United States (49.7 pmp) and opt-in Japan (1.1 pmp) likewise.<sup>[1]</sup> If consent law alone explained outcomes, these gaps would not exist. The Spanish trajectory, examined in the case-study section below, is the canonical illustration: the donation gain followed institutional reform by a full decade, not the 1979 legal change.

**Table 1.** Selected national donation rates by consent model, 2024

COUNTRY	CONSENT MODEL	DONORS (PMP)
Spain	Soft opt-out (presumed consent)	53.9
United States	Opt-in (informed consent)	49.7
Portugal	Hard opt-out (presumed consent)	36.7
Czech Republic	Hard opt-out (presumed consent)	34.3
Belgium	Soft opt-out (presumed consent)	32.6
Croatia	Soft opt-out (presumed consent)	30.3
Finland	Soft opt-out (presumed consent)	28.9
United Kingdom	Soft opt-out (presumed consent)	20.4
Australia	Opt-in (informed consent)	20.2
New Zealand	Mandated and required choice	13.2

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COUNTRY	CONSENT MODEL	DONORS (PMP)
Iran	Regulated payment for living donors	13.0
Germany	Opt-in (informed consent)	11.7
Israel	Reciprocity-based systems	10.4
Republic of Korea	Opt-in (informed consent)	7.7
China	Opt-in (informed consent)	4.7
Romania	Opt-in (informed consent)	3.7
Singapore	Opt-out with reciprocity	4.8
Bulgaria	Soft opt-out (presumed consent)	2.4
South Africa	Opt-in (informed consent)	1.4
Japan	Opt-in (informed consent)	1.1

Sources: <sup>[1, 8, 13, 15, 22, 26]</sup>. Germany and Australia 2025; others 2024. pmp = deceased donors per million population.

England's 2020 transition to soft opt-out — the Organ Donation (Deemed Consent) Act 2019, in force from 20 May 2020 and popularly known as Max and Keira's Law — provides a contemporary natural experiment. Family consent rates, which had stood at approximately 68% pre-transition, fell to approximately 59% by 2024.<sup>[10,27]</sup> Total UK donor rates declined modestly between 2023 (22.3 pmp) and 2024 (20.4 pmp), and the waiting list reached a record 8,096 patients.<sup>[27]</sup> The pattern is consistent with the wider Wales experience, where opt-out legislation enacted in 2015 produced no immediate increase in family consent rates but was associated with gradual gains over several years.<sup>[28]</sup>

### 3.3 What does predict donation rates?

Across countries, the structural factors that consistently distinguish high- from low-performing programs — controlling for legal model — are: hospital-based transplant coordinators with protected intensive-care time and explicit accountability for donor identification;<sup>[12,13]</sup> standardized clinical triggers for early referral to donation services and audit of missed referrals;<sup>[8]</sup> family-approach protocols that allow time, privacy, and clinician seniority commensurate with the gravity of the conversation;<sup>[10]</sup> sufficient intensive-care capacity to support potential donors through the diagnostic and procurement phases without compromising other care;<sup>[29]</sup> and national-level registry, audit and

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benchmarking infrastructure, typically delivered by a single accountable agency.<sup>[11]</sup>

Family consent rates cluster among the structural top performers — Spain 85%, Belgium 83%, Sweden 78%.<sup>[13]</sup> Under opt-in, the United States reaches 77%, supported by first-person authorisation laws that make registered donor status authoritative: registered US donors yield approximately 90% family consent; unregistered, 50–60%.<sup>[14]</sup>

## 04 · COUNTRY CASE STUDIES

# Nine national systems in detail

### 4.1 *Spain — the soft opt-out benchmark*

Spain combines a soft opt-out legal default, an ONT-coordinated national infrastructure, and a deeply embedded clinical culture that frames donation as the routine endpoint of unsuccessful intensive care. By 2024 Spain held the world's highest deceased-donor rate (53.9 pmp) and led internationally in the diversification of donor pathways.<sup>[1,14,30]</sup>

The Spanish trajectory is the most-cited piece of evidence that legal default alone does not explain national performance. Spain adopted an opt-out statute in 1979, but donation rates remained essentially flat for a decade. The sustained rise began only in 1989, following the establishment of the Organización Nacional de Trasplantes (ONT) and the deployment of hospital-based transplant coordinators — typically intensive-care physicians with protected time and direct accountability to the ONT.<sup>[12,13]</sup> Spanish authorities themselves consistently attribute the country's performance to the ONT model rather than to the legal default; opt-out legislation, in their phrasing, is 'mysteriously viable' precisely because its causal contribution is so frequently overstated.<sup>[12]</sup> Spanish family-consent rates — approximately 85% of approached families agree to donation — remain the highest reported anywhere, an outcome that Spanish authorities themselves attribute to the trained coordinators rather than to the legal default.<sup>[13]</sup>

The mechanism that the Spanish data have made most visible is the time the coordinator is given with the family. Spain's 85% family consent rate is the global benchmark; ONT data show that families approached by a coordinator for less than one hour agree at approximately half the rate of families given three or more hours, with the difference largely independent of the family's prior orientation

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toward donation.<sup>[13]</sup> The share of the population that has registered an objection has fallen from approximately 28% in 1992 to 14% in 2019 — evidence that the policy has shifted the underlying cultural disposition, not only the legal default.<sup>[11]</sup>

## *4.2 The United Kingdom — a transition under stress*

The UK adopted soft opt-out in stages: Wales in 2015, England in 2020 (Max and Keira's Law), and Scotland and Northern Ireland following soon after.<sup>[27]</sup> Initial consent rates following the English transition were encouraging in headline terms but masked a decline among the 'deemed consent' subgroup, where families approached without prior registration agreed at lower rates than those approached after explicit registration. By 2024 the UK donor rate had fallen by approximately 3% year-on-year, and the active waiting list had reached an all-time high.<sup>[27]</sup> Commentary in the British literature attributes the disappointing outcome to insufficient coupling of the legal change with investment in coordination, public communication, and intensive-care pathway redesign.<sup>[10,31]</sup>

## *4.3 Germany — the identification gap under opt-in*

Germany operates under the Transplantation Act (Transplantationsgesetz, 1997), revised most recently in 2020 to introduce a national online registry and to require physicians to ask patients about donation at primary-care visits. Successive Bundestag debates — most prominently the January 2020 vote — have rejected a transition to opt-out.<sup>[32]</sup> German performance, at 11.7 pmp in 2025 with a registered population approaching 36% and a family consent rate of approximately 75%, is constrained primarily by donor identification: the rate at which potential donors in German intensive-care units are referred to procurement organizations remains low relative to peer countries.<sup>[6,32]</sup>

## *4.4 The United States — high-volume opt-in*

The United States demonstrates that opt-in regimes can achieve world-class rates when supported by population-scale registration mechanisms and dense procurement infrastructure. Approximately 58% of US adults are registered through Department of Motor Vehicles integration, and the country reported 16,989 deceased donors in 2024 (49.7 pmp) — the highest absolute volume globally.<sup>[1,4]</sup> The US first-person authorisation framework gives the deceased's registration legally binding force, so families are typically asked to confirm rather

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than to decide; this design feature lifts effective consent rates above 90% for registered donors.<sup>[4]</sup>

## *4.5 Reciprocity-based systems — Israel and Singapore*

Reciprocity-based systems award priority on the transplant waiting list to candidates who have signaled their own willingness to donate, formalizing the intuition that those who would give should be more likely to receive. Two countries operate explicit reciprocity provisions today, built on opposite legal defaults: Israel on opt-in, Singapore on opt-out.

**Israel — opt-in with reciprocity.** Israel’s 2008 Organ Transplant Act, in force from 2010, allocates priority points on the waiting list to candidates who have registered as donors for at least three years, who have donated as living donors, or whose first-degree relatives have donated. Implementation produced a sustained increase in card registrations and incremental improvement in deceased donation activity, though the country remains in the mid-tier of OECD performers. <sup>[1,17]</sup> The Israeli model has prompted ongoing ethical debate about whether non-medical criteria should influence allocation; the answer, in Israeli policy as enacted, is that limited reciprocity is acceptable provided medical urgency remains the primary criterion. <sup>[18,19]</sup>

**Singapore — opt-out with reciprocity under HOTA.** Singapore’s Human Organ Transplant Act (HOTA, 1987; amended 2004 and 2008) combines an opt-out legal default with a reciprocity-based allocation overlay. The opt-out provision applies automatically to all citizens and permanent residents aged 21 and over who are not mentally incapacitated, including (since the 2008 amendment) Muslims. Citizens who opt out lose waiting-list priority for two years following withdrawal of their objection, after which priority is restored. <sup>[34,35]</sup> Singapore’s reciprocity layer thus operates as a corrective rather than a primary lever — most citizens are donors by default, and the system rewards remaining in the default rather than penalizing active dissent. Despite the legal architecture, Singapore’s modest donation rate reflects the same lesson as elsewhere: legal default alone is insufficient where coordinator capacity and identification pathways are limited.

The two countries together illustrate that reciprocity is best understood as an overlay on a chosen default rather than as a stand-alone system. Both produce measurable behavioral effects — Israeli card registration rose meaningfully after

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implementation; Singapore's opt-out rate has remained low — but neither has produced transformative gains in deceased-donor numbers absent the operational infrastructure that drives high-performing soft-opt-out countries.

## *4.6 New Zealand — license-linked recorded choice*

New Zealand combines an opt-in legal default with a recorded-choice prompt at driver-license application. Approximately 51% of adults carry a 'donor' designation, but the license designation is informational rather than determinative: families retain decision-making authority at the bedside, consistent with the Human Tissue Act 2008.<sup>[16,33]</sup> The country reported 13.2 pmp in 2024, with a family consent rate of approximately 75% — high for an opt-in country.<sup>[16]</sup>

## *4.7 Japan — legal opt-in within a culturally constrained system*

Japan's Organ Transplantation Act (1997, revised 2010) is technically opt-in but reflects exceptional cultural circumstances. Until the 2010 revision, organs could not be procured from a brain-dead donor without the donor's prior written consent, and the 1997 statute produced only 86 brain-death donations over thirteen years.<sup>[36]</sup> The 2010 amendment permitted family consent in the absence of prior expressed wish and authorized pediatric donation, prompting a moderate increase. Even so, Japan remains an outlier: the total deceased donor rate is only 1.1 pmp — reflecting persistent cultural resistance to brain-death determination and a registration rate of 10-12%.<sup>[1,36]</sup>

## *4.8 Iran — regulated paid living donation*

Iran's compensated living kidney donor program is unique — and its most-cited achievement is that it eliminated the national kidney transplant waiting list by 1999, a feat no other country has matched.<sup>[20]</sup> The program, established in 1988 and reformed in 1997 to bring brokerage under state control, pairs each donor with a recipient through the Iranian Society of Organ Donation (an NGO), with a government-fixed payment plus one year of state health insurance, supplemented by additional charitable transfers.<sup>[20,21]</sup>

Defenders of the model point to access. Iran achieves transplant rates that most middle-income countries do not reach through opt-in or opt-out frameworks, and the elimination of the waiting list removed the mortality-on-waiting-list problem

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that defines transplantation in nearly every other country. Because the program is state-regulated rather than informal, defenders argue that it protects donors better than the unregulated trade that exists illegally in countries where compensated donation is prohibited. <sup>[20,21]</sup>

Critics counter that the donor population is socioeconomically narrow. Kidney donation in Iran is overwhelmingly undertaken by individuals from low-income backgrounds, raising the classical coercion concern — whether a payment offered against the alternative of debt or hardship constitutes a meaningful choice. Long-term donor follow-up data are incomplete, and several recent analyses note that the original waiting-list elimination has been partially eroded as transplant demand has grown faster than the donor supply. <sup>[22,24]</sup>

The deceased donor pathway, opened by the 2000 Brain Death Act, has been growing steadily and reached 13.0 pmp in 2023. <sup>[22,23]</sup> The Iranian model remains internationally controversial under the 2008 Declaration of Istanbul, which classified compensated donation as transplant commercialism and called for its prohibition. The most recent Iranian transplant literature, however, documents a clear policy shift away from compensated living donation and toward expansion of the deceased donor system — a trajectory that aligns with the same ethical concerns that motivated the Declaration. <sup>[22,24]</sup>

## 05 · THE UNIVERSAL FEATURE

# Family override across every legal regime

An empirical regularity often overlooked in popular discussion of consent systems is that virtually every country, irrespective of legal default, treats sustained family objection as decisive. This is true by statute in soft opt-out countries and by practice in hard opt-out and opt-in countries alike. A 2023 survey of Council of Europe member states found that families are routinely consulted in 95% of countries, and that organ retrieval is rarely pursued in the face of family objection even where the legal framework would permit it. <sup>[8]</sup>

The reason is operational and ethical rather than narrowly legal. Procurement against the expressed wishes of grieving relatives risks public-trust damage of a magnitude that would compromise the entire program. Jurisdictions that have approached this question — including the United Kingdom, the Netherlands, and

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Australia — have consistently concluded that the marginal organ procured by overriding a family represents an unacceptable trade for the systemic loss of trust. The implication is that the formal taxonomy of consent models, while important, occupies less of the operational space than the language of opt-in versus opt-out implies. The bedside conversation, conducted by trained personnel under conditions of trust, is the proximate site at which donation is made or lost.

## 06 · IMPLICATIONS

# For policy and future reform

## *6.1 For high-income countries considering legislative change*

For high-income countries weighing reform, the case studies above point to one decisive operational lesson: legislative change yields its promised gains only when paired with investment in coordinator infrastructure, family-approach training, and intensive-care pathway design. Wales, England and Nova Scotia provide the most informative recent natural experiments; their early experiences are mixed and contingent.<sup>[10,28]</sup> Where the existing infrastructure is already strong, opt-out legislation may yield modest additional benefit by signalling donation as the social default; where the infrastructure is weak, opt-out is likely to disappoint.

## *6.2 For low- and middle-income countries*

For most low- and middle-income countries, the choice of consent model is largely irrelevant in the absence of foundational requirements: brain-death legislation, a national transplant authority with audit responsibilities, intensive-care and laboratory capacity sufficient to support potential donors, and a sustainable financing model for post-transplant immunosuppression. Sub-Saharan Africa illustrates the point starkly: Nigeria and Kenya, between them representing more population than the European Union's top ten donor nations, reported zero deceased donors to the Global Observatory in 2023 and 2024, irrespective of their nominal opt-in legal frameworks.<sup>[1,37,38]</sup> The first-order policy task is structural, not legal.

## *6.3 Ethical considerations*

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All consent systems carry ethical implications that extend beyond their effects on donation rates. Hard opt-out raises the most acute concerns about meaningful consent, particularly where registry awareness is uneven across socioeconomic and demographic groups.<sup>[2]</sup> Reciprocity-based systems, including Israel's and Singapore's priority provisions under HOTA, introduce non-medical criteria into allocation and require careful policy design to avoid undermining the principle of need-based distribution.<sup>[18]</sup> Compensated living donation, as implemented in Iran, sits outside the international consensus and is widely understood to risk exploitation of socioeconomically marginalised donors.<sup>[24]</sup> Mandated and required choice models demand most of the population — including those who are uncertain or ambivalent — and warrant attention to the quality and neutrality of the choice architecture.<sup>[3]</sup> In each case, the ethical framework needs to keep pace with the operational details of implementation.

## 07 · CONCLUSION

### What the evidence supports

The international comparative evidence assembled here, drawing on the Global Observatory's 2024 and 2025 reports together with the contemporary peer-reviewed literature, supports a now-settled finding: the legal architecture of consent is one input among many, and not the most powerful one, into the production of deceased organ donors. Spain, the United States, Australia, Belgium and Croatia perform near the top of the global league table under different legal regimes; Bulgaria, Greece, Romania and Japan perform near the bottom under different legal regimes. The variance attributable to legal model is small relative to the variance attributable to organizational, clinical and cultural factors. Policy debate that focuses on legal default to the exclusion of these structural determinants risks misallocating the political capital required for genuine reform. The lesson of the Spanish model — that legislation creates a framework which coordinators fill with results — remains the most reliable guide to where future investment should be directed.

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## **DISCLOSURE**

*This synthesis was prepared with the assistance of generative artificial intelligence. Source materials were limited to open-access peer-reviewed publications, government and registry websites, and other publicly available databases. Every reference cited in this article was independently reviewed, verified against its primary source where available, and curated by the WOD Collaborative. The AI tool was used for drafting, restructuring, and consistency checking; all factual claims, attributions, and editorial decisions remain the responsibility of the WOD Collaborative.*

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