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INSIDE

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Latest study shows significant cost savings with early palliative care

Relevant "right from the beginning of the disease"

Earlier palliative care consultation during hospital admission is associated with lower costs for patients admitted with an advanced cancer diagnosis, according to a recent study.[1]

"The earlier in the hospital stay the patient gets factual information about their illness and treatment options, the sooner the care delivered actually matches patient priorities," says **Diane E. Meier**, MD, one of the study's authors and director of the Center to Advance Palliative Care in New York City.

Researchers investigated costs in 969 adult patients with an advanced cancer diagnosis who were admitted to five U.S. hospitals from 2007 to 2011. Of this group, 256 patients were seen by a palliative care consultation team; 713 received usual care only. Palliative care consultation within two days of hospitalization reduced hospital costs by 24%. If the consultation occurred a few days later, cost savings were only 14%.

"The earlier that palliative care was consulted, the larger the savings — even adjusting for how long people live. Saving 24% of the total hospital bill is hardly trivial," says **Thomas J. Smith**, MD, one of the study's authors and

EXECUTIVE SUMMARY

Earlier palliative care consultation during hospital admission is associated with lower costs, according to a recent study which adds to a growing body of research on the benefits of early palliative care intervention. Other study findings include:

- Patients often associate the term "palliative care" with end of life.
- Even physicians misunderstand the difference between palliative care and hospice.
- Bioethicists can define the term "palliative care" whenever it is used.

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director of palliative medicine at Johns Hopkins Medical Institutions in Baltimore.

The results contribute to the growing evidence base on the importance of timing in palliative care, says lead author **Peter May**, PhD, a research fellow at Trinity College Dublin's Centre for Health Policy & Management in Ireland.

"We have been surprised by quite how important timing turns out to be from a methodological standpoint in accurately estimating an intervention's cost effects," he says.

While providers would not hesitate to call a cardiologist for a heart failure patient, they often don't view hospice and palliative medicine as the same sort of specialty help. "We hope that this will give oncologists and hospitals more reason to say, 'She's really sick and her family is having a hard time adjusting. Let's get some experts in to help us manage this,'" says Smith.

May expects to see an increase in earlier referrals, as the benefits of palliative care are better understood.

Most of the time, early palliative care "translates into the desire for care that will improve function and quality of life, as opposed to endless rounds of subspecialty consultations, imaging studies, and blood tests in the hospital," says Meier.

Associated with end of life

"No, you don't need that yet. It's much too early for you." If patients ask about palliative care, they're sometimes discouraged by well-meaning physicians who mistakenly associate it solely with end-of-life care, experts say.

"Even among medical professionals, the stigma exists. How can we expect patients and families to understand the relevance and importance of early palliative care if they are getting mixed messages from providers?" asks **Camilla Zimmermann**, MD, PhD, head of the Palliative Care Program at University Health Network in Toronto, Ontario.

One obstacle is physicians' lack of understanding of the difference between palliative care and hospice. "Older physicians — in my age group — trained before palliative care existed in hospitals. Many of us are stuck in old ways of thinking," says Meier. More recently trained physicians tend to be more comfortable working in partnership with palliative care professionals.

Confusing palliative care with end-of-life care is a primary obstacle to earlier referrals. "Although that was the original meaning of palliative care many moons ago, it's now changed," says Zimmermann. "People have to recognize that palliative care is relevant right from the beginning of the disease."

Zimmermann says physicians shouldn't shy away from using the term "palliative care." "The more we normalize it, the more people will realize that it's something everybody needs if they are diagnosed with serious illness," she says.

Bioethicists can make a point of explaining the term. "If you mention palliative care, people freeze up," Zimmermann says. "It's not something that can be mentioned on its own without reassuring people."

Physicians might say, for instance, "By palliative care, I don't mean the end of life. What I mean is pain management and symptom management and care for you and your family, in terms of coping with the illness and getting the support that you need." "Everyone wants

palliative care if you phrase it that way. It's just that they don't want to die right now," says Zimmermann.

Standardization is needed

Some have argued that it's simply not possible to offer palliative care to all patients diagnosed with a life-threatening illness. "There is the idea of, 'Who is going to provide all this palliative care?'" says Zimmermann. "I don't think palliative care needs to be provided only by palliative care physicians."

Instead, nurses and physicians in the primary care setting can take on this role with appropriate training. "Every physician should know how to provide pain and symptom management and arrange home care," says Zimmermann.

In order for referrals to happen earlier in a hospital stay, the process of identification of patients who can benefit from palliative care needs to be standardized, says Meier. "At present, it remains dependent on the whims of the attending physician," she explains. "Referral depends on individual doctor biases and the luck of the draw."

Some systems are using checklists or trigger tools to identify all patients who might benefit from palliative care. "I hope we will see more of this, as a result of our findings on the benefits of early palliative care," says Meier.

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Conflicts can result in clinicians' moral distress

Act in real-time

Ethical conflicts within a care team are not uncommon — nor are they particularly surprising. "Providers have their own individual set of values and moral commitments," notes **Autumn Fiester**, PhD, director of the Penn Clinical Ethics Mediation Program and faculty in the Department of Medical Ethics & Health Policy at Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

Fiester says the question is how to navigate such conflicts constructively, without creating "moral winners and losers."

Bioethicists can most effectively address professional conflicts if they're seen as a member of the team, says **Nneka O. Sederstrom**, PhD, MPH, FCCP, director of the Center for Ethics at MedStar Washington Hospital Center in Washington, DC. "When the team sees you as a needed and respected resource, they are more willing to engage in conversation," Sederstrom says. "The bottom line is, ethics consultation teams need to be trusted."

Rounding allows bioethicists to do "real-time" training on cases where conflict is likely. "The team addresses issues immediately instead of holding up care," says Sederstrom. Here are some common situations involving ethical conflicts that can cause moral distress within the clinical team:

• A patient who lacks decision-making capacity has no advance directive.

This is one of the most common clinical team conflicts encountered by **Paul Hofmann**, DrPH, FACHE, when conducting ethics rounds. Hofmann is president of Hofmann Healthcare Group, a Moraga, CA-based consulting firm specializing in healthcare ethics, and a former hospital CEO.

"Nurses believe one or more physicians are providing non-beneficial invasive treatment, and family members are receiving mixed messages," he says.

Hofmann utilizes these strategies:

--determining which physician is responsible for coordinating and leading the treatment decision-making process,

--clarifying the patient's prognosis,

--understanding the reasons for concerns expressed by nurses,

--facilitating a meeting to reconcile conflicting opinions,

--obtaining an agreement regarding which physician will be the primary communicator with the family, and

--arranging a meeting with family members and clinicians to discuss the care plan.

• Palliative sedation is being used in a terminal patient whose suffering cannot otherwise be relieved.

"It is certainly difficult to watch a patient's respiratory drive slow down and become agonal," says **Dennis M. Sullivan**, MD, MA (Ethics), director of the Cedarville (OH) University's Center for Bioethics.

Though emotionally difficult, it is important to treat the patient who has expressed wishes for only comfort care. "Inappropriately reacting to the emotional distress of caregivers may merely prolong the dying process," says Sullivan. "A skilled physician can help families and nurses better understand this difficult form of palliative treatment."

It is essential to hold ongoing conversations with anyone involved in the care of the patient from the start of the palliative sedation process, says **Julie M. Aultman**, PhD, director of the Bioethics Certificate Program at Northeast Ohio Medical University in Rootstown.

"It is not uncommon for caregivers to question the goals of palliative sedation — whether to hasten death or relieve suffering — as this controversial practice has both benefits and burdens," says Aultman.

Ethicists can identify moral conflicts that may arise. "As part of the process of palliative care, it is essential to regularly check in with caregivers to determine how they are coping with the care of their patients," says Aultman.

• Surgeons disagree with intensivists on end-of-life care.

"This is the most common conflict we face," says Sederstrom.

From the surgical perspective, the patient's heart stabilizing or bowels starting to function again are signs of improvement. "But the intensivist sees a global disaster — every other organ is failing," says Sederstrom. This leads to interprofessional conflict on what's in the patient's best interest. "We get called often to address these issues," says Sederstrom.

• Nurses and physicians disagree over the need to shift to comfort care measures.

Nurses spend much more time at the bedside than physicians do. "So they feel they have a better overall understanding of what the patient's condition is," says Sederstrom. Typically, nurses are the first to understand the patient is dying. Thus, they advocate for shifting to comfort care measures sooner.

"Many times, the physicians are going more by the lab values reported by the residents than actual experience from patient examination," says Sederstrom.

It is typically during rounds that the nurses bring up their discomfort with continued interventions. "It is a good attending who asks for their opinion," says Sederstrom.

Ethicists can help facilitate any disagreement or conflict that may arise. "There have been a few cases where the nurse was incorrect and continuing to be aggressive was the right path," notes Sederstrom. "These cases always make for great discussion."

• A resident feels unable to voice his or her position due to institutional hierarchy.

One OB/GYN resident experienced moral distress after a court order was obtained, overriding the rights of a woman to refuse a cesarean section.[1] "Disempowered by his status, he felt as though he was silenced by the medical team and institution," says Aultman.

The resident believed the right approach was to find out why the patient was refusing the c-section, calm her fears, and ultimately support her decision for a vaginal birth despite the potential risks.

While moral distress has been cited most often in the nursing literature, notes Aultman, all types of healthcare professionals and students experience such distress. She suggests bioethicists take these approaches in such cases:

• Facilitate discussions and provide forums for healthcare professionals to express situations in which they felt as

EXECUTIVE SUMMARY

Ethical conflicts within the clinical team may involve patients without advance directives, differing opinions on continuation of life-sustaining interventions, and residents feeling voiceless. To prevent clinicians' moral distress, bioethicists can:

- Do "real-time" training so conflicts can be addressed immediately.
- Hold ongoing conversations on the care of terminally ill patients.
- Encourage attendings to ask nurses' opinions on shifting to comfort measures.

though they were disempowered.

• Hold brief real-time ethics discussions. "Invite all members of the healthcare team to weigh in on the dilemma," says Aultman.

• A clinician believes he or she was hindered from providing emotional support to patients.

After a rape victim presented to an emergency department (ED), a nurse practitioner provided emotional support. However, her patient was hesitant to report the crime because she feared for her safety.

When the rape crisis expert came to the patient's bedside, the patient refused to discuss the incident. "The nurse practitioner was released from her duties in caring for this patient, despite her resistance," says Aultman.

The nurse knew that her support could help empower the patient to report the crime and ultimately secure the police protection she needed. "The nurse practitioner felt that patient care was diminished by inflexible rules and positions of power," says Aultman.

Bioethicists are a critical resource in such cases. "It is critical that ethics education uncovers the ways healthcare institutions and persons in authority, knowingly or unknowingly, contribute to the moral distress of healthcare professionals," says Aultman.

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Proposed changes on human subjects research raise some ethical concerns

Long-awaited NPRM raises many questions

Reduced administrative burdens and greater protection for human subjects are the goals of proposed revisions to the Federal Policy for the Protection of Human Subjects, also known as the Common Rule.

Changes in the Notice of Proposed Rulemaking (NPRM) "focus heavily on promoting the ethical principle of autonomy, in hopes of building public trust in the research enterprise," says **Karen Hale**, RPh, MPH, director of the Office of Responsible Research Practices at The Ohio State University in Columbus.

The current regulations were developed in 1991, when research studies generally took place at a single site. Updated requirements were needed, according to the U.S. Department of Health and Human Services, due to the expansion of research into new scientific disciplines, such as genomics; an increase in multisite studies; and technological advances. The following are some of the proposed changes, released in September 2015:

• Redefining "human subject" so that most research involving biospecimens would be subject to the Common Rule.

To date, there is no clear guidance regarding informed consent and storage of biospecimens. "This change is long overdue. There is ample evidence that people care about the future use of their biospecimens," says **Ruth Macklin**, PhD, professor in the Department of Epidemiology and Population Health at Albert Einstein College of Medicine in Bronx, NY.

Researchers analyzed 109 comments submitted after the federal government published its Advance Notice of Proposed Rulemaking in 2011.[1] This proposed mandated consent for use of all biospecimens regardless of how they were collected.

"Most of the comments were from

researchers or IRB [Institutional Review Board] or other oversight members, who argued it would hinder important research in significant ways," says **Jean Cadigan**, PhD, the study's lead author. Cadigan is an assistant professor in the Department of Social Medicine at the University of North Carolina, Chapel Hill.

The researchers found little support for the proposal to mandate consent. "This is quite a departure from the current way researchers can get and use specimens," notes Cadigan. If specimens are de-identified, their use is not considered human subjects research, and even if they are identifiable, an IRB can waive the requirement for consent for their use if certain criteria are met. "Most commenters felt strongly that there was no need to change the current process of de-identifying specimens and/or letting researchers use them without consent," says Cadigan.

A small minority of the comments analyzed by the researchers came from the general public, and tended to support mandated consent. "So we have a potential disconnect between how those in the research establishment view use of biospecimens and how the general public views their use," Cadigan says.

• Specifically excluding certain categories of activities from research within the scope of the Common Rule.

Hale says the implication of allowing such activities to proceed without further administrative or IRB review seems trivial, in that many are already carried out "in parallel" in non-research settings without additional regulatory scrutiny.

"Presumably, there is little additional 'protection' added by review of these activities," says Hale. "It makes sense to focus efforts elsewhere, such as on review of more complex research activities and on researcher and participant education."

However, Macklin sees this as a "serious flaw" in the proposed changes, which would exclude IRB review of some social science research, such as interviews, surveys, and focus group discussions.

"The assumption is that this type of research is minimal risk and therefore does not require IRB review," Macklin explains. Numerous circumstances exist that can place human subjects of such research at more than minimal risk, however. "The risks of such research are not only those of revealing confidential results of the studies, as the proposed change assumes," Macklin says. Some examples are questionnaires or in-depth interviews regarding intimate partner violence, and studies of sexual behavior, rape or sexual abuse.

"Just as many developing countries have begun to include ethical review of social science studies, the U.S. will be moving backwards," says Macklin.

As a member of her institution's IRB for the past 35 years, as well as a member of committees at the World Health Organization, Macklin has reviewed many social science studies that could place potential participants at greater than minimal risk.

"If it is left to social science researchers to determine the risk level of their proposed studies, there can be no oversight of this type of research," says Macklin.

The proposed requirements would also exclude public health surveillance. "Arguably, public health surveillance is not research but is public health practice," says Macklin. Governmental authorities collect such information as part of their responsibility to protect the health of the public.

"However, surveys and questionnaires conducted by social science researchers directly involve human participants in research that is not designed to benefit them individually," says Macklin.

• Informed consent requirements would highlight the most important information and make consents shorter, to make it easier for a prospective subject to decide whether to participate in research.

"Success would be judged by having improved participants' understanding of their choices before enrolling in research," says Hale.

Currently, the complexity and length of consent forms make it unlikely that potential participants actually review and understand all the information. "If this is successfully accomplished, it might result in research participants actually reading the consent forms," says Macklin.

This goal is "laudable as written," says **Susan L. Rose**, PhD, executive director of the Office for the Protection of Research Subjects at University of Southern California, Los Angeles — but it's difficult to assess how it would actually be implemented at this point.

"Many clinical trials routinely have consents in the 20-plus page category," she notes. "This creates a useless consent." Alternative, novel consents are one possibility, says Rose, "but the NPRM is silent on emerging technologies."

The complete proposed revisions can be reviewed at https://federalregister.gov/a/2015-21756 and are open for public comment through Dec. 7, 2015.

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Could efforts to stop opioid abuse harm patient/physician relationship?

"Climate of distrust" is ethical concern

I'm in severe pain." "My pain is 10 on a scale of 1 to 10." "I really need some pain medication."

Due to a growing epidemic of opioid addiction, it's possible that physicians will react to such statements skeptically.

"Efforts to address widespread opioid abuse can have a potentially corrosive effect on patient-physician interactions," says **Bette Crigger**, PhD, director of ethics policy for the Chicago-based American Medical Association (AMA) and secretary for the AMA's Council on Ethical and Judicial Affairs.

If physicians perceive they are distrusted by law enforcement authorities or state medical boards, this can negatively affect both professional morale and patient care.

"When physicians are dissuaded from providing care for chronic pain through fear of being subjected to disciplinary action, or even possible criminal prosecution, patients suffer," says Crigger. Constant messages about the dangers of overprescription of opioids, and stories of disciplinary action taken against physicians, risks creating a "climate of distrust," she adds.

"Physicians can too readily become skeptical of patients who present with pain, even when the physician is willing to provide pain care," says Crigger. Some physicians ask patients to adhere to a pain contract or submit to routine drug screening, as a condition to maintain a patient/physician relationship. "This can undermine both dignity and trust," says Crigger.

Nearly nine out of 10 physicians said they "strongly supported" requiring patients to get opioids from a single prescriber and/or pharmacy, two-thirds strongly supported the use of patient contracts, and more than half strongly supported the use of urine testing for chronic opioid users, according to a June 2015 study from Johns Hopkins Bloomberg School of Public Health that surveyed 1,000 primary care physicians.[1]

Another ethical concern is the prospect of physicians functioning as informants for, or agents of, law enforcement. "Prescription registries are not intended for this purpose, of course, but do carry implications for patient confidentiality," says Crigger. Even the perception that registries could compromise privacy or the primacy of the patient's interests can be damaging, she says.

The AMA Council on Ethical and Judicial Affairs has identified the following issues of concern with respect to opioid abuse:

• The possibility of inappropriate prescribing.

"The possibility for inappropriate prescribing online exacerbates this concern," says Crigger. Conducting an appropriate examination and diagnostic assessment is necessary to ensure that physicians fully understand the patient's medical condition. "This is the foundation for a comprehensive, effective plan of pain care before issuing an opioid prescription," says Crigger.

• The need for appropriate monitoring of the patient's condition and response to the care plan so that treatment can be adjusted as needed.

• The need for accurate, timely documentation of clinical findings and the details and rationale of the specific care plan.

Physicians may lack the ability to recognize drug-seeking behavior and respond appropriately. "Efforts may be needed to ensure that physicians have access to appropriate training and resources to refine their skills in this area," says Crigger.

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Ethical challenges in assessing adolescents' decision-making capacity

Debate centers on "mature minor" doctrine

An adolescent disagreeing with a parent over treatment is uncommon in the clinical setting, according to **Douglas S. Diekema**, MD, MPH, attending physician and director of education at the Treuman Katz Center for Pediatric Bioethics at Seattle (WA) Children's Hospital.

"You can count those cases on one hand, and I don't think I've ever had one when the adolescent wants one thing and the parent wants another," he says.

More common are cases of adolescents refusing treatment with a parent fully supporting them. Diekema is aware of multiple cases in which an adolescent went to court to refuse cancer treatment. "In every one of these cases, the parent is backing the child," says Diekema. While the media focuses on the child who is refusing treatment, the legal decision maker is also refusing care, he notes.

"My bottom line on this, is that if we would not let a parent make the decision, we should not let minors make this decision," says Diekema.

Diekema's views are grounded in what is known about the adolescent brain. "The traditional approach ethicists have taken is based on studies that were done some 35 years ago," he says. One study suggested that by age 14, adolescents have the cognitive ability to make adult-like decisions. This led to the ethics community taking the position that adolescents 14 and older should be considered to at least possibly have adult capacity.

"That never quite sat right with me," says Diekema. "Anybody that knows adolescents recognizes that even if they have the decision-making ability, they often don't use it." Recent studies that had adolescents participate in decision-making while on MRI scanners suggests that in fact, the part of the brain involved in adult decision-making isn't fully mature yet, and also, that adolescents are more susceptible to peer pressure than adults.[1,2]

"When you consider this, and you look at these cancer cases, it's not a surprise that there is usually a parent behind these decisions not to receive treatment," says Diekema. He points to the recent Cassandra C. case, where both a 17-year old and her mother refused potentially life-saving cancer care. The state's Supreme Court justices unanimously rejected their argument that the court should adopt the "mature minor" doctrine. "My feeling is, it should be a very rare case in which a judge would allow a minor to make a decision that we wouldn't allow a parent to make," he says.

A possible exception, in Diekema's view, is a case involving a 16-year-old who went to court and was declared a mature minor, giving him the right to refuse a liver transplant. He had undergone two unsuccessful liver transplants previously. "This is the only case I can recall where there was a dispute between parents and adolescents," he says. There is a difference between an adolescent who has lived with a disease for years than one with a new diagnosis, he adds.

"I do think context matters a lot," he says. "This is a kid who was looking at a third liver transplant who knew what he was talking about because he had been through it twice." With less serious healthcare issues, Diekema generally respects adolescents' decisions — not because he believes they have decision-making capacity but moreso due to the principle of beneficence.

Human papillomavirus (HPV) vaccine is an example. If a parent asks for this and a teenager refuses, "I'm not going to hold him or her down to give them that shot," he says. "The ethical cost of not respecting his decision at that point doesn't justify the use of force."

Instead, Diekema attempts to convince the adolescent. The same approach is taken if parents ask him to screen their adolescent for substance abuse. In one case, a teenager refused

to have his genitals examined. "It had some degree of importance in terms of making a diagnosis, but there was no way I was going to call in our Code Strong team to hold him down," he says.

This compromised Diekema's ability to provide the best possible care. "But I didn't feel I was dealing with a list of possibilities that were so bad that it justified my assaulting him," he says.

A recent paper focusing on autonomous decision-making capacity of adolescents offers a different look at this issue, based on the expertise of a group of international professionals working in the field of bioethics, developmental psychology, neurosciences sociology, and medicine.[3] The paper's recommendations stem from a June 2014 meeting of 20 professionals from all continents, working in the field of adolescent medicine, neurosciences, developmental and clinical psychology, sociology, ethics, and law.

"This paper provides an international view on how to address ethical issues in the care of adolescents," says **Pierre-André Michaud**, MD, the paper's lead author and a professor of adolescent medicine at the University Hospital Center in Lausanne, Switzerland.

Many U.S. states provide age limits for granting minors specific rights, such as confidentiality regarding contraception, or the right to refuse a treatment. However, many countries rely on healthcare providers to assess the extent to which the minor has the capacity to make decisions, as the law does not provide any specific age limit. "In the United States and in some other countries, there is a tendency to rely on the judgment of the court or to ask the opinion of a psychiatrist or a psychologist when dealing with the question of competence or autonomous decision-making capacity," notes Michaud. The paper's authors advocate for a "respectful, compassionate dialogue" between the young person and the healthcare provider.

"The feeling of our group was that it was better to rely on the healthcare provider's opinion, who knows his patient and is often aware of the family, school, and social environment, than to ask for the opinion of 'experts' who may make arbitrary decisions regarding competence," says Michaud.

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Researchers accused of unethical practices: Psychiatric patients "extremely vulnerable"

Ethics of enrollment are "serious and challenging"

In 2003, psychiatric researchers at the University of Minnesota recruited a mentally ill young man, Dan Markingson, into a study on an antipsychotic drug. Months later, the patient violently committed suicide; multiple allegations of unethical practices ensued. A March 2015 report from the state's Legislative Auditor included evidence of coercion, conflicts of interest, and a deeply flawed research oversight system.[1] University of Minnesota's Human Research Protection Program has been placed under pending accreditation status.

"These are extraordinarily vulnerable patients," says **Carl Elliott**, MD, PhD, a professor at the University's Center for Bioethics. Many of the ethical issues in the Markingson case are likely occurring in many other academic health centers, he adds. These include financial conflicts of interest, poor institutional review board oversight, improper recruitment incentives, inadequate clinical care, and questionable study design.

"But the issue that really has not emerged at other institutions yet is the recruitment of subjects under an involuntary commitment order," says Elliott. Markingson was under a "stay of commitment" that legally required him to abide by the treatment recommendations of his psychiatrist.

"How can consent under those circumstances be valid?" asks Elliott.

"It is really difficult to see how anyone who has been involuntarily confined to a locked unit can give the kind of voluntary consent that one would like to see."

The University of Minnesota announced late September that it would end recruiting of patients under 72-hour emergency holds into research studies. Spokesperson Dan Gilchrist says the University of Minnesota is committed to the highest ethical standards in its human research protection program, and is currently implementing more than 60 changes to its program.

"Regarding the specifics of the Markingson case, our president, Eric Kaler, has apologized to the family, and there are numerous public statements and appearances by him addressing this case and events of the past 11 years that have led us to where we are today," says Gilchrist.

It's unclear if other institutions are currently recruiting involuntarily committed patients for research studies. "No one is really monitoring recruitment, and the Common Rule [the Federal Policy for the Protection of Human Subjects] makes no mention of the issue," says Elliott.

The appropriateness of enrollment in research in lieu of standard therapy is a central ethical concern for psychiatric patients enrolled in clinical trials, says **Andrew Childress**, PhD, assistant professor at Baylor College of Medicine's Center for Medical Ethics and Health Policy in Houston.

"The Dan Markingson case is a good example of an ethically problematic decision to enroll an allegedly acutely psychotic patient into a study instead of providing him standard therapy for his first psychotic episode," says Childress.

Researchers have an ethical obligation to ensure the safety of participants, adds Childress. Some patients with mental illness are at higher risk of self-harm or noncompliance with the protocol's requirements.

"It would be problematic, from a safety standpoint, to include them without rigorous safeguards for monitoring them while they are in the study," says Childress. A clearly unethical practice would be to enroll and retain a patient with mental illness in a study despite his or her objections, he adds.

"Since the aim of research is not to directly benefit the patient, but to produce generalizable knowledge, it would be unethical to override the objections of a patient whether they are decisionally capacitated or not," Childress says.

Several reviews of the Markingson case have been completed. "Despite the many reports that now exist, none of them address what to me are some of the outstanding ethical issues related to psychiatric clinical research at the University of Minnesota," says **Leigh Turner**, PhD, associate professor in the University's Center for Bioethics.

It is unknown how many individuals were recruited while involuntarily confined to locked psychiatric units, or if others were recruited over the objections of family members who believed the individual lacked decision-making capacity, he says.

"Another key question is whether aggressive recruitment practices resulted in patients being enrolled in clinical trials when they should not have been approached, or when there were serious problems with how they were approached," says Turner.

"The University's psychiatric research scandal is on the course syllabi of numerous bioethics courses taught at other institutions," notes Turner. "The Markingson case has been the subject of at least one ethics grand rounds."

It is unclear, however, if other institutions are revising policies and practices in light of the issue. "I suspect senior officials at other universities have a habit of thinking that scandals which occurred elsewhere could not happen at their own institutions," says Turner.

Researchers face "serious and challenging" ethical considerations when recruiting and enrolling psychiatric patients into clinical trials, says Turner. He says these reforms are needed to adequately protect patients with mental illness from research misconduct:

• Guarding against aggressive recruitment tactics.

While many individuals with mental illness have capacity to decide whether to participate in clinical research, mental illness can undermine decision-making capacity. "Patients need to be able to say no if they do not want to participate in clinical research," says Turner. "They should not be badgered, they should not be pressured, and they should not be asked to participate again and again."

• Assessing decision-making capacity carefully and thoroughly.

"The assessment needs to be done by individuals who have no stake in whether or not patients decide to participate in clinical studies," adds Turner.

COMING IN FUTURE MONTHS

- Dramatically increase utilization of clinical ethics consults
- Ethics of clinicians disclosing errors made by others
- How bioethicists can improve ethical decision-making in nursing homes
- The biggest ethical concerns involving HIV self-testing

• Disclosing conflicts of interest to patients, research subjects, and other stakeholders.

"Furthermore, some conflicts of interest should not be allowed to exist," says Turner. "Transparency, while important, does not solve all ethical issues."

Conflicts of interest are "rampant" in academic psychiatry, adds Turner. "These can result in patients and research subjects being treated in an instrumental fashion rather than as living, suffering humans who deserve our care and respect," he says.

• Listening and responding to the concerns voiced by family members.

This doesn't mean that relatives' concerns should trump choices of autonomous patients, or that family members' concerns are always justified. "Still, these concerns should not be ignored or casually dismissed," says Turner.

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CME QUESTIONS

1. Which is recommended regarding palliative care, according to Camilla Zimmermann, MD, PhD?

A. Physicians should stop using the term "palliative care" because it misleads patients.
B. Physicians should make referrals later in the process as this is linked to increased quality of life.
C. Bioethicists should routinely explain the meaning of the term "palliative care."
D. Only palliative care specialists should provide palliative care, even in the early stages of diagnosis.

2. Which is a proposed change to regulations for human subjects research?

A. A lengthier process would be used for informed consent.
B. Research involving identifiable biospecimens would no longer need IRB review.
C. Public health surveillance would no longer need IRB review.
D. Social science research would require a more stringent IRB review process.

3. Which is recommended for assessing adolescents' capacity for autonomous decision-making, according to Douglas S. Diekema, MD, MPH?

A. Courts should generally allow minors over 14 to make treatment decisions because research shows they have adult decision-making capacity.
B. Providers generally have an ethical obligation to respect adolescent's decisions whenever possible due to the principle of beneficence.
C. The need to respect the minor's autonomy requires providers to allow minors to make decisions, even if a parent wouldn't be allowed to make a similar decision on the minor's behalf.
D. Providers have an ethical obligation to respect parents' wishes for the medical care of an adolescent in almost all cases, even if the use of force is required.

4. Which is an ethical practice for recruitment of psychiatric patients for clinical trials, according to Leigh Turner, PhD?

A. Recruiting patients under involuntary commitment orders, to ensure this population isn't excluded.
B. Repeatedly asking individuals for consent to encourage participation.
C. Enrolling individuals without examining their decision-making capacity too closely, as this typically deters individuals from participating.
D. Disclosing conflicts of interest to patients, research subjects, and other stakeholders.

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