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IN THIS ISSUE

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Growing movement to measure quality of palliative and end-of-life care

Much work still needs to be done to identify a core set of quality metrics that are feasible, scalable to large health care systems, and can be used to improve palliative and end-of-life care, according to **J. Randall Curtis**, MD, MPH, professor of medicine and director of the UW Palliative Care Center of Excellence at University of Washington in Seattle.

"Measurement of the quality of end-of-life care is an important area of focus for us to ensure that all patients and their families receive the type of end-of-life care they would want if fully informed about the options," says Curtis.

Quality of end-of-life care has multiple domains that need to be measured, he emphasizes. These include:

- effective and sensitive advance care planning to identify patients' informed goals of care;
- provision of care that matches the patients' goals;
- comprehensive symptom assessment and management;
- emotional and spiritual support;
- support for the family.

Providers have an ethical responsibility to provide high-quality care for those with serious illness and at the end of life, underscores **Christine S. Ritchie**, MD, MSPH, professor of medicine and Harris Fishbon Distinguished Professor at the University of California, San Francisco.

EXECUTIVE SUMMARY

There is a growing focus on identifying a core set of quality metrics that can be used to improve both palliative and end-of-life care.
- Measuring care can lead to improved quality and reduced costs.
- Palliative care and hospice are increasingly viewed as adding value and cost-effectiveness to health systems.
- Individual variability in goals of care must be considered.

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"By developing measures for this population and for this field, we will be able to better ascertain where we can most improve," she says.

"Steady growth" in measures

Quality of care has been a concern of hospice and palliative care for many years, says Ritchie, adding that in 2001, the National Consensus Project was one of the first initiatives to establish a set of expectations regarding quality of care for those with serious illness (http://www.nationalconsensusproject.org).

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EDITORIAL QUESTIONS

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"Since then, there has been a steady growth of quality measures developed for palliative care, especially for cancer patients," says Ritchie. "Many measurement gaps remain, however."

Some of the measures have been endorsed by the National Quality Forum and other quality metrics organizations. The American Academy of Hospice and Palliative Medicine's "Measuring What Matters" initiative will recommend five to 10 measures for palliative care programs to use for program improvement.

"The goal of Measuring What Matters is to develop population-level measures that are not site- or condition-specific, but apply to all patients in need of palliative care, whether primary or specialty," says Ritchie.

There is increased focus on palliative care and hospice as programs that add value and are cost-effective to an integrated health care system in every setting, she notes. Ritchie and a colleague are currently identifying specific quality measures relevant to adults with multiple illnesses with functional limitations who receive primary and/or palliative care in the home.

"This is an important time to make sure that high-quality palliative care is provided across all sites and settings — in the hospital and the home," she says.

Payment reform underscores need to measure

The focus of the Affordable Care Act (ACA) on improving the quality and value of health care provides an important opportunity for measurement of quality of end-of-life care, according to Curtis.

"Since end-of-life care consumes a considerable portion of our health care budget, it is an important target for efforts to improve value, and, therefore, quality," says Curtis.

That the Affordable Care Act requires the quality measurement of hospice care is "an important first step," says **Joan M. Teno**, MD, MS, professor of health services, policy, and practice at Brown University's Warren Alpert School of Medicine in Providence, RI.

The continued growth of new payment approaches underscores the importance of measuring the quality of end-of-life care. "It is important that we examine how a vulnerable population such as the dying receives medical care at the close of life that respects their values and goals," says Teno.

She notes that the U.S. health care system is currently in the process of payment reform, with continued increase in the number of Medicare Advantage Plans and Accountable Care Organizations.

"In the future, dying persons will be cared for in those new types of payment innovations with virtually no quality measures," says Teno. "There is limited research examining the quality of care of vulnerable

populations, many who are cognitively impaired."

Many patients with serious illness receive more intensive and expensive care than they would choose if they were fully informed and provided with high-quality palliative care, adds Curtis. "Therefore, measuring and improving palliative and end-of-life care becomes an opportunity to simultaneously improve quality and reduce costs," he says.

One ethical concern, however, is that cost reduction will be the sole focus, without improving or at least maintaining quality. Curtis says another important ethical consideration is that any system of measurement of quality of end-of-life care must incorporate individual variability in goals of care, which vary by race, ethnicity, socioeconomic status, religion, and culture.

"It is important that we develop systems of measurement that incorporate the individual's goals of care and not focus on the 'average' goals of care," says Curtis. ■

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Patients and providers have misconceptions about end-of-life care

Providers have so many myths and misconceptions about end-of-life care "that it's hard to know where to begin," says **Alan Meisel**, JD, Dickie, McCamey & Chilcote professor of bioethics and director of the Center for Bioethics and Health Law at University of Pittsburgh (PA).

Health care providers aren't to blame for having misunderstandings about what the law requires, adds Meisel, as "it's complicated, and it's not their primary professional concern."

"Expecting health care providers to know all the ins and outs of end-of-life law is no more realistic than expecting even educated lay people to know sophisticated details of medical care, or how their cars operate, or any one of the large number of other complicated areas in a complex world," he says.

Here are some common misconceptions held by providers regarding end-of-life care:

• Providers may believe that the termination of life-sustaining treatment is murder or manslaughter, euthanasia, or aiding suicide.

As long as termination of life-sustaining treatment is done with proper informed consent — from a patient who possesses decision-making capacity or from the surrogate of a patient who lacks decision-making capacity — "health care professionals who participate in it are not acting illegally or unethically," says Meisel.

• Providers may not realize that close family members — and sometimes others — have the legal authority to make decisions for a patient who lacks decision-making capacity, even without appointment by a court as a guardian.

Most states now have a statute designating the order of priority of relatives and others to make decisions for such patients.

"Only when there is some conflict among potential surrogates, no one to serve as surrogate, or a potential surrogate whom health care providers believe not to be acting in the patient's best interest, does a court-appointed guardian need to be sought," says Meisel.

• Nursing homes are frequently reluctant to permit patients who can't swallow not to have a feeding tube, because they believe that federal and state regulations requiring that they provide patients with adequate nutrition require feeding tubes.

"In this conclusion, they are definitely wrong if the feeding tube has been declined by a competent patient or by the legally authorized surrogate of a patient who lacks decision-making capacity," says Meisel.

The U. S. Supreme Court — and some state courts — have ruled that feeding tubes are medical treat-

EXECUTIVE SUMMARY

Health care providers frequently have misconceptions about legal requirements of end-of-life care. By educating providers about how to make decisions when people lose capacity, fewer formal ethics or legal consults will be needed.

• Providers may believe that the termination of life-sustaining treatment is murder or manslaughter, euthanasia, or aiding suicide.

• Providers may not realize that close family members have the legal authority to make decisions for a patient who lacks decision-making capacity, even without appointment by a court as a guardian.

• Providers may believe that in order to forgo life-sustaining therapy, they need to have complete knowledge of a patient's actual wishes.

ment, and that they can be withheld or withdrawn on the same basis as any other form of medical treatment.

This is consistent with the position statements of many associations of health care professionals, including the American Medical Association, notes Meisel.

"And as Justice Sandra Day O'Connor observed, it's not even necessary to classify feeding tubes as medical treatment in order to allow for their rejection," says Meisel. "This is because any nonconsensual interference with a person's body — which a feeding tube is — is a legal wrong."

The official position of Catholic bishops in the United States, notes Meisel, is that both Catholic and non-Catholic patients in Catholic health care institutions must have a feeding tube if they are unable to be adequately fed orally, unless they are "actively dying."

"Although there is some judicial authority that a patient who rejects a feeding tube has the right to remain in the facility even if it violates the facility's policy, this matter is still largely unresolved," says Meisel.

• Providers have misconceptions about terminal sedation and double effect. When a feeding tube is removed — or not placed in a patient who can no longer swallow — patients are sometimes sedated to the point of unconsciousness so that they experience no discomfort from dehydration.

"Concern is sometimes expressed by health care professionals that doing so might hasten the patient's death," says Meisel. If there is informed consent from the patient or surrogate, the fact that the medication might hasten the patient's death is immaterial, he explains.

The U.S. Supreme Court has stated that one reason for its refusal to rule that there is a constitutional right to physician-aid-in-dying is the fact that terminally ill patients can choose to stop eating and have terminal sedation.

"The fact that the sedation might hasten the patient's death does not make it illegal, as long as the purpose in providing the patient with sedation is to assure the patient's comfort," says Meisel. "This is an application of the 'doctrine of double effect,'" which is often invoked to explain the permissibility of an action that causes a serious harm, such as the death of a human being, as a side effect of promoting some good end. It is claimed that sometimes it is permissible to cause such a harm as a side effect (or "double effect") of bringing about a good result even though it would not be permissible to cause such a harm as a means to bringing about the same good end.[1]

Furthermore, says Meisel, the failure to provide adequate palliative care under such circumstances might itself be a violation of the patient's rights.

• Providers may believe that in order to forgo life-sustaining therapy, they need to have complete knowledge of a patient's actual wishes.

"People often think that if somebody hasn't made their wishes crystal clear, then you are obligated to continue all medical treatments," says **Timothy E. Quill**, MD, professor of medicine, psychiatry, and medical humanities at University of Rochester (NY)'s Palliative Care Program.

Providers might feel on firm ethical ground withholding CPR, says Quill, "but the more you get to things like feeding tubes or antibiotics, the more there is a belief that you can't stop those treatments once started, when, in fact, you can," he says. "Some providers will feel the need to keep going."

Bioethicists can educate providers about how to make decisions when people lose capacity. "From a legal point of view, the approach is generally agreed upon. This is pretty well-worn terrain," says Quill.

If the person has an advance directive, "that's the marching orders, because that is the patient's voice," says Quill. If there is no advance directive, clinicians should rely on family members to try to imagine what the patient would want using what is known of the patient's own values and preferences. Only if the patient's wishes are not knowable should clinicians revert to "best interest" standard, he says.

There will always be tough cases, such as in adults who never had legal capacity, because there are a lot of built-in protections for those patients. "But once you know the agreed-upon ethical standards, it solves 80% of the cases so they don't need formal ethics or legal consults," says Quill. ■

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Ethical concerns of collecting data on physicians' prescribing

Before a drug rep approaches an individual physician with a sales pitch, it's likely that he or she is already fully aware which antihypertensive medications a physician prefers for diabetics, or which

antidepressants the physician typically prescribes to elders.

This is because prescribing data is routinely purchased from most pharmacies in the United States, with physicians identified through information purchased from the American Medical Association.[1]

"This information is combined with patient medical history information purchased from insurance companies," says **Adriane Fugh-Berman**, MD, an associate professor in the Department of Pharmacology and Physiology at Georgetown University Medical Center in Washington, DC. The two sources of information are used to tailor drug marketing to physicians.

"In other words, prescription tracking is used to manipulate physicians' choices of therapies," says Fugh-Berman, director of PharmedOut, a project that promotes rational prescribing. "Obviously, this has major implications for the health of patients."

Use of data on physicians' prescribing by pharmaceutical companies is a serious ethical problem, according to **David Orentlicher**, MD, JD, co-director of the William S. and Christine S. Hall Center for Law and Health at Indiana University in Indianapolis.

"That is why Vermont, New Hampshire, and Maine passed statutes to restrict it," Orentlicher says. "Unfortunately, the Supreme Court rejected the statutes on First Amendment grounds."

One possibility is for Congress to amend the Health Insurance Portability and Accountability Act to change the definition of confidential information to include prescription data.

"The problem is that we know that drug company promotions increase the likelihood that patients will get prescribed a drug they don't need, a more expensive drug, a less effective drug, or one with more side effects," Orentlicher says.

Drug companies promote drugs that still have patent protection, decreasing the likelihood that a patient will be prescribed a generic drug. "Prescription data mining allows drug companies to make their promotions more efficient," says Orentlicher. "They can target doctors better because they see what their preferences are."

A related ethical concern is that the companies are doing so with information that is part of the physician-patient and pharmacy-patient relationship.

"Patients need assurance that relationships with providers are not only confidential, but also that private information will be used only for the patient's own benefit, not the benefit of others," explains Orentlicher.

As drug companies using this information can undermine patient interests, says Orentlicher, "it really is a misuse of this information." ■

EXECUTIVE SUMMARY

Data on physicians' prescribing is routinely purchased from pharmacies, with physicians identified through information purchased from the American Medical Association. Some ethical concerns of prescription data mining:

- Prescription tracking can be used to manipulate physicians' choices of therapies.
- Drug company promotions can increase the likelihood that patients will get prescribed a drug they don't need.
- Since drug companies promote drugs that still have patent protection, patients are less likely to be prescribed a generic drug.

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"Stem cell" tourism continues despite efforts to curb unethical practices

Primary ethical concern is potential for fraud

In February 2014, an appeals court upheld the Food and Drug Administration's (FDA) ability to regulate manipulated stem cells as drugs. However, this may not put a stop to "stem cell tourism," in which patients often pay thousands of dollars for unhelpful treatments, says **R. Alta Charo**, JD, Warren P. Knowles professor of law and bioethics at University of Wisconsin Law School in Madison, WI. Charo served as senior policy advisor in the Office of the Commissioner of the FDA between 2009 and 2011.

"The primary ethical concern with stem cell tourism is the potential for fraud," says Charo.

Many responsible medical practices have used adult stem cells for years to treat a limited range of conditions. There are a growing number of well-designed, properly overseen clinical trials to test the use of these cells for a wider range of conditions, or to test the use of other kinds of stem cells, notes Charo.

"Unfortunately, there are also a growing number

of clinics around the world advertising therapeutic applications that have not been subjected to well-controlled trials, nor appear to be overseen by any regulatory authority," says Charo.

Patients are enticed to spend large sums of money but are not getting what they believe was advertised, she explains. "Giving the impression to patients that these treatments are regulated, proven, and safe will, in many cases, be a form of misrepresentation," says Charo.

Extent of harm unknown

"Stem cell tourism" is most prevalent outside the United States. "There are some limited examples of domestic clinics that offered therapies that were subject to FDA regulation but which had not been submitted to FDA for the required review and approval before being offered to the public," says Charo.

A major ethical concern is that patients can be harmed physically by unproven interventions, says **Zubin Master**, PhD, assistant professor at the Alden March Bioethics Institute at Albany (NY) Medical College. "There have been reports of tumors and even deaths," he adds. "We don't know the full extent of harm, because we are relying largely on anecdotal information."

People are also being harmed financially and emotionally by clinics, says Master, as patients sometimes have to collect money from community donations or take out loans to pay for expensive treatments.

"We are also starting to see research reporting that some patients are skeptical about unproven stem cell interventions," he reports.[1]

Increase in confusion

Unethical practices of clinics are likely to add to the public's confusion about stem cell treatments, according to Master.

EXECUTIVE SUMMARY

A growing number of clinics around the world are advertising therapeutic applications for stem cell treatments that have not been subjected to well-controlled trials.

- The potential for fraud is a primary ethical concern, with some patients paying thousands of dollars for unhelpful treatments.
- Patients are given the false impression that offered treatments are regulated, proven, and safe.
- Patients may have difficulty distinguishing between established therapies, legitimate clinical research, and unproven interventions.

"Right now, there are a handful of established stem cell therapies," he says. "While much research is in clinical stages, the majority of research is still in preclinical stages being done in the laboratory."

As stem cell research is being translated into clinical applications, patients may have a hard time distinguishing what is an established therapy, what is legitimate clinical research, and what are unproven and potentially fraudulent interventions. "It's a complicated landscape," says Master. "Patients may just see someone in a white coat who is trying to help them and not be able to distinguish a registered clinical trial from an unproven intervention."

Public concerns about reported deaths from fraudulent stem cell interventions could become more prevalent and have a chilling effect on legitimate clinical research, adds Master. "To some degree, the clinics are playing on hype over stem cell research," he says. "It's really the premature selling of science."

Master also adds that the term "stem cell tourism" itself is misleading because it suggests a parallel to "medical tourism." "Getting a treatment in another country may be fine if a treatment is legitimate and they are following good practices," he says. "With people travelling for stem cell treatments, most of these things are just complete scams."

Patient's consent cannot be informed

It is a basic doctrine of law and bioethics that patients should have an opportunity to give informed consent. "But where there is confusion about whether a treatment has been developed or offered in full accordance with legal requirements, a patient's consent cannot be informed," says Charo.

If a treatment option is simply not reasonable, it really doesn't make any difference how well the provider informs the patient, says Master.

"It has to be based on scientific evidence," he says. "If there is no evidence that something will work, then you just ought not to be offering it to patients."

Bioethics can educate physicians by encouraging them to talk with their patients openly about unethical practices involving stem cell treatments, suggests Master.

"While educating patients and the public is likely to help them make better informed decisions, it is unclear whether patients will change their minds about seeking unproven interventions," says he adds.

Patient advocacy groups can get involved by sending similar messages about stem cell 'tourism' to their patient population. "Bioethicists can continue to conduct research and develop better ways of curtailing this practice," says Master. ■

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IC is ethical issue with comparative effectiveness research

It's harder to distinguish research from clinical care

Comparative effectiveness research (CER) has the potential to improve outcomes for individual patients as well as groups of patients, as well as lower costs.[1]

"I am encouraged to see that it is gaining traction more and more," says **Ryan Spellecy**, PhD, associate professor of bioethics at Medical College of Wisconsin in Milwaukee. "The key ethical concern is how to best convey to patients that this is research."

Patients may become overwhelmed

Patients becoming research subjects after enrolling in a research study when coming to a medical center or doctor's office for clinical care is nothing new, but it is common in CER to compare two treatments that are commonly used.

"Since both treatments could be considered standard of care, or perhaps within the range of standard of care, it is that much harder to distinguish research from clinical care," says Spellecy.

In clinical care, a physician prescribes a course of treatment based on the best evidence available. In CER, a subject might be randomized to one of two treatment arms. "There is now good evidence showing that when it is not known which treatment is better or worse, randomization does not increase risk," says Spellecy.

However, he cautions, the research subject still needs to know that he or she is participating in research, and that the goals of research are different from the goals of clinical care.

"I worry that many voices in the current debate over CER focus primarily on risk and ignore respect for persons and the right of research subjects to informed consent," says Spellecy. "Informed consent matters, regardless of risk."

Spellecy says the challenge is how to best present the research subject with enough information, in the proper manner, to decide whether or not to participate in the research.

There is a risk that patients may become overwhelmed with the length of the consent form. "Unfortunately, consent forms are getting longer and longer, and there comes a point at which, in the name of completeness, we sacrifice comprehension," says Spellecy.

There have been some novel proposals to include in CER consent forms only the information that is unique to the research study.

"That is, if the standard of care information is already covered in clinical conversations, the consent form and conversation should focus on the risks, benefits, and other aspects that are unique to the research," says Spellecy.

"One size fits all" won't work

Chris Feudtner, MD, PhD, MPH, the Steven D. Handler endowed chair of medical ethics at The Children's Hospital of Philadelphia, says that thinking through the appropriate informed consent process for CER, and obtaining it, is more complicated than for a more routine clinical trial, since CER compares two potentially useful therapies to each other and not to a placebo.

"But I wouldn't think of the standards for CER informed consent any differently than the standards we hold ourselves to in other clinical studies," says Feudtner.

While in some cases CER poses minimal risk and informed consent is potentially waivable, says

EXECUTIVE SUMMARY

Comparative effectiveness research (CER) has the potential to improve outcomes and lower costs, but one key ethical concern is how to best convey to patients that they are participating in research.
- It is common in CER to compare two treatments that are commonly used.
- It is harder to distinguish research from clinical care since both treatments could be considered standard of care.
- Some proposals suggest including only the information that is unique to the research study in consent forms.

Feudtner, in other cases, fully obtained informed consent is "absolutely essential," just like with any other clinical trial.

"In other words, 'one size fits all' will not be suitable across the range of what a CER study might investigate," says Feudtner. "We have already have thought through, in human subjects protections, conditions in which informed consent can be waived, and I think that guidance still applies."

Feudtner adds, "most of the hullabaloo has occurred because people are not fully aware of all of the clinical decisions that are made in routine, and quite standard, clinical practice, based on a provider's personal habits or a hospital's clinical care pathways. These inevitably entail risks, but rarely get fully described to families as such."

In a sense, he argues, CER is simply revealing the deficiencies of informing people about the prognosis and risks of treatment and potential benefits in regular clinical practice.

Argument for waiving consent

One circulating argument is that CER will grind to a halt if providers go through the process of obtaining consent in all cases, because many participants would refuse to participate.

"I would never accept the argument that CER is so important that consent always has to be waived," says Feudtner. "That is a bad argument at many levels."

In some cases, however, CER clearly imposes no significant marginal increased risk of a bad outcome for a patient, which is one of the hallmarks of a situation in which consent could be waived.

If the risks posed by the two treatments under study are roughly the same, and researchers are trying to sort out whether one treatment might be more effective than the other, or the benefits might be greater, there is an argument for waiving consent, Feudtner says.

"I don't think CER should get a free pass — it's not so important that we have to facilitate it by uniformly waiving consent," Feudtner says. "But on the other hand, I don't think that CER truly warrants more scrutiny than other clinical trials."

A broader solution for how to appropriately manage the process of informed consent for minimal, marginal risk CER is to have a global consent at the time of entering a hospital. "This would alert people that treatments are continually compared to determine if one is more effective than another, and that consent will be sought if it is believed that there is a difference in the risk or benefit," says Feudtner. The consent could also state that most of the time, treatments are well-established, and in those cases, patients will not be approached for consent.

"There would be a transparency in doing this," says Feudtner. "We are letting people know that we do CER and QI work, and that they can ask us questions about that."

Feudtner says that this is sufficient to protect ethical standards, which include both the protection of human subjects and the prudent improvement of clinical practice to improve patient outcomes.

Involve patients and families

A number of issues have been identified with CER that require careful ethics and regulatory consideration, says **Robert M Califf**, MD, vice chancellor of clinical and translational research at Duke University in Durham, NC. He says these are several of the most important:

- How should it be determined that a CER protocol adds minimal risk to what is encountered in usual clinical care?
- If consent is modified to make it simpler and more feasible for large studies, how should that be done?

The NIH Health Care Systems Research Collaboratory and the Patient Centered Outcomes Research Network provide forums to sort through these issues. "They are far from settled," notes Califf.

Califf says there is no short, easy answer to the question of how trials that randomize to two or more "standard of care" interventions should be designed and reviewed, other than "carefully and with major expertise."

Involving patients and their families will likely make the studies both more relevant and more feasible, according to Califf.

"We are embarking on several major surveys of the American population very soon to find out what they think as they become better informed about the uncertainties of clinical practice and the promise of developing better evidence to improve clinical care," he reports. ■

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Research data not currently used to make coverage decisions

The Affordable Care Act invested significantly in comparative effectiveness research (CER), but at the same time, states that no decisions coming out of CER should determine what treatments are covered by insurers, notes **Norman Daniels**, PhD, professor of ethics and population health at Harvard School of Public Health in Boston, MA.

"So there is a real aversion to letting evidence play a role in thinking about what we should do," he says. "Ethically, I find that really problematic."

Daniels says one ethical concern with CER is that it can't answer the question of whether an increase in the effectiveness of some drugs is worth the extra price. "There are some people who are trying to introduce cost in the process — but if you look at the actual definitions, they don't include cost," he says.

CER can determine whether one drug or intervention is more effective than another, but it won't tell you anything about the extra value you get compared to the cost, he explains. Similarly, if there is only one intervention for a certain condition, which is often the case for a period of time, then CER doesn't tell you whether the price of that treatment is worth the value or cost.

"CER could be helpful in telling us that something works better than something else, or doesn't work any better, and that might help us avoid some forms of waste, but may not tell us whether it's worth the price," says Daniels.

Always offering the more effective treatment regardless of price is an unsustainable system, says Daniels, and this is an important issue ethically.

"The kind of constraints that have been imposed on processes for making those judgments, by people who think of it as a kind of death panel, is really to tie both hands behind the back of decision makers in making any kinds of value judgments about health investments," says Daniels.

A fragmented health care system makes it more difficult to come to grips with making difficult but necessary choices about cost, argues Daniels. "If we were in a system in which payments for services all came out of the same pot, then you would have to make these choices," he says.

While insurers make all kinds of decisions about what's covered or not, "there are no processes or tools for the government to do so, says Daniels. "That strikes me as very bad thinking for how to value health investments."

Denial of access is ethical concern

CER involves comparing the outcomes of different treatment options for a specific medical condition for a specific population of patients, notes **Lisa S. Parker**, PhD, associate professor of human genetics and director of graduate education at the University of Pittsburgh's Center for Bioethics and Health Law.

Thus, it is important to ensure that the results of CER are then applied in practice to the same sort of patients as the population that was studied, she says, or, alternatively, that the potential for "slippage" of applicability of study results to the present population be taken into account.

"While treatment A may be found to work better than treatment B — the type of finding that results from CER — this finding is applicable primarily to the CER-study population," says Parker. That population may differ from the clinical population in a different health care system or different demographic group.

"Indeed, for a particular individual patient, it may be that treatment B would be superior," says Parker.

CER yields epidemiological results (i.e., results that are accurate at the population level, but that are not necessarily true of every member of even the population studied), explains Parker.

Therefore, a categorical denial of access to treatment B — or the decision to place A on a hospital's formulary and never prescribe B — may not best serve an individual patient's interests.

"Depending on the circumstances, it may be appropriate to review appeals from individual patients who want access to an option that does not emerge from CER as the superior intervention," says Parker. ■

SOURCES

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Right to privacy key concern with anonymous gamete donation

Some argue children should have access to information

The vast majority of gamete donations are made anonymously, but a growing number of countries are enacting laws allowing children access to identifying information about their gamete donor.

"Several ethical values are at stake," says **Inmaculada de Melo-Martín**, PhD, professor in the Division of Medical Ethics at Weill Cornell Medical College in New York, NY. These include the right of privacy of the donor, parental autonomy and privacy of the parents, and the interest of donor-conceived children in knowing their genetic origins.

"Depending on the importance that is given to these different ethical values, one might be more or less inclined to approve of anonymous donations, policies, and practices," says de Melo-Martín. Here are several ethical justifications for the permissibility of anonymous gamete donations:

• That donors should be able to choose whether or not to share personal information.

"The argument is that donors should be able to protect themselves against unwanted intrusions," says **Leslie P. Francis**, JD, PhD, distinguished Alfred C. Emery professor of law and distinguished professor of philosophy at University of Utah in Salt Lake City. For example, a donor at age 22 might not want to be contacted 20 years later, when he or she has moved on in life and established a family.

"Allowing donors to remain anonymous protects them from becoming involved at all stages," should there be any problems with the pregnancy or the child develop a disease at any age, says **Rebecca A. Marmor**, MD, a resident in the Department of Surgery at University of California San Diego.

"It protects the donor as the genetic offspring grow up from having to participate in the rearing of the child, either emotionally or financially," adds Marmor.

• That the possibility of anonymity must be present to encourage a ready supply of donors.

A 2014 study from Denmark found that if given the choice of remaining anonymous, or becoming known to their genetic offspring, 70% of sperm donors wished to remain anonymous.[1]

"Importantly, among those who wished to remain anonymous, only 17% stated they would continue to donate if their anonymity could not be assured," says Marmor.

Allowing children access to information

The main justification usually given for allowing children access to identifying information on gamete donors, says de Melo-Martín, is that such information is needed for the formation of a healthy identity.

"Access to the identity of the genetic progenitors is thought to be necessary to help make sense of one's physical characteristics, talents, or interests," she adds. "It can give context to questions about family resemblance."

Ethical justifications for allowing children access to identifying information include a belief that knowledge of their genetic makeup may serve to improve their health and lead to more stable family relationships and a stronger self-identity. "There is a paucity of evidence to support any of these claims," says Marmor.

In a 2014 Hastings Center Report, de Melo-Martín questions the ethical justifications that are often thought to ground a right to know one's genetic origins.[2] She argues that although some of the interests that such right is intended to protect — strong family relationships and health — can be recognized as weighty ones, there is no evidence that such interests are set back by anonymous gamete donations.

"Anonymous donations do not prevent parents from disclosing donor-conceived individuals' mode of conception," adds de Melo-Martín. Similarly, anonymous donations allow donor-conceived people access to relevant health information.

"Furthermore, even the evidence that failing to disclose one's mode of conception adversely affects these interests is, at best, ambiguous, and at worst, nonexistent," says de Melo-Martín.

Some argue that lacking access to identifying information can hinder the forging of healthy identities in donor-conceived children.

EXECUTIVE SUMMARY

While the vast majority of gamete donations are made anonymously, a growing number of countries are enacting laws allowing children access to identifying information about their gamete donor. Key ethical concerns are:
• right of privacy of the donor;
• parental autonomy;
• the interest of donor-conceived children in knowing their genetic origins.

"The understanding of identity in this argument has been questioned — is identity tied to genetic origins, or social, or constructed in some other ways?" asks Francis. "Another question about this argument is whether the interest in identity formation is stronger than the donor's interests in autonomy and privacy."

Another argument is that medical history information may be very important to the health of any children born from the donation. "Perhaps the most compelling reason that offspring ought to have access to identifying information about their donors is on the grounds that such information could be used to promote the health of the offspring," says Marmor.

However, says Francis, "it is, of course, possible to arrange for medical history updates about the donor to be shared with offspring without having the donor's identity itself shared."

The age a child should be allowed access is another unresolved question. "Some argue that children under the age of majority should not receive information that they might not be able to handle psychologically," says Francis.

Childrens' autonomy interests

Some argue that parents of minor children have rights regarding what information is shared with their children, and that their desire for donor anonymity must be respected. "When children become adults, however, their own autonomy interests arguably are what should be considered in revealing donor identity, not the interests of their parents," says Francis.

A study from Sweden, where legislation has mandated that children have access to identifying information about their donors since 1985, revealed that 89% of parents had not informed their children of their status.[3]

"Studies such as this illustrate that mandating the availability of identifying information for donor offspring is not a very effective way to increase the acceptance and understanding of this form of conception," says Marmor.

In fact, even when offspring are guaranteed some basic information about their gamete donors, most parents still do not reveal that their children were conceived from gamete donors.

"Not surprisingly, children born to lesbian and gay couples are often more informed about their status as donor offspring," says Marmor.

A recent study from Belgium examined the place of the gamete donor in children born to lesbian couples. In some families, the donor was viewed as an "instrument," necessary for the child's conception, whereas other families offered a more personalized account of the donor.[4]

"This illustrates a fundamental point: A child's knowledge and acceptance of his or her genetic origins is often modulated by the narrative developed by parents, should they choose to divulge the circumstances of his or her conception," says Marmor. ■

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COMING IN FUTURE MONTHS

■ Quality attestation for clinical consults
■ Use of sedation at the end of life
■ Approaching families for organ donation
■ Disclosure of adverse events affects patient-physician relationship

CME QUESTIONS

1. Which is true regarding legal requirements for end-of-life care, according to **Alan Meisel**, JD?
   A. Even close family members have no legal authority to make decisions for a patient who lacks decision-making capacity, except with appointment by a court as a guardian.
   B. Only when there is some conflict among potential surrogates, no one to serve as surrogate, or a poten-

tial surrogate whom health care providers believe not to be acting in the patient's best interest, does a court-appointed guardian need to be sought.
C. Federal and state regulations requiring that patients are provided with adequate nutrition always require feeding tubes, even if the feeding tube has been declined by a competent patient.
D. In order to forgo life-sustaining therapy, providers need to have complete knowledge of a patient's actual wishes.

2. Which is true regarding use of physicians' prescribing data by pharmaceutical companies, according to **David Orentlicher**, MD, JD?
A. There is clear evidence that drug company promotions decrease the likelihood that patients will get prescribed a more expensive drug.
B. Drug companies primarily promote drugs that still have patent protection, decreasing the likelihood that a patient will be prescribed a generic drug.
C. Prescription data mining does not utilize information that could be considered as part of the physician/patient relationship.
D. Drug companies' use of the information is ethical because there is no possibility of it undermining the interests of individual patients.

3. Which is true regarding ethical concerns with "stem call tourism" according to **R. Alta Charo**, JD?
A. Where there is confusion about whether a treatment has been developed or offered in full accordance with legal requirements, a patient's consent cannot be informed.
B. All currently advertised therapeutic applications for stem cell treatments have been subjected to well-controlled trials, even outside the United States.
C. There have been no cases of domestic clinics offering therapies which had not been submitted to the Food and Drug Administration for the required review and approval before being offered to the public.
D. Evidence shows that increasing focus on "stem cell tourism" is helping the general public to distinguish a registered clinical trial from an unproven intervention.

4. Which is true regarding ethical considerations involving comparative effectiveness research (CER), according to **Chris Feudtner**, MD, PhD, MPH?
A. There is no evidence that CER has the potential to improve outcomes, either for individual patients as well as groups of patients.
B. There are no cases in which CER clearly imposes no significant marginal increased risk of a bad outcome for a patient.
C. It is common in CER to compare two treatments that both could be considered standard of care.
D. Risks for subjects are increased significantly when it is not known which treatment is better or worse.

CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.
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Medical Ethics Advisor

2014 Reader Survey

In an effort to learn more about the professionals who read *Medical Ethics Advisor*, we are conducting this reader survey. The results will be used to enhance the content and format of this publication.

Instructions: Please fill in the appropriate answers and answer open-ended questions in the space provided. Either fax the completed questionnaire to 404-492-5933, or return it in the enclosed postage-paid envelope. The deadline is **July 1, 2014**.

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O A. very satisfied O B. somewhat satisfied O C. somewhat dissatisfied O D. very dissatisfied

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9. end-of-life care	O A	O B	O C
10. patient autonomy	O A	O B	O C
11. organ donation/transplantation	O A	O B	O C
12. spiritual/pastoral care	O A	O B	O C
13. committee orientation/education	O A	O B	O C
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O A. fewer than 10 minutes O C. 21-30 minutes O E. more than an hour

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