# REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS[1]

CEJA Report 13-A-25

Subject: Presumed Consent & Mandated Choice for Organs from Deceased Donors

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Referred to: Reference Committee on Ethics and Bylaws

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This report is offered in response to a referred resolve clause from resolution 017-A-24, "Addressing the Historical Injustices of Anatomical Specimen Use." It asked that our AMA amend Opinion 6.1.4 "Presumed Consent & Mandated Choice for Organs from Deceased Donors" as follows:

> Physicians who propose to develop or participate in pilot studies of presumed consent or mandated choice should ensure that the study adheres to the following guidelines:
>
> (a) Is scientifically well designed and defines clear, measurable outcomes in a written protocol.
>
> (b) Has been developed in consultation with the population among whom it is to be carried out.
>
> (c) Has been reviewed and approved by an appropriate oversight body and is carried out in keeping with guidelines for ethical research.
>
> ~~Unless there are data that suggest a positive effect on donation, n~~ Neither presumed consent nor mandated choice for cadaveric organ donation should be widely implemented.

## BACKGROUND

Increased organ donation from deceased donors results in lives saved, as one deceased organ donor can save up to eight lives through organ transplantation and improve the lives of up to 75 persons through tissue donation [1]. Although organ donation upholds utilitarian ethical principles, many deceased persons (prior to death) and their families as their surrogates (after death) choose not to donate. The most common reasons cited for choosing not to donate organs include mistrust of doctors, hospitals, and the organ allocation system as well as fears that the deceased persons organs will be sold on a black market or go to someone who does not deserve the organ (i.e. someone who brought on their own illness or is a "bad person") [2]. The widespread mistrust and fear associated with organ donation results in 17 people in the US dying every day while on the waiting list for an organ transplant [1].

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[*1] Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Reference Committee on Ethics and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

Our AMA policy, including the *Code of Medical Ethics*, supports increasing the organ supply (Opinion 6.1.2) and promoting organ donation awareness (D-370.997) while also recognizing the need to "continue to monitor ethical issues related to organ transplantation" (H-370.967). Obtaining consent for organ donation, while an ethical imperative, may present a barrier to increasing organ supply (Opinion 6.1.2). There are three common methods of obtaining consent employed to facilitate organ donation including: 1) voluntary consent; 2) mandated choice; and 3) presumed consent. Although the voluntary consent model is traditionally used in the US and supported by *Code* guidance, our AMA has policy which supports "studies that evaluate the effectiveness of mandated choice and presumed consent models for increasing organ donation" (H-370.959). Additionally, the *Code* provides guidance for physicians who propose to develop or participate in pilot studies of presumed consent and mandated choice (Opinion 6.1.4).

## ETHICAL ISSUE

Resolution 017-A-24, Resolve 7 proposes striking the phrase "unless there are data that suggest a positive effect on donation . . ." from the guidance regarding the use of presumed consent and mandated choice models for organ donation as outlined in *Code* Opinion 6.1.4. Removal of this phrase would remove a caveat which provides an opportunity for implementing presumed consent or mandated choice when data suggest a positive effect on donation. This ethical analysis weighs the benefits and burdens of adopting a more restrictive informed consent model for organ donation.

## ETHICAL ANALYSIS

The *Code of Medical Ethics* requires that informed consent be obtained from the patient or their surrogate prior to organ donation. Among the three methods of informed consent for organ donation (voluntary consent, mandated choice and presumed consent), the *Code* supports voluntary consent (Opinion 6.1.2); however, each of the three methods of consent has advantages and drawbacks. Voluntary consent prioritizes individual autonomy by having potential donors make a voluntary decision to donate organs. While voluntary consent upholds autonomy, its opponents claim it results in a lower donation rate due to passive decision-making. Mandated choice takes consent to a more stringent level by requiring everyone to state their organ donation preference when executing a state supported document, such as receiving a driver's license, potentially resulting in a higher donation rate; however, this system also raises concerns of coercion which may undermine voluntary consent [3]. Conversely, presumed consent operates under an opt-out system which assumes consent to donate unless a person has explicitly registered their refusal to donate. While opt-out systems have the potential to result in the highest yield for organ donation, these systems may exacerbate distrust in the health care system and place additional stress on families who may not be aware of their deceased loved ones wishes regarding organ donation [4]. Additionally, opt-out systems raise ethical concerns surrounding respect for autonomy and voluntary consent.

In a 2005 CEJA report on Presumed Consent and Mandated Choice for Organs from Deceased Donors, the model of voluntary consent was adopted due to the need for data from research studies regarding whether ethically appropriate models of presumed consent or mandated choice would result in a positive effect on organ donation [5]. In the 20 years since this CEJA report was adopted, different models of consent have been utilized worldwide with varying impacts on organ donation models. A 2019 study assessing the effect of opt-out and opt-in approaches to organ donation across 35 similar countries found no significant difference in deceased-donor rates in per million populations [6]. However, a 2019 systematic review of opt-out versus opt-in consent models found that opt-out consent increases both deceased donation rate and deceased transplantation rates [7]. At a macro level, studies comparing aggregate donation rates across countries have reached different conclusions, a trend which is also observed when looking at donation systems at a micro level. For example, in 2015 Wales introduced an opt-out system which over time significantly increased organ donation consent [8]. Whereas Chile, Singapore, and Sweden provide examples of opt-out systems failing to increase donation [9].

While the data regarding whether opt-in versus opt-out models of consent increase deceased organ donation remain inconsistent, ethics concerns with each model persist which require consideration. From an ethical perspective, voluntary consent upholds patient autonomy and maximizes trust and transparency within the health care system; whereas presumed consent systems may undermine patient autonomy and diminish trust in the health care system [10]. However, voluntary consent models require healthcare professionals to obtain consent from the families of potential donors at the bedside during an emotionally difficult time. This is often without the knowledge of what the patient would have wanted. It is estimated that obtaining family voluntary consent at the bedside for organ donation results in an estimated 15-45 percent loss in potential deceased donors in the US [10].

## CONCLUSION

The *Code of Medical Ethics* requires that informed consent be obtained from the patient or their surrogate prior to organ donation and prioritizes the voluntary choice model of consent. Due to the low rate of organ donation and high need in order to save lives, there is an active call to increase organ donation supply through the implementation of mandated choice or presumed consent models. Currently, the *Code* provides guidance that "unless there are data that suggest a positive effect on donation, neither presumed consent nor mandated choice for cadaveric organ donation should be widely implemented." However, the *Code* also recognizes that "these models merit further study to determine whether either or both can be implemented in a way that meets fundamental ethical criteria for informed consent and provides clear evidence that their benefits outweigh ethical concerns" (Opinion 6.1.4).

If the phrase "unless there are data that suggest a positive effect on donation" is removed, *Code* guidance on the utilization of presumed consent and mandated choice models for organ donation will become more stringent and effectively result in guidance to not widely implement either of these two consent models, even when data suggest a positive effect on donation. Given the pressing need for an increase in organ donation and the paucity of conclusory data regarding the effect of consent model type on donation, effectually disallowing a model of informed consent for organ donation when data suggest a positive effect on organ donation would undermine the well-being of potential recipients waiting for a lifesaving organ donation. However, it is important to ensure that regardless of what the data show, the chosen consent model must be ethically implemented to respect both the donor and the recipient and must keep with ethics standards on informed consent and guidance for organ transplantation from deceased donors (Opinion 6.2.1).

## RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the referred Resolution of 17-A-24 not be adopted and the remainder of this report be filed.

Fiscal Note: Less than $500

## REFERENCES

1. Organ Donation Statistics. Health Resources & Services Administration. Accessed February 17, 2025. https://www.organdonor.gov/learn/organ-donation-statistics
2. Morgan SE, Harrison TR, Afifi WA, Long SD, Stephenson MT. In their own words: the reasons why people will (not) sign an organ donor card. *Health Commun*. 2008;23(1):23-33. doi:10.1080/10410230701805158
3. Symons X, Poulden B. An Ethical Defense of a Mandated Choice Consent Procedure for Deceased Organ Donation. *Asian Bioeth Rev*. 2022;14(3):259-270. Published 2022 Apr 29. doi:10.1007/s41649-022-00206-5
4. Molina-Pérez A, Rodríguez-Arias D, Delgado J. Differential impact of opt-in, opt-out policies on deceased organ donation rates: a mixed conceptual and empirical study. *BMJ Open*. 2022;12(9):e057107. doi:10.1136/bmjopen-2021-057107
5. American Medical Association. 6.1.4 Presumed Consent & Mandated Choice for Organs from Deceased Donors. https://code-medical-ethics.ama-assn.org/sites/amacoedb/files/2022-08/6.1.4%20Presumed%20consent%20%26%20mandated%20choice%20for%20organs%20from%20deceased%20donors%20--%20background%20reports.pdf. 2005
6. Arshad A, Anderson B, Sharif A. Comparison of organ donation and transplantation rates between opt-out and opt-in systems. *Kidney International*. 2019;95(6):1453-1460. doi:10.1016/j.kint.2019.01.036
7. Ahmad MU, Hanna A, Mohamed AZ, et al. A Systematic Review of Opt-out Versus Opt-in Consent on Deceased Organ Donation and Transplantation (2006-2016). *World J Surg*. 2019;43(12):3161-3171. doi:10.1007/s00268-019-05118-4
8. Madden S, Collett D, Walton P, et al. The effect on consent rates for deceased organ donation in Wales after the introduction of an opt-out system. *Anaesthesia*. 2020;75(9):1146-1152. doi:10.1111/anae.15055
9. Matesanz R, Domínguez-Gil B. Opt-out legislations: the mysterious viability of the false. *Kidney International*. 2019;95(6):1301-1303. doi:10.1016/j.kint.2019.02.028
10. Etheredge HR. Assessing Global Organ Donation Policies: Opt-In vs Opt-Out. *Risk Manag Healthc Policy*. 2021;14:1985-1998. doi:10.2147/RMHP.S270234.