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INSIDE

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Better Communication with Family in ICU Reduces Intensity of End-of-life Care

Simple interventions may reduce the prolongation of dying

Palliative care physicians acting as communication facilitators in the ICU reduced intensity of end-of-life care and length of stay, found a recent study.[1]

"Our findings suggest that improving communication with the families of critically ill patients provides an opportunity to reduce the prolongation of dying in the ICU, and minimize the provision of non-beneficial care," says lead author **J. Randall Curtis**, MD, MPH. Curtis is director of Cambia Palliative Care Center of Excellence at UW Medicine in Seattle.

The researchers were well aware that families often report inadequate communication with clinicians. Previous research also has shown that better communication is linked to less distress among family members.[2]

"But we don't know the best way to improve this communication," says Curtis.

The researchers hypothesized that a communication facilitator could

EXECUTIVE SUMMARY

Having palliative care physicians facilitate communication or round on high-risk patients in the ICU reduces intensity of end-of-life care and decreases hospital length of stay, according to recent studies. To improve communication with the family of critically ill patients:

- encourage bedside clinicians to lead conversations on goals of care,
- give family a point person to get updated information from, and
- address conflicting information given by providers.

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improve family outcomes, and also reduce the prolongation of dying often seen in the ICU.

"The biggest surprise from this study was the degree to which the communication facilitators were associated with a reduction in length of stay in the ICU for patients who died," says Curtis.

A follow-up study suggests that the expense of a communication facilitator is covered by the associated cost savings, even when only considering the direct variable components of healthcare costs.[3]

"Even in ICUs that have already tried to improve communication with family members, there are dramatic cost savings that can be associated with improving communication," says Curtis.

ICU bedside nurses see their involvement in discussions of prognosis, goals of care, and palliative care as a key element of quality patient care, found a survey of 598 ICU bedside nurses in five academic medical centers.[4] This doesn't always translate into clinical practice, however.

"We were struck by how few nurses engaged in discussions of prognosis and goals of care," says lead study author **Wendy Anderson**, MD, MS. "Also, it was striking that nurses identified such a high rate of emotional toll as a barrier."

The study's findings emphasized the need to clarify roles of different professionals in communication about prognosis and goals of care, says Anderson, a palliative care physician at UCSF Medical Center in San Francisco.

"It's important not to relegate all the communication about prognosis and goals of care to ethicists or palliative care clinicians," she says. Anderson worked with colleagues to develop the organization's Integrating Multidisciplinary Palliative Care into the ICU (IMPACT) project. This trains ICU bedside nurses to lead goals-of-care conversations.

"Another key piece has been rounding at the bedside," says Anderson. Palliative care nurses or educators ask questions such as, "What is the family's understanding of the patient's prognosis?" or, "Where does the family need support?"

Often, bedside providers only call for help from ethicists or palliative care if conflicts are already intractable. Anderson would like for that to change. "Things have to be really bad for that to happen. What we'd like is a less formal way to reach out about a situation," she says.

A quick phone conversation might suffice for a particular situation, as opposed to calling a formal consult. "If it doesn't work, that's the time to have an ethicist or palliative care expert speak directly to the patient or family," says Anderson.

Families sometimes report conflicting messages from people involved in the patient's care. "The surgeon, nephrology consultant, infectious disease consultant, or surgical subspecialist, are all speaking from different perspectives," says Anderson. Sometimes it's just that the same information is being communicated differently. "At the same time we're engaging different disciplines, we need to give similar messages to patients and families," notes Anderson.

Other times, there are true disagreements among clinicians. The ICU physician may have a different perspective from the surgeon, for instance. "Families are amenable to hearing those different perspectives," says Anderson. "But it needs to be communicated."

Families often lack a designated

person to go to with questions. A bedside nurse, resident, or even a medical student can serve as a "quarterback," involving others as needed, or scheduling discussions with physicians. "What many family members tell us is that they have to sit at the bedside constantly to be sure they catch the doctor," says Anderson.

When a palliative care clinician interacted with ICU physicians on daily rounds for 103 high-risk patients, family meetings occurred earlier and more frequently, found a recent study.[5]

"At this point, everyone in critical care medicine agrees that communication with patients and family is really important," notes **William J. Ehlenbach**, MD, MSc, one of the study's authors. Ehlenbach is assistant professor of medicine in the division of pulmonary and critical care medicine at University of Wisconsin School of Medicine and Public Health in Madison.

Multiple professional societies recommend that meetings be held early in the ICU stay. "But we know from the literature that these meetings aren't happening as early as they should," says Ehlenbach.

The intervention designed by the research team is a simple interface with the ICU team during morning rounds. "Our hypothesis was that this could prompt the critical care team to think about the palliative care needs of the patient, and put those a little bit higher on the priority list," Ehlenbach explains.

In Ehlenbach's experience, when intractable conflicts occur between clinicians and families, "if we could go back in time and improve the quality of communication and make it happen earlier, I think a lot of that could be avoided."

Problems arise when the team waits too long to honestly communicate with families of patients who are not doing well. Often, all the professionals taking care of a patient know how poor the prognosis is, but days or even weeks go by with no communication. "By the time they do communicate it, it may be brand-new news to the family," says Ehlenbach. "They might have been thinking for weeks that the person was going to recover."

For patients who died in the hospital, ICU and hospital length of stay were significantly shortened, found the researchers. "Our interpretation of that finding is that discussions about prognosis were happening earlier," Ehlenbach says. For some patients who were not doing well, it moved decisions about goals of care earlier in the course of the hospital stay. "That's an important outcome," says Ehlenbach. "To spend two or three weeks in the ICU during a terminal hospitalization really doesn't have much value."

> "WE DON'T THINK THAT THE DECISIONS BEING MADE ABOUT CONTINUING LIFE-SUSTAINING THERAPY WERE ANY DIFFERENT — IT JUST CHANGED THE TIMING."

Notably, the researchers saw no difference in mortality rates. "We don't think that the decisions being made about continuing life-sustaining therapy were any different," says Ehlenbach. "It just changed the timing." ■

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Study Uncovers Deep-rooted Stigma About Palliative Care

Patients reluctant to tell others they're receiving palliative care

There is a very strong stigma attached to palliative care — and it can persist even after positive experiences with an early palliative care intervention, found a recent study.[1]

"We conducted a randomized, controlled trial on early involvement of palliative care in the outpatient setting for patients with advanced cancer," says lead author **Camilla Zimmermann**, MD, PhD, FRCPC, head of the palliative care program at the University Health Network and the Princess Margaret Cancer Centre, both in Toronto, Canada.

The group that received early palliative care alongside their usual cancer care had improved quality of life, compared to the group that received routine cancer care alone.

"At the end of the four-month study period, we did a sub-study of this larger trial, on perceptions of palliative care," says Zimmermann. The researchers conducted interviews with patients in the early palliative care group and their caregivers, as well as patients and caregivers in the usual care group.

"We wanted to explore perceptions of palliative care in both groups," says Zimmermann. Researchers were interested in where these perceptions came from, and whether perceptions changed in the group that received early palliative care.

"Some findings were as we predicted, and others were surprising," says Zimmermann. The researchers hypothesized that patients and their caregivers would equate palliative care with end-of-life care. "And indeed they did," she says.

The perceptions of palliative care were largely of death, hopelessness, dependency, and end-of-life comfort care for inpatients.

"What impressed us was the degree to which the participants reported that their perceptions were influenced by healthcare providers," says Zimmermann.

Some participants gave compelling accounts of how physicians and nurses portrayed palliative care as only being relevant at the end of life. Other participants described how healthcare professionals explained to them that palliative care was relevant throughout the illness. These clinicians encouraged early contact with palliative care.

"So we, as healthcare providers, have a profound influence on how palliative care is portrayed and provided," says Zimmermann.

Control group participants generally thought it was pointless to rename palliative care. However, many participants in the group which had early palliative care felt that a different name was necessary in the outpatient setting.

The researchers asked what name the patients would choose, but none came up with any suggestions. "We then asked what they thought of the name 'supportive care,' and there was a mixed response," says Zimmermann.

Most patients who thought the name should be changed were enthusiastic about this terminology. Others — mostly those who thought the name didn't need to be changed — said it was too vague.

"Overall, all patients thought there should be rebranding, while a subset thought the name should be changed," says Zimmermann. This group was generally supportive of the name "supportive care."

The researchers were surprised at the degree to which many patients felt stigmatized by the label "palliative care."

"They avoided mentioning to friends, and even family members, that they were being cared for by a palliative care team," says Zimmermann. "This serves to underline how we need to redefine palliative care on a broader societal level."

While healthcare providers know, or should know, that palliative care is relevant throughout the course of the illness, "that is not how it is seen on a larger social scale," says Zimmermann.

Zimmermann says the study's main ethical implications involve stigma and access. "Patients should not feel afraid to access palliative care, or to disclose to others that they are receiving palliative care," she says.

Because palliative care has such a negative connotation — reinforced in many cases by healthcare professionals — patients and their families do not get access to important services from which they could benefit. These include expert pain and symptom management, psychological support, and assistance

with navigating a complex healthcare system.

"We need to work together to undo this stigma and advocate for access to palliative care throughout the cancer journey," says Zimmermann. ■

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Study: Social Media is Affecting Patients' Access to Investigational Drugs

"Heightened awareness" of ethics is needed

Patients and families are increasingly turning to social media to facilitate expanded access to unproven drugs. This raises many ethical concerns, says **Tim K. Mackey**, MAS, PhD, director of the Global Health Policy Institute and assistant professor at UC San Diego's School of Medicine. Researchers examined 23 case studies of social media used to facilitate "compassionate use" of investigational drugs.[1] "There was a high degree of variability in how much engagement and media coverage they got," says Mackey, the study's lead author. "Even those that did get a lot of attention, did not necessarily get patients the access they sought."

Patients' social media discussions centered on the following topics:

- rapid deterioration of patient's health, indicating an immediate and urgent need for experimental treatment,
- lack of any alternative treatment options,
- description of the devastating effect of the condition on the patient's family in order to encourage public support,
- identifying a drug manufacturer or the FDA as the primary barrier to access, and
- overwhelmingly positive characterization of experimental drugs petitioned. "This included characterizing an experimental drug as a 'wonder drug,'" says Mackey.

The study didn't report the outcome of the patients involved in the social media campaigns. "But we took a look at it in our original data analysis," says Mackey. Of the 23 case studies, reports from families or the news indicated that at least half of the patients had died from their diseases. This included patients who received access, but who were either disqualified or had to discontinue.

Mackey says this suggests the overall premise that social media works as an alternative forum to gain access to investigational drugs is "questionable at best."

Mackey expects to see continued attempts to pass federal right-to-try legislation, "despite the fact that there is little evidence that this form of policy intervention actually helps anyone."

Mackey says the public rhetoric behind "compassionate use" is fueling policy that is not evidence-based. He says policy should instead be focused on the following:

- **Ensuring decisions are communicated to patients in a reasonable timeframe.** "This is critical to ensuring a patient's dignity and managing expectations," says Mackey.
- **Greater transparency regarding companies' expanded access programs (EAPs).**
- **Creating a standardized, streamlined process for requesting access through myriad EAPs.**

"Based on coverage of 'successful' social media campaigns — which may have not been successful at all — patients are likely to continue to try to compel access when they don't have other options," says Mackey.

This may not be the best use of their time, given the study's findings. "What seems clear is that patients use social media due to uncertainty and desperation," says Mackey. He names the following ethical concerns:

- **There are inherent risks associated with use of any unproven drug outside of a structured clinical trial.** "There is the potential for greater harm to the patient if treatment is not effective or has a poor safety profile," adds Mackey.
- **Scarce resources are being used for access that might not benefit any of the stakeholders: the patient, the clinician, or the manufacturer.**
- **EAPs may engender false hope among patients and their families.** "In fact, the chances that they actually

gain access — or even that the drug may work — may be completely unknown and unlikely," says Mackey.

M. E. Blair Holbein, PhD, BCAP, chief of the division of regulatory science and assistant professor in the department of clinical sciences at UT Southwestern Medical Center in Dallas, is lead author of a paper which concluded that the FDA's EAP is a reasonable option for patients for whom all other therapeutic interventions have failed.[2]

The FDA has three expanded access options that provide ways to access investigational drugs. "Having an IRB [institutional review board] included in the approval process assures an unbiased review," notes Holbein. This can provide at least some protection for a vulnerable patient.

"The FDA has access to information that is proprietary and not available outside the FDA or the manufacturer," adds Holbein. Thus, the FDA review can consider whether the proposed use exposes the patient to unreasonable risk.

"Most importantly, this process maintains the best scientific, as well as ethical, review possible under the circumstances," says Holbein.

Ethical issues include assuring the patient that there is a considered estimation of the most beneficial course, that the patient determines his or her choices, and that there is equitable access to investigational products.

"Patients seeking investigational agents are a vulnerable population that requires a heightened awareness of potential ethical problems," says Holbein.

It is easy to understand that a person with a serious, even life-threatening, disease wants to have access to any potentially beneficial treatment possible. "The question becomes, how do we establish a balance between the risk of the intervention versus the disease?" says Holbein.

Holbein says the very best way to gain access to a drug in development is to participate in a clinical trial. "Every effort should be made to find a trial," she says.

Multicenter clinical trials have already been carefully reviewed to ensure the best utilization of the investigational drug, and have had a thorough ethics review. "Usually, this would also be the most timely, least expensive, and most equitable access option," says Holbein. ■

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Ethics of Gene-altering Research on Human Embryos

Gene editing technology uses an adaptive defense mechanism from bacteria for a novel new purpose: the precise editing of isolated genetic defects in DNA. The technology, clustered regularly interspaced palindromic repeats (CRISPR)/Cas9, "has been widely studied in animals, and may one day be very beneficial in humans. But use of this technology in human beings is premature," says **Dennis M. Sullivan**, MD, MA (Ethics), director of the Cedarville University's Center for Bioethics.

In 2015, Chinese researchers used this method to treat beta-thalassemia in excess embryos from fertility treatments.[1] "Even though they did this research in tripronuclear zygotes, which are not implantable, they received worldwide condemnation," notes Sullivan.

The National Academies of Sciences, Engineering, and Medicine held a summit on human gene editing in December 2015, and called for an international moratorium on human CRISPR research.[2]

"Amazingly, within a few months, the Human Fertilization and Embryo Authority in the U.K. approved using CRISPR in human embryos up to 14 days, completely bypassing the ethical concerns of the Washington forum," says Sullivan.

Charis Eng, MD, PhD, FACP, chair of the Genomic Medicine Institute and director of the Center for Personalized Genetic Healthcare

at Cleveland (OH) Clinic, notes that many researchers use CRISPR/CAS9 technology as a tool to engineer mutations in cancer cell lines to study the effects.

"This is not controversial, nor unethical," she says. "What is controversial is the research on human embryos, or even earlier stages, to alter genes to 'play God.'"

The following are some frequently voiced ethical objections:

• If human embryos are used, these will affect the germ line and all subsequent generations if the embryos are implanted.

"The central ethical concern relates to the unknown consequences for future generations," says Sullivan.

• Unwanted and unpredictable side effects are likely.

Eng explains, "When one edits, often there are 'off target' effects." Other changes, or even mutations, might be introduced in the gene of interest, or even elsewhere.

• Informed consent of any affected offspring will be impossible to obtain.

This can only be mitigated by ensuring that germ line therapies are as safe as possible. "But the full risks and/or benefits of such treatments will not be known until its first recipients grow into adulthood," says Sullivan.

Sullivan cautions that, although CRISPR/CAS9 holds great promise, "we should not open this Pandora's Box until we truly understand what we may unleash."

Eng believes that the "hoopla" is best addressed by forming international committees for guidelines on appropriate use of the technology for the greater good.

Eng points to a similar controversy surrounding recombinant DNA years ago, which was resolved by adherence to guidelines.

"Much good has come, to the point that one doesn't even think twice about using this technology in research routinely," she says. ■

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Teleconsent Boosts Recruitment of Rural Research Participants

One barrier to recruitment of qualified research participants for clinical trials is the cumbersome, time-consuming consent process. Another is the lack of access to participants in remote locations.

Teleconsent, a novel solution developed by researchers at the Medical University of South Carolina (MUSC) in Charleston, addresses both of these difficulties.[1]

"We developed teleconsent to address a major challenge, which was to recruit and consent research participants in a largely rural state," says **Brandon M. Welch**, MS, PhD, assistant professor at MUSC's Biomedical Informatics Center.

The researchers began exploring alternative ways to obtain consent that didn't require travelling, either for the researcher or participant. They came up against similar difficulties with mail, fax, and electronic consents: There is no easy way to verify that the participant actually understood what he or she signed. It's also difficult to verify the prospective candidate is the one completing the form.

"Having the ability to actually see the participant while they are completing the document is the key innovation over other solutions," says Welch.

Not everyone has a computer with an internet connection, which is needed for a teleconsent call. This raises ethical concerns involving access. "We are currently addressing this issue by making teleconsent available on smartphones," says Welch.

The group is working on a way for researchers to design and build their own electronic consent documents. "We're also interested in integrating other features that support clinical research, such as survey forms, and devices for data collection and transfer," says Welch.

Researchers still obtain consent in person in the vast majority of cases.

They use teleconsent only when the participants can't be accessed in person.

"Teleconsent is intended to complement, not replace, the traditional consent process," notes Welch. Teleconsent makes it easier for researchers to recruit rural participants, who are typically underutilized in research.[2]

"I've heard researchers make the argument to our IRB that they are ethically bound to use teleconsent to be as inclusive as possible of those who are typically not represented in research studies," notes Welch. ■

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Analysis Looks at the First Open Payments Data

Industry payments to physicians varied widely by specialty during the first half-year of The Centers for Medicare & Medicaid Services' Open Payments program, found a recent study.[1]

"For many years, federal policymakers have tried to increase the transparency of industry-physician financial relationships through legislative action," says **Jona Hattangadi-Gluth**, MD, the study's senior author and assistant professor of radiation medicine and applied sciences at UC San Diego Health System.

In 2010, the Physician Payment Sunshine Act was signed into law under the Affordable Care Act. This led to the establishment of the Open Payments program, making data on all industry payments to physicians and teaching hospitals publicly available.

The researchers analyzed the first release of these data, which included $3.7 billion in total value for industry payments made during the latter half of 2013. "These data really need to be interpreted in their specialty-specific context," Hattangadi-Gluth cautions. Some key findings include the following:

• Cardiovascular specialists and neurosurgeons were most likely to receive general payments. Pathologists were least likely.

• Internal medicine physicians and orthopedic surgeons received the greatest total value of payments. "But in internal medicine, this value was split over a much greater number of doctors," Hattangadi-Gluth notes.

• Payments were mostly in cash or cash equivalent. "We also found that payment data are quite skewed," says Hattangadi-Gluth. "There are a few physicians in some specialties who receive very high payments." This was especially true for orthopedic surgery and neurosurgery, she says.

• Ownership interest was limited to very few physicians within each specialty. "The median values of these interests, per physician, tended to be on the order of several thousands of dollars," notes Hattangadi-Gluth.

• The most common reason for payments were for food or beverage.

"But when we looked at the proportion of total value of general payments, much of these were for consulting, speaker fees, royalty, and license payments," Hattangadi-Gluth says. The study didn't examine whether financial relationships that were disclosed are harmful or inappropriate.

"In fact, without critical relationships between physicians and biomedical industry, innovation in healthcare with respect to drug and device development would suffer," she adds. However, some financial conflicts of interest among physicians may be problematic. "This is especially true if they affect patient care and drive up costs," says Hattangadi-Gluth.

Now that industry payments are legally required to be reported, it might deter physicians from engaging with industry. "That may or may not be a good thing," says Hattangadi-Gluth.

The data suggest that specialties with a greater amount of intervention, like cardiology and orthopedic surgery, received a greater value of payments from industry. "This implies a closer relationship with device and drug companies," Hattangadi-Gluth says.

Another study looked specifically at orthopedic surgeons and found that financial ties were highly prevalent in this specialty.[2] A small subset of surgeons received large royalties.

"The most surprising finding of the study, for me, was not necessarily the size of payments to surgeons, but the fact that the vast majority of payments were concentrated in a few

surgeons," says lead author **Sravisht Iyer**, MD, an orthopedic resident at New York City-based Hospital for Special Surgery.

A small subset of surgeons received large royalties. "This can represent a meaningful interaction with industry that serve to advance the state of the art in the orthopedic science and patient care," notes Iyer.

Further studies which incorporate quality and utilization data are needed, concludes Hattangadi-Gluth, "to improve our understanding of these industry-physician financial relationships and how these may affect the healthcare system." ■

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Human Trafficking Training is an Ethical Concern

There's a clear need for medical students, residents, and healthcare providers across disciplines to be informed on human trafficking, but there are no formal requirements for psychiatrists to be educated on this, a recent paper concluded.[1]

"This was a recognition of the horrors of human trafficking, and a determination to aim to do something about it even in some very small way," says **John H. Coverdale**, MD, the paper's lead author. Coverdale is a professor of psychiatry and behavioral sciences and of medical ethics at Baylor College of Medicine in Houston.

"The outrage that we experience when coming across a victim about how they have been treated drives us to aim to make a difference," says Coverdale.

Another motivator was that the paper's authors realized there was a lack of literature on this topic in psychiatric and educational journals. "This dearth of literature perhaps reflects a lack of teaching about how to recognize victims, and about the related ethical issues," Coverdale suggests.

Clinicians may be conflicted between the patient's wish not to involve the police or authorities, and the provider's desire to get those agencies involved. "Issues around confidentiality then are one of the challenges that physicians confront," says Coverdale. Healthcare organizations should ensure that providers have the support necessary to manage these situations on a case-by-case basis, he recommends.

> "THE OUTRAGE THAT WE EXPERIENCE WHEN COMING ACROSS A VICTIM ABOUT HOW THEY HAVE BEEN TREATED DRIVES US TO AIM TO MAKE A DIFFERENCE."

Another ethical concern is that physicians may view human trafficking victims negatively or less than compassionately, labelling them as prostitutes. "Physicians may eschew a careful and thorough inquiry into their specific social circumstances and sexual histories, or not take seriously the possibility that they may be trafficked," says Coverdale.

Victims' stories can be very painful and distressing to hear. "Bioethicists should be available to assist the multidisciplinary teams in working through these challenges, and manage the emotional responses that have the potential to undermine treatment," says Coverdale. ■

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Report: Family Caregivers Often Unprepared

A diverse group of family caregivers in New York participating in discussion groups in 2015 reported feeling unprepared for the complex medical and nursing tasks they were expected to perform at home for their family member, according to a recent report.[1]

"The findings weren't surprising, but they were profoundly disturbing. We really do need to pay attention here," says **Carol Levine**, MA, the report's co-author. Levine is director of the United Hospital Fund's Families and Health Care Project in New York City.

One participant reported being "scared, really scared" when she had to clean the drains from her husband's surgical wounds. Another participant reported that he had to learn how to take care of a central catheter inserted through the patient's arm with only a "lady on the phone" to guide him.

Caregivers offered feedback on how video instruction and other training materials could help them perform tasks with less anxiety and stress. "They were expected to do very complicated things, but had not been considered as part of the clinical team," says Levine.

Many caregivers expressed feeling isolated and completely overwhelmed, with nowhere to turn for help with complex tasks and everyday frustrations. "All the new buzzwords — 'patient-centered care' and 'family-centered care' — didn't seem to apply here," says Levine.

Most caregivers of critically ill patients reported high levels of depressive symptoms, which commonly persisted up to one year and did not decrease in some caregivers, found a recent study.[2]

"Institutions, healthcare providers, and payers have to reconsider what is being expected, and even required, of family members," says Levine. The same is true for family caregivers themselves. "They have to be willing to say, 'I can't do this. I'm willing to do whatever I can, but I can't do the whole job and I can't do it alone,'" says Levine.

She sees greater awareness of the problem of caregiver distress. However, this hasn't yet translated into widespread changes in discharge planning and follow-up.

One issue is that family caregivers have no legal standing unless they are designated healthcare proxies. "As a family caregiver, you are not a beneficiary, you are not a patient, you are not a client. There is no fiduciary or financial relationship with clinicians," says Levine.

This doesn't mean that clinicians have no ethical obligation to ensure family caregivers are prepared. "In order to see the patient as a full human being, you need to see the whole social context in which the person lives — and that includes caregivers," says Levine.

If caregivers aren't prepared, the patient's health will inevitably suffer. Levine sees a clear ethical obligation on the provider's part to be reasonably certain that the caregiver they're sending out to care for the patient is competent or will be fully trained.

"If you're really interested in outcomes for patients, is it right for you to send an untrained person home to do this job?" she asks.

Bioethicists who serve on hospital policy committees have a potential role to play. "They can ask for a review of practices related to family caregivers so that some crises can be averted and others resolved," Levine suggests. ■

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Digital Pills Raise Informed Consent, Privacy Concerns

The FDA recently declined approval of what would have been the first mass-marketed drug to include an ingestible sensor.[1] Once the patient takes the medication, a signal is transmitted to healthcare providers with the goal of improving patient adherence and clinical outcomes. Regardless of this recent setback, it is likely that digital pills will soon become available, experts suggest.

Empowerment, or 'Big Brother?'

"Whether digital medicine is a tool for the empowerment or subjugation of patients will depend on how it is used," says **Ann Munro Heesters**, director of Bioethics at University Health Network in Toronto, Ontario. "The control patients have over the information is key."

Sean Young, PhD, executive director at the University of California Institute for Prediction Technology at UCLA, sees setting expectations as a central concern. "One of the big ethical questions is, 'How are people informed beforehand about risks and benefits?'" he says.

Ethical issues include the following:

• "Smart" pills could empower patients.

Patients may be able to remain at home longer, for instance. "Digital pills might be seen as akin to robot caregivers or reminder systems for those with memory impairment owing to acquired brain injury, dementias, or brain metastases," notes Heesters.

Heesters says digital pills are most helpful when patients are willing to participate, and stakes for missed doses are high — as with chemotherapy, anti-rejection drugs for transplant patients, or patients vulnerable to psychosis.

• The patient/physician relationship might be negatively affected.

"The potential for a significant change to the therapeutic relationship seems to be unexplored in this context," says Heesters.

Patients might find digital pills allow them to reduce burdensome visits to healthcare providers. "But if the clinician can see the patient's data without seeing the patient, this may come at a significant and unappreciated cost," says Heesters.

Patients' Perceptions

More personalized care and better monitoring of adverse risks are two clear benefits to patients, in Young's view. "The biggest risk for patients is being monitored, and who gets access to that information," he adds.

People have become accustomed to tracking their own health and fitness with wearable devices. There is now some limited use of invasive medical devices giving physicians access to health data on their patients. "But digital pills are something different. When people are taking a drug on a daily basis, and for chronic disease, the implication is that you will be monitored for life," explains Young.

A lot is at stake. "Cost associated with drugs forgotten, not taken, or improperly taken is enormous," notes Heesters. Between $100 and $300 billion of avoidable healthcare costs in the U.S. annually are attributed to nonadherence, representing 3% to 10% of total healthcare costs.[2]

"Now that we have the ability to measure medication adherence, we run the risk of people making judgments against people who don't adhere," says Young.

Insurers might use the cost savings as a reason to deny coverage, or to charge particular patients more for it, Heesters says. "There is a theoretical potential for insurers to insist on this use: 'Take the digital pill for blood pressure or we will raise your premiums,'" she adds.

If people are sanctioned in any way for not complying with recommendations to take digital pills, Young foresees significant public backlash. "We are monitoring in a way that people are not used to, and a lot of people won't be comfortable with it," he says.

On the other hand, people are becoming increasingly accepting of companies monitoring their behaviors. "Researchers will be studying this, but we don't have clear answers right now," says Young. "All we have are questions." ■

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CME/CE QUESTIONS

1. **Which is true regarding palliative care physicians and communication in the ICU, according to recent research?**

   A. End-of-life care intensity increased because family became aware of options for life-sustaining therapies.
   B. Families were distressed because they learned too early of the patient's prognosis.
   C. The communication facilitators were associated with a reduction in length of stay in the ICU for patients who died.
   D. Length of stay increased significantly for patients who were discharged home from the hospital.

2. **Which is true regarding stigma about palliative care, according to a recent study?**

   A. Most patients reported positive impressions of the term "palliative care."
   B. Patients' initial negative impressions changed after a positive experience with an early palliative care intervention.
   C. Strong stigma about palliative care persisted even in cases where patients had positive previous experiences.
   D. As reported by patients, most healthcare professionals encouraged early contact with palliative care, markedly decreasing negative perceptions.

3. **Which is true regarding use of social media to facilitate expanded access of unproven drugs, according to a recent study?**

   A. There is now strong data showing that use of social media can facilitate equitable access to drugs.
   B. Patients tended to identify drug manufacturers or the FDA as the primary barrier to access.
   C. There was a direct correlation between the amount of media coverage social media users received, and access to unproven drugs.
   D. Of the cases studied, the majority of patients who used social media to facilitate "compassionate use" of investigational drugs ultimately had successful treatment of their disease with the drugs.

4. **Which is true regarding teleconsent for research participants, according to Brandon M. Welch, MS, PhD?**

   A. Teleconsent is not a viable option for rural participants due to technology limitations.
   B. Mail, fax, and electronic consents have been shown to be more effective approaches for remote consent than teleconsent.
   C. Teleconsent should replace the traditional in-person consent process due to strong evidence patients prefer it.
   D. An advantage of teleconsent is the ability to verify patients' understanding while they're completing the document.