Presumed Consent as an Option to Improve Ethiopian Organ Donation Law

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Abstract

There are two types of legislation underlying organ donation that may be based on *presumed consen*t and *expressed consent*. In expressed consent, individuals are donors when deceased only if they had registered their consent while alive. In presumed consent, any individual is presumed as a donor when deceased unless "no" is registered. Ethiopia operates under *Expressed Consent* regime. However, the country is under a severe shortage of organs and tissues for transplantation. One of contributing factors for the shortage relates to the legal regime. Based on qualitative research methodology, I argue in favour of modest legislative modification or the need for policy measures because *presumed consent* is believed to fill the gap between supply and demand for organ donation.

Key terms: Organ donation · Presumed consent · Expressed consent · Ethiopia

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1. Introduction

> "Human Nature is not a problem that can be fixed by rules and regulations. All solutions to the existing problems must be based on how people behave, not on how we think they should behave." (Kirk Chisholm)

There are negative and positive left-outs in laws depending on the context of the choice. Mostly the left outs make a room for inaction that can adversely affect social welfare even though inaction in some cases might be of great value if it is harnessed wisely. A noble prize-winning concept about choice architecture influencing choice –a libertarian paternalistic approach– has come up with a solution in changing the context.[1] The notion of changing the context to influence choice can be traced to the works of Sunstein and Thaler. A policymaker may want to do something to influence choice between two options –from Option-A to Option-B. The *first tool* that is popular with policymakers and governments is the *notion of restriction*[2] by simply banning Option-A. When this is done, it leaves people with no option but to choose Option-B. The challenge with the restrictions approach is that they often create a backlash. Mostly, people contend who is the government, after all, to decide what is good for me.

The *second tool* policymaker can exercise is a *carrot and stick option,*[3] incentives. When this option is exercised the policymaker can create a positive incentive such as subsidy or reward, to move the target public from Option-A to Option-B, or the policymaker could create a negative incentive for people that choose to stay at Option-A, such as taxing them. The *third tool* that one can use in pushing choice from Option-A to Option-B is awareness creation. If the majority is at Option-A, the policymaker tries to give enough information about why the majority should be at point B. The above three tools are fairly traditional approaches in influencing behavior. The *fourth scheme*, the focus of this article, is the *notion of choice architecture*.[4] The

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[1] Cass R. Sunstein & Richard H. Thaler, (2003). "Libertarian Paternalism is not an Oxymoron", *The University of Chicago Law Review* , Vol. 70, No. 4 (Autumn, 2003), pp. 1159-1202

[2] A restriction is an official rule that limits what you can do or that limits the amount or size of something. *Restriction definition and meaning, Collins English Dictionary*, https://www.collinsdictionary.com (Last visited: Jan 23, 2022).

[3] The 'carrot and stick' approach is a method of persuasion or coercion characterized by both the offer of reward and the threat of punishment, Carrot-and-stick Definition & Meaning - Merriam-Webster, https://www.merriam-webster.com (Last visited: Jan 23, 2022).

[4] Choice architecture is a method to retain consumer sovereignty (the right to choose) but nudging consumers to make certain choices. The idea of choice architecture originated

policymaker can influence choice without changing economic incentives, without imposing restrictions, and without promotions. This is through wisely harnessing the defaults or the area that remains behind the options. Accordingly, the planner needs to seek the legislative option which is responsive or engaging.

These tools need to be carefully examined in the realm of organ donation in Ethiopia so that the most viable option can inform legislative reform because there are currently many patients seeking different organs to stay alive. There is very wide mismatch between the demands for organ donation *vis-à-vis* very few donors. The problem for the legislature and policy makers is, therefore, how to increase the number of donations and how that can be achieved. Whether the existing system of organ donation in Ethiopia is appropriate given the number of patients deserves further investigation is the central question addressed in this article. To this end, there is a need to examine the options of presumed consent *vis-à-vis* seeking expressed consent, the type of legislative measure that will help Ethiopia to secure more organ donation, and the legislative measures that can secure more organ donation. It is also necessary to examine whether the legislative measure does not have drawbacks, the possible challenges encountered in adopting the legislative measure, and the benefits of such legislative measures.

Most, organ donation laws including Ethiopian legislation are limited to the aspect of allowing donation when the donors give consent. Such laws are criticized for not giving due attention to the vast majority of potential donors. In expressed consent system, explicit endorsement of consent is at the center of the system. On the other hand, the Presumed Consent system presumes the donor's consent from the very beginning. This article focuses on the Libertarian Paternalistic Choice Architecture in the spectrum of organ donation. This approach envisages a law that is responsive to the needs and interests of all subjects of the law, and this is done through enacting laws cognizant of social dynamics or behaviors.

There is a rising interest by regulators, administrative agencies, as well as public administrations towards a better understanding of human behavior based on the results produced by decades of experimental research.[5] Accordingly, there is enhanced attention towards the behavioral dimension of

in a book *Nudge: Improving Decisions about Health, Wealth, and Happiness*. https://www.economicshelp.org (Last visited Jan 23, 2022).

[5] Eldar Shafir (2013). *The Behavioral Foundations of Public Policy*, Princeton University Press, 440 https://doi.org/10.2307/j.ctv550cbm.

legislative enactment. In the past, policymakers usually approached human behavior from the perspective of the rational agent model, which relies on prior analysis. The model assumes that people make insightful, well-planned, highly controlled, and calculated decisions guided by considerations of personal utility.[6] This has (for a long time) been ineffective in terms of the result aspired, if not to an erroneous conclusion. This by and large underscores the need to give emphasis to how law-governed subjects actually react to specific legislation.

The next section outlines the overview of Ethiopia's organ donation legislation. Section 3 discusses the reason why the country needs to reconsider its organ donation law. Section 4 attempts to deliberate on the notion of libertarian paternalistic choice architecture. Section 5 compares presumed consent and expressed consent organ donation laws. Section 6 attempts to examine the possible challenge faced in the course of adopting presumed consent regime, followed by concluding remarks.

2. Overview of Ethiopia's Organ Donation Legislation

Consent is at the very heart of individuals' rights in their bodies. Every individual has the right to do whatever they like with their body, in order to protect and preserve health and personal privacy. Therefore, any examination or treatment done on a person involving any interference with physical integrity is unlawful unless it is done with consent; it constitutes the crime of assault and the tort of trespass to the person.[7]

> According to Article 18/1, "The act by which a person disposes of the whole or a part of his body shall be of no effect … where such act is to be carried out *before (his) death* … (and) if such act (causes) *a serious injury* to the integrity of the human body." The exception to this rule is an act accepted by medical practice (Art. 18/2). A promise for the disposition of one's body in whole or in part before or after death is revocable (Art. 19/1).[8]

Anyone can dispose of the whole or part of his body upon death. However, Article 19(1) of the Civil Code stipulates the revocability of "the act by which he [the donor] has disposed of the whole or a part of his body." This phrase relates to the intention for organ donation and essentially refers to the existence of some act that shows the consent of the donor. The regulation

[6] Ibid

[7] *See* Art 18-22 of the Civil Code of Ethiopia, 1960

[8] Elias N Stebek (2009). *Ethiopian Law of Person*, *Introduction, Exercises and Materials* (Justice and Legal Systems Research Institute, Addis Ababa) p. 146.

enacted by the Ethiopian Food Medicine & Health Care Administration & Control Authority (FMHACA)[9] embodies similar provisions. This authority is currently the Ethiopian Food and Drug Authority (EFDA) which is "established as an autonomous federal government body" based on Article 66 of Proclamation No. 1263/2021,[10] and accountable to the Ministry of Health.[11]

An executive organ and inspector tasked to oversee food, medicine, and health care in Ethiopia was established by Proclamation No. 661/2009.[12] Its mandate includes the issuance of a regulation, and accordingly, it has enacted Food, Medicine and Health Care Administration and Control Council of Ministers Regulation No. 299 in 2013. The regulation can be cited as the first transplantation act to discuss deceased donation in a clear manner. Particulars of the regulation require permits for transplant to be undertaken only at hospitals that have been issued with transplant license. They also require that living donation must be between individuals related by blood or marriage. Moreover, the National Transplant Committee must review and approve donor and recipient pairs before surgery.

Moreover, the regulation provides for the possibility of deceased donation. In such a case, organ donation can be done without the need to be related by blood or marriage.[13] The provisions applicable in the case of deceased donation under Art 60 of the Regulation include the following:

1) Where a person has consented to donate his organs or tissues upon his death, the organs and tissues that can be used for transplantation may be collected upon his death.
2) No health institution may collect organ, and tissues pursuant to sub-article (I) of this Article without obtaining a special license from the Authority
3) Where there is no written evidence showing express prohibition of donation made by the deceased, while alive, and where the spouse, children or parents or siblings of the deceased, in the order of their list,

[9] *See* EFDA – Ethiopian Food and Drug Administration, http://www.fmhaca.gov.et/ (last visited Feb 20, 2022).

[10] Definition of Powers and Duties of the Executive Organs Proclamation No. 1263/2021, Art. 66.

[11] Id., Art. 95

[12] Food, Medicine and Health Care Administration and Control Proclamation No. 661/2009

[13] Food, Medicine and Health Care Administration and Control Council of Ministers Regulation No. 299/2013, Art-59 (2) 'Any person may donate or prohibit the removal of his organs or tissues in any other way while alive or after his death.

> agree with the donation, organs and tissues that can be used for transplantation may be collected from the deceased. …

Articles 59 to 62, *inter alia*, deal with organ donation and transplantation in Ethiopia and they require consent. The law requires express consent which can be revoked by the promisor. And as cited above, Article 60(3) of the Regulation allows family members and relatives of the deceased to agree with the organ donation unless the deceased expressly prohibits such donation.

Even though it is not expressly stated in the law, Ethiopia's current organ donation law, therefore, follows the *Expressed Consent* system, also known as Opt-In. Under this system the person himself should agree or expressly consent to donate an organ upon death and/or their family must decide to donate the deceased's organ. This principle works under "presumptions of non-consent"[14] in the absence of express consent. Therefore, anyone satisfying the law of status under the Civil Code of Ethiopia and the requirements of capacity is legible to donate or promise to donate his/her organ. In the absence of a deceased's consent while alive, it's up to the transplant professional to obtain the permission of the deceased's family members, in the order of their list stated under Article 60(3) of the Regulation.[15]

3. Do We Need to Re-consider the Organ Donation Law?

Various factors can enhance or reduce the magnitude of organ donation in a country. The supply of organs is a crucial element in the continued success of organ transplantation. However, the express consent system fails to meet the ever-growing demand for transplantable organs. The current express consent organ donation system in Ethiopia fails to procure enough organs, at least in part, because it operates under the assumption that individuals are not organ donors in the absence of their express consent.

Even though organ donation should not necessarily give prime attention to public altruism,[16] it should not lead to realities whereby many organs end up in the graveyard. Normally, the number of potential deceased donors is higher than the number of living donors motivated by sense of altruism. The vast majority of organ donation in Ethiopia comes from living donors. In addition

[14] Maxwell J. Mehlman (1991). "Presumed consent to organ donation: a reevaluation", 1 *Health Matrix* 31.

[15] Regulation No. 299/2013, Article 60(3)

[16] Altruism is when we act to promote someone else's welfare, even at a risk or cost to ourselves. Altruism Definition | What Is Altruism, https://greatergood.berkeley.edu/topic/altruism/definition (last visited Feb 21, 2022).

to the unavailability of deceased donations, Ethiopia has not established a legal framework that recognizes a brain death.[17] Recognizing brain death is the best way to procure a large number of organs. Recognition of brain death in Ethiopia is of paramount importance in enhancing the presumed consent.

Although Medical science has made possible the transplantation of various organs such as kidneys, liver, lungs, heart, pancreas, intestines, hands and eyes, Ethiopian hospitals are only capable of transplanting eyes and kidneys. Facilities that provide dialysis is a recent phenomenon in the country, and it started in 2001.[18] Transplantation of the kidney –which started in 2015– is the most recent experience in Ethiopia. The same is true for corneal grafting.[19] Even after the availability of these services, the service-providing centers have encountered a huge gap between the supply and demand for organs.

In the year 2016, there were 30 hemodialysis centers with a total of 186 hemodialysis chairs and approximately 800 patients on hemodialysis.[20] Cost of a single hemodialysis session is unaffordable for the majority of the patients. Among the patients on maintenance dialysis, a study conducted in 2013 indicated that only about one-third received treatment.[21] In medical treatment, the best treatment for chronic kidney disease is renal transplantation or kidney transplantation. However, from 2015 to 2018 only 85 kidney transplantations were made by the National Kidney Transplantation

[17] Brain death is defined as the irreversible loss of all functions of the brain, including the brainstem. The three essential findings in brain death are coma, absence of brainstem reflexes, and apnoea. An evaluation for brain death should be considered in patients who have suffered a massive, irreversible brain injury of identifiable cause. A patient determined to be brain dead is legally and clinically dead.

[18] Yewondwossen T. Mengistu & Addisu M. Ejigu, *Global Dialysis Perspective: Ethiopia*, KIDNEY360 10.34067/KID.0006902021, 4 (2022), https://kidney360.asnjournals.org/lookup/doi/10.34067/KID.0006902021 (Last visited: Aug 11, 2022).

[19] Corneal transplantation, also known as corneal grafting, is a surgical procedure where a damaged or diseased cornea is replaced by donated corneal tissue (the graft). B. E. Frueh & M. Böhnke, *Corneal grafting of donor tissue preserved for longer than 4 weeks in organ-culture medium*, 14 CORNEA 463–466 (1995).

[20] Ahmed, Momina M.; Tedla, Fasika M.; Leichtman, Alan B.; Punch, Jeffrey D. (2019), *Organ Transplantation in Ethiopia*, https://journals.lww.com/transplantjournal/Fulltext/2019/03000 (last visited Mar 23, 2019).

[21] Tamiru Shibiru, Esayas Kebede Gudina, Belete Habte, Amare Deribew & Tewodros Agonafer (2013), *Survival patterns of patients on maintenance hemodialysis for end stage renal disease in Ethiopia: summary of 91 cases*, BMC Nephrol 14, 127 https://doi.org/10.1186/1471-2369-14-127.

Center (NKTC). Even though, the data until 2018 showed 800 patients in 30 hemodialysis centers, only 85 of them got transplantation,[22] *inter alia*, owing to low donation rates.

As indicated in a study conducted in 2017, between 130 and 150 corneas are reported to be collected yearly.[23] In a national blindness study released in 2006, 300,000 Ethiopians were blind due to corneal scarring. From 2003 to 2017 the Eye Bank distributed 1,818 corneas for transplant, and out of these 1,192 transplants were done during the six years following its partnership with SightLife and HCP. [24] Even though these figures are not based on current data, they show the existing disparity between demand and supply of corneal grafting. The best option to rehabilitate impaired vision is corneal transplantation. However, the potentially limiting factor in planning transplantation is the shortage of donated corneas. It is also aggravated by the availability of inefficient domestic eye banks, lack of potential donors, and weak cooperation of close relatives to collect pledged cornea.[25]

The increased success of organ transplantation has led to the steadily rising demand for organs which substantially exceeds the supply.[26] As organ donation remains unchanged, the rise in the death toll and patients on the waiting list worsen the scarcity of organs. Professionals are thus continually expressing their expectations of legislation that enhances the availability of organs commensurate with the need.

4. The Notion of Libertarian Paternalistic Choice Architecture

Although Ethiopia has enacted laws that allow donation, the law does not sufficiently address the demand for organ transplantation. Choices will inevitably be influenced by default rules, framing effects, and starting points, and therefore, libertarian paternalists attempt to steer people's choices in welfare-promoting directions without eliminating freedom of choice.[27] This is most common in organ donation law. For instance, in the Opt-In (*Expressed*

[22] Ahmed et al., *supra* note 19.

[23] Mohammed Seid Hussen, Kbrom Legesse Gebreselassie, Asamere Tsegaw Woredekal & Nebiyat Feleke Adimassu (2017). *"Willingness to Donate Eyes and Its Associated Factors among Adults in Gondar Town, North West Ethiopia," BMC Ophthalmology* 17 (Last Visited March 3, 2021), https://doi.org/10.1186/s12886-017-0577-1

[24] "Eye Bank of Ethiopia Celebrates 15 Years of Service," Last Visited March 25, 2021, https://www.cureblindness.org/eye-on-the-world/news.

[25] "Eye Banking: An Introduction", https://www.ncbi.nlm.nih.gov/pmc/articles/ (Last Visited March 26, 2022)

[26] Observation of St. Paul's Hospital Millennium Medical College- SPHMMC

[27] Sunstein & Thaler, *supra* note 1, at 1162.

Consent) system, the framing mostly entails "If you subscribe to donate, you will be a donor" and the underlying default position is a non-donation. Hence the system is highly criticized for letting the majority of potential donors to be non-responsive.

In any legislative process, there is an inevitable presence of choice architecture. This architecture always struggles in articulating options. In organ donation laws too, the architecture has a choice to frame an option between laws upholding strict freedom of choice or maintaining societal wellbeing via default rules. The choice architecture thus crafts the options in a way that enhances societal welfare. In crafting the choice there should be some level of paternalism that will take into consideration societal welfare. In addition to being paternalistic, it should be libertarian. This is to say, there has to be some level of freedom of choice maintained. What a libertarian paternalistic choice architecture (the legislature in our case) can do –in making organ donation law– is to presume the consent of all. If individuals are not willing to donate their organs upon death they can simply *opt out* from the presumption. In this case, the paternalistic approach is *meant* to save life and the notion of libertarianism involved is the *opt-out* option. Libertarian paternalism does not avoid freedom of choice, but it will *nudge*[28] individuals. It makes individuals cautious in the process rather than being passive.

A default is a very powerful nudge, as it requires one to actively object the system to make it non-functional. Sometimes, it's possible to design situations where decisions need to be made in a way that if you decide automatically, you naturally make the right choice. The default is set up in a way that if you do nothing, you'll still do the right thing by sticking to the pre-set standard. As Cass R. Sunstein notes:

> Whether or not we notice them, default rules are omnipresent. He argues that defaults establish settings for many activities and goods, including cell phones, rental car agreements, computers, savings plans, health insurance, and energy use. In countless domains, they identify the consequences if choosers do nothing. In part because of the power of inertia, default rules tend to stick.[29]

[28] "[A] nudge is a *subtle shift in the way options are presented***,** making the preferential choice the most attractive, to help people make the best decision. Nudges are quite powerful, as they tend to take advantage of people's existing intentions and make it easier to enact them.": https://www.itcilo.org/pt/node/1506

[29] Cass R Sunstein (2013). "Deciding by Default", 162 *University of Pennsylvania Law Review* 57.

In most organ donation laws, donation can take place based on the free will of the donors. It is few who do not desire to donate, while the vast majority ignore the system. So, it is necessary to bridge the gap between ignorance and the system. Nowadays, default is a common practice employed to bridge the gap. For instance, in most online platforms including social media, the apps will gather users' information unless the user prohibits such interference. Accordingly, in organ donation laws too, the default rule suggests presumption of consent unless the presumed donor *opts out* from the presumption. The following section discusses the two most common consent regimes in the sphere of organ donation.

5. Presumed vs. Expressed Consent

The shortage of organs available for transplant has been a serious worldwide problem since such surgeries were first made feasible and safe several decades ago.[30] Countries relied on different strategies to alleviate this problem with varying levels of success. There is visible disparity in having higher or lower rates of organ donation mainly owing to the kind of the legislation that is adopted.[31] Two most common types of legislation underlie organ donation. The *opt-in* and *opt-out* systems, are also known as *informed consent* and *presumed consent* regimes respectively. In countries following opt-out consent, anyone is a potential donor upon death.[32] On the contrary, in the *explicit consent* or *opt-in system*, individuals are donors when deceased only if they had registered their consent while alive. The opt-out system is present in some European countries, although it is not uniformly enacted in these countries.

The opt-in or opt-out legislation has its own default area. However, defaults in the two systems vary according to the context adopted. Consequently, any proposed amendment whether opt-in or opt-out legislation is an amendment of context regarding what should be the default position. The option regarding

[30] Sheldon Zink, Rachel Zeehandelaar & Stacey Wertlieb (2005), "*Presumed vs Expressed Consent in the US and internationally*", 7 *AMA Journal of Ethics* 610–614, https://journalofethics.ama-assn.org/article/presumed-vs-expressed-consent-us-and internationally/2005-09 (last visited Feb 19, 2022).

[31] Lee Shepherd, Ronan E. O'Carroll & Eamonn Ferguson (2014). *an international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study*, 12 BMC MED 1–14, https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-014-0131-4 (last visited Jan 28, 2022).

[32] The meaning of default options for potential organ donors, https://www.pnas.org/content/109/38/15201 (last visited Jan 28, 2022).

the default position highly determines the response to that legislation. Any law with an effort to increase the consent for donation needs to plan on default or the grey area.

5.1 Expressed consent laws

In the *expressed consent* system, individuals are considered as donor when deceased if their consent is registered while alive. So, the default position in such a system is non-donation because silence amounts to the non-acceptance of the donation. Failure to enrol in the donation scheme (irrespective of the reason) automatically classifies a person as a non-donor, and in effect, there is a lesser probability of individuals to engage in organ donation. The presumption is non-donation, and individuals can easily avoid the effort to give their consent. Therefore, the probability of securing higher donation rate is narrow, as the system depends on those individuals who take the initiative to register their consent. Unlike the opt-out system, legal next-of-kin are eligible for authorization in the expressed consent system. Yet, the consent of the donor is given priority, and family consent is consulted upon the death of the donor.

The United States, Denmark, the United Kingdom, Canada, and Brazil are some of the countries that operate under a model of expressed consent. A Gallup poll found that 70 percent of the US respondents said they wanted to donate their organs; however, the proportion that is registered to do so is significantly lower.[33] Similarly, in the UK, only 15 percent of the public formally join the National Health Service Organ Donation Register.[34] Despite public opinion polls, the actual donors' rate registered for donation is very low. The opt-in or Express Consent regime thus presents difficulties in securing many organs. The barriers include factors such as family consent, psychological factors, and awareness.

5.1.1 Family consent

In opt-in system, family consent and family refusal is a major limiting factor in the success of organ transplantation.[35] Family's refusal should not be underestimated in this regard. The Ethiopian Eye Bank acknowledges this problem. Weak family cooperation in the procurement of deceased cornea is

[33] Zink, Zeehandelaar, and Wertlieb, *supra* note 30 at 612.
[34] Ibid.
[35] Laura A. Siminoff, Nahida Gordon, Joan Hewlett, and (2001). "Factors Influencing Families' Consent for Donation of Solid Organs for Transplantation," *Jama* 286, no. 1: 71–77.

one of the impeding factors in eye graft. It also has an adverse impact in the course of implementing the decision of posthumous organ procurement promised by the deceased. In Ethiopia, donor must express his/her consent to the authority before his death. When he/she dies family will be asked for their consent as per Art 60(3) of the Regulation as cited earlier in Section 2.

Family consent is highly dependent on whether the family is aware of the deceased's wishes.[36] If a family member who is registered to donate his/her organ has not informed the legal next of kin, there is a high probability of refusal from family members. The family of the deceased might feel harassed or pressured in the event of being asked about their consent.[37] Admittedly, it adds stress on relatives of the deceased when they are asked about the procurement of the organ. Thus, it is difficult for hospitals to get the consent of family members.

5.1.2 Psychological factor

There are no data on public perception of organ donation and transplantation in Ethiopia. Countrywide investigation is required to know the society's perception. For the purpose of some insights, I have tried to explore the perception of individuals on my network. In doing so, I created a poll on Facebook. The question presented on the poll created is, whether the participants responding to the poll are willing or promise to donate their organ upon death. The poll provided two options, i.e., whether the respondent is willing or not. 75% of participants were willing to donate.[38] But none of them took a step to get registered for donation.[39] What accounts for such disparity between intention and action is, at least partially, because many people fear to envision their own death but they don't fear to respond to the issue at a conceptual level. [40]

Further, research conducted on a willingness to donate cornea in Gondar by Hussein (in 2017) proved the same. A community-based cross-sectional

[36] Jennifer Chandler (2005). *Priority Systems in the Allocation of Organs for Transplant: Should we Reward Those Who Have Previously Agreed to Donate?* 13

[37] Siminoff et al., *supra* note 35.

[38] The sample size is 2432 Facebook friends. However, participants are only 122 friends. What has to be underlined here is not about the validity of the sample size, but is meant to show the disparity between intention and action. (1 November 2022).

[39] This is identified from subsequent conversation made with friends.

[40] Fady Moustarah (1998), *"*Organ procurement: let's presume consent*"*, *CAN MED ASSOC J* 4.

design study was employed for the study.[41] Around 57% of the participants responded that they have heard about it. However, none of the participants took a step to donate. This indicates the psychological factor that participants want to be buried with their whole bodies.

5.1.3 Difficulty in continuous Awareness Creation

It is difficult to mobilize and allocate sustainable budget to enhance the awareness of the public at large to Opt-In. In one study, it is stated that participants who had the educational status of high school, and College/University were 2.90 and 2.23 times (respectively) more likely to be willing to donate their eyes than those who had no formal education.[42] It was also found that educational status, awareness and religion were identified as statistically significant factors.[43] The study suggests that planning awareness creation programs have strategic importance to mobilize the community. However, this requires the requisite amount of budget.

5.2 Presumed Consent Laws

This model takes the assumption that all individuals are automatically donors unless a "no" is registered. In this form of organ donation, unless an individual votes out from the presumption of being a donor, he/she is presumed to be a donor. The probability of having a higher donation rate is wider than the opt-in regime. The default position in the absence of express objection is a donation. For any country which values the dignified burial of individuals opt-in is an option. On the other hand, for a country that values saving lives, opt-out is the solution.

In the opt-out system, explicit consent is not required. It is sufficient that the deceased person did not object while s/he was alive.[44] An opt-out system can be "hard" or "soft" opt-out system. In a "hard" system, the lack of an objection from the deceased is sufficient authority for organ removal to proceed regardless of the family's wishes, which are neither considered nor

[41] A community-based cross-sectional survey was conducted on 774 adults who were selected using multistage random sampling in Gondar town, North West, Ethiopia. The data were collected through interviews.

[42] Mohammed Seid Hussen et al., *supra* note 23.

[43] Ibid.

[44] Remco Coppen, Roland D. F Riele1, Richard L. M Arquet1, Sjef K. M. Gevers (2005), "*Opting-out Systems: No Guarantee for Higher Donation Rates," Transplant International 18*, no. 11 (November): 1275-1279.

requested.[45] In such a system the consent of the legal next of kin will not be considered. The presumption here is outright, disregarding the consent of the deceased family.

Few countries however strictly follow this "hard" system, with most presumed consent nations using the "soft" model, whereby physicians still consult with family members, such that they have the opportunity to explain the law to relatives and ask them if they know whether the patient had an unregistered objection to organ donation.[46] In a soft system, families are consulted about the likely fate of the organ procurement even though no objection is registered by the deceased. Whether or not an opt-out system can be ethically and legally defended as a feasible option for Ethiopia depends on various issues. The first issue that can be considered is whether presumed consent would lead to increased availability of donor organs and tissue in the country. On the Bulletin of the World Health Organization (WHO) 16 December 2014, it was elucidated that:

> Explicit opt-out laws have long been among the major interventions used to increase the pool of potential donors in countries such as Austria, Belgium, the Czech Republic, Finland, France, Greece, Hungary, Israel, Italy, Luxembourg, Norway, Poland, Slovenia, Spain, Sweden, and Turkey. There is evidence that supports the association between presumed consent and increased donation rates and that countries with opt-out laws have rates 25 to 30% higher than those in countries requiring explicit consent. However, presumed consent appears to be only one of several influential factors.[47]

WHO in its bulletin underlined the significance of adopting the opt-out system. It was noted that the increase in donation rate from 25-30% increase in donation than those countries following opt-in system. It is argued that switching to a presumed consent law would increase the organ donation rate, the basic idea behind this being that the presumed consent system benefits from the organs of donors who have not declared any preference for a

[45] Jennifer Dolling (2009), *Opting in to an opt-out system: presumed consent as a valid policy choice for Ontario's cadaveric organ shortage*, (LLM thesis, Faculty of Law, University of Toronto) 18.

[46] Jennifer M. Krueger (2000). "Life Coming Bravely Out of Death: Organ Donation Legislation Across European Countries" 18 *Wis. Int'l L.J.* 321 at 331

[47] WHO | Increasing organ donation by presumed consent and allocation priority: Chile, WHO, https://www.who.int/bulletin/volumes/93/3/14-139535/en/ (last visited Mar 21, 2019).

donation while living.[48] Comparisons between countries are difficult to interpret because there is a myriad of other factors (necessary to ensure a successful transplant program) which are highly variable from country to country. Such factors include the predominant cause of death, the availability of trained staff and transplant surgeons, and the number and characteristics of patients on the waiting lists.[49] Yet, it is possible to say that legislation takes the lion's share.

It is not easy to evaluate the proposition that an opt-out system leads to increased availability of donor organs, given the number of variables that can impact donor rate.[50] However, it important to go through the experience of a country in adopting an opt-out system. For example, the experience in Spain shows the highest donation rate through adopting opt-out legislation among European countries. Spain adopted the opt-out system in 1979, and it appears that the decision to appoint donor transplant coordinators to every ICU in the country, not only those hospitals with a transplant unit, contributed largely to Spain's success by increasing the likelihood that opportunities would not be missed to recover organs from potential organ donors who died in smaller hospitals.[51]

One can find arguments that the success in opt-out countries is not because of the legislative measure taken. Kennedy stated that factors other than legislative defaults have been hypothesized to affect deceased donation rates, including the level of wealth, religious and cultural responses to death and the body after death, social norms, education, and the social security system.[52] Furthermore, Price states that "a highly organized and well-resourced system, employing large numbers of transplant coordinators in a decentralized system,

[48] Philippe Fevrier and Sebastien Gay (2004). *"Informed Consent versus Presumed Consent: The Role of the Family in Organ Donations*".

[49] Kathleen Robson, "*Systems of Presumed Consent for Organ Donation - Experiences Internationally*" 9 (Scottish Parliament Info Center (SPICe), Briefing No. 05/82, (January 29, 2023), http://www.scottish.parliament.uk/business/research/briefings-05/SB05-82.pdf at 11.

[50] Teri Randall (1991). "Too Few Human Organs for Transplantation, Too Many in Need and the Gap Widens," *Jama* 265, no. 10: 1223–1227.

[51] Sean T. Gallagher (2004). "The Spanish Model's Capacity to Save Lives by Increasing Organ Donation Rates" 18 *Temp. Int'l & Comp. L.J*. 403 at 411.

[52] I Kennedy, RA Sells, AS Daar, RD Guttmann, R Hoffenberg, M Lock, J Radcliffe-Richards, N Tilney (1998). The case for "presumed consent" in organ donation, 351 *The Lancet* 1650–1652.

can itself have a major impact on donor rates."[53] Convincing evidence that presumed consent can lead to higher procurement rates is found in a study by Abadie and Gay, who constructed a dataset on organ donation rates and potential factors affecting organ donation and used a panel of twenty-two countries over the ten years, between 1993 to 2002, to analyze the impact of presumed consent laws on donation rates.

> Abadie and Gay recognized other factors that appeared to have had an impact on donation rates, such as the predominant cause of death, the availability of beds and staff in ICUs, the number and efficiency of transplant coordinators, the number of transplantation surgeons, the number of specialized units in the region, and the number and characteristics of patients on waiting lists, including which organs they required, as well as religious and cultural views of and attitudes towards death and the body. However, using regression analysis they found that although these factors accounted for some of the variations in the donor rates, presumed consent laws had "a positive and sizeable effect on organ donation rates," and when other determinants of donation rates were accounted for, presumed consent countries had on average roughly 25–30% higher donation rates than informed consent countries ...[54]

Therefore, irrespective of various contributory factors stated above, there is a robust justification for Ethiopia to amend its legislation towards presumed consent system.

6. Challenges on Ethiopia's Possible Success

6.1 Ethical Concerns

Questions concerning the boundary between life and death have cultural roots in many societies. Bowman and Richard note that "the space between life and death is socially, culturally and politically constructed, and is fluid and open to dispute."[55] Ethiopian society has its own perspective on deceased donation. A study conducted in Gondar to identify willingness to donate eyes revealed that 25.7% of participants want dignified burial (without losing any part of their body), and 15.1% of the participants believe there is religious restriction. In the meantime, extensive awareness creation program should be conducted,

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[53] David Price (2000). Legal and Ethical Aspects of Organ Transplantation (Cambridge University Press).

[54] Dolling, *supra* note 45

[55] Kerry Bowman and Shawn Richard (2004). "Cultural considerations for Canadians in the Diagnosis of Brain Death*"* 51:3 *Can. J. Anesth*, at 273, 274.

to enhance the view that such thoughts do not have a religious basis. For example, a Muslim scholar, Dr. Zakir said that in Islam it is not necessary to die maintaining physical integrity.[56] Likewise, in the Holy Bible, there is no verse that deals with organ donation.[57] If individuals are hesitant, they can opt out from the system.

6.2 Disregard of consent in the Opt-Out system

Some argue that the presumption of consent is misleading and in fact, in the opt-out system there is no consent at all. Under presumed consent, the argument goes, the language of presumed consent is adopted even when there is no basis for this presumption, and according to the critics, it is not possible to presume that everyone who has not executed an opt-out, in fact, would want to have their organs used.[58]

The opt-out system is also criticized for relying on an individual's silence. In this regard some argue that silence may not be "universally indicative of a deliberate undertaking[59] because it cannot be considered as agreement, and it may be construed otherwise. Accordingly, critics argue that it is not fair to consider tacit consent as if it is deliberate intention.

On the other hand, the Committee on Increasing Rates of Organ Donation stated that silence could be valid and effective consent, depending on the nature and structure of social practices, as well as the competence and understanding of those whose silence was presumed to be consent, and the

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[56] There is no verse in the Holy Qur'an that directly prohibits or allows organ donation, and it is silent on that issue. There were various conferences conducted on this issue by various Ulemas throughout the world, including Malaysia, Jeddah, Riyadh, and India. According to these conferences, organ transplantation is allowed, if it satisfies 3 conditions. First, the organ donated to a recipient should be directed to save life. Only if life of an individual is in danger, and seeks donation. Second, the person donating the organ should not do it for economic reasons. Third, organ donation should not cause loss of the donor's life.

[57] The Bible, especially the New Testament provides guiding principles that can be applied to all situations at all-time rather than separate rules for every segment of life. As a result, Christians can apply the general rules to their day-to-day activities. The same principle applies concerning organ donation. There is no Bible verse that prohibits organ donation, and charity is rather encouraged. What is required is that organ donation should be based on the donor's free will, and not by coercion.

[58] Robert M. Arnold MD, *et al* (1995), editors. *"Procuring Organs for Transplant: The Debate over Non-Heart Beating Cadaver Protocols",* Baltimore: The Johns Hopkins University Press, at 202.

[59] Marie-Andrée Jacob (2006). "Another Look at the Presumed –Versus-Informed Consent Dichotomy in Postmortem Organ Procurement" 20(6) *Bioethics*, at 294-295

voluntariness of their choices.[60] Accordingly, the opt-out system can duly imply tacit consent because the donor is empowered with the lifetime right to opt-out in objection of donation. Under this view, failure to opt-out can be considered as the presumption of consent. This can be plausible assuming that the deceased in question –was during life– aware of the regime and the implications of action or inaction, had a reasonable time within which to object, and that the potential effects of refusing were not extremely detrimental.[61]

It is hardly possible to secure the consent of all citizens of Ethiopia and we cannot assume that all would agree. However, after in-depth awareness creation, it is possible to enforce an opt-out system. To those anti-libertarians who are suspicious of freedom of choice and would rather prefer to embrace welfare, it is often possible for paternalistic planners to make common cause with their libertarian adversaries, by adopting policies that promise to promote welfare and at the same time make room for freedom of choice.[62]

Although some critics of presumed consent claim that a presumption of organ donation takes away an individual's freedom and violates their personal autonomy, one can argue that presumed consent does not negate the right of individuals with respect to their bodies, as a means of refusal is always provided and individuals are given ample opportunity to object during their lifetime. A person can do little before their death to ensure that their organs will not be donated by their family after death, but under an opt-out system, that person is better able to control the situation because there would be a formal mechanism to record their objection that would have to be respected.[63]

6.3 Differing interests

A country's choice between the opt-in and opt out options in organ donation depends on which interest is needed to be addressed. There is the interest of the deceased in only having their organs donated following their prior wishes, the interest of society in overcoming the organ shortage, the interest of the

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[60] James Childress and Catharyn Liverman (2006), editors. *Committee on Increasing Rates of Organ Donation, Organ Donation: Opportunities for Action*, Washington D.C.: The National Academies Press, at 209

[61] J. Childress (1988). "*Ethical Criteria for Procuring and Distributing Organs for Transplantation" in D. Mathieu, ed. Organ Substitution Technology: Ethical, Legal and Public Policy Issues*, Boulder: Westview Press, 87 at 96.

[62] Sunstein & Thaler, *supra* note 1.

[63] M. A. Somerville (1985). "*'Procurement' vs 'Donation'--Access to Tissues and Organs for Transplantation: Should 'Contracting out' Legislation Be Adopted?"* Transplantation Proceedings 17, no. 6 Suppl 4 (December): 53–68.

recipient in being saved, and the interest of the family of the deceased in having their emotional stability preserved at a time of loss.[64] Accordingly, the choice between the two systems certainly expresses the weight given to the preferred interest.

Whether consent for organ donation should be expressed or presumed depends on how one weighs the interests of those awaiting organ transplants. Although utility as well need not be neglected in the political process of lawmaking, utility alone would not justify the ethics of choice. Organs from the dead are a potential source of life for others. Thus, from a utilitarian perspective, enhancing the opportunities for organ donation is highly valuable with the potential to save lives. [65] Yet, presumed consent or opt-out regime does not consider human dead bodies as 'spare parts'. On the other hand, the societal importance attached to donated organs in an opt-out policy puts the burden on those who object to organ donation to register their objection. Jennifer claims that this regime does not radically deviate from traditional humanistic values because "by making the basic presumption, one which favors life and thus putting the burden of objecting upon persons who would deny life to another, the policy of saving human life is given priority."[66]

6.4 Implementation Issues

The burden of registering refusal to donate need not be unduly heavy to impose on individuals and that simple mechanism for registering an objection could easily be made available so as to provide ample opportunity for objection to organ donation.[67] Legislative change should be duly communicated to citizens about the opt-out legislation and the means to opt-out. Moreover, it would be necessary for public education to precede reform, with a sufficient period of time prior to the enforcement of presumed consent legislation to ensure that people had enough time to register their objections.[68] After the introduction of opt-out legislation, a rise in donation rates would

[64] Kelly Ann Keller (2002). "The Bed of Life: A Discussion of Organ Donation, Its Legal and Scientific History, and a Recommended Opt-Out Solution to Organ Scarcity," *Stetson L. Rev*. 32: 855.

[65] *See*, for example, Abadie, Alberto and Gay, Sebastien, The Impact of Presumed Consent Legislation on Cadaveric Organ Donation: A Cross Country Study (July 2004). NBER Working Paper No. w10604, Available at SSRN: https://ssrn.com/abstract=563048

[66] Dolling, *supra* note 45.

[67] Ibid

[68] Ibid

have to be anticipated in advance so that hospitals are prepared to handle additional operations and post-operative care for transplant patients.

Moreover, implementing opt-out considerably requires cost for building suitable infrastructure. This includes the cost for public awareness and subsequent education. Capital expenditures would also be required for the development and establishment of a secure database, running costs, the cost of the initial data entry, and the ongoing training of healthcare professionals.[69] Indeed, there is shortage of hospitals in Ethiopia in quality and quantity, and this certainly exerts pressure on them to work beyond their capacity. Yet, enhanced organ donation and organ transplantation rates can, for example, reduce dialysis cost approximately three times as compared to the cost of successful transplantation.

7. Conclusion

The advance in the transplantation of human tissue and organs is of a paramount societal benefit in saving lives. This demands societal cooperation and further requires behaviourally informed legislative frameworks. Laws adopted in any society are, *inter alia*, expected to enhance the level of care and concern for members of the society at large. In the Ethiopian context, many die and remain blind due to the shortages in organ donation because the supply of organs is dependent upon living donation.

The donation rate within a society can be attributed to different contributing factors. As the discussion above shows, the adoption of a presumed consent system can indeed enhance organ donation rates. Therefore, we must be cognizant of the ramifications of our public policy choices and the failure of the current *opt-in* system to bridge the gap between the supply of organs for transplant *vis-à-vis* the hope and despair of many patients who are under imminent danger of losing their lives. A modest legislative modification or designing policy that presumes consent in terms of deceased organ donation can thus save many lives.

[69] R. Rieu (2010), "The Potential Impact of an Opt-out System for Organ Donation in the UK," *Journal of Medical Ethics* 36, no. 9 (September 1): 534–38.

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