MEDICAL ETHICS ADVISOR®

For 25 years, your practical guide to ethics decision making

August 2014: Vol. 30, No. 8
Pages 85-96

IN THIS ISSUE

Statement of Financial Disclosure: **Arthur R. Derse**, MD, JD (Consulting Editor), **Shelly Morrow Mark** (Executive Editor), **Leslie Hamlin** (Managing Editor), and **Stacey Kusterbeck** (Contributing Editor) report no consultant, stockholder, speakers' bureau, research, or other financial relationships with companies having ties to this field of study.

AHC Media

POLST forms linked with "much higher level" of meeting patients' wishes for end-of-life care

Patients got specific care they asked for

Patients get the specific care they want at the end of life when they document their wishes using a physician orders for life-sustaining treatment (POLST) form, according to a just-published study that examined death records for 58,000 people who died of natural causes in 2010 and 2011 in Oregon.[1]

"This is the strongest data that we have had. It's associated with a much higher level of meeting patients' wishes than anything anyone else has developed," says **Susan W. Tolle**, MD, FACP, one of the study's authors and director of Oregon Health & Science University's Center for Ethics in Health Care in Portland.

The study of 17,902 decedents with a POLST form in the state's registry included multiple care settings, says Tolle, "which no other study has done. It matches orders marked on your POLST form and where you died."

Of the decedents' orders for scope of treatment, 26.7% were for "limited additional interventions" and 6.4% were for full treatment. Of the 66% with orders for comfort measures only, 6.4% died in the hospital, compared with 44.2% of those with orders for full treatment and 34.2% for those with no POLST form in the registry.

EXECUTIVE SUMMARY

Patients get the specific care they want at the end of life when they document their wishes using a physician orders for life-sustaining treatment (POLST) form, according to a recent study.

- The form allows patients to request or refuse certain medical treatments.
- Only 6.4% of participants who marked "comfort measures only" died in the hospital, compared with 44.2% of those with orders for full treatment.
- Bioethicists can correct misconceptions, such as that POLST is focused only on limiting treatment.

"The results are somewhat surprising only because we have not found advanced directives to be nearly as effective as what is suggested in this study for POLST," says **Reid Blackwelder**, MD, president of the American Academy of Family Physicians.

The researchers were surprised that individuals who marked "full treatment" on the POLST form had a 10% higher rate of death in the hospital than those who had no POLST form at all. "Personally, I hadn't expected it to be higher than no POLST form, which is a default to full treatment," says Tolle.

Medical Ethics Advisor® (ISSN 0886-0653) is published monthly by AHC Media, LLC, One Atlanta Plaza, 950 East Paces Ferry Road NE, Suite 2850, Atlanta, GA 30326. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Medical Ethics Advisor®, P.O. Box 550669, Atlanta, GA 30355.

AHC Media, LLC is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media, LLC designates this enduring material for a maximum of *18 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.

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.- 4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $519. Add $19.99 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Back issues, when available, are $83 each. (GST registration number R128870672.)

Editorial Director: **Lee Landenberger**.
Managing Editor: **Leslie Hamlin** (leslie.hamlin@ahcmedia.com)
Executive Editor: **Shelly Morrow Mark** (shelly.mark@ahcmedia.com).

AHC Media

EDITORIAL QUESTIONS

Questions or comments? Call Leslie Hamlin at (404) 262-5416.

Increased utilization

Tolle expects that the new data will result in increased utilization of POLST, especially in the 43 states where POLST programs already exist or are in development. "In other states, this will give more support to bringing coalitions together to solve policy problems in their state, when existing policies make dissemination more difficult," she says.

While several states are currently developing POLST programs, only Oregon and West Virginia have mature programs that have had the chance to grow and develop. "Hopefully, states with new programs will see similar results," says Blackwelder. "A central registry is needed to ensure immediate access to these orders, regardless of location. This will be challenging in some states."

Obstacles to POLST

Some state laws do not recognize the POLST form as a legal form of advance planning, and therefore do not provide needed legal protections to doctors and facilities for withholding care pursuant to the form, says **Jason W. Manne**, JD, Dr.PH, an adjunct professor at the University of Pittsburgh Law School.

"Bioethicists need to be the ones making sure that hospitals and other medical providers have a quality POLST process, so we can be assured that the form expresses authentic and stable patient preferences," he adds.

There are logistical issues related to the storage and retrieval of POLST forms, including lack of systems that capture advance care planning documents in electronic medical records. "Unlike Oregon, most states do not have statewide registries. The program relies on the transfer of a paper form," says **Susan E. Hickman**, PhD, senior affiliate faculty at Indiana University Health's Charles Warren Fairbanks Center for Medical Ethics in Indianapolis.

Culturally, use of POLST requires recognition that there are limits to what providers can do, says Hickman, and a willingness to talk about difficult decisions.

"We are starting to see more attention to the need for difficult discussions, as well as increased training opportunities to help health care providers build skills," says Hickman. "But more work is needed to help ensure high-quality decisions."

Many misconceptions

POLST is often confused with an advance directive, says **Patricia A. Bomba**, MD, FACP, program direc-

tor of New York's medical orders for life-sustaining treatment (MOLST), an endorsed POLST program launched in 2004. It is often not recognized that there are different target populations for the different forms.

"Ethicists should become educated themselves," urges Bomba. "They need to understand the difference between advance directives and medical orders, the different appropriate populations for each type of form, and the processes for completing each."

The main misconception about the POLST is that it is appropriate for individuals not near the end of life, according to Manne. "Although some states have adopted laws recommending the form for people with up to five years of life expectancy, this is not a proper use of the form," he says.

As with many end-of-life discussions and orders, the potential exists for patients, family members, and even providers to forget that the patient always has the right to change their mind and revoke such forms, says Blackwelder.

"From my perspective, such forms create a forum for discussion, and a reminder that the health care team should always explore these issues and verify preferences," he says.

One out of seven POLST forms entered in the Oregon registry are revisions of an existing form. "The message that you can change your mind at any time needs to be clear," says Tolle. "It's not unusual to fill out more than one POLST form as you are nearing the end of your life."

Another common misconception is that POLST is focused only on limiting treatment. "This isn't about saying you can't have treatment — it's about documenting what treatment you want," says Tolle. "Lots of people who are not really close to death are marking 'yes' to CPR."

Many hospitals and systems do not have bioethicists on staff, but they may have an ethics committee. "Such committees will need to be involved in the education about and use of POLST forms," says Blackwelder.

Communities vary in terms of aggressiveness of practices at the end of life, notes Tolle. "National ethics leaders need to move beyond saying patients have a right to have their wishes respected, and make sure it's happening in the community where they live," she urges. "The time is now and the tools are here." ■

REFERENCES

1. Fromme EK, Zive D, Schmidt TA, et al. Association between physician orders for life-sustaining treatment for scope of treatment and in-hospital death in Oregon. *Journal of the American Geriatrics Society* 2014; doi: 10.1111/jgs.12889.
2. Hickman SE, Nelson CA, Moss AH, et al. The consistency between treatments provided to nursing facility residents and orders on the physician orders for life-sustaining treatment form. *Journal of the American Geriatrics Society* 2011;59(11): 2091-2099.

SOURCES

• **Patricia A. Bomba**, MD, FACP, Vice President & Medical Director of Geriatrics, Excellus BlueCross BlueShield & MedAmerica Insurance Company, Rochester, NY. Phone: (585) 238-4514. E-mail: Patricia.Bomba@lifethc.com.
• **Susan E. Hickman**, PhD, Senior Affiliate Faculty, Fairbanks Center for Medical Ethics, Indiana University Health, Indianapolis. Phone: (317) 274-0032. E-mail: hickman@iu.edu.
• **Jason W. Manne**, JD, Dr.PH, University of Pittsburgh (PA) Law School. Phone: (412) 648-1285. E-mail: jwm78@pitt.edu.
• **Susan W. Tolle**, MD, FACP, Director, Center for Ethics in Health Care, Oregon Health & Sciences University, Portland. Phone: (503) 494-4466. E-mail: tolles@ohsu.edu.

Can bioethicists help to decrease preventable readmissions?

Movement to formalize role of family caregivers

Family caregivers often find themselves unable to care for a patient after a hospital discharge, but health care providers are typically completely unaware of the problem.

"It may be because of the family caregiver's job responsibilities or their own health, or any number of reasons. It's better to know those barriers upfront," says **Carol Levine**, director of United Hospital Fund's Families and Health Care Project in New York City.

A 2012 study found that more than one-third of caregivers wanted more training on wound care.[1] "If wound care is part of the discharge plan, the

EXECUTIVE SUMMARY

Bioethicists can advocate for improved communication with family caregivers when a patient is going to be discharged from the hospital.
- Health care providers are often unaware of a family member's inability to provide needed care.
- Many patients who access "safety-net" public hospitals have worse outcomes of hospitalization, including readmissions.
- Bioethicists can advocate for more partnerships between hospitals and community-based programs.

last thing you want is a situation in which it's done poorly, because that will end badly for everybody," says Levine.

Some preventable readmissions occur simply because family caregivers aren't involved with care planning before the day of discharge, she says.

"A lot of times, there is a lot of disrespect, even if unintended, shown to patients or family caregivers, based on providers' frustration," adds Levine. "The attitude is, 'This has got to get done and you're the one who's got to do it.'"

Tool formalizes role

A new tool for hospitals, Understanding and Enhancing the Role of Family Caregivers in the Re-Engineered Discharge, prepared by United Hospital Fund in collaboration with Project RED at Boston University Medical Center,[2] formalizes the role of family caregivers.

"Involving families before discharge supports patient- and family-centered care, which views the patient not as a collection of diseases or conditions but as a whole person," says Levine, one of the tool's authors.

The tool structures the process of working with family caregivers into five steps: identifying the family caregiver, assessing the family caregiver's needs, integrating the family caregiver's needs into the after-hospital care plan, sharing family caregiver information with the next setting of care, and providing telephone reinforcement of the discharge plan.

"Many physicians and other health care providers have a rather negative attitude about families. They are worried they will be difficult to deal with or will somehow sabotage the care plan," says Levine. The tool stresses how important communication with the patient's caregivers is to preventing a needless hospital readmission. "This makes it more likely that the care plan will be followed and the patient won't come back to the ED. It also allows family caregivers the opportunity to explain what they can and can't do," says Levine. "It's not a consent process, but at least it gives them a voice."

Giving family caregivers an opportunity to participate in care planning is "a matter of justice," according to Levine. "If you are going to put a responsibility on somebody, you ought to let them have a say in whether they can do this or not," she says. "The health and well-being of the caregiver is certainly an ethical issue as well."

Bioethicists can help to identify systemic problems, such as systems not properly identifying the family caregiver. "They can be a very strong voice to make sure the patient's and family's views are heard," says Levine. "They can be the mediator between more clinically-oriented people and the patient and family."

Gaps are overlooked

Hospital-based discharge interventions that focus on traditional aspects of care may overlook social and functional gaps in post-discharge care at home for vulnerable older adults, according to a 2014 study.[3]

Researchers interviewed 24 vulnerable older adults in a patient-centered qualitative study, in which participants described their experiences of recovery at home and their needs for successful transition.

The study's findings reinforced that many patients who access "safety-net" public hospitals have worse health and worse outcomes of hospitalization — including but not limited to readmission, says **S. Ryan Greysen**, MD, the study's lead author and an assistant professor of medicine at University of California — San Francisco.

"They live in unhealthy areas with poor social support and inadequate resources to get well and stay well, or at least maintain a certain level of health, as opposed to continually worsening with their chronic conditions," says Greysen.

Bioethicists could advocate for more partnerships between hospitals and community-based programs, he suggests. "There is an ethical obligation to do a better job of guiding patients and families through the post-discharge period, as a matter of beneficence," says Greysen. ■

REFERENCES

1. Reinhard SC, Levine C, Samis S. Home Alone: Family caregivers providing complex chronic care. (Washington, DC: AARP Public Policy Institute, 2012).
2. Project RED Tool 7: Understanding and enhancing the role of family caregivers in the re-engineered discharge. Available at http://www.nextstepincare.org/Provider_Home/Project_RED.
3. Greysen, SR, Hoi-Cheung D, Garcia V, et al. "Missing pieces"—Functional, social, and environmental barriers to recovery for vulnerable older adults transitioning from hospital to home. *Journal of the American Geriatrics Society* 2014: doi: 10.1111/jgs.12928.

SOURCES

• **S. Ryan Greysen**, MD, Assistant Professor of Medicine, University of California — San Francisco. Phone: (415) 476-5924. E-mail: rgreysen@medicine.ucsf.edu.
• **Carol Levine**, Director, Families and Health Care Project, United Hospital Fund, New York City. Phone: (212) 494-0755. E-mail: clevine@uhfnyc.org.

Experience with end-of-life care makes advance care planning more likely

Older individuals who have experience with end-of-life care of others demonstrate greater readiness to participate in advance care planning, according to a recent study.[1]

Of 304 participants, 84% had one or more personal experiences or experience with others. This was associated with greater readiness to complete a living will and health care proxy, discuss life-sustaining treatment with loved ones, and discuss quantity versus quality of life with loved ones and with physicians.

Halima Amjad, MD, MPH, the study's lead author, was surprised that personal experiences with serious illness or surgery were not associated with increasing readiness to engage in most forms of advance care planning. Amjad is a post-doctoral fellow at Johns Hopkins University School of Medicine's Division of Geriatric Medicine and Gerontology in Baltimore, MD.

"Intuitively, it would make sense that for an older adult, having his or her own personal illness experience might lead to reflection on end-of-life care and outlining or discussing what treatments would or would not be accepted," she says. However, it was the end-of-life experiences with others that were associated with greater readiness to participate in advance care planning rather than personal experiences. "Actually witnessing end-of-life care and decision-making may be more important than an older individual's own illness experience," says Amjad.

Another surprising finding was that knowing someone who had a bad death due to too little medical care was associated with greater readiness to complete a living will and/or health care proxy, and to discuss life-sustaining treatment and quantity versus quality of life with loved ones.

In contrast, knowing someone who had a bad death due to too much medical care was associated with increased readiness for only one of six advance care planning behaviors — discussing quantity versus quality of life with a physician. "We typically think of advance care planning as a way to limit unwanted interventions at the end of life, so this finding was the opposite of what we expected," says Amjad.

It was unclear whether participants felt that loved ones died with uncontrolled symptoms, and therefore received too little medical care, or if they were motivated to specify life-sustaining treatments they would accept at the end of life.

"For bioethicists often grappling with difficult end-of-life issues, advance care planning can address some of the most pressing questions and allow individuals to make their wishes known when they cannot speak for themselves," says Amjad. "It is unfortunately still underused." She says the study's findings have these implications for bioethicists:

- In discussing advance care planning and end-of-life care with individuals, a discussion of their previous experiences with loved ones, rather than focusing on personal illnesses, may be more productive.
- Recognition that individuals without prior end-of-life experiences with others may be less ready to engage in advance care planning can help tailor these important discussions to each individual and his or her stage of readiness.
- Bioethicists can promote advance care planning with other providers who may be interacting with older patients and conducting end-of-life care discussions, including health care providers, social workers, and chaplains.

These providers should be encouraged to step back, reflect with the older patient on end-of-life experiences he or she has had with others, and assess how ready the individual is to engage in different forms of advance care planning, advises Amjad.

"Rather than using a generic script or starting with discussion of the patient's own health experiences, this approach may lead to a more individualized and fruitful discussion on extremely important issues," she concludes. ■

REFERENCE

1. Amjad H, Towle V, Fried T. Association of experience with illness and end-of-life care with advance care planning in older adults. *Journal of the American Geriatrics Society* 2014. doi: 10.1111/jgs.12894.

SOURCE

• **Halima Amjad**, MD, MPH, Division of Geriatric Medicine and Gerontology, Johns Hopkins University School of Medicine, Baltimore, MD. Phone: (215) 896-2534. E-mail: hamjad1@jhmi.edu.

Ethics at forefront of predictive genetic testing in children

Change in recommendation caused "firestorm"

The Clinical Sequencing Exploratory Research Consortium's Pediatrics Working Group compared recent recommendations on predictive genetic testing of children from the American Academy of Pediatrics (AAP) and American College of Medical Genetics and Genomics (ACMG). The group focused on operational and ethical issues specific to decision making for children.[1]

"The big debate is about the goals of testing, and who decides it," says **Ellen Wright Clayton**, MD, JD, a member of the work group. Clayton is also Craig-Weaver Professor of Pediatrics and professor of law at Vanderbilt University's Center for Biomedical Ethics and Society in Nashville, TN.

The position taken in the AAP/ACMG paper is that predictive genetic testing should not be done unless intervention to protect the health of the child is needed before adulthood.[2]

"A major justification for this position is that children may not want to know when they reach adulthood, a decision many adults make," says Clayton. "They make some cautious exceptions in the case of adolescents who want testing, and serious family distress."

In contrast, a separate ACMG policy statement concerning reporting of "incidental findings" when genomic sequencing is performed as a diagnostic test justifies predictive genetic testing for adult-onset disorders — even when not needed for the child's personal health care during childhood, in order to make the information available to other family members who may be at risk.[3]

"They argue, among other things, that there is benefit to the child in having adult relatives not get sick," says Clayton.

Both organizations agree that information on a non-treatable disorder such as Huntington's disease should not be reported, and that variants should not be reported if it's unclear whether the disorder would cause problems or if it is not known if the particular variant clearly causes disease.

"What has changed is that for a select group of disorders that you know can cause significant morbidity or mortality, and where if you knew about it, you could take some sort of action, there is a recommendation to test for and report these in children undergoing clinical exome sequencing," says **Gail E. Herman**, MD, PhD, FACMG, FAAP, president of the ACMG.

The ACMG recommendation is that, for these specific conditions, the benefit to the family and possibly future health of the child outweighs the concern regarding testing a child for an adult-onset disorder. "We would not specifically perform a single gene test in a child for these adult disorders unless they were symptomatic," says Herman. "However, when exome sequencing is performed, the data are there and can be analyzed."

The ACMG now recommends testing for and reporting of 56 disease-associated variants for 24 adult-onset disorders, mostly inherited cancer syndromes and cardiovascular disorders. "It caused a firestorm. Ethicists, lawyers, and some clinicians were very upset about this whole issue," says Herman.

At the ACMG's March 2014 annual meeting, the recommendations were updated to allow for families to opt out of receiving this information when they give consent for the original genetic testing.[4]

Incidental findings from the ACMG's list would likely be reported for 2%-3% of children tested, according to recent studies.[5,6] "It's not huge, but it is still significant as people do more and more of this," says Herman. "We've done over 100 clinical exome tests at our own institution. Some of the larger centers have done over 1000 as a clinical test."

Even now, some well-informed families are asking about risks of finding other disorders when this type of testing is performed, reports Herman.

Ethicists should participate on panels that review the results of whole exome and genome sequencing, advises Herman. "They should talk about it to medical students, and to the public, and other providers,"

EXECUTIVE SUMMARY

The American Academy of Pediatrics (AAP) and American College of Medical Genetics and Genomics (ACMG) recommended in 2013 that predictive genetic testing for adult-onset disorders should not be done in children.

- A subsequent ACMG statement recommends predictive genetic testing for a select group of adult-onset disorders when clinical exome or genome sequencing is performed on a child.
- The primary ethical issues are who defines the best interest of the child and to what extent can the interest of others supersede the child's interest.
- Bioethicists can serve on panels analyzing test results and help families understand the implications of testing.

she says. "There is a lot of work to be done educating everyone as the technology advances."

Balance benefits and harms

The overriding principle of the 16 recommendations in the March 2013 statement, Ethical and Policy Issues in Genetic Testing and Screening of Children, is that the best interests of the child should be the primary standard with which to make decisions, says **Jonathan M. Fanaroff**, MD, JD, director of the Rainbow Center for Pediatric Ethics at Rainbow Babies & Children's Hospital in Cleveland, OH.

"From an ethical standpoint, genetic information can provide medical benefits and medical harms, as well as psychosocial benefits and psychosocial harms," he says. When making decisions for others, providers must balance the potential benefits against the potential harms before deciding to proceed with predictive testing, emphasizes Fanaroff.

When the condition being tested for is a childhood-onset condition, the parents are generally able to authorize such testing, along with the assent of the child, it is hoped, if he or she is old enough to do so, he says.

"When the condition being tested for is an adult-onset condition, and there is nothing to be done in childhood that may decrease morbidity, predictive testing should generally be deferred until that child is old enough to choose for themselves whether to get tested," says Fanaroff.

The primary ethical issues, says Clayton, are who defines the best interest of the child and to what extent can the interest of others supersede the child's interest. "This is very much going to be debated," she says, pointing to a new grant opportunity from the National Institutes of Health to explore the benefit of expanding the definition of "benefit of treatment" beyond the traditional medical model, in the context of newborn screening.

"It's one thing when you have a family that knows they are at risk. Then you can have a conversation about this," says Clayton. "But to do additional testing, as proposed by the ACMG, is really opportunity screening."

Another issue is how parents can make informed decisions about preventive genetic screening.

"When testing is performed on a child, the choice of whether or not to test at all is taken away from that individual, and this is a significant decision," says Fanaroff. Many adults, when offered genetic testing for untreatable conditions such as Huntington's disease, choose not to get tested, as they would rather not know the information.

Many patients and family members have very limited understanding of genetics. They may, therefore, underestimate the impact of the decisions they are making with respect to predictive genetic testing, says Fanaroff.

"Bioethicists can help families understand the implications of choosing whether a child gets tested or not, and can help advocate for the best interests of the child," he advises. ■

REFERENCES

1. Clayton EW, McCullough LB, Biesecker LG. Addressing the ethical challenges in genetic testing and sequencing of children. *Am J Bioeth*. 2014; 14(3):3-9.
2. American Academy of Pediatrics Committee on Bioethics, Committee on Genetics, American College of Medical Genetics Social, Ethical and Legal Issues Committee. Ethical and policy issues in genetic testing and screening of children. *Genetics in Medicine*. 2013;131(3):620-622.
3. Green RC, Berg JS, Grody WW, et al. ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing. *Genet Med*. 2013; 15(7):565-574.
4. American College of Medical Genetics and Genomics. Incidental findings in clinical genomics: A clarification. *Genet Med*. 2013;15:664-666.
5. Jarvik GP, Amendola LM, Berg JS, et al. Return of genomic results to research participants: The floor, the ceiling, and the choices in between. *Am J Hum Genet*. 2014;94(6):818-826.
6. Yang Y, Muzny DM, Reid JG, et al. Clinical whole-exome sequencing for the diagnosis of mendelian disorders. *N Engl J Med*. 2013;369(16):1502-1511.

SOURCES

• **Ellen Wright Clayton**, MD, JD, Craig-Weaver Professor of Pediatrics, Professor of Law, Center for Biomedical Ethics and Society, Vanderbilt University, Nashville, TN. Phone: (615) 322-1186. E-mail: ellen.clayton@vanderbilt.edu.
• **Jonathan M. Fanaroff**, MD, JD, Associate Professor of Pediatrics, Case Western Reserve University School of Medicine, Cleveland, OH. Phone: (216) 844-3387. E-mail: jmf20@case.edu.
• **Gail E. Herman**, MD, PhD, Professor, Center for Molecular and Human Genetics, The Research Institute at Nationwide Children's Hospital, Columbus. Phone: (614) 355-3483. E-mail: gail.herman@nationwidechildrens.org.

Controversy over "comfort feeding only" for dementia patients

It's a "very contentious area"

Should advance directives enable people with advanced dementia to refuse food and water as a way of hastening death? A 2014 paper examined this issue.[1]

"It's a very contentious area. There are big ethical controversies," says **Paul T. Menzel**, PhD, co-

author of the paper and professor of philosophy emeritus at Pacific Lutheran University in Tacoma, WA. Menzel is also affiliate professor in University of Washington's Department of Bioethics and Humanities.

Menzel's interest in the issue stemmed from seeing a number of people over the years who had very much wanted their lives not to extend into long years of progressive dementia, "and then lo and behold, that would happen."

In some cases, this even occurred when individuals had well-equipped proxies, made their wishes clear to family members, and had a plan of action in place. "These situations often do not have the kind of acute crises where, because they had an advance directive of withholding life-sustaining treatment, their life would end," says Menzel. Years may pass without an acute care incident.

"The clash that occurs then is that you have a person who, at that time, is not consciously holding the view that it would be best if their life didn't end in years of this, and that it would be better if it ended sooner," he says. The individual with dementia isn't cognitively capable of having such wishes, Menzel explains, although he or she had expressed these wishes strongly in the past, and in a certain sense, they are still theirs.

"So you've got a tremendous clash between treating a person only on the basis of their current experienced interest, and caring for them on the basis of their past wishes," he says.

Menzel argues that if the patient's past wishes aren't taken into account at all, "we are treating them as a person who has never been competent. If we treat them only as the incompetent person they are now, and nothing more, I don't think that is proper treatment of a human being."

While past wishes don't automatically trump the patient's current experienced interests, says Menzel, they can outweigh them. "When do they outweigh them? That's the question," he says. He believes that at some point in severe dementia, it happens, when survival no longer holds much, if any, subjective value to a person.

It's well-known that progressive dementia will ultimately lead to feeding problems, notes Menzel. The question is how much assistance providers should then give. "There are a lot of very determined and artful things that a caregiver can do to get a person to eat," he says.

A 2003 study of Oregon hospice nurses reported that the number of patients under their care who had chosen to die by not eating was greater than the number of patients who had chosen to die by physician-assisted suicide.[2] "Dying by not eating is not uncomfortable, and some people actually find it better and more comfortable than lethal aid-in-dying," says Menzel.

No specific guidelines

Could dying by not eating be accomplished in severe dementia by advance directive? One challenge is to make advance directives clear enough for providers to act on them, says Menzel.

Courts have long determined that patients have the legal right to refuse medically assisted tube feeding because it is considered medical treatment. Competent patients can also refuse to eat. "But nursing homes still usually see food and water as personal care, not the kind of treatment that is covered by an advance directive," says Menzel.

It is perfectly legitimate to provide only enough feeding to keep a person comfortable, not to keep them alive long-term, if residents have a directive or clear directions from a proxy stating "comfort feeding only" for severe dementia, says Menzel. "Such 'comfort feeding only' need not be a violation of good care. It is already the practice in some nursing homes, but it may become more widespread."

Actual practice guidelines on respecting advance directives that specify no food and water by mouth when an individual reaches a defined stage of severe dementia are likely to come only after cases have made their way through the court system, however.

"But legal rulings on this may be a long time in coming," says Menzel. "The circumstances it would take to get a legal battle on this are probably fairly rare."

Aggressive care as defaults

Daniel Brauner, MD, associate professor of

EXECUTIVE SUMMARY

Advance directives enabling people with advanced dementia to refuse food and water as a way of hastening death are controversial.

- The individual with dementia isn't cognitively capable of having such wishes, although he or she had expressed these wishes in the past.
- One challenge is to make advance directives clear enough for providers to act on them.
- Patients have the legal right to refuse medically assisted tube feeding, but nursing homes tend to see food and water as personal care.

medicine and co-director of the bioethics consultation service at University of Chicago, says that if a person has an advance directive that says to withhold food and water if he or she has severe dementia, then it should be respected if the patient is no longer expressing any desire to eat or drink.

"My only problem is that you shouldn't need an advance directive," he says. "Feeding tubes have been clearly shown not to improve matters in persons with advanced dementia and who have stopped eating."

If a patient with advanced dementia stops eating, the standard of care should be to offer them comfort feeding, argues Brauner. The real problem, he says, is that patients shouldn't need to decide in advance that they don't want unhelpful therapies.

"We have had enough experience with [gastrostomy] tubes to realize that they are not indicated in patients with advanced dementia who stop eating," says Brauner.

A choice between a therapy that doesn't help you, and withholding that therapy, is not really a choice at all, says Brauner. "Framing it as a choice maintains the illusion of patient autonomy," he says. "But it just reinforces the notion that we really do have a therapy that can help you — and puts the onus on the patient and their 'values,' to decide."

Patients are forced to opt out with advance directives to forego therapies that don't make sense to begin with, according to Brauner. "Without opting out, patients are given aggressive care as defaults," he says. "The advance directive paradigm doesn't really work."

Patients need to choose a durable power of attorney to help them make decisions in the future when they can't, says Brauner, "but the real answer is to improve medical care in the present — care that moves away from the default application of inefficacious therapies." ■

REFERENCES

1. Menzel PT, Chandler-Cramer MC. Advance directives, dementia, and withholding food and water by mouth. *Hastings Center Report* 2014;44:23–37.
2. Ganzini L, Goy ER, Miller LL, et al. Nurses' experiences with hospice patients who refuse food and fluids to hasten death. *N Engl J Med* 2003;349(4):359-365.

SOURCES

• **Daniel Brauner**, MD, Associate Professor of Medicine, University of Chicago (IL). Phone: (773) 702-6985. E-mail: dbrauner@medicine.bsd.uchicago.edu.
• **Timothy Kirk**, PhD, City University of New York-York College, Jamaica, NY. Phone: (718) 262-5316. E-mail: tkirk@york.cuny.edu.
• **Paul T. Menzel**, PhD, Professor of Philosophy Emeritus, Pacific Lutheran University, Tacoma, WA. E-mail: menzelpt@plu.edu.

Organ donation consent rates much lower among minorities

Certain groups less likely to consent, but reasons unclear

The number of Hispanic Americans on the U.S. organ waiting list has more than doubled, but that population is still 60% less likely than whites to donate organs, according to a 2014 study.[1]

In a 2013 study, researchers used data provided by the Organ Procurement and Transplantation Network to analyze the 35,823 organ procurement organization-reported eligible deaths from January 1, 2008, to October 31, 2011. "We did the study, in part, to validate, confirm, or refute smaller studies which showed lower consent rates in blacks and Hispanics," says **David S. Goldberg**, MD, MSCE, the study's lead author and an instructor at Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

The researchers confirmed these previous findings, and also reported a significant lower consent rate among Asians. It was unclear, however, whether lower consent rates were due to cultural beliefs, or whether they were due to problems with communication, language barriers, or lack of information.

"Due to the nature of the data, we couldn't necessarily pinpoint the exact reasons why certain racial or ethnic groups are less likely to consent," says Goldberg.

Qualitative research, including interviews with families who have consented and those who haven't, is needed to determine this, according to Goldberg. "Bioethical research can help in this regard, to help to empirically evaluate the internal and external influences which may alter a family's decision to consent to donation," he says.

EXECUTIVE SUMMARY

Organ donation consent rates are significantly lower among Hispanics, blacks, and Asians compared to whites, according to recent studies.
• It unclear if lower consent rates are due to cultural beliefs or communication problems.
• Other research reported lower transplant rates in Hispanic and Asian patients.
• Qualitative research is needed to determine the reason for lower consent rates.

Differences in access

A 2010 study evaluated the outcomes of patients placed on the waiting list for liver transplant after a change in allocation policy occurred in 2002.[3] It was determined that the model for end-stage liver disease (MELD) score reliably predicted mortality on the liver transplant waiting list.

"This was thought to be a more objective allocation policy method, as two patients with the same MELD score had the same risk of dying, and, therefore, should have equal access to transplant regardless of other factors," explains **Amit K. Mathur**, MD, MS, the study's lead author. Mathur is assistant professor of surgery and senior associate consultant for transplant surgery at Mayo Clinic in Phoenix, AZ.

The goal was to remove the subjectivity from the assessments used to assign waiting list priority. "Additionally, it prevented gaming of the system," says Mathur. The concern was that doctors could admit their patients in order to increase their wait list priority.

"The study findings were quite surprising, actually," says Mathur. In the pre-MELD era, there were notable disparities in access to transplant from the waiting list, with African-American patients transplanted at a much lower rate than Caucasian patients.

"We found that after adjusting for where patients live, there was no significant difference in liver transplant rates between African-Americans and white patients," says Mathur.

The researchers did find, however, that Hispanics had a significantly lower transplant rate than non-Hispanic white patients. Asian patients with the highest MELD scores had lower transplant rates compared to their white counterparts. "These findings are concerning," says Mathur.

Approaches on horizon

Having more organ donors overall would increase access to transplant in general, says Mathur. However, empirical bioethical work is needed to understand the underlying reasons for racial and ethnic differences in consent rates.

"I think technologies to increase utilization and optimize liver transplant outcomes from otherwise marginal organs, such as livers with excess fat content or those recovered after cardiac death, have significant promise to increase donor yield," he adds.

There are regulatory and payer issues that threaten innovation on other fronts, says Mathur, particularly in living donor liver transplantation.

"Whatever gets proposed for organ allocation, at the end of the day, we are trying to allocate a scarce resource," says Mathur. "Balancing individual justice to transplant the sickest patient first must be balanced with utility." ■

REFERENCES
1. Salim A, Ley EJ, Berry C, et al. Increasing organ donation in Hispanic Americans: The role of media and other community outreach efforts. *JAMA Surg*. 2014;149(1):71-76.
2. Goldberg DS, Halpern SD, Reese PP. Deceased organ donation consent rates among racial and ethnic minorities and older potential donors. *Crit Care Med*. 2013;41(2):496-505.
3. Mathur AK, Schaubel DE, Gong Q, et al. Racial and ethnic disparities in access to liver transplantation. *Liver Transpl*. 2010; 16(9):1033-1040.

SOURCES

• **David S. Goldberg**, MD, MSCE, Department of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia. E-mail: David.Goldberg@uphs.upenn.edu.
• **Amit K. Mathur**, MD, MS, Assistant Professor of Surgery/Senior Associate Consultant, Transplant Surgery, Department of Surgery, Mayo Clinic, Phoenix, AZ. E-mail: mathur.amit@mayo.edu.

FDA holds hearings on new method of assisted reproduction

Ethical concerns were voiced during the Food and Drug Administration's (FDA) February 2014 hearings on oocyte modification in assisted reproduction for the prevention of transmission of mitochondrial disease.

"The goal of the hearings was to determine whether any additional research is needed before proceeding to clinical trials," says **Mark V. Sauer**, MD, division chief of reproductive endocrinology and infertility at Columbia University Medical Center in New York City, who attended the hearings. Sauer is a member of the American Society for Reproductive Medicine's Ethics Committee.

As a researcher who is looking to extend mitochondrial manipulation trials into the clinical arena, Sauer sees the FDA hearings as a missed opportunity. "As is commonly the case with innovative technologies involving cell manipulation, the focus was on the abuse and dangers of the technology," he says.

Profound ethical challenges

The FDA stated that looking into ethical issues involved in mitochondrial manipulation is not part of their mandate. "But it creeps in, because this is such a big issue. This is one of the most controversial areas of

human genetic technology," says **Marcy Darnovsky**, PhD, executive director of the Center for Genetics and Society in Berkeley, CA.

Altering genes that are passed down to future generations is prohibited by more than 40 countries, she notes. "When policymakers, scientists, and bioethicists looked at this issue and decided that it made sense to prohibit it, the main reason is to avoid high-tech eugenics," says Darnovsky. "This would be a precedent for genetic modifications of other kinds."

A different standard is used to evaluate the safety and efficacy for a patient facing a terminal diagnosis with no other options, she argues. "You do risky experiments on people when you are trying to save people's lives. This is not the case here. This doesn't alleviate the suffering of anybody with mitochondrial disease," Darnovsky says.

Darnovsky says that there is a need to weigh the benefit "of having a genetically related child, applicable to very few people, against the profound social and ethical challenges that this presents."

Only a small subset of women with mitochondrial diseases would be candidates for mitochondrial manipulation, she adds, raising the question of whether there would be enough people to enroll in the clinical trial. "Many scientists have asserted that such a move at this time would put women and children at risk," adds Darnovsky.

Issues were lost

The hearing's goals of understanding where the technology is, what it promises to do, and whether or not it is ready for translational research to the bedside was "somewhat lost" during the FDA public forum, according to Sauer.

Sauer has done previous controversial research, such as using assisted reproduction to achieve postmenopausal pregnancies and defending the payment of egg donors as research subjects. "So I am sensitive to the concerns of the public. Not everyone agrees with how we practice assisted reproductive technology," he says. "But this has been a world-class effort of scientists coming together with clinicians with a common goal."

The research has been carefully reviewed by the researchers' own institutional review boards and ethics committees, adds Sauer. "What I and my colleagues are hoping for is an understanding not just of our work, but of others, and a dialogue on how we can move it along," he says.

Although the FDA has not issued an official ruling yet, the consensus seemed to be heading in the direction of recommending that more research be done before going ahead with clinical trials.

"But how much research is going to placate their worry?" Sauer asks. "When you do innovative work, you do get to a point where you have to take some risks. That is why it's so important that it's done correctly."

Sensational headlines such as "three-parent IVF," "designer babies," and "cloning technology" are counterproductive to the advancement of science, adds Sauer. "All that does is just make people think that what we are really doing here is trying to clone human beings," he says. "That is not even remotely or tangentially related to what we are doing."

While some regulators, in closed-door conversations, encouraged the researchers to continue their work, Sauer says it's questionable how long that can continue when progress is being made in other countries. Mitochondrial replacement has been under consideration in Britain for some time, and may be approved there at some point in the near future.

"Restraint is not always a bad thing," says Sauer. "But to say 'Based on what they do, then maybe you can do it,' when we are in a better position to advance the science, that's a sad day," he says. ■

SOURCES

• **Marcy Darnovsky**, PhD, Executive Director, Center for Genetics and Society, Berkeley, CA. Phone: (510) 625-0819 ext. 305. E-mail: darnovsky@geneticsandsociety.org.
• **Mark V. Sauer**, MD, Division Chief of Reproductive Endocrinology and Infertility, Columbia University Medical Center, New York City. Phone: (212) 305-9175.

EXECUTIVE SUMMARY

The Food and Drug Administration recently held hearings on mitochondrial manipulation to determine whether additional research is needed before proceeding to clinical trials. Ethical concerns include:
- Sensational headlines may result in misconceptions.
- Few women with mitochondrial diseases would be candidates for mitochondrial manipulation.
- There is a possibility of setting a precedent for other types of genetic modifications.

COMING IN FUTURE MONTHS

- ■ Why some patients' wishes not honored
- ■ What the VA scandal means for bioethics
- ■ Ensuring culturally competent end-of-life care
- ■ Ethical concerns of direct-to-consumer genetic testing

CME QUESTIONS

1. Which is true regarding the effectiveness of POLST forms in honoring patients' wishes for end-of-life care, according to a 2014 study?
   A. Patient wishes were rarely honored outside the nursing home setting.
   B. Most patients with orders for "comfort measures only" had to be transferred to the hospital anyway.
   C. Individuals who marked "full treatment" on the POLST form had a higher rate of death in the hospital than those who had no POLST form at all.
   D. POLST forms were only effective for honoring wishes of patients who wanted to limit treatment.

2. Which is true regarding advance directives of individuals with severe dementia, according to **Paul T. Menzel**, PhD?
   A. It is unclear whether patients have the legal right to refuse medically assisted tube feeding.
   B. Nursing homes consider food and water as treatment that is covered by an advance directive.
   C. There is evidence that feeding tubes improve outcomes in persons with advanced dementia who have stopped eating.
   D. Comfort feeding only for patients with severe dementia is already the selective practice in some nursing homes.

3. Which is true regarding organ donation consent rates, according to a 2014 study?
   A. Hispanic-Americans are 60% less likely than whites to donate organs.
   B. Consent rates in blacks and Hispanics have significantly increased.
   C. Asian-Americans have higher consent rates than any other racial or ethnic group.
   D. There is no evidence of any disparity in organ donation rates in any particular racial or ethnic group.

4. Which is true regarding recommendations on predictive genetic testing in children from the American Academy of Pediatrics (AAP) and American College of Medical Genetics and Genomics (ACMG)?
   A. Both organizations recommend that information on Huntington's disease should always be reported.
   B. Both organizations agree that variants should always be reported, even if it's unclear if the particular variant causes disease.
   C. The AAP's position justifies testing for adult-onset disorders in most cases.
   D. The ACMG justifies predictive genetic testing for adult-onset disorders even when not needed for the child's personal health care during childhood.

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. Scan the QR code below, or log on to www.cmecity.com to take a post-test; tests can be taken after each issue. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice, or renewal notice.
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.