

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 7 - A-05

Subject: Presumed Consent for Organ Donation
(Resolution 2, A-04)

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Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Art L. Klawitter, MD, Chair)

1 At the 2004 Annual Meeting of the House of Delegates, Resolution 2, “Presumed Consent for
2 Organ Donation,” introduced by the Pennsylvania Delegation, called for the American Medical
3 Association to “support presumed consent for organ donation as a means of increasing the number
4 of organs available for transplantation” and to “pursue national implementation of such a policy.”
5 This resolution was referred to the Board of Trustees, and assigned to the Council on Ethical and
6 Judicial Affairs for report back to the House of Delegates in June 2005.

7 8 BACKGROUND

9
10 Since the introduction of organ transplantation in the 1950s, the number of individuals who could
11 benefit from this procedure continually has outstripped the number of available donor organs.
12 Despite ongoing efforts to address unmet needs, the disparity has increased with time. Developing
13 strategies to increase organ donation remains a priority for the transplant field and the medical
14 profession; innovative approaches always are being considered.

15
16 One approach that has received attention over the last several decades involves changing the
17 standard of consent for donation from deceased donors. Currently, organ procurement in the
18 United States is structured around an opt-in system of informed consent: individuals with adequate
19 decision-making capacity are regarded as voluntary donors if they expressly have indicated their
20 willingness to donate. In the absence of explicit consent from a potential donor, the next-of-kin
21 generally are granted the authority to determine whether organs may be donated.

22
23 Since 1968, the proposal to implement a system of presumed consent for organ donation has been
24 debated.¹ Under such a model, individuals’ willingness to donate would be assumed unless they
25 specifically opted out by withdrawing their consent. Under some variations, absent registered
26 objections to donate by the decedent, families still would be notified at the time of death that
27 organs were going to be removed, offering a final opportunity to communicate known objections.

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29 Presumed consent, which supporters believe would help increase deceased donation substantially,
30 has been implemented in some European and South American countries. Some studies seem to

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1 validate the effectiveness of a presumed consent model in those countries.² Other findings,
2 however, indicate that presumed consent has resulted in only a modest increase of transplantable
3 organs.^{3,4} Moreover, it is not known whether presumed consent would be accepted as readily in
4 the United States, set apart by our distinct culture of pluralism, individualism, and self-
5 determination.⁵

6
7 **OPINION E-2.155, “MANDATED CHOICE AND PRESUMED CONSENT FOR CADAVERIC**
8 **ORGAN DONATION”**

9
10 Since 1994, the Council on Ethical and Judicial Affairs has had a policy that addresses presumed
11 consent for deceased donation. Opinion E-2.155, “Mandated Choice and Presumed Consent for
12 Cadaveric Organ Donation,” (AMA Policy Database) states that “a system of presumed consent for
13 organ donation, in which individuals are assumed to consent to be organ donors after death unless
14 they indicate their refusal to consent, raises serious ethical concerns.”⁶ Instead, the policy
15 recommends a system of mandated choice as an ethically appropriate way to encourage donation.⁶
16

17 In the Opinion, the lack of an effective mechanism to document individuals’ decisions to withdraw
18 consent is identified as a significant barrier to adopting a presumed consent model.⁶ While solving
19 this shortcoming may be surmountable, it is worth noting the limited success of attempts in our
20 current system at documenting individuals’ donation preferences in a systematic fashion.
21 Moreover, even an operational registry would be useful only if all members of the public were
22 aware of the policy of presumed consent and had easy access to the registry. At present, for
23 example, most states depend on their Departments of Motor Vehicles (DMV) to make contact with
24 citizens regarding organ donation. However, DMVs do not reach all individuals, because many
25 adults do not hold a driving license or other state identification card. Even for those who access the
26 DMV, the setting is less than optimal to provide information regarding donation.
27

28 In the report that served as the basis for the Opinion E-2.155, several additional concerns were
29 identified.⁷ Among them were the possibility that relying on presumed consent might remove an
30 incentive for physicians to initiate discussion of organ donation with their patients.⁷ Moreover,
31 individuals reluctant to think about death and dying might avoid reflecting on their attitudes toward
32 donation and be wrongly assumed to be willing donors.⁷
33

34 In lieu of a presumed consent model, the Opinion recommended a mandated choice system,
35 whereby individuals are required to express their preferences regarding organ donation.⁶ Mandated
36 choice may prove effective in increasing number of donations for several reasons. It reduces the
37 stress of asking grieving families to decide whether an individual would have chosen to donate and
38 it enables a time sensitive process to advance faster. Under mandated choice, there is greater
39 assurance than under presumed consent that individuals’ autonomy will be protected, because they
40 specifically would have made known their wishes concerning organ donation.
41

42 **ADDITIONAL CONSIDERATIONS REGARDING PRESUMED CONSENT AND**
43 **MANDATED CHOICE**

44
45 A review of the recent literature reveals that both presumed consent and mandated choice have
46 repeatedly been considered as strategies that might help increase the number of deceased
47 donations. Given the finding that most people are supportive of donation but fail to act on their
48 intentions, both systems could substantially increase the donor pool.⁸ Either system, then, might
49 prevent some deaths and relieve the suffering that results from organ failure.⁹

1 *Presumed Consent*

2

3 Many have argued in favor of presumed consent.⁹⁻¹¹ Along with the reasons already cited in this
4 report, the claim has been made that presumed consent would better protect individuals' autonomy
5 than the current system. Indeed, the current system tends to rely not on the preferences of the
6 decedent, but on those of their surviving family members,⁹ and assumes that the absence of express
7 consent indicates a refusal to donate. Yet, this assumption is not corroborated by surveys that find
8 most members of society favor donation.

9

10 Presumed consent also might increase the number of deceased donors simply because many people
11 would avoid having to make an active decision on a topic that can be difficult and stressful to
12 contemplate.² For this reason, presumed consent is seen by some as an affront to individuals' right
13 to make decisions and to exercise self-determination.^{5, 12} The presumed consent model may also be
14 perceived as culturally or religiously insensitive.

15

16 The assumption that individuals will be proactive in considering their options under a presumed
17 consent system is doubted by many, even when members of a community are aware that presumed
18 consent is the accepted standard and know of easily accessible and effective mechanisms to register
19 withdrawal of consent. There is also concern that presumed consent ultimately could contribute to
20 distrust of the health care system and the medical profession, causing some individuals, previously
21 inclined to donate, to document their refusal.¹³

22

23 *Mandated Choice*

24

25 Generally, mandated choice seems to avoid the limitations both of a presumed consent model,
26 which relies on the assumption that people are aware of the system and that their inaction reflects
27 an inclination to donate, and of our current system, which allows people to remain apathetic. By
28 requiring all people to consider whether they would agree to donation, mandated choice can help
29 ensure that their preferences will be known and respected. Thus, mandated choice has the potential
30 to promote individual autonomy, while also helping to increase the number of deceased donors.

31

32 Mandated choice has been criticized, however, on a number of grounds, including the requirement
33 for individuals to make a decision, whether they want to or not. Because individuals *must* choose,
34 a default option must be in place for those who decline to make a decision, either presuming
35 consent, with its attendant problems as noted above, or presuming refusal, which would probably
36 result in a lower number of deceased donors.

37

38 Moreover, a policy of mandated choice might be met with resistance because family consent would
39 no longer be an important element of organ donation.¹³ For a variety of reasons, including distrust
40 in the health care system and the threat of legal repercussions, members of the public, health care
41 teams, hospitals, and organ procurement organizations may be reluctant to support a system that
42 limits or discounts families' preferences regarding such a sensitive area as organ procurement
43 following death.¹³

44

45 Findings in the states of Virginia and Texas, both of which have tested the impact of having a
46 mandated choice policy in the last two decades, suggest that such a system could be detrimental to
47 organ procurement. When the state of Virginia adopted a policy of mandated choice, more than
48 24% refused to report a preference.¹⁴ In Texas, a law enacting mandated choice for Texans was

1 repealed after almost 80% of the people chose not to donate organs, provoking a decrease in the
2 number of available organs.¹³

3
4 THE NEED FOR DATA FROM RESEARCH STUDIES

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6 Even if ethically appropriate models of presumed consent or mandated choice for deceased
7 donation could be implemented, it remains unknown how they would affect the number of organ
8 donations. Properly designed studies, performed at a small scale, could help provide factual
9 evidence that would inform the debate regarding the merits of either policy.

10
11 For presumed consent, for example, studies could measure the change in number of organ
12 transplants, the number of donations, awareness among the public that a presumed consent system
13 was in place, number of documented refusals to donate, how often families claimed to know of
14 refusals, and acceptance by the population of the undermining of individual self-determination.
15 For mandated choice, studies could measure the change in number of organ transplants, the
16 frequency of reaching individuals to offer the opportunity to consent or refuse, the number of
17 documented consents and refusals to donate, understanding of donation by those making choices,
18 the incidence of refusal to make a choice, and acceptance of the mandate by the population being
19 studied.

20
21 The Council believes that unless data from well designed studies suggest a positive effect on
22 donation, neither presumed consent nor mandated choice for deceased donation should be widely
23 implemented. This would help avert the costs of implementing a new system that could fail to
24 increase the number of transplantable organs.

25
26 CONCLUSION

27
28 The present organ procurement system has failed to meet the continuously increasing demand for
29 donor organs, despite intense educational efforts. Part of the problem has been attributed to the
30 fact that individuals do not make known whether they would want to donate their organs.

31
32 One possible way to increase the number of deceased donors involves changing the consent
33 process for organ donation to a system of mandated choice or to a system of presumed consent.
34 While such policies could be implemented in an ethical manner, both models face obstacles that
35 make it necessary to obtain data that suggest a positive effect on donation.

36
37 RECOMMENDATIONS

38
39 The Council on Ethical and Judicial Affairs recommends that the following recommendations be
40 adopted in lieu of Resolution 2 (A-04) and that the remainder of this report be filed:

41
42 The supply of organs for transplantation to treat end-stage organ failure is inadequate to meet
43 the clinical need. Therefore, physicians should support the development of policies that will
44 increase the number of organ donors. Two prominent proposals aimed at increasing organ
45 donation would change the approach to consent for deceased donation: mandated choice and
46 presumed consent.

47
48 Under a presumed consent model, deceased individuals are presumed to be organ donors
49 unless they indicate their refusal to donate. Such donations would be ethically appropriate

1 only if it could be determined that individuals were aware of the presumption and if effective
2 and easily accessible mechanisms for documenting and honoring refusals to donate were
3 established. Moreover, physicians could proceed with organ procurement only after
4 verifying that there was no documented prior refusal by the decedent and that the family was
5 unaware of any objection to donation by the decedent.

6
7 Under a mandated choice model, individuals are required to express their preferences
8 regarding organ donation at the time of performing a state-regulated task. This contrasts with
9 the widespread model of voluntary organ donation under which individuals are afforded an
10 opportunity to indicate their preferences. A mandated choice model would be ethically
11 appropriate only if an individual's choice were made in accordance with the principles of
12 informed consent, which would require a meaningful exchange of information. Physicians
13 could proceed with organ procurement only after verifying that an individual's consent to
14 donation was documented.

15
16 It is not known whether implementation of ethically appropriate models of presumed consent
17 or mandated choice for deceased donation would positively or negatively affect the number
18 of organs transplanted. Therefore, physicians should encourage and support properly
19 designed pilot studies, in relatively small populations, that investigate the effects of these
20 policies. Unless there are data that suggest a positive effect on donation, neither presumed
21 consent nor mandated choice for deceased donation should be widely implemented.

22
23 In all models, education of individuals to facilitate informed consent is requisite.

24
25 (New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than \$500 to implement.

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