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RELIAS MEDIA

Ethics Consults Center on Conflicts Surrounding ECMO Withdrawal: 'Dilemma Is When to Stop'

Ethicists are seeing increasing numbers of consults involving extracorporeal membrane oxygenation (ECMO), the most aggressive life-sustaining technology available.[1] With ECMO, which is currently offered by about 250 U.S. hospitals, some patients are saved who would otherwise die.

"ECMO is great technology. We can buy time and keep them alive," says **Shunichi Nakagawa**, MD, director of inpatient palliative care services at Columbia University Irving Medical Center. However, for some of those patients, Nakagawa says "the ethical dilemma is when to stop ECMO."

The authors of one study analyzed ethical issues involving ECMO in a cardiothoracic surgery ICU at a large academic hospital between 2013 and 2015.[1]

"The biomedical ethics literature was primarily focused on 'novel' ethical dilemmas in these cases," says **Andrew Courtwright**, MD, PhD, one of the study's authors and an assistant professor of clinical medicine at University of Pennsylvania's Perelman School of Medicine. For example, case studies reported on awake patients stranded on ECMO without a chance for recovery or transplantation, or appropriate code status for a patient on venoarterial ECMO without intrinsic cardiac rhythm.

"But it was unclear to what extent these types of cases were actually occurring," Courtwright notes.

Researchers also wanted to know how decision-making authority was determined if there was a conflict about whether to withdraw ECMO. "We also wanted to highlight our experience in integrating routine ethics consultation into the care of ECMO patients," Courtwright adds.

During the study, 113 patients were placed on ECMO. Of that group, 45 were seen by the ethics committee, but the percentage increased over time. In 2013, 21.7% of ECMO patients went through ethics consults; by 2015, almost all patients (93%) did. Not surprisingly, the most common ethical issue was

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AUTHOR: Stacey Kusterbeck
EDITOR: Jonathan Springston
EDITOR: Jill Drachenberg
EDITORIAL GROUP MANAGER: Leslie Coplin
ACCREDITATIONS MANAGER: Amy M. Johnson, MSN, RN, CPN

disagreement on whether ECMO should be continued. There were conflicts between the healthcare team and surrogates, between surrogates, and within the healthcare team.

"We found that the vast majority of cases were similar to more 'traditional' ethics consult cases that involve disagreement over life-sustaining treatments such as tracheostomy, medical nutrition and hydration, and dialysis," Courtwright reports.

Most conflicts were about whether sufficient time had passed to decide whether a reasonable trial of ECMO had been attempted.

"Ethicists seemed to be most helpful in mediating consensus around time-limited trials of ongoing support, with clear criteria for what would constitute meaningful physiologic improvements," Courtwright says.

In another study, researchers reviewed medical records of adults treated with ECMO at the Mayo Clinic from 2010 to 2014, specifically adults from whom ECMO was withdrawn.[2]

"We have been finding that an increasing fraction of ethics consults now involve questions about the withdrawal of advanced cardiac technologies," says **Daniel P. Sulmasy**, MD, PhD, MACP, professor of biomedical ethics and acting director of the Kennedy Institute of Ethics at Georgetown University.

Investigators were surprised by how frequently ECMO is used as a "bridge to decision," which often translates into a "bridge to nowhere."

"The ethical consequence is that fully one-quarter of all ECMO treatments started were eventually withdrawn with the expectation of patient death," Sulmasy says. Of 235 ECMO-supported patients, 62 requested withdrawal. No patient had decisional capacity. For most patients (82%), ECMO had been initiated as a "bridge to decision" as opposed to a bridge to transplant or mechanical circulatory support.

"It was also surprising that so many patients had DNR [do-not-resuscitate] orders, when ECMO amounts to a continuous form of resuscitation," Sulmasy says.

Of the "bridge to decision" group of patients, 29% had a DNR order in place. "We are uncertain what DNR means in such circumstances," Sulmasy adds.

Ideally, ethicists are part of the discussion about trying ECMO, and can discuss with the patient and family the possibility that it might not work. But the decision to withdraw ECMO should not rest solely on the shoulders of the family.

"Above all, do not abandon patients or families to their own autonomy," Sulmasy cautions. "Urge the clinicians to make recommendations to withdraw ECMO if that seems best."

There are several scenarios that arise during ethics consults:

• For some patients, ECMO becomes a "bridge to nowhere." ECMO may be temporary for some. It either leads to recovery, transplant, or another device.

For others, none of that is possible. At that point, patients can be kept alive only on ECMO and only in the ICU.

"They can't get out of the ICU, out of the hospital, and cannot get home. For those patients, we are able to buy time, but only in the ICU," says Nakagawa, who co-authored a paper on this topic.[3]

The ethical issue becomes: How long should the patient be kept in this condition when there is no exit? Columbia University Irving Medical

Center's clinical team calls on ethics to help resolve conflicts regarding when to stop ECMO. Some patients ask to stop treatment and die naturally, but the medical team thinks it is still too early.

"Some patients are sick now, but can still get better," Nakagawa observes.

Some patients still say they cannot continue. In one such case, the patient stated many times that he did not want to continue life on ECMO. Ethicists mediated several discussions among the patient, family, and medical team. The team discussed the possibility of the patient undergoing left ventricular assist device (LVAD) surgery, which would mean months of recovery.

"We emphasized that even in the best case scenario, medically, his quality of life would be significantly worse," Nakagawa recalls.

The patient would end up on dialysis and a feeding tube. "In order to survive, that was the only choice. He did not want that surgery. He did not want to go through it," Nakagawa says.

The man's wife disagreed and insisted this was unlike the person she knew. "We told her that while that might be true, he does have decision-making capacity and is clearly expressing he is suffering, and we need to respect his wish," Nakagawa says.

The patient continued to request withdrawing ECMO. Several days later, ethicists discussed withdrawal at a family meeting. Ultimately, ECMO was withdrawn, and the patient died in a few hours.

"Thorough and extensive discussions among the patient, family, and medical team, with the help of the ethics team, helped the family fully understand his suffering," Nakagawa adds.

• Clinicians struggle to decide whether a patient is a candidate for ECMO. "A multitude of factors are at play," says **Robert D. Truog**, MD, director of the Center for Bioethics and professor of medical ethics, anaesthesia, and pediatrics at Harvard Medical School.

These include: Is the disease reversible? Even if it is, what are the chances of recovery? What are the patient's baseline comorbidities, and how should they be weighed in the decision? Does the patient have the physical and cognitive resources that prolonged recovery from ECMO will require?

At Boston Children's Hospital, a small group of surgeons and intensivists have agreed to be on a WhatsApp group chat. Whenever there is a question about whether a patient is an ECMO candidate, the relevant clinical details are sent to the group.

"Whoever is available to respond weighs in with their thoughts, questions, and opinions," Truog says. "The response rate tends to be high, even on nights and weekends."

In this manner, the group seeks to come to a consensus on whether ECMO should be offered. It often stimulates discussion about factors that might otherwise have been overlooked.

"While the system is not perfect, it does remove the decisional burden from just one person," Truog says.

• If patients cannot participate in decision-making, the family has to decide to stop ECMO. For some families, this is not a difficult decision. Members say they know the patient would not want to live this way, that it does not make sense to prolong the suffering, and ask that the clinical team let the patient go.

"Some families have difficulty accepting that reality. They cannot give up, and are hoping for a miracle," Nakagawa notes.

In certain instances, this is the case even when the patient obviously is dying. The patient starts to develop pressure sores and needs to be turned regularly by nurses. "Sometimes, the digits and toes become ischemic and necrotic. It becomes really miserable for the patient and for the people who provide care. That creates an ethical dilemma," Nakagawa says.

If there is a conflict between the patient, family, and medical team, clinicians first try to resolve it on their own or with a palliative care team. "But for very difficult cases, we ask for the ethics team's help," Nakagawa explains.

Conflicts arise in part because ECMO changes the perception of death. "Before that, if the heart stopped people died. But now we are able to keep them alive," Nakagawa says.

This makes it harder for the patient and family to accept death. "It is very ironic. The more medical technology advances and we can make people live longer, the more difficult the end of life is going to be," Nakagawa adds. ■

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EHRs Raise Ethical Concerns on Autonomy, Trust

Electronic health records (EHRs) "will thoroughly change our ethical understanding of the doctor-patient relationship, and will probably require us to rethink it within this digital framework," says **Tania Moerenhout**, MD, PhD, a general practitioner and former researcher in the departments of public health and primary care and the department of philosophy and moral sciences at Ghent University in Belgium.

Researchers interviewed 14 primary care physicians about EHRs and identified some common themes.[1] "Ethical questions that arise with daily use of the EHR within our work remain underexamined. This study tried to fill that gap," says Moerenhout, the study's lead author. The physicians interviewed brought up a few issues:

• A shared record raises ethical questions on autonomy and trust. Patients interviewed by Moerenhout seemed to appreciate when someone asked for their input on what should be included in the EHR.

"This does not happen often enough in patient-doctor interactions," Moerenhout shares. One clinician included a patient's difficult background of rape, prostitution, and homelessness in the EHR. He did it because some would write off the patient as "difficult." This clinician hoped the information would provide some added insight. "He had clearly given it a lot of thought, but he had not considered talking to her about it," Moerenhout says.

The physician wanted to help the patient, but there also was the potential for harm. "Both the lack of information, and access to all information, could lead clinicians in the wrong direction — for example, through anchoring bias," Moerenhout adds.

• A shared EHR may cause certain healthcare providers to avoid seeking help for sensitive issues. "We usually do not think of care providers in a help-seeking role," Moerenhout observes. Some hospitals grant doctors' records a higher level of protection. "But we should really think about whether it is sufficient, and whether we should pay more attention in general to doctors-as-patients within the digital medical world," Moerenhout offers.

• The EHR can disturb rapport with patients, but also can support patient/doctor interactions. Some physicians strongly believe EHRs are getting in the way of relationships with patients. "The best way for clinicians to tackle these issues is to open up a conversation about [EHRs] with their patients," Moerenhout says.

The study's findings are a clear indication that more ethical design of EHRs is needed, according to Moerenhout. "We need to go back to the drawing table with IT people, healthcare providers, ethicists, and patients to reconsider what we want to do with our EHRs," she says.

The additional workload EHRs create for physicians — specifically, the need to respond to messages delivered via EHR-based inboxes — is another ethical concern. "Physicians are becoming increasingly burned out, which can negatively impact patients," says **Daniel R. Murphy**, MD, MBA, who authored a paper on this topic.[2] Murphy is an assistant professor and medical director in the department of medicine at Baylor College of Medicine. Researchers later interviewed 2,104 primary care physicians about the problem. Many believed there was insufficient time to respond to all inbox notifications.[3] "While our findings largely confirm anecdotal concerns that have been voiced by physicians about EHR inboxes, we were surprised to find the magnitude of the problem," says Murphy, a health services researcher at the Center for Innovation in Quality, Effectiveness, and Safety at the Michael E. DeBakey VA Medical Center in Houston.

Most respondents (69%) expressed concerns about receiving messages that were not actionable for patient care or relevant to the clinician. "This suggests physicians are getting a large amount of messages that they really do not need, not unlike spam emails," Murphy says. This takes up time that could be used for patient care. Currently, managing inbox messages is a nonreimbursed service.

"Healthcare organizations and payers need to recognize the importance and prevalence of this non-face-to-face activity on the quality of patient care," Murphy says.

As it stands now, many physicians end up responding to all their inbox messages on their own time. "Physicians are pushed toward doing these activities after clinic hours — now, commonly called 'pajama time' in healthcare — or to rush through it without giving it the attention it needs," Murphy says. ■

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Left Ventricular Assist Devices Pose Informed Consent Challenges

More patients are receiving left ventricular assist devices (LVADs), but informed consent is challenging.

"LVADs are indicated only for patients with severe, end-stage heart failure. These patients are often very sick, often in intensive care," says **Larry A. Allen**, MD, MHS, professor of medicine and medical director of advanced heart failure at the University of Colorado Anschutz Medical Campus in Aurora.

Most patients learn about the the option of LVADs when they are facing the possibility of death, either from progressive heart failure into cardiogenic shock or from a major surgery. "Emotion is high, and biases of cognition are prevalent. The LVAD itself is usually foreign, with complex physiology and tradeoffs," Allen says.

All these issues pose challenges to ethical decision-making and informed consent. "Patients and their families almost always have some time to consider their options," Allen says.

One reason is that durable LVADs usually are put in stabilized patients, whereas unstable patients are treated with temporary devices. "Device implantation is expensive, and there is a preauthorization process with insurers," Allen adds.

Additionally, LVADs are offered only at 180 specialized centers in the United States, all with a multidisciplinary team in place to educate the patient and obtain consent. "Ideally, patients and family are able to talk to many members of the team, and often even meet a patient who has an LVAD," Allen says.

Device companies typically create educational materials, and LVAD teams give these to patients while presenting options. "One potential issue is that in fee-for-service care with private insurers, implantation of an LVAD is very lucrative," Allen notes. "The potential for bias exists."

To minimize this, clinicians use decision aids when LVAD is considered. *(Editor's Note: For an example of this aid, see one created by the Colorado Program for Patient Centered Decisions online at this link: http://bit.ly/2W2tPob.)*

First, a group makes a formal decision to evaluate a patient for LVAD. "This is often signified by a team decision leading to a request for preauthorization from the health insurer for LVAD evaluation," Allen says.

Next, the nursing coordinator for mechanical circulator support sets up a series of meetings with the patient and family for evaluation and education. That is usually when the decision aids are shared with the patient.

"The decision aids set the stage for what is to come, including framing this as a decision," Allen explains.

The decision aids help guide subsequent discussions with patients, according to a recent survey of 48 clinicians.[1] The authors of another study conducted in six LVAD implanting centers from 2015 to 2017 found that patients who received pamphlet and video decision aids had substantially lower implantation rates of LVADs compared to a control group.[2]

LVAD patients are essentially reliant on the device for survival. "If the device is turned off, the vast majority of patients die within 20 minutes," says Allen, who co-authored a recent paper on LVAD withdrawal.[3]

Many patients whose devices are deactivated are awake and alert. "Thus, discontinuation of care in this scenario feels very significant to clinicians, families, and patients," Allen says.

Ethically, LVAD withdrawal sometimes is viewed as different from withdrawing other forms of life-sustaining treatment.

"Among a small minority, there is a belief that LVAD withdrawal is closer to euthanasia because the LVAD, unlike intubation or vasopressors, is a long-term, durable form of support," says **Samuel D. Slavin**, MD, who was the lead author on the Allen paper.[3]

Most ethicists believe LVAD withdrawal should be considered similarly to stopping other life-sustaining measures. "A good analogy might be the decision to stop hemodialysis," says Slavin, an internal medicine resident at Massachusetts General Hospital.

Other investigators examined what end of life is like for patients with LVADs.[4] "There has been significant effort placed on developing LVAD technology and expanding access, with relatively little inquiry into the inevitable end-of-life process," says **Colleen McIlvennan**, DNP, MS, BSN, the study's lead author and an assistant professor at University of Colorado Anschutz Medical Campus.

Trial and registry data have revealed causes and timing of death of patients with LVADs. "The main motivation for this study was to provide a more granular view of the process of death with an LVAD," McIlvennan explains.

Of 18,733 patients implanted between 2008 and 2016, 4,916 were known to have died. "We found

variability in patients' causes of death over time, as well as their health-related quality of life," McIlvennan observes.

Education on the end-of-life process should begin before LVAD implantation. "Although many patients and families may not want to hear this information or even remember the discussion, it should be an important part of decision-making," McIlvennan says.

Rigorously developed educational materials, for clinicians as well as patients and families, are needed, McIlvennan offers. She and colleagues also found that of the LVAD patients who died, 76.9% died in the hospital. Most patients prefer to die outside the hospital.[5]

"The reasons for patients with LVADs dying in the hospital are likely multifactorial," McIlvennan offers. These include clinicians' low threshold to admit these patients, known complications associated with LVAD therapy, and poor understanding of patient preferences.

"We, as a community, need to focus on bolstering education and systems of care that address end-of-life needs in this population," McIlvennan says. ■

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Data Tell the Story of Ethics' Increasing Workload

Many clinical ethics services are seeing a surge in requests for consults. At the same time, they worry about losing resources.

"This has been a challenge with decreases in overall healthcare budgets across the health sector," says **Blair Henry**, BSc, MTS (Bioethics), a senior ethicist at Sunnybrook Health Sciences Centre and North York General Hospital in Toronto.

Data on the volume of ethics work can make the difference. Since 2006, a database at Sunnybrook Health Sciences Centre has tracked all the ethics department work. "Our database metrics go beyond just collecting information on consultations," says Henry, an assistant professor in the department of family and community medicine at University of Toronto.

Ethics also logs its educational activities, debriefings, policy support, committee support, and academic work. Still, numbers showing higher work volume are not enough to support more ethics resources. "A more strategic plan is needed," Henry says.

Each month, **Claudia R. Sotomayor**, MD, DBe, drafts a report for administrators with the number of consults and rounds ethicists conduct. "I compare our current information with previous years to show the growth of the activity of the ethics consultation service," says Sotomayor, a clinical ethicist at Georgetown University's Edmund D. Pellegrino Center for Clinical Bioethics.

The ethics consultation service created its own database using Microsoft Access. "Our database is very simple, but easy to use. It gives us the tracking information we need," Sotomayor reports.

At Houston Methodist Hospital, logs for the ethics consultation service date back to 1997. "At that time, they were all handwritten, paper-based logs," says **Joseph Sayegh**, MBA, administrator of Baylor College of Medicine's Center for Medical Ethics and Health Policy. The Baylor ethics center provides clinical ethics services to Houston Methodist and Baylor St. Luke's Medical Center.

The current database for the Houston Methodist Hospital was developed in 2014, and has gone through several major revisions. "We actually have two platforms that we use," Sayegh reports.

Houston Methodist uses a web-based application to track ethics consults, which was developed internally. Baylor St. Luke's Medical Center had been using an Excel spreadsheet to track ethics consults. In 2019, a new database was developed. "Both databases mirror each other in terms of the information collected," Sayegh says. This allows ethicists to evaluate service lines as a whole or by hospital.

Between the two programs, ethics perform about 600 consults a year.

"The goal here is to create a database that allows for streamlined data entry from the consultants, while not being burdensome on them," Sayegh says.

That means it is crucial to collect the right data. "We have spent the past few year refining that," Sayegh notes.

The main data points now collected by ethics are: the number of consults, the type of provider requesting the consult, which unit or service the request comes from, and the ethical issue. Ethicists look at these data over a 24-month period, and compare the current 12 months to the previous 12 months. "This lets us identify easily when there is an increase or decline in any of those main buckets," Sayegh says.

Particular units may request fewer consults compared to the previous year. For example, in 2019, ethicists noticed fewer consults from the medical ICU at one hospital. "That helps us identify the need for engagement with that particular unit to provide more education or face time," Sayegh says. Data on which topics are cropping up also leads to action. Decision-making issues were arising more often at Houston Methodist and Baylor St. Luke's, so ethicists gave targeted education on that topic during grand rounds.

At North York General Hospital, surrogate decision-maker concerns make up 20% of consults. "In the coming year, we are doing a lot of education to staff around surrogate decision-maker issues," Henry reports.

The most common reason for consults is medical assistance in dying. In 2019, 30 consults were called for this reason. "This justified funding a one-year ethics fellowship to support ethics work," Henry says.

At North York, there were 131 consultations in 2017 with a full-time ethicist in place. The service dropped from full-time status to a 0.5 full-time equivalent (FTE). Consult numbers declined during the next two years, but recently climbed to 102. "However, increasing the consultation numbers was not sufficient to add more FTEs," Henry notes.

The annual number of consults increased at Houston Methodist from 120 in 2011 to 450 in 2013. Baylor St. Luke's Medical Center handled about 20 consults in 2017; that number has reached 150 per year. "Both of those spikes in volume were a direct result of a coordinated education campaign for providers, nursing, and hospital staff," Sayegh observes.

Ethicists promoted the service by attending unit meetings to give quick education sessions, developing and distributing information on the ethics service to units, contributing an active voice in multidisciplinary rounds, and making themselves available for questions. Sometimes, the type of ethics consults changes. "Understanding the reason behind a trend helps tell the story of what is happening," Sayegh offers.

In 2019, ethicists noted that a significant number of consults involved DNR orders. This was due to a new law that changed how these orders are handled. Ethics proactively provided education sessions on the change, but many formal consults still were requested. "We were able to manage these requests with our current staffing," Sayegh says. "But we added a tag in the database so we could track the issue."

If service lines open or expand within the hospital, the consult volume should be noticeably higher, according to Sayegh. If volume remains flat, it is a sign that ethics needs to engage in outreach to that service. "When it comes to telling that story to hospital administration, we have had success by presenting what the volume trends have been and what we think is driving the trends," Sayegh says.

Ethicists also forecast what they expect for the next several years in terms of volume. "We then try and match that volume to our staffing to see if there is an imbalance, to justify additional resources," Sayegh explains.

If a new service line is added, ethics normally receives additional funding to increase the FTEs to manage the additional consults. "Based on the data we collect, we can demonstrate the need to support the increased volume," Sayegh adds. ■

Unique Ethical Concerns for Study Participants in Neuroscience Research

Innovative neuroscience research is vital, but individuals with mental illness pose some unique ethical concerns in terms of their participation.

The results of a recent study provided some reassurance on the decision-making processes of individuals.[1] Researchers surveyed 25 individuals with a mood disorder and 55 individuals without a mood disorder about four psychiatric research projects: an experimental medication (pill form), noninvasive magnetic brain stimulation, experimental medication, (IV infusion), and implantation of a device in the brain.

Respondents rated the research projects as somewhat to highly risky, regardless of their health status. The more risk they perceived, the less willing they were to participate, regardless of whether they had a mood disorder.

Neuroscience researchers have to consider several issues, according to **James J. Giordano**, PhD, MPhil, chief of the neuroethics studies program at the Georgetown University Edmund D. Pellegrino Center for Clinical Bioethics.

• Whether the pathology itself in some way interferes with the individual's capability be fully informed.

"The absence of neuropsychiatric capacity renders these patients incompetent. By definition, the incompetent patient does not understand what information is being provided and, therefore, they can't consent," Giordano says. A person with medical power of attorney to make decisions for that patient may be able to provide consent for the individual under those circumstances.

• Whether patients are entering the trial with "therapeutic misconception."

Many research participants have an underlying assumption that they are going to receive treatment. This may be particularly prevalent in neuropsychiatry patients.

"What tends to happen is that patients participate in a clinical trial with implicit hope that the trial will give them some benefit," Giordano explains.

This is a difficult problem to address fully. "Even where it's actively and explicitly addressed, misconceptions about incurred benefit of treatment rendered in a clinical trial seem to loom on as a potential emotional bias," Giordano observes.

There are two points that are especially important to convey: What assignment to treatment and control groups entails, and that participants will not know which group they are in.

"Even so, many still believe that participation in the trial will gain them some therapeutically beneficial outcome," Giordano adds.

• That any patient with any form of cognitive compromise, where they cannot fully comprehend what is involved in the protocol, is part of a vulnerable population.

"There are particular concerns and caveats that researchers must attend to when dealing with vulnerable populations, particularly as it relates to possibilities for implicit coercion and relative burden and harms that may be inflicted," Giordano says.

Inclusion of such vulnerable patients often is important, as they might be the population targeted for potential therapeutic effect.

"Necessary precautions need to be taken so that these individuals are fully informed, to the extent of their capacity, about all phases and methods of the study and their ability to withdraw without penalization," Giordano says. Most individuals working in this area are keenly aware of necessary safeguards that are incumbent to the research. Still, things can go wrong.

"There may be some misapprehension on whether subjects are fully comprehending," Giordano notes. "Therefore, it is best to be overtly cautious and diligent in ensuring active informed consent."

Big data also pose ethical issues unique to neuropsychiatric research. On the positive side, it "increases the scope, types, and extent of information capable of being gathered and synthesized in psychiatric research," Giordano offers.

For researchers, the ability to use massive amounts of diverse data certainly is appealing.

"However, it's important to realize the information that we are gaining in current studies may be useful, and utilized, for studies in the future," Giordano says.

The way the data are used could change depending on how they are correlated with other future findings.

"In some cases, such data may be de-anonymized, both at present and in the future," Giordano suggests. "This has implications medically, socially, and perhaps legally for research subjects."

For example, information collected today may be correlated to emerging data to infer pre-existing neuropsychiatric disorders.

"That could incur problematic issues for individuals' insurability, access to care, employability, and social regard and treatment," Giordano explains.

For researchers, this means patients and subjects need to be fully informed on how their data could be used. "A comprehensive informed consent process needs to address each area that may be a potential issue or problematic," Giordano says. ■

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Primary Care MDs Field Questions on Direct-to-Consumer Genetic Testing

After paying hundreds of dollars for direct-to-consumer genetic testing (DTC-GT), people need someone they trust to explain what the results actually mean. Many turn to their physicians.

"The problem for clinicians is that they do not know what kind of lab did the test or how reliable it is," says **Kenneth W. Goodman**, PhD, FACMI, FACE, professor and director of the Institute for Bioethics and Health Policy at University of Miami's (FL) Miller School of Medicine.

The results often are not clinically informative. Patients might interpret it in a way that makes them worry when they should not, or not worry when they should. "This is why credible genetic testing includes the service of genetics counselors," Goodman observes. As for DTC-GT, Goodman says, "clinicians should make clear that many of these tests are more like parlor games than medical assessments."

The added question of who is using the consumer's genetic testing data, and for what purpose, also is ethically concerning. "If a patient is curious about DTC, it should be with eyes wide open, not wide-eyed," Goodman suggests.

Researchers recently surveyed 1,502 primary care and specialist physicians to learn how often patients were bringing in DTC-GT results. Thirty-five percent of primary care physicians and 12% of specialist physicians had received at least one from a patient in the past year.[1]

A previous study concerned how well customers of DTC-GT understood their results.[2] "In that study, and others that have looked at the topic, we found that for the most part, interpretation of test results from DTC-GT is fairly good," says **Scott McGrath**, PhD, a clinical informatics education specialist at Providence Health & Services in Renton, WA.

Customers correctly interpreted the tests about 75% of the time. "But what was surprising was that the people we looked at were highly educated and above average means," McGrath says.

The mean income in the study was more than $90,000. "The study was done when the tests were largely a novelty," McGrath notes.

Investigators expected that as more people purchased the testing, medical professionals would be fielding questions about the results. "One of the problems with that model is that there is a shortage of genetic specialists in the medical field," McGrath reports.

Therefore, primary care providers would be the ones hearing the questions. "We wanted to look at what primary care providers thought about that," McGrath says.

Researchers were interested in how the primary care doctors rated their own ability in interpreting genetic test results. When asked to evaluate their comfort levels, the primary care doctors doubted their confidence to a greater extent compared to genetic counselors.

Researchers also studied how the primary care doctors' ability to correctly interpret the tests compared to genetic specialists. These specialists interpreted DTC-GT results correctly 83% of the time, but primary care providers did so 74% of the time.[3] "It was reassuring that there wasn't a huge gap in the ability to properly interpret these results between primary care providers and the specialists," McGrath says.

However, the two groups of physicians differed much more in another aspect. Primary care doctors were more likely to trust the results returned from DTC-GT. Genetic specialists were more skeptical. "Some of these tests may not be as rock-solid as they would be comfortable with when advising patients," McGrath offers.

One genetic counselor put it this way: "If you are asking whether I think the data is accurate, the answer is generally yes. But if you were asking do I think the descriptions and recommendations are comprehensive, the answer is no."

Several genetic counselors expressed a wish to explore the results more. One commented, "It is alarming how much information the DTC reports give without giving any sort of context of the nuances that go into interpreting results."

Genetic specialists clearly remain the "gold standard" when it comes to interpreting genetic test results. However, the study's findings suggest primary providers are a reasonable option, too.

"The overall primary care providers can step in to provide assistance in interpreting these tests if there is high demand," McGrath says.

One ethical concern is whether genetic data should be included in medical records if there is a risk it is going to be misinterpreted by a medical professional without specific expertise. The findings alleviate this concern somewhat, since it shows that medical professionals who are not domain experts interpret the results reasonably well.

"But it also shows the benefits of having more experts, genetic counselors, and clinical geneticists, given the rapidly developing environment of genetic and genomic research," McGrath adds. ■

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Ethical Concerns if Seriously Ill Patients Turn to Alternative Medicine

Many seriously ill patients are taking complementary and alternative medicine (CAM) treatments. Not all tell their physicians, and not all physicians ask about it. "It is safe to assume that the majority of adults are employing some forms of CAM, regardless of whether they are honest in admitting so to their doctors," says **Philip M. Rosoff**, MD, MA, professor emeritus of pediatrics and medicine at Duke University.[1] CAM use, whether used openly or "under the table," raises potentially serious medical issues. "The most obvious is the potential for dangerous pharmacological interactions with prescribed drugs," Rosoff offers. There is the potential for erosion of mutual trust between patient and physician. "If the patient is taking nonprescribed substances and is not honest about this with the physician, this already implies a lack of confidence in the doctor," Rosoff says.

Many physicians convey strongly negative views about CAM use to patients, either explicitly or implicitly. "This undermines the profound trust that must exist for optimal treatment outcomes," Rosoff notes.

Doctors should acknowledge that CAM use is widespread and only ask for honesty, with the attitude of working with (not against) the patient. "In my experience, patients disclose CAM use if they are asked about it in a nonconfrontational and nonjudgmental way," Rosoff reports. "Otherwise, they may not disclose."

Fay J. Hlubocky, PhD, MA, a clinical health psychologist and research ethicist at University of Chicago Medicine's MacLean Center for Clinical Medical Ethics, says, "Although our goal in medicine is always to respect patient autonomy, clinician-patient conflicts may arise in the context of CAM." Physicians are obligated to protect patients

CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

1. Discuss new developments in regulation and healthcare system approaches to bioethical issues applicable to specific healthcare systems;
2. Explain the implications for new developments in bioethics as it relates to all aspects of patient care and healthcare delivery in institutional settings;
3. Discuss the effect of bioethics on patients, their families, physicians, and society.

COMING IN FUTURE MONTHS

- Controversial court ruling on end-of-life care affects ethics
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from harm, including dangerous therapeutic modalities. "Many seriously ill patients are at risk of making a treatment decision based upon inaccurate information," says Hlubocky, who authored a recent paper on this topic.[2]

Some patients choose unproven CAM over conventional treatment that has demonstrated efficacy. "Patients may attempt to pursue any avenue or use any resource that offers hope for a potential cure especially when faced with a chronic, life-threatening illness or a poor prognosis," Hlubocky says.

Ideally, says Hlubocky, a "rigorous" informed consent discussion takes place, covering both the patient's beliefs regarding CAM and the clinician's recommendation. "Recognition of patient reluctance to self-disclose this information due to fear of clinician judgment is key," Hlubocky offers. "For the clinician, it is also important to disclose what they value and can or cannot commit to if the patient does pursue CAM." ■

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Updated Ethical Guidance for Medical Marijuana Requests

More patients are asking for medical marijuana, but some physicians are ethically conflicted or unsure how to respond. A recent paper offers an ethical guidance to physicians in managing these requests.[1]

The guidance came about after ethicists at Western Michigan University received a consult request from an outpatient physician. A patient had requested medical marijuana, and the physician was inclined to assist. "He thought that it might be legitimately helpful for the patient," says **Michael J. Redinger**, MD, co-chief of the program in medical ethics, humanities, and law at Western Michigan University Homer Stryker M.D. School of Medicine.

The physician asked, "Is this request something I could honor if I wanted to? Would that be ethically permissible?" The doctor asked ethicists if there were any institutional prohibitions against it (there were not). Ethicists explored whether the physician had any personal objections (he did not). The matter was easily resolved, with the physician complying with state requirements to attest that the patient's condition was one of the qualifying illnesses that meet criteria for a medical marijuana prescription. "But we realized it was a good question," Redinger notes.

A literature search revealed there were some professional guidelines, but none answered the kind of questions the physician had asked. "There really wasn't anything out there to help guide an individual physician to respond to those factors," Redinger reports.

Physicians must weigh the quality of medical evidence for use of medical marijuana for various conditions. "Ethical obligations might be different for somebody who presents with chronic pain as opposed to glaucoma or chemotherapy-induced nausea," Redinger explains.

Physicians also have to judge whether they have any personal reasons for being uncomfortable with the request, and whether there are any relevant institutional policies. One of the physicians who peer-reviewed the paper commented, "This is something that's come up in my clinic."

"It's something that resonated and felt very practical," Redinger offers.

Physicians who feel ethically conflicted about medical marijuana are unlikely to call a formal ethics consult over it. The guidance is meant to be a resource to help those doctors sort out the relevant ethical issues. "This is an issue that outpatient physicians are more likely than inpatient physicians to encounter. They may need some tailored education in that setting," Redinger notes.

Ethicists might consider providing some proactive education on medical marijuana requests. "We often livestream our in-hospital noon-hour ethics education so outpatient physicians and staff can participate. Occasionally, we tailor the topics to better address their needs," Redinger says. ■

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CME/CE INSTRUCTIONS

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CME/CE QUESTIONS

1. **Which is an ethical concern regarding informed consent for patients with left ventricular assist devices (LVADs)?**
   a. Most patients are presented with the option of LVADs too early in the disease process.
   b. Patients typically need to make an immediate decision.
   c. Devices are offered inappropriately in some cases due to no preauthorization required by insurers.
   d. There is the potential for bias in fee-for-service care with private insurers because implantation of an LVAD is lucrative.

2. **What did the authors of a recent study find regarding interpretation of direct-to-consumer genetic tests?**
   a. Genetic specialists did somewhat better with interpretation, but primary care physicians also did reasonably well.
   b. Low-income consumers interpreted the tests accurately without any physician involvement.
   c. Primary care doctors were overly confident in their ability to interpret results.
   d. Genetic counselors are less skeptical about the tests due to requirements that consumers be provided with comprehensive recommendations.

3. **In a recent study, what was the most common ethical issue in consults involving patients on extracorporeal membrane oxygenation (ECMO)?**
   a. Awake patients stranded on ECMO without a chance for recovery or transplantation
   b. Patients on venoarterial ECMO without intrinsic cardiac rhythm
   c. Disagreement on whether ECMO should be started
   d. Disagreement on whether ECMO should be continued

4. **What did the authors of a recent study learn regarding patients from whom ECMO was withdrawn?**
   a. ECMO is rarely used as a "bridge to decision."
   b. One-quarter of all treatments started eventually were withdrawn.
   c. None of the patients had do-not-resuscitate orders because ECMO is a continuous form of resuscitation.
   d. Most patients had decisional capacity at the time ECMO was withdrawn.