MEDICAL ETHICS ADVISOR®

FOR OVER 25 YEARS, YOUR PRACTICAL GUIDE TO ETHICS DECISION MAKING

JANUARY 2018 Vol. 34, No. 1; p. 1-12

## INSIDE



RELIAS
Formerly AHC Media

# Ethical Controversy Persists in Medical Aid in Dying Laws

*Ethicists see both growing acceptance and continued opposition*

Recently passed state laws allowing physician-assisted death are in conflict with a newly updated position statement from the American College of Physicians (ACP) objecting to the practice.

"These issues are unresolved. But laws continue to appear and to chip away at what was, and has until recently been, a rather general medical opposition to physician assistance in suicide," says **Thomas S. Huddle**, MD, PhD, professor of medicine at UAB School of Medicine in Birmingham, AL.

Physician-assisted death is currently legal in the District of Columbia and six states: Oregon, Washington, Vermont, California, Montana, and Colorado.

"Widespread legal acceptance, if that occurs, is likely to precede general physician willingness to participate," says Huddle.

> "IT'S BECOMING GRADUALLY ACCEPTED, BY MORE TERMINALLY ILL PATIENTS AND THE PHYSICIANS WHO CARE FOR THEM, AS A LEGITIMATE END-OF-LIFE OPTION."

Inequities in access to providers offering this option to patients is one ethical concern. "Currently, best access is for white, educated, insured, male, and terminal patients," says **Catherine Sonquist Forest**, MD, MPH, medical director of Stanford (CA) Primary Care at Los Altos.

A related concern: Not all patients can afford medical assistance in dying. "The costs of the drugs have skyrocketed, making them out of reach for many dying people —



**Financial Disclosure:** Consulting Editor **Arthur R. Derse**, MD, JD, Editor **Jill Drachenberg,** Editor **Jesse Saffron,** Editorial Group Manager **Terrey L. Hatcher,** and Author **Stacey Kusterbeck** report no consultant, stockholder, speakers' bureau, research, or other financial relationships with companies having ties to this field of study.

MEDICAL ETHICS ADVISOR®

*Medical Ethics Advisor®,*
ISSN 0886-0653, is published monthly by
AHC Media, a Relias Learning company
111 Corning Road, Suite 250
Cary, NC 27518

Periodicals Postage Paid at Cary, NC, and at additional mailing offices.
GST Registration Number: R128870672.

**POSTMASTER:** Send address changes to:
*Medical Ethics Advisor*
Relias Learning
111 Corning Road, Suite 250
Cary, NC 27518

**SUBSCRIBER INFORMATION:**
Customer Service: (800) 688-2421.
Customer.Service@AHCMedia.com.
AHCMedia.com
Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.- 4:30 p.m. Friday.

**SUBSCRIPTION PRICES:**
U.S.A., Print: 1 year (12 issues) with free CE hours, $519. Add $19.99 for shipping & handling. Online only, single user: 1 year with free CE, $469. Outside U.S., add $30 per year, total prepaid in U.S. funds.

**MULTIPLE COPIES:** Discounts are available for group subscriptions, multiple copies, site licenses, or electronic distribution. For pricing information, please contact our Group Account Managers at Groups@AHCMedia.com or (866) 213-0844.

**ACCREDITATION:** Relias Learning is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Relias Learning designates this enduring material for a maximum of 1.5 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This activity is intended for acute care physicians, chiefs of medicine, hospital administrators, nurse managers, physician assistants, nurse practitioners, social workers, and chaplains. It is in effect for 36 months from the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

**AUTHOR:** Stacey Kusterbeck
**EDITOR:** Jill Drachenberg
**EDITOR:** Jesse Saffron
**EDITORIAL GROUP MANAGER:** Terrey L. Hatcher
**SENIOR ACCREDITATIONS OFFICER:** Lee Landenberger



**EDITORIAL QUESTIONS**
Questions or comments?
Call **Jill Drachenberg** at (404) 262-5508

especially since not all insurance is covering them," says **Joanne Lynn**, MD, a Washington, DC-based geriatrician, and director of the Center for Elder Care and Advanced Illness at Ann Arbor, MI-based Altarum.

## Gradual Acceptance

The overall trend is toward acceptance of medical assistance in dying, both by the general public and healthcare providers.

"It's becoming gradually accepted, by more terminally ill patients and the physicians who care for them, as a legitimate end-of-life option," says **Ben A. Rich**, JD, PhD, emeritus professor of medicine (bioethics) and school of medicine alumni association endowed chair of bioethics at University of California, Davis School of Medicine in Sacramento.

In Forest's view, the barrier to participation typically is more hesitance than resistance. "This has been the case for most shifts in medical practice," she says.

Forest gives the analogy of anesthesia administered to women in labor, altering the "normal" course of birth. "Medical culture will shift, as experience widens, to increase access and develop best practices for terminal patients that choose medical assistance in dying," she predicts.

Some physicians who conscientiously object to medical assistance in dying may withhold information or referrals to patients who would choose it, based on the physician's own belief system. "This falls in the same category as not referring for experimental treatment, or sterilization, or termination of a pregnancy," says Forest.

## Reaffirmed Opposition

In Canada, the expectation is that a physician who has a conscientious objection to medical assistance in dying will provide a referral for patients. "However, this is currently being contested in court by a group of faith-based physicians," says **Blair Henry**, D.Bioethics, a senior ethicist and assistant professor at the University of Toronto. The physicians claim that such a referral represents a degree of cooperation and assistance in the process which they feel is unconscionable.

The overarching ethical question is what allowances faith-based institutions have when they also are mandated to treat the larger public. "Can they conscientiously object, as is now allowed with abortions?" asks Henry. "Or has the fabric of society changed such that all of this needs to be revisited?"

## EXECUTIVE SUMMARY

Medical aid in dying is now legal in six states, the District of Columbia, and Canada, with several of the laws recently passed. Some ethical considerations include the following:

- Not all patients have access to providers offering this option.
- There is the possibility of coercion for vulnerable patients.
- Physicians may withhold referrals or information because of their own beliefs.

In a recently updated position paper, the ACP reaffirmed its opposition to the legalization of physician-assisted suicide and affirmed a professional responsibility to improve the care of dying patients.[1]

"Physician-assisted suicide alters the physician's role as healer and comforter and the medical profession's role in society. It affects trust in the patient-physician relationship and the profession," says ACP president **Jack Ende**, MD, MACP, the Schaeffer professor of medicine at University of Pennsylvania's Perelman School of Medicine in Philadelphia.

There have been many changes in the legal landscape since 2001, when the ACP first published a position paper opposing the legalization of physician-assisted suicide. "There is increased public interest in the topic, and continuing problems with access to palliative and hospice care," notes Ende.

The updated paper considers clinical practice, ethics, law, and policy. Ende says that withdrawal of treatment, based on patients' wishes, respects the patient's bodily integrity and right to be free of unwanted treatment. In contrast, physician-assisted suicide is performed with the intent to end the patient's life. "This distinction is ethically and legally important," says Ende.

Medical ethics and the law support a patient's right to refuse treatment, including life-sustaining treatment. The intent is to avoid or withdraw treatment judged by the patient as unduly burdensome and inconsistent with his or her health goals and preferences. "Death follows naturally after the refusal, due to underlying disease," says Ende.

The position paper emphasizes the importance of good palliative and hospice care. Access to this is not uniformly available. "Progress has been made, but the principles and practices of hospice and palliative medicine have not been fully realized," says Ende.

If a patient requests aid in dying or expresses fear about suffering, those concerns and reasons for the request should be thoroughly discussed, according to the position paper. "Requests for physician-assisted suicide are unlikely to persist when compassionate, supportive care is provided," says Ende.

> "PATIENTS WHO UTILIZE AID-IN-DYING LAWS ARE NOT SUICIDAL IN ANY LEGITIMATE PSYCHIATRIC SENSE. THEY DO NOT WANT TO DIE, BUT THEIR DEATH FROM AN UNDERLYING TERMINAL ILLNESS IS IMMINENT."

**Aaron Kheriaty**, MD, associate professor of psychiatry and director of the bioethics program at University of California, Irvine School of Medicine, says the lack of requirement for psychiatric evaluation is a big ethical concern.

"The desire to end one's life, or the request for assisted suicide — or aid in dying, as proponents prefer — is almost always a cry for help. And it should be interpreted as such by the physician," says Kheriaty.

Kheriaty says that the desire or request to die is a distress signal indicating that something in the patient's situation is not adequately being attended to. This might be untreated depression, fear or anxiety about the medical condition or the future, untreated pain, or a family or relationship strain or conflict.

"Efforts aimed at suicide prevention for vulnerable individuals, particularly those diagnosed with a serious or terminal medical condition, may be weakened by the laws," says Kheriaty.

Kheriaty adds that the idea that serious mental health issues could be overlooked in the application of the law is not merely theoretical. "Consider the case of Michael Freeland, an Oregonian who had a 43-year history of depression and prior suicide attempts. Yet, the physician who prescribed for him the deadly drug did not deem it necessary to refer for psychological counseling," he says.

In Canada, medical assistance in dying was legalized in 2016. "Our legal framework is less restrictive than the California statute, in that neither a terminal diagnosis or set prognostic period are required to meet eligibility," notes Henry. Neither law requires an assessment by a mental health specialist. "The premise used is the same as all encounters requiring informed consent — that it is the practitioner's responsibility to make that determination of capacity," says Henry. Two independent assessments by a physician and/or nurse practitioner are required.

"Only if the clinician feels that an underlying psychiatric condition might be impacting the patient's

decision-making capacity is a referral to psychiatry expected," says Henry.

Rich supports well-crafted medical assistance-in-dying laws, but objects to the often-used term "physician-assisted suicide." "Patients who utilize aid-in-dying laws are not suicidal in any legitimate psychiatric sense. They do not want to die, but their death from an underlying terminal illness is imminent," says Rich.

The goal is to control the time and manner of the patient's closely approaching death so as to preserve his or her dignity and prevent potentially refractory pain and distress, says Rich: "None of the aid-in-dying laws in the U.S. use the term 'suicide.'"

Forest says it's important to evaluate for coercion of patients whose lives may not be as valued by society. These include disabled individuals, or those with low socioeconomic status. "Protecting vulnerable groups for all medical decisions is crucial," says Forest.

Lynn says the most serious ethical concern with physician-assisted dying is that it will become "ordinary — and just part of what patients are offered."

Patients who need long-term care may feel that physician-aided dying is their only option, if there is no apparent alternative. "Will people feel that 'choosing' physician-aided dying is expected of them, as a way to cut short the burdens on family and public funds?" asks Lynn.

## Looking Forward

Rich notes, "The politics of the aid-in-dying debate, which is permeated with 'ethics talk,' has changed markedly over the last five years or so." Notably, prior to the passage of the California law, the California Medical Association changed its position from opposed to neutral.[2]

"Opponents argue that making aid-in-dying available to competent, terminally ill patients will place society on a slippery slope, eventually leading to providing aid-in-dying to incompetent, non-terminally ill patients," says Rich.

Rich says that data from Oregon's Death With Dignity Act, in place for two decades, refutes this, and also counters arguments that legalizing lethal prescriptions will threaten vulnerable populations and that those who seek assistance in dying have not received adequate palliative care.

"The vast majority of individuals who have obtained and utilized a lethal prescription are well-educated, adequately insured, enrolled in hospice, and have been deemed by two physicians to have decisional capacity uncompromised by depression or the undue influence of another person," says Rich.

A broader ethical objection is that aid-in-dying violates a core principle of medical ethics: that physicians must not intentionally be the cause of a patient's death. "The medical profession continues to be divided among those who strongly support aid-in-dying, those who strongly oppose it, and those somewhere in between on the continuum of opinion whose views are evolving," says Rich. ■

### REFERENCES


1. Sulmasy LS, Mueller PS. Ethics and the legalization of physician-assisted suicide: An American College of Physicians position paper. *Ann Intern Med* 2017; 167(8):576-578.
2. California Medical Association removes opposition to physician aid in dying bill. California Medical Association; 2015. Available at: http://bit.ly/2C23olj. Accessed Dec. 13, 2017.


### SOURCES


- **Jack Ende**, MD, MACP, Schaeffer Professor of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia. Phone: (215) 662-8989. Email: jack.ende@uphs.upenn.edu.
- **Catherine Sonquist Forest**, MD, MPH, Medical Director, Clinical Associate Professor of Medicine-Family Medicine, Stanford (CA) Primary Care at Los Altos. Email: csforest@stanford.edu.
- **Blair Henry**, D. Bioethics, Department of Family and Community Medicine, University of Toronto, Ontario. Phone: (416) 480-6100 ext. 7178. Email: blair.henry@sunnybrook.ca.
- **Thomas S. Huddle**, MD, PhD, Professor of Medicine, Division of General Internal Medicine, UAB School of Medicine, Birmingham, AL. Email: thuddle@uab.edu.
- **Aaron Kheriaty**, MD, Associate Professor of Psychiatry/Director, Bioethics Program, University of California, Irvine School of Medicine. Phone: (714) 456-8774. Email: akheriat@uci.edu.
- **Joanne Lynn**, MD, Director, Center for Elder Care and Advanced Illness, Altarum, Washington, DC. Phone: (202) 776-5109. Email: joanne.lynn@altarum.org.
- **Ben A. Rich**, JD, PhD, Emeritus Professor of Medicine (Bioethics)/School of Medicine Alumni Association Endowed Chair of Bioethics, UC Davis School of Medicine, Sacramento. Phone: (916) 734-6010. Fax: (916) 734-1531. Email: barich@ucdavis.edu.

# Study: Residents Want to Be Involved in Error Disclosure

*Informal learning had biggest effect on skills*

Residents' error disclosure skills have improved over time, found a recent study.[1] Researchers compared residents' skills in 2012 and 2013 with the skills they had in 2005, and found significant improvement.

"This was surprising and a relatively novel finding, in that no prior studies had been able to demonstrate such improvement," says **Brian M. Wong**, MD, FRCPC, associate professor in the department of medicine at University of Toronto.

The researchers were curious to know whether the training that they'd provided to residents over the years was the reason for the improvement. "Of course, we hoped we would find residents who had received this training would have better disclosure skills," says Wong. However, this wasn't the case.

"In some ways, though, this was more disappointing than surprising," says Wong. "It really should not surprise us that a single half-day workshop might not have a major impact on error disclosure skills."

This raised the question as to what — if not the training — had improved the residents' error disclosure skills. "To further explore this, we interviewed nine residents from three different training programs: internal medicine, pediatrics, and orthopedic surgery," says Wong.

The researchers asked the residents about their experiences learning how to disclose errors. The residents felt that faculty role-modeling and debriefings were helpful. Residents also turned to one another for peer support and mentoring.

"It turned out that while formal training was acknowledged as having some role, the more important learning experiences were the informal ones," says Wong.

Some residents reported that they felt personally responsible for disclosing errors, and wanted to be a part of the conversation with the patient or family. "For us, this was perhaps the most surprising finding," says Wong. "The residents saw disclosing errors as an important professional responsibility that they wanted to be directly involved with."

Some even revealed that they'd disclosed errors independently without faculty present. This raises the ethical question of whether it's ever permissible for residents to disclose errors on their own.

"When residents want to take ownership of the error disclosure process, it is our job as faculty members to ensure that they are prepared to disclose, and negotiate with them when they are ready to communicate effectively without direct supervision," notes **Lynfa Stroud**, MD, MEd, another of the study's authors. Stroud is associate professor in the Department of Medicine at the University of Toronto and a general internist at Sunnybrook Health Sciences Centre.

Timely and candid communication with a patient or family after a medical error can help limit harm, and is a professional and organizational ethical imperative, says **Jonathan D. Stewart**, JD, director of risk management and patient safety at Alamo, CA-based Beta Healthcare Group.

"Silence by organizations and physicians following medical injury compounds the harm experienced by patients and families. But clumsy 'disclosure' of an actual or apparent error can be even worse than silence," says Stewart.

Ideally, clinicians have some preparation before disclosing an error to a patient or family. This might take the form of formal pre-event training with an opportunity to practice. "At a minimum, the clinician should have just-in-time training, with the benefit of a team huddle to prepare," says Stewart.

The team should review the known facts and identify questions that still must be answered. "Avoiding

## EXECUTIVE SUMMARY

Residents' error disclosure skills have improved over time, largely due to informal learning experiences, found a recent study. Researchers learned that residents:

- turned to each other for peer support and mentoring;
- feel responsible for disclosing errors;
- want to be a part of conversations surrounding error disclosure.

engaging in confusing and potentially counterproductive speculation in front of the patient or family is very important from an organizational risk management perspective," says Stewart.

Ideally, initial communication with a patient or family about a serious harm event happens within an hour.[2] Organizations should identify individuals to support clinicians in preparing for these often difficult initial and follow-up conversations, says Stewart: "Medical ethicists may be well-suited for these roles."

Ethicists may bring valuable skills to the pre-conversation meeting, in which the team agrees on the goals of the communication, attunes their message to the patient's or family's level of sophistication, and possibly rehearses the conversation.

"When an organization makes — and internally communicates — its commitment to timely and transparent communication after harm, it becomes possible to prepare for a swift and consistent response to such events," says Stewart. ■

## REFERENCES


1. Wong BM, Coffey M, Nousiainen MT, et al. Learning through experience: Influence of formal and informal training on medical error disclosure skills in residents. *J Grad Med Educ* 2017; 9(1):66-72.
2. Agency for Healthcare Research and Quality. Disclosure Checklist: AHRQ Communication and Optimal Resolution Toolkit. Available at: http://bit.ly/2C6nyLd. Accessed Dec. 14, 2017.


## SOURCES


- **Jonathan D. Stewart**, JD, Director, Risk Management and Patient Safety, Beta Healthcare Group, Alamo, CA. Phone: (925) 314-7618. Email: jonathan.stewart@betahg.com.
- **Lynfa Stroud**, Department of Medicine, University of Toronto. Email: Lynfa.Stroud@sunnybrook.ca.
- **Brian M. Wong**, MD, FRCPC, Department of Medicine, University of Toronto. Email: BrianM.Wong@sunnybrook.ca.


# Study: Timing of Advance Directive Linked to Aggressive End-of-Life Care

*Study's findings support earlier discussions*

Did a patient complete an advance directive in his or her last months of life? If so, there is a greater chance of choosing aggressive care, found a recent study.[1]

"We undertook this study to better understand the relationship between timing of advance directive development and patient preference for aggressive care," says **Susan Enguidanos**, PhD, MPH, the study's lead author. Enguidanos is associate professor of gerontology at University of Southern California in Los Angeles.

Nearly three-quarters of advance directives were completed a year or more before death. Younger age, being a racial/ethnic minority, having lower education, a diagnosis of cancer or lung disease, and an expected death were associated with completing an advance directive within the three months before death.

"Our findings support recommendations to begin advance care planning discussions early in the disease trajectory," says Enguidanos.

Minorities, those with lower education, expected death, and timing of advance directive completion were associated with electing aggressive care. "These factors may reflect poor discussions around care decisions, perhaps conducted during a medical crisis," says Enguidanos.

Mechanisms to promote patient-physician discussion on end-of-life care and subsequent documentation of this discussion through an advance directive are needed, says Enguidanos: "This may increase patient knowledge and better reflect patient values in their decision-making — and, ultimately, in the care they receive at end of life."

In another recent study, researchers found that 46% of decedents had completed an advance directive. Blacks had 75% lower odds of completing an advance directive than whites, and Hispanics had 70% lower odds than whites. Of blacks completing an advance directive, 24% elected prolonged care, compared with 13% of Hispanics and 3% of whites.[2]

Based on previous studies, the researchers expected lower rates of advance directive completion among minority groups. However, they didn't expect the gap between whites and minorities to be so wide.

"We were surprised at the size of the difference in odds between whites and African-Americans and Hispanics," says Enguidanos.

It's unclear to what extent this gap is an indication of fewer advance care planning conversations between physicians and minority patients. This is a potential ethical issue, says Enguidanos: "Although outside of the scope of this study, these findings point to the need for further investigation along these lines." ■

## REFERENCES


1. Enguidanos S, Ailshire J. Timing of advance directive completion and relationship to care preferences. *J Pain Symptom Manage* 2017; 53(1):49-56.
2. Portanova J, Ailshire J, Perez C, et al. Ethnic differences in advance directive completion and care preferences: What has changed in a decade? *J Am Geriatr Soc* 2017; 65(6):1352-1357.


## SOURCE


- **Susan Enguidanos**, PhD, MPH, Associate Professor of Gerontology, University of Southern California, Los Angeles. Phone: (213) 740-9822. Email: enguidan@usc.edu.


# ED Patients' Documented DNR Status Might Conflict With Family's Demands

*Clinicians 'fulfilling a promise made to the patient'*

Even if an ED patient's do not resuscitate (DNR) status is well-documented, family members may demand resuscitation — sometimes vehemently.

"Allowing for family to dictate the care of a patient against the patient's wishes is a violation of the patient's dignity," says **Jay M. Brenner**, MD, FACEP, associate professor in the department of emergency medicine at State University of New York, Upstate Medical University in Syracuse.

If a clinician performs an intervention on a patient against his or her clearly stated wishes, adds Brenner, it may be perceived as an assault. "If a clinician does not attempt resuscitation in spite of a surrogate decision-maker's objections to honoring a patient's wishes, then the clinician is fulfilling a promise made to the patient from the healthcare system," adds Brenner.

It's not uncommon for distraught family members to threaten to sue the clinician refusing to attempt resuscitation. "But as long as the clinician has clear evidence of the patient's wishes, then the clinician is safe from a malpractice accusation," says Brenner.

Violence against healthcare providers always is a possibility, depending on the family's ability to cope with the clinician's interpretation of the patient's decision. "The clinician should be prepared with security measures," says Brenner.

A difficult scenario is when the surrogate decision-maker says that he or she would like to disregard a DNR order because he or she believes that it is best, yet the patient's documentation is not available. "Electronic MOLST [Medical Orders for Life-Sustaining Treatment] forms, or an equivalent, can avoid the situation where the clinician does not have access to the DNR form," says Brenner.

When conflicts arise over an ED patient's DNR status, Brenner uses the following approaches:

- sitting down at the same level as family, regardless of the heightened anxiety surrounding the situation;
- use of scripted, yet personalized, phrases, such as, "I am trying to do what your loved one (fill in relationship or name) would have wanted;"
- involving social workers and chaplains to help alleviate the family's stress.

Recently, a wife asked clinicians to disregard her husband's preferences because she couldn't bear to see him go. "When her adult children arrived soon after, they were able to persuade her to allow me to honor his wishes," says Brenner.

In another case, two sons both claimed to be healthcare proxy. They did not agree on whether their mother would have wanted to be put on a ventilator. It became clear that the son who wanted the ventilator was basing the choice on what he thought was best. "The other brother was able to persuade him to base his recommendation on what their mother would have wanted," says Brenner.

Verified DNR orders should be followed in the ED unless the patient has stated wishes to the contrary, says **Catherine A. Marco**, MD, FACEP,

professor in the department of emergency medicine at Wright State University in Ohio.

However, many patients present to EDs with terminal conditions without any advance care planning whatsoever. "In these cases, it may be appropriate for the emergency physician to work directly with the patient, family, and treating physicians to determine the prognosis and the patient's goals of therapy," says Marco. In some cases, a DNR order is instituted in the ED, provided it clearly is the patient's wish.

A formal ethics consultation may be helpful in cases in which the patient's wishes are unclear, but it's challenging in the ED setting. "This often takes some time and may require inpatient consultation," says Marco. "I have never personally used an ethics consultation in the ED, because of the timeliness issue."

At times, the patient is unresponsive or otherwise unable to participate in medical decision-making. "If there is disagreement with family wishes and a pre-existing advance directive, state law should be followed," says Marco. "Many states confer immunity for healthcare providers who follow an approved advance directive."

It's possible that a surrogate decision-maker presents convincing evidence that a patient changed his or her mind about DNR status. In this case, says Brenner, the clinician's decision to attempt resuscitation is ethically justified.

The patient might have had a recent conversation with the surrogate after a change in health status. "If the surrogate decision-maker's statement is based on the patient's wishes, then it ought to be followed," says Brenner. "If it is based on what the surrogate decision-maker thinks is best, then the patient's expressed wish ought to be followed, provided that the form is valid."

If the clinician suspects that the surrogate decision-maker is acting maliciously — for example, prolonging a relative's life for the sake of collecting Social Security checks — then the clinician should potentially invalidate the role and seek another surrogate decision-maker, says Brenner.

"In absence of a surrogate decision-maker, then clinicians ought to follow the patient's stated wishes on a valid MOLST form," says Brenner. "Without a surrogate decision-maker or a MOLST, the clinician should attempt resuscitation." ■

### SOURCES


- **Jay M. Brenner**, MD, FACEP, Associate Professor, Department of Emergency Medicine, State University of New York, Upstate Medical University, Syracuse. Email: brennerj@upstate.edu.
- **Catherine A. Marco**, MD, FACEP, Professor, Department of Emergency Medicine, Wright State University, Ohio. Phone: (937) 395-8839. E-mail: catherine.marco@wright.edu.


# Report Examines How Research on Donated Organs Can Be Ethically Performed

*Thousands of available organs discarded annually*

More than 115,000 transplant candidates are on a waiting list for organs — but only about 33,500 organs were transplanted in 2016. These numbers tell an unfortunate story: that every year, thousands of people die waiting for an available organ.

"We are all aware of the substantial gap between organs that are needed and organs that are available. There is a huge gap between supply and demand," says **James F. Childress**, PhD, John Allen Hollingsworth professor of ethics and emeritus/founding director of the Institute for Practical Ethics and Public Life at University of Virginia in Charlottesville.

Much of the discussion to date has centered on how to increase the number of organ donors. Few people are aware of the need to improve the quality of the organs that already are available.

"Many in the transplant community have proposed that we research ways to improve donated organs for transplantation, in order to improve transplant outcomes and reduce the gap," says Childress.

Almost 5,000 organs from deceased donors were discarded in 2015 because they were deemed unsuitable for transplantation.[1] Some donated organs are used solely for research because they don't meet the criteria for transplantation. "Research is needed on how to best optimize

organs for transplantation," says Childress.

Interventions on the organs while they are still in the donor's body or shortly after removal could improve the chances of a good outcome for the recipient. "Some research has been done, with some good results. But there are some perceived obstacles to doing this research," says Childress.

## A Delicate Balance

In 2016, The National Academies of Sciences, Engineering, and Medicine assembled an expert panel to examine the ethical, legal, regulatory, policy, and organizational issues related to research in the United States involving deceased organ donors. The committee looked at how this important research can be performed ethically, in adherence with the regulatory and legal rules currently in place.

"Our task was to determine: Can this research be conducted ethically, within those frameworks? And if so, how? It's a delicate balance," says Childress, chair of the study committee.

The resulting October 2017 report, Opportunities for Organ Donor Intervention Research: Saving Lives by Improving the Quality and Quantity of Organs for Transplantation, offers recommendations for conducting organ donor intervention research in a way that maintains high ethical standards, ensures dignity and respect for deceased organ donors and their families, and provides transparency and information for transplant candidates who might receive a research organ.[2,3]

Trustworthiness of the organ donation system, and of research involving human subjects, is heavily emphasized. "We depend on the public to donate organs and to participate in research to generate knowledge and benefit others," says Childress. Some of the committee's recommendations include the following:

**• The Uniform Anatomical Gift Act should be clarified to allow people to understand that donated organs might be used for research and transplantation.**

"It's not a single purpose, but a combined purpose," says Childress. "People need to understand as much about this as possible so they don't end up feeling that their trust has been violated."

**• Donor registries and departments of motor vehicles should use consistent language to communicate about this type of research to potential donors and surrogates.**

**• Recipients of organs that have been subjected to research interventions and are now being studied for their function, efficacy, and safety should be treated as research participants.**

Deceased organ donors are not characterized as research subjects because federal regulations for research protection only apply to living individuals.

"Nevertheless, it's important to respect individuals and surrogates in making decisions about organ donation, and to determine if they are willing to donate for this purpose," says Childress.

The committee contended that under most research protocols, patients who receive organs that were subject to a research intervention are research subjects. "This raised a lot of issues," says Childress. "For instance, research informed consent may be very difficult to obtain when organs need to be transplanted quickly."

## Realities of Transplantation

A robust clinical informed consent process that includes specific regulatory requirements already exists for transplantation, says **Alexandra K. Glazier**, Esq., president and CEO of New England Donor Services in Waltham, MA.

For donor research where the transplant recipient does not fall under the regulatory definition of human subject, the clinical consent model — rather than the consent model used for human research subjects — best balances clinical innovation, transparency, and protection of patients, she argued in a recent paper.[4]

"The ability to conduct research trials to evaluate interventions on the deceased donor, or donor organ, remains complicated and fraught with regulatory ambiguity," says


## EXECUTIVE SUMMARY

Research on how to improve the quality and quantity of organs available for transplant poses multiple ethical challenges. A new report recommends that:

- clear and consistent information be used to inform potential donors that donated organs may be used for both research and transplant;
- a single IRB be used for review, approval, and oversight;
- recipients of organs subjected to research interventions should be considered as human subjects.

Glazier, who co-authored the paper.

Characterizing recipients of organs that have been subjected to a research intervention under existing regulatory requirements is one example. "The need for a precise legal and ethical analysis that maps the regulatory language and the complex process of donation and transplantation was needed," says Glazier.

## Facilitate Informed Consent

Much of the discussion in the field regarding deceased donor intervention research has been predicated on the assumption that recipients of these organs are human subjects — even if no research intervention or interaction will take place after transplantation. "The implications of that conclusion are numerous," says Glazier.

Regulatory requirements for institutional review board (IRB) review and human research subject informed consent emphasize beneficence, autonomy, and transparency. "While these goals are appropriate, the process required does not comport with the realities of transplantation," says Glazier.

Many ethical concerns will not be resolved merely by categorizing transplant recipients as human subjects. For example, the time-critical process of organ offers and the transplant candidate's health status greatly reduce the ability for effective informed consent. Many individuals are incapacitated at the time of organ offer.

"Requiring human research subject informed consent at the time of organ offer could raise issues of undue influence, when the ability to receive an organ transplant is predicated on consent to participate in human subject research," says Glazier.

Glazier would like to see changes that allow for vital research to be conducted, while addressing recipient informed consent in an ethically meaningful and realistic manner, given the complexities of the transplantation process.

> "THE ABILITY TO CONDUCT RESEARCH TRIALS TO EVALUATE INTERVENTIONS ON THE DECEASED DONOR, OR DONOR ORGAN, REMAINS COMPLICATED AND FRAUGHT WITH REGULATORY AMBIGUITY."

"Although we conclude that transplant recipients of research organs may not be human subjects if no research intervention or interaction will take place, the need for effective informed consent remains ethically paramount," says Glazier.

To expedite organ donor intervention research, the committee recommended that a centralized review process with a single IRB be used. "This would eliminate the need to have a separate IRB for each transplant center sign-off on it," explains Childress.

To reduce delays, the committee recommended the following two-stage process of disclosing information to potential transplant recipients:

- The first stage would consist of informing potential recipients, at the time of intake or listing, about the possibility of being offered organs that were part of a research project, the different levels of risk associated with such organs, and the risks of declining an offer of a research organ.

Potential transplant recipients can indicate at that time whether they would be willing to consider a research organ, if offered. "Or, it could be more nuanced than that. For instance, the person might be willing to consider a minimal-risk organ," says Childress. If a potential recipient declines, he or she will not be notified when a research organ becomes available.

- Transplant candidates who have agreed to consider research organs will be notified when a research organ becomes available, and will be informed about its risk level.

Giving patients the option of accepting a research organ mirrors the ongoing debate regarding older organ donors.[5] "This is another factor like that, but in the research setting," says Childress.

Currently, if a person wouldn't consider a research organ at all but is offered one without anyone knowing the person's preference, the organ is declined. The transplant team has lost a lot of time — and the organ is likely to be discarded.

"What this proposal does is reduce the chance that someone will decline an available organ when it is offered," says Childress. ■

### REFERENCES

1. Organ Procurement and Transplantation Network. National data. Available at: http://bit.ly/29MwOt8. Accessed Dec. 14, 2017.

2. National Academies of Sciences, Engineering, and Medicine. Opportunities for organ donor intervention research: Saving lives by improving the quality and quantity of organs for transplantation. Washington, DC: The National Academies Press, 2017.
3. Childress JF. Organ donor research: Overcoming challenges, increasing opportunities. *JAMA* 2017 Oct 10. doi: 10.1001/jama.2017.16442. [Epub ahead of print]
4. Heffernan KG, Glazier AK. Are transplant recipients human subjects when research is conducted on organ donors? *Hastings Cent Rep* 2017; 47(5):10-14.
5. Querard AH, Foucher Y, Combescure C, et al. Comparison of survival outcomes between expanded criteria donor and standard criteria donor kidney transplant recipients: a systematic review and meta-analysis. *Transpl Int* 2016; 29(4):403-415.

## SOURCES

- **James F. Childress**, PhD, John Allen Hollingsworth Professor of Ethics and Emeritus/Founding Director of the Institute for Practical Ethics and Public Life, University of Virginia, Charlottesville. Phone: (434) 924-6724. Email: jfc7c@virginia.edu.
- **Alexandra K. Glazier**, Esq., President & CEO, New England Donor Services, Waltham, MA. Email: aglazier@neds.org.

# Ethics if Patient Wants to Transfer Embryos With Genetic Anomalies

*Patient autonomy conflicts with physician autonomy*

Pre-implantation testing of embryos can detect genetic anomalies linked to serious health-affecting disorders. While patients rarely request that such embryos be transferred, it does happen.

"The ethical conflicts are patient autonomy conflicting with physician autonomy, and controversy about what is in the best interest of a resulting child," says **Elizabeth S. Ginsburg**, MD, professor of obstetrics, gynecology, and reproductive biology at Harvard Medical School in Boston. Ginsburg also is medical director of the assisted reproductive technologies program at Brigham and Women's Hospital.

A recently updated policy statement from the American Society for Reproductive Medicine addresses this difficult situation. The statement concludes that in most cases, it is ethically permissible for providers to assist, or decline to assist, in transferring such embryos.[1]

"Patients electing to have their embryos screened for a particular genetic disease are always carriers for that disease, and have had extensive genetic counseling prior to IVF treatment," notes Ginsburg, one of the policy statement's authors. In some cases, both parents are healthy but carry a recessive genetic mutation. In other cases, one parent may have a disease due to a dominant gene.

Patients who otherwise are fertile generally would not request transfer of an embryo with a known genetic disease. "If they were willing to risk having a baby with the disease, they would conceive on their own without IVF," says Ginsburg.

The dilemma arises for women or couples who are not fertile and may be choosing a baby affected with a disease over having no baby.

"Another patient population who may choose to have an embryo transferred is a patient who is a carrier of a dominant gene that increases risk of disease, but does not definitively cause disease," says Ginsburg. A common example includes BrCA 1 and 2 mutations, which greatly increase lifetime risk of developing cancers — particularly breast and ovarian cancer in women.

"Some IVF practitioners may not be comfortable knowingly transferring embryos that will cause a baby to have a chronic illness such as cystic fibrosis, and may elect not to perform such a transfer," says Ginsburg.

Patient counseling is critical in all cases. "At the outset of treatment, the patient should be informed of that clinic or practitioner's practice," says Ginsburg. ■

## REFERENCE

1. Ethics Committee of the American Society for Reproductive Medicine. Transferring embryos with genetic anomalies detected in preimplantation testing: an Ethics Committee Opinion. *BMC Med* 2017; 15(1):28.

## SOURCE

- **Elizabeth S. Ginsburg**, MD, Medical Director, Assisted Reproductive Technologies Program, Brigham and Women's Hospital, Boston. Phone: (617) 732-4222. Email: eginsburg@bwh.harvard.edu.

MEDICAL ETHICS ADVISOR®





# CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions:

1. Read and study the activity, using the provided references for further research.

2. Log onto AHCMedia.com and click on My Account. First-time users must register on the site. Tests are taken after each issue.

3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.

4. After successfully completing the test, your browser will be automatically directed to the activity evaluation form, which you will submit online.

5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

# CME QUESTIONS

1. **Which is true regarding physician aid in dying, according to Catherine Sonquist Forest, MD, MPH?**

   a. Insurance companies are legally required to cover drugs used in medical assistance in dying.
   b. White, educated, male, and terminal patients have the best access to providers.
   c. All existing state laws require mental health evaluation.
   d. Long-term data show that most patients seeking assistance in dying have not received any palliative care.

2. **Which is true regarding residents and error disclosure, according to a recent study?**

   a. Residents' error disclosure skills showed no improvement over time.
   b. Formal training was much more important as a learning experience than informal methods.
   c. Residents want to be involved in error disclosure conversations.
   d. Medical residents demonstrated better error disclosure skills than surgical residents.

3. **Which is true regarding advance directives, according to a recent study?**

   a. Patients who completed advance directives in the last months of life have higher odds of choosing aggressive care.
   b. Minorities were less likely to choose aggressive care.
   c. Most advance directives were completed within a month of death.
   d. Hispanics were equally likely as whites to complete advance directives.

4. **In which scenario is it ethical for an ED clinician to attempt resuscitation despite a well-documented DNR order, according to Jay M. Brenner, MD, FACEP?**

   a. Any time a family member in extreme emotional distress demands that the patient's DNR status be disregarded.
   b. If there is convincing evidence that a patient has changed his or her mind about DNR status.
   c. In cases where a surrogate threatens legal action against the clinician.
   d. If the patient has decision-making capacity and requests DNR status, but the designated surrogate objects.