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INSIDE

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Lawsuits Allege Patients' End-of-Life Wishes Ignored

Courts are recognizing unwanted care as compensable harm

A 91-year-old woman presented to an ED, advance directive in hand, indicating her end-of-life instructions. In addition, her granddaughter stressed to caregivers that no heroic measures were to be taken. Despite these efforts, the woman was intubated and operated on, and the family sued the hospital.

"Our client was very much aware of advance directives, having had a family member suffer unnecessarily, and insisted on having hers in her hand whenever she went to see the doctor," says **Harry Revell**, JD, an attorney at Augusta, GA-based Nicholson Revell, who represented the patient's family.

The patient's advance directive was never added to the patient's chart. "However, it was documented in the chart that there should be no intubation without first contacting the patient's agent," says Revell.

> "THERE WAS, WE THOUGHT, A FLAGRANT AND OBVIOUS CONSCIOUS CHOICE TO IGNORE THE PATIENT'S INSTRUCTIONS, BOTH WRITTEN AND VERBAL."

The hospital had appropriate policies in place for advance directives. "The problem was, they didn't follow them," says Revell. "There was, we thought, a flagrant and obvious conscious choice to ignore the patient's instructions, both written and verbal."

The hospital filed a motion for summary judgment, which the trial court denied. That ruling was later affirmed by both the Georgia Court of Appeals and the Georgia Supreme Court.[1,2] The case

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EDITORIAL QUESTIONS
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settled for $1 million shortly before trial — an amount that the family insisted would not be confidential. "We feel it's important for the public to be informed about this issue, and for healthcare providers to be mindful of this," says Revell. "The amount will hopefully get everybody's attention."

The legal team searched for similar cases or settlements, but found none. "There was literally nothing out there," says Revell. "We hope this case being out there in the public domain will inform others who are thinking of taking these kinds of cases."

'Absolute, Unqualified' Right

Robert Schulte, JD, an attorney at Schulte Booth in Easton, MD, recently handled a similar case. An 83-year-old woman, who had completed a Medical Order for Life-Sustaining Treatment (MOLST) form stating she wanted no life-sustaining interventions, was found in cardiac arrest and successfully resuscitated. The woman's son sued, alleging assault, negligence, and intentional infliction of emotional distress.

"An adult has an absolute, unqualified right to refuse medical treatment," stresses Schulte. Schulte doesn't believe healthcare providers are deliberately ignoring patients' wishes; rather, it's that clinicians are hardwired to save lives. "When they find a patient in distress, in the face of ignorance of the patient's wishes, they are going to default to saving the patient's life," says Schulte.

Hospitals are vigorously defending these "wrongful prolongation of life" cases, arguing that no compensable harm was done. "Hospitals do wonderful work, but they are businesses and protect their interests," says Schulte. "They don't like these cases, and they are defending them aggressively."

The defense argued that the doctors and hospital had not harmed the patient and, in fact, saved the patient's life. "The hospital argued that we may have violated your rights, but at the end of the day we did not harm you," says Schulte.

Schulte says this is a flawed argument. In this particular case, the woman recovered fairly well with a reasonable quality of life. "But if you change the facts a little bit, it can get very dicey," says Schulte. For instance, the woman could have suffered another stroke after being resuscitated against her wishes, putting her into a persistent vegetative state, and lived another 10 years at the cost of $100,000 a

EXECUTIVE SUMMARY

Several recent lawsuits alleged that patients were harmed by unwanted care because their end-of-life wishes were disregarded by the clinical team, with one case resulting in a $1 million settlement against the hospital. To ensure ethical and legal obligations are met:

- ensure hospital policies on advance directives are followed;
- avoid giving families the unnecessary burden of deciding to withdraw care that was already refused by the patient;
- take a "time out" to confirm patients' code status.

month. "Who owns that? According to the hospital, not them — they saved your life," says Schulte.

In most states, if a healthcare provider withholds or provides treatment consistent with the patient's stated wishes on a MOLST or POLST (Physician Orders for Life-Sustaining Treatment) form, they are immune from lawsuits alleging negligence. "That is a pretty powerful defense to any subsequent claim from family members saying, 'Why didn't you intubate?' or 'Why didn't you give them heart stimulant drugs?'" says Schulte.

While providers have immunity for acting in accordance with patients' wishes, providers are legally exposed if they contradict patients' wishes. If a patient has a documented MOLST or POLST form, says Schulte, "You get immunity for following it, but you don't have immunity for violating it."

Previous court rulings have looked at whether receiving unwanted care can be recognized as a compensable injury. Most have said it does not.[3] "The queasiness of the courts in these cases reflects, in my judgment, a collision of philosophy, religion, and of medical ethics," says Schulte. "But I think the ice is cracking a bit." This may be due in part to a growing awareness of the medical and financial consequences that follow a decision to give aggressive end-of-life care against a patient's stated wishes.

A recently filed lawsuit involved an 89-year-old woman who was resuscitated despite having DNR and DNI orders, and lived another six months. The woman's daughter sued, claiming that her mother endured unwanted pain and suffering as a result of the prolonging of her life.[4]

"The law does give us the undeniable right to say what is to happen when our final hour comes," says Schulte. "Unfortunately, in practice, I don't think we're quite there yet. It may take some more cases."

Ryan R. Nash, MD, MA, FACP, FAAHPM, director of the division of bioethics at The Ohio State University College of Medicine in Columbus, is aware of several lawsuits alleging patients were harmed by unwanted treatment.

"Generally, the cases aren't outlandish. They are not claiming anything other than the physician or hospital failed to follow their own policies," says Nash.

In addition to ensuring that policies on advance directives are followed, Nash says physicians and staff should be making an effort to confirm the patient's code status.

"If you have a patient with a poor prognosis, not knowing the code status at handoff is not meeting the standard of care," says Nash. A common example: A patient is admitted from the ED and an advance directive noting the patient's DNR status is provided — but physician orders don't reflect this.

"If they give resuscitative efforts when patients have explicitly stated they don't want it, then they are not meeting the standard of care," says Nash. Often, information on the patient's wishes is available somewhere — whether on a paper document handed to an admissions person, or somewhere within the electronic medical record (EMR) — but isn't readily available when it's time to make a decision. "We don't need to be making default decisions. Right-sizing of care is what we want, for the right treatment that is desired, not refused treatment," says Nash.

Nash encourages resuscitation teams to use a "time out," similar to the approach used prior to surgeries, to make an effort to determine the patient's code status: "It could be someone's job to decide if this is right care, or already-refused care."

Clinicians may prefer to "err on the side of caution" by providing care, believing that no harm will be done since the family always can reverse the decision at a later point in time; however, this is ethically problematic.

"It's not just the burden of ongoing life that is the main problem," says Nash. "It's that these were refused treatments."

Providing aggressive care against the patient's wishes forces surrogates to make a decision to withdraw it — when the decision was already made by the patient. "It does harm to the family member, by forcing them to make a decision they never wanted to make and should not have to make," says Nash.

Recognition by Courts

The widely publicized wrongful prolongation of life cases could thwart efforts to promote advance care planning. "If the whole idea is to avoid the treatment you don't want and get the treatment you do want, it's going to be harder to sell that if it's not true," says **Thaddeus Mason Pope**, JD, PhD, director of the Health Law Institute and professor of law at Mitchell Hamline School of Law in St. Paul, MN.

The recent "wrongful prolongation of life" lawsuits share the following fact patterns:

- the patients clearly rejected some type of life-sustaining treatment, such as intubation or CPR;
- the patient and/or surrogate communicated this to treating clinicians verbally or in writing, or both;
- the patient received the very

same intervention they'd expressly said was unwanted.

"We are seeing more and more of these cases, and that's not a surprise because we keep promoting the promise of advance care planning," says Pope.

The right to refuse treatment, even if it's life-sustaining treatment, has been an ethical and legal right since the landmark 1976 *Quinlan* case. Still, patients' wishes are not always followed. "I think it happens a lot, not usually intentionally," says Pope. Often, it's a system or communication problem at issue — the advance directive or the POLST form isn't entered into the chart, or isn't easily accessible in the hospital's EMR. "It's more negligence instead of a deliberate wrongful act," says Pope. "Still, the prevalence is reasonably high of not honoring recorded preferences of incapacitated patients."

By providing unwanted treatment, often someone is kept alive who otherwise would have died. "In the past, the courts were not sure what to do with that — how is it a harm to be alive?" says Pope.

As the recent cases show, courts now are recognizing unwanted care as a compensable injury. A surge in similar cases is likely, says Pope. "This is both because the law supports it, and the dollar value of the cases makes it economically feasible to bring these cases. There is actually real money here." ■

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Disclosure of Errors Not Documented — Even if Patient Seriously Harmed

Very few disclosures of medical errors or apologies to the patient or relatives were documented in medical records, found a recent analysis of malpractice claims.[1]

To provide preliminary estimates of incident disclosure behaviors on medical malpractice claims, researchers analyzed data on 434 claims between 2012 and 2013. Rates of disclosure did not increase between 2011 and 2013, despite efforts to encourage disclosure of adverse events during this time period.

"Frequently, it's very difficult to know whether an error occurred or not. So timing also plays a part in this," says **Luke Sato**, MD, one of the study's authors. Sato is senior vice president and chief medical officer at CRICO, the patient safety and medical malpractice insurer for the Harvard medical community, and an assistant clinical professor of medicine at Harvard Medical School in Boston.

Of the 434 medical malpractice claims, only 20 medical errors had been disclosed to the patient at the time of the error; 26 were followed by disclosure and apology. Of the disclosed errors, 26% led to an adverse reaction, and 17% were fatal. No apology statement was issued in 55% of medical errors classified as high severity. Volume of malpractice claims also remained unchanged.

The motivation for the study was to see how frequently the disclosure process was documented when a malpractice claim occurred, says Sato.

Massachusetts' Health Payment Reform Act, which became effective in November 2012, requires disclosure of unanticipated outcomes with a significant medical complication. However, at the time the study was conducted, there was no formal disclosure process. "Therefore, even if an error was disclosed, it was rarely documented in the medical record. Our findings

were not unexpected," says Sato.

The researchers expected the rate of error disclosure to be very low, based on the timing of the state's law. "Given the timing of this, we were not at all surprised the practice was not ubiquitous," says Sato. "If we were to repeat the study and still see somewhat low incidents of disclosure now, that would be problematic."

There is growing evidence to support early disclosure of errors. Every error should be evaluated for whether it needs to be disclosed, says Sato.

"The nuances are challenging. We are currently learning how best to do it," says Sato. "A tremendous amount of learning has been accumulated over the past five years."

At Brigham and Women's Hospital, providers encourage patients to seek legal counsel in some cases, says Sato. This saves time and money for everyone involved. In some cases, the attorney discourages the patient from moving forward with a frivolous complaint. On the other hand, valid cases are resolved more quickly with early discussion and transparency.

"Resolution of those cases tends to be a lot smoother, and more compassionate for the patient's family and for the caregivers involved," says Sato.

Training Is Helpful

Error disclosure, teamwork, and safety culture all improved over a three-year period during which disclosure training was provided to key faculty at the Austin-based University of Texas Health System.[2]

"If a healthcare organization does not have a disclosure culture, it is possible that providers will be less likely to disclose errors and patients will be less likely to know about issues that have impacted their healthcare," says **Eric J. Thomas**, MD, MPH, one of the study's authors.

The intervention did not involve a large number of clinicians at the institutions. Therefore, the improvement in disclosure culture was a pleasant surprise.

"But the clinicians we chose were leaders, and they likely impacted others through additional training," says Thomas, a professor of medicine at the University of Texas Houston Medical School and director of the UT Houston-Memorial Hermann Center for Healthcare Quality and Safety.

More clinicians perceived their work environment as being supportive of disclosing errors after the training. Self-reported likelihood to disclose errors also improved.

"The results are encouraging in that they indicate that specific training on error disclosure was associated with intent to disclose an error," says **Jason Etchegaray**, PhD, the study's lead author and a senior behavioral and social scientist at the Rand Corporation in Santa Monica, CA.

This is an important first step in changing behavior. "Ideally, a follow-up study would demonstrate a specific relationship between error disclosure training and actual disclosure behavior from providers," says Etchegaray. ■

EXECUTIVE SUMMARY

Medical errors or apologies were infrequently documented even if patients were seriously harmed, found a recent study.

- The study was conducted prior to enactment of the Massachusetts law requiring disclosure of unanticipated outcomes with a significant medical complication.
- Disclosure documentation has presumably increased significantly after the 2012 law was passed mandating this practice.
- Safety culture improved after disclosure training was provided to physician leaders.

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'Feel-Good Approach' Is Not Enough: Assess Quality of Ethics Consults

Poorly performed consults can harm patients

Quality of clinical care routinely is assessed using myriad established approaches, with patient safety issues addressed with such proven methods as root cause analyses. On the other hand, quality of ethics consultations often is not addressed at all.

"My perception is that I don't think most places do assess the quality of their consults," says **Timothy Kirk**, PhD, assistant professor of philosophy at the City University of New York-York College in Jamaica.

Lack of required expertise and unclear criteria make such assessment challenging, but Kirk says it's important to remember that a bad consult is worse than no consult at all. Poorly performed, ethics consults can lead to the wrong people being involved in decision-making, violation of patients' rights, and exposure to legal risk.

"Consults are not neutral. Like any intervention, they can bring both benefit and harm," says Kirk. "If you are not tuned into that, you may not see the value of quality assessment."

"What are you trying to assess?" and "What are the best ways to assess it?" are surprisingly difficult questions to answer when it comes to measuring the quality of ethics consults.

"If you are going to assess anything, you have to identify the quality measures up front," says Kirk. "Only if you have clear goals can you afterward assess if the goals were met."

A well-crafted ethics consult policy can help with this. Are ethicists required to review the chart and consult with stakeholders, and hold family meetings? If so, says Kirk, "one way to assess quality is to assess those process measures."

Timeliness of consultants' responses also is easy to quantify, with a feedback mechanism from users on how quickly requests for consults were met. For instance, the policy might state that a consultant should respond to a request within six hours. If only three consultants responded in the target time frame for 24 requests, it could reveal a problem in how requests are coming in. "It might be that they are coming in through an email portal, and it's difficult to check because none of the consultants have access to it from their smartphones," says Kirk. In this case, it might be better for requests to come in through phone calls.

Outcomes measures are harder to assess. "Policies don't always identify what the outcomes of a successful consultation would be," says Kirk. Some policies aren't clear enough on this point. Another confounding factor is that the outcomes measures for a successful consult differ, depending on the issue at hand.

If family members disagree with one another on a treatment plan for their mother, it would seem logical to use resolution of the conflict as an outcome. "But even that is not necessarily a realistic outcome to hope for," says Kirk.

Even if the ethicists employ top-notch mediation skills during a lengthy family meeting, the outcome could be that the family still disagrees. "I'm not sure that means it was a bad consult. It means it was a hard family," says Kirk.

Kirk says that the question of whether the ethics consult affected the care that was delivered is particularly difficult to answer. Categorizing consults, then identifying an outcome associated with the type of consult, is a possible approach. "In healthcare, the question, 'Was the infection resolved?' is yes or no. With ethics consults, it's not that easy," says Kirk.

Another obstacle is that the skill set required to be a good ethics consultant is very different from the skill set required to perform data analysis. "If someone comes to ethics through philosophy or theology, they probably have zero statistics training and very little experience in quantitative analysis," says Kirk.

While ethicists probably agree with the notion that it's good to perform quality reviews, many have no idea how to accomplish it. "But that's not insurmountable," says Kirk. "It may be a stretch, but somebody in

EXECUTIVE SUMMARY

Assessing quality of ethics consultations is difficult due to lack of resources and easily measurable outcomes. Some approaches include the following:

- include specific process measures in policies;
- look for trends in timeliness of responses to requests;
- enlist the help of colleagues with data analysis skills.

the organization is doing quality work and they can learn from that person."

Without clear criteria to strive for, ethics is in danger of relying on a "feel-good approach," says Kirk. "You just talk about things that are hard, and hope that afterward things are better. But you don't have clear aims."

Cases can be reviewed monthly, quarterly, or annually to get a general idea of whether consultants are meeting expected standards of practice. "Other approaches are finer-grained, and might delve into evaluation of individual chart notes written by consultants," says **Joshua Crites**, PhD, a bioethicist at Cleveland (OH) Clinic.

Some ethics consult services have developed tools so evaluation can look for the presence of recommendations and ethical analysis. "A few services across the country are going even further to begin assessing the thoroughness of such analysis," says Crites.

Little has been done to compare data across ethics consult services nationally. "As a result, quality assessment has largely been siloed, outside of efforts to ensure quality through the certification of individual consultation through a standardized process," says Crites.

An added challenge: There is no consensus on the single best method to evaluate ethics consults. "The current methods we employ all seem to have drawbacks," says **Courtenay R. Bruce**, JD, MA, assistant professor of medicine and medical ethics at the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston. Some approaches and limitations include the following:

• Documentation in the medical record doesn't tell the whole story.

An ethicist can write a stellar note, yet have terrible interpersonal skills. "This 'error' would not be picked up through a chart review," says Bruce. "Chart notes can only tell us so much about what occurred in a case."

• Debriefing sessions rely on ethicists' willingness to criticize colleagues who often are present during the discussion.

"Out of a need to maintain respect and professional relations, clinical ethicists may feel obligated to be 'nice' to their colleagues who conducted the case," says Bruce. This undermines the purpose of a rigorous review.

• Spot-checking cases means many consultations aren't evaluated.

• Peer review, with ethicists watching colleagues conduct cases, makes the case prone to observer effects.

Bruce says the solution is for ethics quality improvement to include all these methods, supplemented with feedback from clinicians, patients, and families: "By using a combination of methods, you can identify the strengths and weaknesses of cases and consultants."

Most markers of high quality in ethics consultation come from expert consensus, rather than from empirical data. "This is not surprising, given that ethics consultation grew largely organically out of, but separately from, healthcare delivery," says Crites. Thus, the outcomes, structure, and processes of ethics consultation have largely been derived from within the practice itself.

This has resulted in a situation where defining and measuring quality is performed by ethics consultants themselves. "I think it would be more effective, in some ways, to have greater input from users — patients, families, and care providers — about what they believe would be most helpful from ethics consultation," says Crites.

These data can then be used to determine what is meant by "quality," and assess if the service is delivering consults that are high-quality in the eyes of those who utilize the consults.

The Cleveland Clinic's ethics consult service surveys stakeholders to gauge their satisfaction with the ethics consult. "Our efforts have attempted to extend beyond simple satisfaction, such that we are trying to assess 'value-oriented' satisfaction," says Crites. This is an attempt to evaluate, from the end-user's perspective, what value was added to a patient's care by including an ethics consultation.

"Data gathered about various types of satisfaction help ethicists see areas for improvement that may not have been as apparent through other methods of assessing quality," says Crites.

Clinicians might want ethicists to help them handle similar ethical issues in the future, for example. A retrospective chart review wouldn't reveal this, but asking clinicians, "How can the ethics consult service do things differently in the future?" might.

Conducting retrospective case reviews does allow ethicists to identify patterns of requests in specific areas of the hospital. "Ethicists can then plan targeted education in those units to improve care providers' ability to manage ethical issues on their own," says Crites. ■

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'Decision-makers of Last Resort' Pose Unique Ethical Challenges

Surrogates sometimes vehemently disagree, despite all attempts to resolve the conflict. In other cases, there's simply no one to speak on the patient's behalf.

Either way, the clinical team is forced to turn to the courts or government if an important medical decision must be made.

"A problem that often occurs when there is court-appointed guardian involvement is that there is an assumption that all conceivable medical treatments be delivered," says **Kenneth Covinsky**, MD, MPH, a professor of medicine at the University of California, San Francisco.

Courts sometimes take this position even if the burdens are great and the chance of benefit is minimal. "There is always an obligation to act in the patient's best interest," Covinsky says. "It is never appropriate to subject a patient to a treatment that can only harm them and not benefit them."

Some patients aren't able to make their own medical decisions and don't have a family member who can make decisions for them. "In my clinical work, this is the most common reason we go to the courts," says **Andrew B. Cohen**, MD, PhD, an assistant professor of internal medicine at Yale School of Medicine in New Haven, CT.

Often, these are patients with undiagnosed cognitive impairments. "They have been living in the community and then have an acute medical issue, so they come to the hospital," says Cohen. Healthcare providers realize the person can't make decisions for him- or herself, but have no idea who to turn to.

At this point, it becomes necessary to petition the court to appoint a guardian or conservator as a surrogate decision-maker. This process can take several weeks. "There can be uncertainty among the clinical team about what to do if decisions have to be made in the meantime," says Cohen.

In Ontario, Canada, the Treatment Decisions Unit of the Office of the Public Guardian and Trustee (OPGT) is at the bottom of the hierarchy of decision-makers.

"If no other surrogate decision-maker is available, they will be the decision-makers of last resort," says **Bob Parke**, BA, BSW, MSW, MHSc (Bioethics), bioethicist at Humber River Hospital in Toronto, Ontario.

Parke frequently works with OPGT to seek consent for treatment that is needed but not emergent. "When we approach them, it is the same as approaching any other surrogate decision-maker," he explains.

The healthcare professional must explain the benefits and the risks of the proposed treatment. The OPGT either will consent to the treatment or deny consent. Part of the process includes determining whether the patient has any values that might affect the decision.

"One of the challenges of working with the PG&T is that they do not like to make DNR [do not resuscitate] decisions. They like to make present-oriented decisions — for example, surgery that is required," says Parke.

Parke has found that OPGT is more likely to make a DNR decision if it is put within the context of a palliative care plan. "On some occasions, they will want to see the patient. Generally speaking, this does not take too much time," says Parke.

The following are three scenarios that necessitate getting the courts involved in medical decision-making:

• A decision must be made as to whether the hospital can discontinue treatment that providers believe is futile.

In this scenario, going to court is "really a last resort," says **Carl H. Coleman**, JD, a professor of law at Seton Hall Law School in Newark, NJ. "I don't think anyone, including the courts, thinks that they are best suited to resolve these issues."

Ethicists can make a last-ditch effort to defuse seemingly intractable conflicts before the courts step in. "I think a lot of these so-called futility cases are about communication and understanding what's really going

EXECUTIVE SUMMARY

Court-appointed or governmental guardians may need to make treatment decisions if surrogates disagree, or if no surrogate is available. Some ethical considerations include the following:

- Courts often assume that all conceivable medical treatments must be delivered.
- There always is an obligation to act in the patient's best interest.
- It is never appropriate to subject a patient to a treatment that can only harm him or her.

on," says Coleman. "People may have misconceptions about what is possible medically."

If mediation is unsuccessful, the ethicist still has a role to play once the courts become involved. "The ethicist should make sure any information that is relevant to the patient's best interest is before the court," says Coleman.

The court will assess the evidence and make a determination. Procedures for this vary depending on the state. "There aren't a lot of cases that have made their way to a judgment to a court, so how a court would make a judgment is still unsettled in a lot of states," notes Coleman. Texas law provides for a process where the hospital is required to provide an opportunity for a patient to be transferred to another facility, if the hospital is refusing to provide requested care.

"In that framework, you wouldn't have a court making a judgment as to whether the judgment of medical futility is correct. It would be more whether they are following the procedural requirements," says Coleman. In states that do not have legislation establishing a procedural framework, the courts may have to decide whether treatment can be stopped that providers believe is futile. "This is an issue that's getting a lot of attention," says Coleman. "More states may consider enacting legislation similar to what Texas has done."

Not surprisingly, legislators are wary of taking a stand on this controversial issue. "When people were not allowed to refuse treatment, that affected an enormous amount of people, and led to a groundswell of public support for legislative changes," says Coleman.

This is the reverse issue — where treatment is being provided, but healthcare providers don't think it's a benefit. "Healthcare providers who refuse to provide futile treatment are unlikely to garner as much public support," says Coleman.

• A patient has no surrogate, and a decision must be made.

Parke recently was involved in the case of Hanna, a woman of European origin who had no family in North America, but close relationships with colleagues at work. "When she did not show up for work, friends sought help and found that she was collapsed at home," says Parke. She was admitted to the hospital without decision-making capacity, and unrepresented. Urgent surgery was required, but this did not meet the legal test of an "emergency." "The surgeon wanted to proceed in a timely way and wanted consent to proceed," says Parke. "Nursing staff facilitated the consultation with myself as the bioethicist."

Parke met with Hanna's friends, who assured him that she would most likely consent to surgery as it was the best chance for recovery and quality of life. "Their perspective helped us to assert that as a capable and 'reasonable' patient, she would consent to surgery," says Parke. The discussion was documented in the patient's health record and available for the surgeon.

Since consent was required to proceed with surgery, Parke then connected the surgeon with the OPGT. Within a few minutes, consent was granted, allowing the team to move forward with surgery.

The entire consultation process was completed in a few hours. "In this particular scenario, the combination of treatment and surgery brought Hanna back to her previous capable self, surrounded by friends and pleased to be recovering," says Parke.

• A patient's equally weighted decision-makers cannot agree on a treatment plan.

If a patient named two people who disagree as power of attorney, the OPGT makes the decision — unless the two decision-makers can find a way to agree. "Almost universally, the surrogates find a compromise when they hear that the government will make decisions on their behalf," Parke reports.

An overwhelmed family caregiver wanted to put her mother in a nursing home. Her siblings — equally weighted decision-makers — disagreed. "After much deliberation and no consensus being arrived at, I informed the patient's children that I would have to turn to the government to make the decision," says Parke.

The three siblings asked for some time together. Shortly afterward, they came up with a compromise: Their mother would go back to the care of the daughter, with the other siblings helping out. If the arrangement didn't work out, admission to a nursing home would be arranged.

"After another attempt at home, their mother was admitted to a nursing home," says Parke. "The caregiving burden was recognized as too great to be managed at home." ■

SOURCES

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'Little Quality Evidence' for Marketing MRT as Fertility Treatment

The doctor who delivered the first "three-parent" baby is seeking to commercialize mitochondrial replacement therapy (MRT) by marketing a treatment to older women who want to produce viable embryos — at a cost of $80,000 to $120,000.[1]

"Among the concerns in commercialization of MRT is that it will be offered beyond the specific indications in its approval by the FDA, if and when that were to happen," says **Jeffrey Kahn**, PhD, MPH, Andreas C. Dracopoulos director of the Johns Hopkins Berman Institute of Bioethics in Baltimore.

Last year, an Institute of Medicine (IOM) committee recommended that such approval be considered only for cases of severe mitochondrial disease, in which there is a high level of certainty it will be passed on by mother to child.[2]

"The concern in commercialization is that the technology would be used beyond that limited approval, to include offering to women for addressing infertility," explains Kahn, who chaired the IOM committee.

The FDA sent a cease and desist letter to the company. "That will limit attempts at such commercialization, so long as they fall within FDA jurisdiction," says Kahn.

MRT used to boost fertility is an experimental and unproven treatment, and it is inappropriate to offer it commercially, according to **Ainsley Newson**, PhD, associate professor of bioethics at University of Sydney in Australia. "Yes, women may say they want it — and yes, IVF is expensive and can be risky with or without MRT. But this does not mean that providers should market treatments for which there is little quality evidence," says Newson.

As there is insufficient data on the long-term safety implications of human use of MRT, adds Newson, "it should be limited to use in couples who are at risk of passing on a disease encoded by mitochondrial DNA, who have no other viable options, and who have engaged in careful counseling with appropriate experts."

Katherine Drabiak, JD, assistant professor in the department of health policy and management at Tampa-based University of South Florida, sees multiple ethical concerns with the commercialization of MRT.

"In the U.S., this provides a prime example of one physician circumventing FDA jurisdiction to integrate risky experimental procedures into clinical care," argues Drabiak.

The available evidence fails to support the finding that MRT would be safe or effective, and demonstrates serious risks associated with the procedure, adds Drabiak. "Most of us hope for science and medicine to treat disease and relieve suffering — mitochondrial disease or infertility," she says. "But this appeal to emotions distracts the public away from evaluating whether the current science supports the safety and efficacy of MRT."

Drabiak argues that promotional claims, not scientific fact, directed the policy outcome relating to MRT both in the U.K. and in the U.S.[3]

"The media has praised physicians engaging in fertility tourism to allegedly dodge unnecessary regulations, while generating publicity to expand a highly profitable commercial market that exploits parents' primal desire to have a biologically related child," says Drabiak.

Approximately 40 countries have adopted legislation prohibiting germline intervention on embryos. Drabiak rejects arguments that the U.S. is falling behind by failing to invest in promising genomic technologies.

"These laws demonstrate the opposite," she says. "Many countries acknowledge the lure of technology, but renounce risky experiments that cross the historical bright line of manipulating future generations." ■

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Pain Research Can Harm Participants

Researchers must pay greater attention to the rights of study participants in pain research, concludes a recent paper by the Ethics Committee of the Pain-Omics Group.[1]

"Patients in pain, particularly chronic pain, are vulnerable by virtue of being in pain and in their desire to be relieved of pain," says **David B. Waisel**, MD, senior associate in perioperative anesthesia at Children's Hospital Boston and associate professor of anesthesia at Harvard Medical School. Waisel authored a recent review which found multiple, continuing ethical issues involving research on patients in pain.[2]

"A narrow path permits providing good clinical care, doing good research, and protecting patients from a desperate headlong rush into research that may prove deleterious to them," says Waisel.

Some of the ethical issues Waisel found are widespread, but also are relevant to pain research. These include scientific misconduct, deception, placebo use, and genomics. Other ethical concerns are unique to pain research, such as research in neonatal pain management. "I approached this paper with the goal of including issues that were not commonly talked about," says Waisel. Some unique ethical concerns in pain research include the following:

• Some studies inadequately manage pain in neonates. "Relatively minor procedures in the neonate, such as heel pricks, can have lifelong consequences," says Waisel. "Too often, neonates do not receive pharmacologic or nonpharmacologic analgesia."

While there are a number of validated analgesic therapies, most studies assessing pain management in neonates do not use these validated therapies in the control group. "This exposes the neonate to unnecessary harm and possible long-term consequences," says Waisel.

This may be due to a misunderstanding that a new intervention needs to be compared to a placebo instead of to current therapies. "That is untrue, and, in fact, harmful to neonates," says Waisel.

• Genetic pain research involving biobanking — the saving of a person's tissue — raises privacy concerns. "This research is both incredibly valuable and very dangerous," says Waisel.

There is a debate about how to ensure proper informed consent regarding privacy, known and unknown long-term harms, and use of the tissue for future undefined studies. "There are no set answers for these questions, but researchers may prioritize the sacred trust of holding individuals' genomes," says Waisel.

• Research fraud. A major scientific misconduct case involving multimodal pain therapy was discovered in 2009.[3] Misconduct in pain research may lead to direct patient harm.

"Or there could be wider patient harm due to invalid data from inappropriate subject recruitment and data fabrication, falsification, or substandard research," says Waisel.

As with all research with human subjects, pain research by responsible investigators must ensure that participants are fully informed of the goals, procedures, and risks of the study before giving their consent. However, there's another important ethical consideration for participants who are in chronic, debilitating pain.

"Researchers have an added obligation that they are not providing consent in desperate situations," says **Robert Guerin**, PhD, a bioethics fellow at Cleveland (OH) Clinic and an adjunct instructor in bioethics at Case Western Reserve University.

Potential participants may feel they have no choice but to enroll in the study in order to relieve terrible pain. "Such desperate situations lead to vulnerabilities to coercive enrollment in clinical trials," says Guerin. He says pain researchers also have an ethical obligation to ensure that research subjects are not subject to stimuli that exceed a subject's tolerance limit; that subjects should be able to escape or terminate a painful stimulus at will; and that minimal intensity of noxious stimuli necessary to achieve the goals of the study must be established and not exceeded.

"This should be discussed during the informed consent process," says Guerin. "This ensures that patients are not subject to unnecessary harm during research."

Trust between investigators and study participants is important in all research with human subjects. Its importance is perhaps more pronounced in pain research. "Participants must feel no pressure to misrepresent their pain for the sake of continuing a trial, or the for sake of discontinuing a trial," says Guerin. ■

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CME/CE QUESTIONS

1. **Which is true regarding hospital liability for providing unwanted treatments that contradict the patient's stated wishes?**

   a. The plaintiff has no course of action if defense can prove the patient's advance directive was never part of the medical record.
   b. If appropriate policies were in place but not followed, only individual practitioners can be held liable, not the healthcare institution.
   c. In most states, healthcare providers are immune from negligence claims if they provide or withhold treatment consistent with the patient's stated wishes on a POLST form.
   d. Courts increasingly are holding practitioners liable for failing to resuscitate patients despite well-documented POLST forms refusing such treatment.

2. **Which is true regarding disclosure of medical errors, found a recent study?**

   a. Safety culture improved after disclosure training was provided to key faculty.
   b. Disclosure training was effective only if all clinicians participated in the training.
   c. Providing training to physician leaders thwarted efforts to disclose errors because frontline clinicians remained unaware of best practices.
   d. Physicians who received training were more fearful of liability exposure.

3. **Which is recommended regarding assessing quality of ethics consultations?**

   a. Peer reviews are the most effective way to track outcomes.
   b. Whether a consultant spoke with stakeholders should not be used as a process measure because documentation often is inaccurate in this regard.
   c. Timeliness of responses should be examined to ensure there are no delays due to consultant barriers to accessing ethics consultation requests.
   d. The percentage of conflicts that are resolved is an appropriate outcome measure because data show that unresolved conflicts reflect poor mediation skills.

4. **Which is true regarding involving the courts in medical decision-making?**

   a. Courts require that all possible medical treatments must be delivered even if the chance of benefit is minimal.
   b. The ethicist should ensure any information that is relevant to the patient's best interest is presented to the court.
   c. Hospitals are not required to provide an opportunity for a patient to be transferred to another facility if one will accept the patient, if the hospital is refusing to provide requested care.
   d. Courts do not allow treatment to be stopped even if providers believe that treatment to be futile.