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INSIDE

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Excluding People with Serious Mental Illness from Research Is Ethical Problem

In caring for patients with serious mental illness, **J. Irene Harris**, PhD, is struck by the difficulty many face when trying to access healthcare. "In addition to their symptoms, they have realistic fears that healthcare providers will not take their concerns seriously," says Harris, a clinician-investigator at VA Bedford (MA) Healthcare System.

Some years ago, in a different setting, Harris referred a patient with schizophrenia to a chronic pain rehabilitation program, where someone said, "We can't take this client in our program. There is no research on the safety or effectiveness of our interventions for people with schizophrenia."

The remaining alternatives were riskier. Harris pushed back. Eventually, the patient was accepted to the program and derived significant benefit. However, without aggressive advocacy, the patient likely would have been limited to medication options.

"When lack of research is used as a justification for exclusion from treatment, but the population is excluded from research, we have a spiral that systematically denies interventions to people with serious mental illness," Harris says.

As a career researcher, grant proposal reviewer, and IRB member, Harris was well aware it was almost standard practice to exclude individuals with serious mental illness from research.[1,2] "Now that I was seeing the impact of that research exclusion from care, I wanted to look more closely into that practice," Harris says.

Harris and colleagues examined patterns of research exclusion for people with serious mental illness.[3] "The practice of routinely excluding all of those people is weakening, but still persists, and needs further careful consideration," Harris says.

Nine percent of studies of substance use disorders, 16% of studies of chronic pain, and 1% of ischemic heart disease studies explicitly excluded serious mental illness. A total of 83% of substance use disorder studies, 55% of chronic pain studies, and 20% of ischemic heart disease studies could exclude people with serious mental illness based on broader criteria.

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Excluding everyone with serious mental illness might have been ethically justifiable at one time, when outcomes were poor. "With current treatment methods, many individuals managing serious mental illness function well, maintain employment, hold valued roles in their communities, and are clearly able to consent and participate in research," Harris notes.

When people managing serious mental illness are excluded from a study, it is important IRBs learn more. "It should be routine procedure to request a rationale for that exclusion," Harris offers.

In some study protocols, the rationale is individuals managing serious mental illness may not be competent to consent, or may not understand and follow study instructions. "That's not a sufficient rationale," Harris says. "Most people who manage serious mental illness can do both of those things most of the time."

Instead of automatic exclusion based on diagnosis, researchers could base exclusion on someone's ability to consent and follow study directions. If the only rationale is concern about capacity to consent and follow directions, that should be assessed, rather than presumed on the basis of a serious mental illness diagnosis. "Routinely excluding potential participants based on a serious mental illness diagnosis violates the principle of justice," Harris emphasizes. "In effect, it winds up limiting access to care for this population." ■

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Patients Can Request Ethics Consults, But Almost None Do

Almost always, it is clinicians (not patients) who call an ethics consult. "The reasons for the small number of patient- and family-initiated consults are multifactorial. This is something our team has spent considerable time thinking about," says **Liz Blackler**, MBE, LCSW-R, program manager of New York City-based Memorial Sloan Kettering Cancer Center's ethics committee.

In a recently published paper, Blackler and colleagues reported if patients are empowered to ask for ethics consults, it can mean more patient-centered care, better shared decision-making, and a stronger patient/physician relationship.[1] "Many patients and families face ethical dilemmas, but, unfortunately, do not have a frame of reference for bioethics or a practical understanding of their availability, means of access, utility, and potential benefit," Blackler observes.

Power imbalances between patients/families and the healthcare team are one obstacle. Some patients and families with ethical concerns worry

about receiving a "disrespectful" or "difficult" label. "They are also worried about potential repercussions for speaking up or expressing contrarian viewpoints," Blackler says.

Patients also might be concerned they will have to pay for an ethics consult out of pocket. "Patients and families are charged for many supportive services, such as counseling or psychiatry," Blackler notes. "They may not realize that ethics consultations are free of charge."

At the vast majority of healthcare organizations, anyone can call an ethics consult. This includes patients and families. "Therefore, bioethicists have an obligation to educate patients and family about the clinical ethics consultation process, [including] its value and its limitations," Blackler says.

It is possible patients might request an ethics consult instead of directly engaging with clinicians. That is a valid concern — but it also presents an opportunity "for the consultant to initiate, facilitate, and hopefully enhance communication between parties," Blackler offers.

About 250 ethics consults are conducted annually at Western Michigan University Homer Stryker M.D. School of Medicine, covering about 750 beds between the two main hospitals. Of those, only five or 10 are requested by a patient or family member.

"When they do call us, often it's from the hospital bed. The patient has some sort of grievance with the medical staff and feels disempowered," says **Parker Crutchfield**, PhD, an associate professor in the department of medical ethics, humanities, and law.

Patients are unhappy about something, and tell their nurse or doctor they want to talk to someone else. A clinician recommends calling ethics. Initially, most patients think ethicists are on the hospital's side. "Maybe at some institutions that is the case. But we are essentially a third-party, independent consultant. We try to make that clear, that we are on no one's side and that we are on the side of preventing harm, whatever that amounts to," Crutchfield explains.

Some patients ask for a consult if they want a specific treatment and the medical staff refuses to provide it, based on the fact the risks outweigh the benefits. Often, recommendations from ethics do end up endorsing the medical staff or hospital position just because it is the reasonable thing to do. "The outcome is almost never what the patient or family wants," Crutchfield says.

Certain patients contact ethics because they want help filing a grievance with the hospital. "They have the attitude, 'Something wrong is being done, and these people will come in and save me,'" Crutchfield notes.

Ethicists explain their role as a neutral third party. They are clear that the goal is not to exact retribution against a clinician the patient thinks is doing something wrong.

Rarely is there a genuine ethical conflict when a patient calls ethics. "But that is true of all consults. We get consult requests all the time that are not ethics-related," Crutchfield reports.

Ethicists direct patients to relevant services, whether it is risk management, probate court, social services, or another area of the hospital. Ethicists also receive calls when there is a misunderstanding, either on the part of the patient or the medical staff. Even though there is no specific ethics question in these cases, ethicists still offer assistance. "Because of our expertise in facilitating communication or clarifying morally relevant statements, ethicists can often be of help," Crutchfield says.

In one recent case, a patient objected to someone using an outdated expression the patient found offensive. Other patients called ethics to report discrimination based on race, religion, ethnicity, or gender. In any case, if things have gotten to the point where the patient has called ethics for help, the patient/physician relationship has deteriorated to the point of adversarial. "Often, there's not anything we do to repair that," Crutchfield laments. "But we have expertise in communicating in a way that takes conflict down a notch. That's something we do all the time in clinical ethics." ■

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Informed Consent Challenges with High-Risk Surgery

When **Susan C. Pitt**, MD, MPHS, FACS, was training in abdominal organ transplant surgery, she observed many patients were not engaged in the informed consent process. The patients were narrowly focused on the possibility of dying of their liver or kidney disease, and on receiving an organ. "This observation made me wonder about the quality of informed consent and informed decision-making in high-risk surgery,"

says Pitt, an associate professor of surgery at the University of Michigan.

To learn more, Pitt and colleagues recorded 90 conversations between patients and surgeons before major procedures (cardiothoracic, vascular, oncologic, and neurosurgical) at three U.S. and Canadian centers.[1] They observed how surgeons often described the nature of the illness, the operation, and potential complications most frequently. However, surgeons often failed to discuss the patients' role in the decision, the patient's daily life, uncertainty, or patient preference.

If patients deferred a final decision on treatment, Pitt and colleagues noted surgeons were more likely to discuss uncertainty and treatment alternatives. For example, a patient might be offered coronary artery bypass graft surgery and want to go home to think about their decision vs. making a snap decision and signing a consent form right in the office.

Overall, surgeons did not always assess how well the patient understood the information. Pitt says surgeons could do this by simply asking the patient, "Do you understand the information that I have shared?"

To receive credit for a specific facet of informed consent or informed decision-making, surgeons had to initiate the discussion. "This method of scoring biases the system toward lower scores. We made sure to highlight this limitation in the manuscript," Pitt notes.

Scores also tended to be lower because the authors did not account for some components of consent in the study, including unspoken communication (e.g., a patient nodding her head in agreement) and buy-in that was not discussed out loud (e.g., previous conversations with staff that laid the groundwork for decision-making). "Because the study was about clinical consent and not informed consent for research, it is hard to draw any direct conclusions about the implications of our findings for researchers and IRB members," Pitt says.

Informed consent for research tends to be more standardized and replicable. "However, research participants may also be desperate to find a cure for their disease, which is why IRB protections exist," Pitt notes.

Clinical trial participants receive a large packet of information about the studies in which they are consenting to participate. In contrast, consent in the clinical world typically involves a signature on paper. Patients often receive little written consent-related communication — or none at all. "Fortunately, research to improve the consent and decision-making processes is underway," Pitt says.

Asking family members to be present to hear the consent discussion is helpful, considering the information is hard to process for patients facing high-risk surgery. Even so, describing what life will be like after surgery is not the same as seeing it firsthand. "Let's say someone comes in with a bad stroke. Sometimes, if you have the luxury of time, you can go to the rehab center in the hospital so they can see what people look like after their course," says **Maya A. Babu**, MD, a neurosurgeon with Cleveland Clinic Florida, Martin Health.

Just telling someone his or her family member might have to reside in a nursing home, might be unable to talk, or may need help going to the bathroom does not always hit home. "Until someone sees it with their own eyes, it's very difficult to understand it," Babu offers.

Using plain language about the activities of daily living also is important. For example, clinicians might explain how the person will be unable to take a bath without assistance, might need an indwelling catheter, or will never be able to move their left arm or leg again. "I try not to proselytize or say, 'Here's what you need to do,'" Babu reports.

Instead, Babu gives the most accurate possible picture of both options. There are some cases where the risk/benefit ratio is clearly slanted toward or against surgery. In those cases, Babu states, "it's very reasonable to proceed because the chance of a decent outcome is fairly high — 50 to 60%."

Still, it is reasonable to decide against surgery if the chance of a decent outcome is fairly low. If family members remain undecided, consulting with others who know the patient can be helpful. "Families who never had a discussion about goals of care may want aggressive treatment upfront. Oftentimes, if they talk to other people that gets scaled back," Babu says.

Problems arise when clinicians are too vague about the reality of high-risk surgery. "The ICU team might say, 'You can have surgery, or you can do medical management,' and it's almost presented as equivalent options, which is problematic," Babu says.

Patients often focus on surgery survival rates without factoring in the serious risks of the aftermath, including pneumonia and pressure ulcers. Babu recalls one surrogate decision-maker who was about to consent for a craniectomy for a relative until she learned the surgery entailed removing half the patient's skull to relieve pressure on the brain. These details brought home the reality of the risks of the surgery, and the family member ended up declining the procedure. "People sometimes ask, 'Why would anyone agree to surgery in this situation?' You almost want them to think in those terms. Do I really want to go through with it?" Babu explains.

Engaging in an honest risk/benefit analysis can prevent decisional regret. Some families make comments such as, "If I would have known this, I never would have gone through with it." This is not something surgeons like to hear. "It makes you feel you didn't do a good job setting the expectations. That's a horrible feeling," Babu says.

Undecided people often put this question to surgeons: "What would you do?" Babu gives them a straight answer — many times, there is no clear answer. She tells the family, "It's impossible to make the wrong choice. Your gut sense is the right sense."

Recently, a daughter declined surgery on her mother's behalf. She made the decision after learning her mother would have to live with permanent one-sided weakness. The daughter said her mother would never want to spend a single week in a nursing home. The mother had been crystal clear and adamant on this point. Babu told the daughter, "You are honoring her the best way you can, by honoring her wishes. I would have chosen the way you chose." ■

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New Data on IRB Members' Perceptions of Violations

Failure to properly store data and neglecting to maintain project records are the two most common IRB violations, according to a recent survey of 242 faculty members at research-intensive universities in the United States.[1]

"Prior research has typically focused on general forms of researcher misbehavior," notes **Michael D. Reisig**, PhD, the study's lead author and a professor in the School of Criminology and Criminal Justice at Arizona State University.

The authors of those previous studies did not examine violations of IRB protocol, or they relied on survey questions that did not allow researchers to assess perceived differences between specific IRB violations thought to be major and minor. "The primary motivation for the study was to capture perceptions of IRB violations, both in terms of prevalence and seriousness," Reisig shares.

Problems with data storage and recordkeeping were viewed as relatively serious violations, especially in the applied sciences when compared to the natural sciences. But such differences were uncommon.

"Perhaps the most surprising set of findings concerned the lack of differences in terms of the perceived prevalence of IRB violations across the social, natural, and applied sciences," Reisig reports.

Considering the many types of studies that are conducted across scientific fields, Reisig and colleagues anticipated some differences might emerge. "Universities and research organizations should provide resources, such as data archiving services, to assist researchers in meeting IRB requirements," Reisig offers.

These findings underscore the importance of making ethics training available to researchers at all career stages, as well as the need to protect human subjects, to educate researchers on the possible consequences of violating protections, and to inform researchers of changing rules and regulations. "Ethicists can play a role in developing and participating in training curricula," Reisig suggests.

Common protocol deviations include missed study visits, taking protocol-prohibited medications, and not following protocol-prescribed drug administration regimens, reports **Michael Linke**, PhD, chair of the University of Cincinnati IRB. The main IRB concerns with these types of deviations is whether they exposed the participants to increased risk or negatively affected the integrity of the study. "IRBs will have to consider whether the violations constitute serious noncompliance," Linke says.

For example, if a participant took a prohibited drug that increased the study risks, or if the protocol was not followed and too much study drug was administered, that would increase risk to the participant. Those could be considered reportable unanticipated problems involving risks to subjects or others. Reports must include a description of the corrective and preventive actions (CAPA) that were taken to prevent the deviations from occurring again. "The CAPA should include a root cause analysis to identify the cause of the deviations to identify appropriate actions," Linke says.

The IRB must review the CAPA to ensure it addresses the problems that led to the deviation. "Even if the deviations do not constitute serious noncompliance or an unanticipated problem involving risk to subjects or others, a CAPA should still be developed," Linke says. ■

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Screening Tests to Determine Study Eligibility Are Not Foolproof

Clinical trial administrators rely on screening tests to determine which participants should be included or excluded, but no screening tests are foolproof. All produce false-positives and false-negatives. This inevitably means some eligible participants are excluded, and some ineligible participants are included.

"In research ethics, when writing regulations or guidelines, there is a gap or discrepancy between what seems ideal and what is practically possible," says **David Wendler**, MA, PhD, head of the section of research ethics at NIH Clinical Center, who authored a paper on this topic.[1]

In 2004, Wendler studied the same gap with respect to informed consent guidelines, which state people have to understand the risks and potential benefits.[2] "The problem is, when you start doing this in reality and enrolling people in clinical trials, it's hard — and sometimes impossible — to know whether they truly understand these things," Wendler laments.

The same issue arises regarding eligibility criteria. "If you look at regulations for research, they will say things like, 'Only eligible people should be enrolled,'" Wendler says. "When people read studies in the literature, they assume that all the people enrolled were actually eligible."

Studies offering payment (or access to experimental treatments) incentivize prospective participants to want to meet the criteria. "At a minimum, investigators or IRBs should be cognizant of that and realize that people may not always accurately characterize themselves or their history," Wendler offers.

In addition, transparency on eligibility criteria is regarded as ethically critical. "However, the problem with that is you just gave the person the information they need to know what to say to be in the study," Wendler says.

In some cases, it might be better not to let people know the criteria in advance. "Obviously, there are ethical worries about that. What IRBs need to do is figure out how to balance these things," Wendler says.

Statisticians may be able to find a way to take into account the fact that some percentage of people in a given clinical trial were not actually eligible. "Even when it's all objective tests, and there are not really a lot of incentives to enroll, there's still this possibility that some ineligible people are going to get in and some will be excluded," Wendler says.

IRBs and investigators need to be comfortable with some degree of uncertainty. The trick is to figure out how much evidence is enough to accept someone met eligibility criteria. "That's going to depend on what's at stake," Wendler notes.

If an ineligible person is accepted into a study and develops a mild rash, that might not be a serious issue. If a heart attack is a possibility, that is far more serious. "Even then, you can't be certain. You have to realize there's going to be a risk," Wendler says.

Inclusion of ineligible participants also affects scientific results. To what extent depends on the particulars of the study. For a large randomized trial with thousands of participants, "it maybe washes out. But a smaller trial with only five people showing a treatment didn't work, you have to consider whether those people were really eligible," Wendler says. "Did they really have the disease? Did they have comorbidities that made them ineligible?"

The issue of uncertainty raises numerous concerns for IRBs. "But it's little discussed. It's something that's flown under the radar," Wendler says. "To a certain extent, investigators are aware of it. But whether or not the awareness feeds back into the design of the study and screening measures, I don't know."

"Screening tests can be an important part of ascertaining whether an individual meets inclusion or exclusion criteria for a particular trial. These criteria may reflect scientific considerations or safety considerations," says **Emily A. Largent**, JD, PhD, RN, assistant professor of medical ethics and health policy at the University of Pennsylvania Perelman School of Medicine. It may be desirable to exclude participants who are taking certain prescription drugs for safety reasons. It makes sense for investigators to screen for those drugs before enrolling individuals.

Screening tests can be especially helpful when subjective self-reporting will not suffice. For instance, investigators may need evidence indicating an individual is not pregnant at the time of enrollment. "For any screening test, you'll have the chance of a false-positive or false-negative conclusion,"

Largent notes. Bias is another concern if screening tools are used to exclude people from trials.

"Screening tools may seem neutral, but in practice they can work to systematically exclude certain groups of people and reduce the representativeness of research samples," Largent reports.

Recruitment barriers become an ethical concern if some groups are systematically excluded.

"For example, many dementia clinical trials have eligibility criteria that disproportionately exclude African American or Hispanic individuals," Largent says.[3] Generally, this practice limits the generalizability of those studies; specifically, it is a particular concern if excluded groups carry a disproportionate disease burden.

"It can reduce the value of research, result in unfairness in subject selection, and potentially alter the risk/benefit radio," Largent cautions.

IRBs and researchers should expand eligibility criteria to diversify representation, remove extraneous inclusion/exclusion criteria, and eliminate some screening tests if they are not strictly necessary (particularly tests that produce many false-negative or false-positive results).

"If these tests cannot be entirely removed, it's worth exploring whether there is an alternative screening test," Largent says. ■

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Researchers Can Remove Recruitment Barriers in Alzheimer's Trials

Recruitment barriers for underrepresented minorities to participate in Alzheimer's disease clinical trials are well-documented.[1,2] The authors of a recently published paper outline ways to remove these barriers.[3]

"Many of the papers focus on certain demographics. We wanted to be a little broader, though we were not fully able to capture every marginalized or minoritized group," says **Jonathan Jackson**, PhD, executive director of the Community Access, Recruitment, and Engagement (CARE) Research Center at Massachusetts General Hospital.

Jackson and colleagues wanted to place more emphasis on barriers researchers can modify easily. "Instead of focusing on elements of healthcare access or trust, which are often beyond the control — and budget — of Alzheimer's research teams, we wanted our colleagues to know that they have a number of barriers they can [remove] to make it easier for underrepresented populations to take part," Jackson shares. Looking closely at eligibility criteria is a crucial step. "This is where we often see the highest rates of rejection for minoritized populations," Jackson reports.

Jackson says study teams and IRBs must scrutinize whether the criteria are necessary. For example, some protocols exclude anyone with "any history of head injury."

"There's a need to balance the risks of inclusion with the risks of exclusion to clinical research. Minoritized populations are suffering from the latter through an overzealous approach to the former, with no end in sight," Jackson laments.

For both IRBs and research teams, the best way to ensure a diverse and representative sample in Alzheimer's disease clinical trials is to "examine every aspect of a study design for flexibility," Jackson offers.

Jackson says IRBs and investigators should be asking what can be consolidated, made simpler, or translated? What data can be collected outside your research setting? How can we communicate better with prospective and current research participants?

Research teams and ethics reviewers should "consider individuals in context," Jackson suggests. Participants must be recruited, compensated, and retained to Alzheimer's research studies alongside their caregivers, families, communities, and neighborhoods. "We as researchers need to widen out, thinking about systems of access and support in research, rather than individuals in isolation," Jackson adds. ■

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Single IRB Concerns Include IT Limitations, Process Variations

If research involves human subjects at multiple sites, a single IRB review process is required under both National Institutes of Health policy and Common Rule guidelines. Previously, each institution used its own IRB to review study protocols, an inefficient and inconsistent process.

Although the switch to a single IRB was challenging for many, new evidence suggests people are becoming more comfortable with the approach.[1] Researchers at the Clinical Trials Transformation Initiative (CTTI), a public-private partnership founded by Duke University and the FDA, interviewed 34 stakeholders on their perceptions of using a single IRB for FDA-regulated research.

Participants identified consistency, standardization, speed and efficiency, and simplification as benefits. Challenges include timeliness of the research review process, insufficient communication, and uncertainty at local institutions. Previous research identified concerns about liability and the time to execute reliance agreements.[2] "The time to execute a reliance agreement was a concern for all involved — sponsors, coordinating centers, investigators, and patients," says **Sara Bristol Calvert**, PharmD, one of the study's authors and a senior project manager at CTTI.

These findings suggest those previously reported perceived barriers have been at least somewhat alleviated. "It was reassuring that some items that were concerns for the use of single IRB earlier on were not concerns, or were mentioned infrequently by participants," Calvert says.

This likely reflects ongoing work by multiple groups to alleviate concerns about single IRBs. Processes and standardized reliance agreements have been developed by the SMART (Streamlined, Multisite, Accelerated Resources for Trials) IRB Reliance platform, the NCI Central Institutional Review Board, and CTTI. Many IRBs still struggle with how to divide responsibilities and establish communication channels between the single IRB and the multiple institutions.

Another persistent concern: How to determine the most relevant aspects of local context, and how that is incorporated into the single IRB review. "Although resources are available to address these challenges, variable processes across single IRBs and institutions still cause confusion and can cause delays," Calvert acknowledges.

Clear communication among investigators, their institutions, and the single IRB can help mitigate all these problems. Notably, some important responsibilities remain under the purview of the local institution, such as investigator qualifications and radiation safety. "Clear communication of the investigator with those responsible at their institution for these reviews, and whether these reviews can be done in parallel with the single IRB's ethics review, can be helpful," Calvert offers.

Standardized processes for asking questions and gathering timely responses (e.g., an online system, hotline, or designated person to communicate) also prevent confusion. These positive changes have created more of a comfort level with the single IRB concept. "The single IRB process has gained efficiency and offers increased standardization," Calvert reports.

In another study, researchers observed IRB meetings and interviewed staff, chairs, and members from 20 boards to explore the issues that arose when serving as a single IRB.[3] IT issues unexpectedly became a central focus. "Part of what we heard ... were the difficulties they faced in managing their IT systems in the context of serving as a single IRB," says **Paul S. Appelbaum**, MD, one of the study's authors and director of the Center for Law, Ethics, and Psychiatry at the Columbia University College of Physicians & Surgeons.

IT-related issues included problems with outside investigators gaining access to submit protocols, lack of interoperability across systems, and legacy systems that were not designed with single IRBs in mind. Based on the findings, IRBs that are anticipating serving as single IRBs for multisite studies "would be well-advised to investigate the extent to which their IT systems are up to the task," Appelbaum advises. "Institutions looking to be functional in this role may need to purchase new software

to allow single IRB functions to be performed efficiently."

Sufficient time and resources must be allocated for staff training on new or modified systems. "This needs to be done thoughtfully and in advance of serving as a single IRB," Appelbaum adds. ■

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Notification Practices Vary for Emergency Research, Few Participants Withdraw

If someone is in the ED with cardiac arrest or severe traumatic injury, he or she is unlikely to be able to make well-reasoned decisions about study participation. Thus, some clinical trials in the emergency setting are conducted under an exception from informed consent (EFIC).

"Research is needed to help improve outcomes in patients with terrible conditions, such as cardiac arrest, strokes, and profound trauma, where it's simply not possible to obtain consent for research interventions that have to be delivered quickly due to patients' clinical needs," says **Jeremy Sugarman**, MD, MPH, MA, professor of bioethics and medicine at the Johns Hopkins University Berman Institute of Bioethics.

Any research conducted under the EFIC falls under many strict requirements. Anyone who is included in an EFIC study (or their legally authorized representative) must be notified about their enrollment as soon as it is feasible. This gives the enrolled patient the chance to either consent to continued participation or opt out.

Sugarman and colleagues analyzed data from 35,442 patients enrolled in five trials over a 12-year period conducted under the EFIC.[1] They found wide variation in time to notification. "IRBs made different interpretations regarding when and how notification may happen, perhaps due to local norms and practices or their interpretation of the relevant regulations," Sugarman reports.

For 33,805 patients who experienced cardiac arrest, time to notification ranged from a median of six to 28 days. For 1,636 patients with traumatic injury, time to notification ranged from zero days to 36 days. "While some of this variability may be reduced with single IRBs, understanding local contexts and being sensitive to the clinical situation of patients is essential," Sugarman stresses. Investigators conducting research under EFIC must plan for the notification process and ensure they have adequate resources to do it.

Only 7.7% of patients with traumatic injury withdrew from studies after they were notified. For patients with cardiac arrest, the rate was just 0.3%. "It was comforting to see that only a small proportion of those who were enrolled under EFIC opted out of continued participation," Sugarman shares.

The most challenging ethical question with emergency research centers on the patient's ability to adequately understand the voluntary nature, risks, and potential benefits of participating, according to **Roger J. Lewis**, MD, PhD, a professor in the department of emergency medicine at Harbor-UCLA Medical Center. Even if patients are awake and can participate in a consent discussion, "their ability to truly think about their decision regarding participation may be severely impacted by their concerns regarding their emergent medical condition," Lewis says.

Previous research demonstrated that patients undergoing evaluation for potentially life-threatening emergencies (including traumatic injuries and myocardial infarction) have markedly diminished cognitive capacity.[2]

"Thus, I see a large risk in the consent processes related to studies for emergency conditions in which there is the appearance of voluntary informed consent, but the patient is sufficiently compromised," Lewis says.

If patients worry declining to participate could affect their treatment negatively, this creates a coercive environment. "Investigators and IRBs alike should think carefully about alternative consent procedures," Lewis argues.

Researchers could give markedly reduced quantities of information to prospective participants, and follow up with more comprehensive information on the research study later. "IRB members, especially those

who haven't personally participated in the consent process in true emergency situations, may not appreciate the difficulty in communicating the key elements of informed consent in that setting," Lewis notes.

That causes some IRBs to fall back on the "default" of insisting everyone use standard consent procedures. "In doing so, the IRB can give the false impression of an ethical consent process that simply isn't," Lewis cautions.

IRBs must determine if clinical trials meet EFIC criteria. "The regulations, which I personally believe are brilliant in the way they're worded, lay out key elements to be considered by the IRB," Lewis says.

To meet EFIC criteria, studies must involve therapies for truly life-threatening conditions for which there is no acceptable and generally effective therapy. There must be a detailed plan in place for obtaining consent for continued participation from a legally authorized representative (when one is available in time) and also for obtaining consent from participants (should they recover and be able to participate in a consent discussion for continued participation).

"In my view, these regulations lay out a very clear path through which IRBs can consider the benefits, risks, and ethical balance of research in emergency settings, and, therefore, reach reasonable decisions even when the patient cannot participate in the discussion," Lewis offers.

But there is an important gap. Emergent conditions can make it impossible for patients to participate meaningfully in a consent discussion; sometimes, the condition does not meet the specific requirements of EFIC. This happens with acute myocardial infarction, severe traumatic injuries, stroke, and extremely painful conditions.

EFIC regulations require the condition to be life-threatening. Existing therapies must be ineffective or unproven. "That latter requirement is a bit subjective, but many consider our treatments for traumatic injuries; myocardial infarction; and, more recently, stroke to be established and demonstrated to be at least partially effective," Lewis notes.

The EFIC regulations envision a person who is unconscious because of illness or injury. For some medical conditions, people may appear to be awake and able to participate in a discussion regarding enrollment. "But more careful examination shows that you aren't really processing the information and making an informed decision the way consent is supposed to work in non-emergency settings. This is, I think, the biggest challenge for IRBs considering emergency research protocols," Lewis says.

The task for IRBs is to find research consent processes that protect and preserve patients' autonomy to the extent possible, while also allowing medical progress to occur and giving participants access to potentially beneficial therapies. IRB members often want everything to fit neatly into the regulations so there is no question the law supports the consent process.

"But some things don't fit, and figuring out how to apply ethical principles appropriately for the benefit of society requires a more creative process than just following the rules," Lewis says.

The rules do allow IRBs to alter the consent process based on the risk level and potential benefits of the trial (e.g., orally presenting information from a short form consent document). "The regulations actually give the IRB quite a bit of flexibility," Lewis observes. "The difference is whether IRBs choose to use that flexibility or to pretend they don't have it." ■

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Ethical Considerations When Nurses Perform 'Slow Codes' at End of Life

Nurses might perform limited resuscitation efforts (known as "slow codes") with no intended benefit of patient survival, often to avoid harming a dying patient with overly aggressive, unwanted end-of-life care.

Slow codes still are not talked about openly. The controversial practice "is often considered deceitful and unethical; therefore, the practice is shrouded in secrecy. Yet, it is still occurring in practice," says **Liz Stokes**, JD, MA, RN, a Washington, DC-based nurse, attorney, and bioethicist.

To better understand this practice, Stokes and a colleague interviewed 24 ICU nurses in 2018 and 2019.[1] In

some cases, they found nurses conduct limited resuscitation efforts with direction from physicians. It happens with or without a medical order.

"There are medical orders that allow some parts of CPR but not others. This is done with patient and family consent — sometimes, at their request," Stokes explains.

End-of-life care medical orders may reflect a patient's decision to choose one resuscitation method, but not another (e.g., opting out of chest compressions). "However, researchers found that is not always the case," Stokes says.

On some occasions, limited resuscitation efforts occurred without the family's knowledge. Not all resuscitation measures are medically beneficial, and clinicians often must decide in the moment if they are clinically appropriate to perform. "This is an ethically complex area of medicine," Stokes notes.

Through their interviews with ICU nurses, Stokes believes the understanding of "slow code" appears to have evolved over time. "Because limited resuscitation is not well researched, the terms associated with it are unclear and misunderstood," Stokes says.

Initially, "slow code" meant CPR that is performed slowly. The nurses interviewed understood it differently. In their view, a "slow code" meant CPR performed swiftly, but key components for survival are eliminated (e.g., chest compressions or defibrillation).

"The historical intent of slow codes, that the patient would not survive the CPR attempt, remained the same," Stokes says.

Most nurses interviewed felt compelled to perform CPR when families demanded it, even if it was not clinically beneficial (or even harmful) to the patient. This practice contradicts guidance from specialty organizations indicating clinicians are not obligated to perform medically inappropriate care.[2]

"Only one nurse described a culture where the healthcare team would not even offer CPR to families unless it was medically indicated," Stokes reports.

Every scenario varies. "Therefore, it is critical for the healthcare team to have frequent, transparent, and culturally sensitive conversations with patients and families around end-of-life preferences to establish mutual goals of care," Stokes says.

Some interviewees expressed support for slow codes because the tactics used to mitigate conflict between clinicians and families regarding end-of-life goals of care were ineffective. Such conflict causes a strong emotional and moral response in many nurses.

"It is important to address these issues as we continue to see nurses face tremendous challenges due to many constraints outside of their control," Stokes offers.

Ethicists play a critical role in conflict resolution at the end of life. "Ethicists are neutral stakeholders who possess communication skills to create a safe and trustworthy space for patients and families to discuss their values for care," Stokes notes.

While taking a neutral stance in the conflict, ethicists can support nurses experiencing moral distress by providing an avenue for the nurse's perspectives to be heard, acknowledged, and addressed. The problem is ethicists are not always readily available. "Most health organizations are critically under-resourced," Stokes laments.

Some hire only one or two ethicists to staff the entire organization. "This is a substantial gap that hospitals must close by providing resources to support ethics consultation, to mitigate conflict with patients and families — but also to provide support mechanisms for clinicians dealing with repeated exposure to death and dying," Stokes explains.

It also is critical that slow codes are not performed secretly. Clinicians should be performing end-of-life efforts openly and transparently with families. "This fosters trust and reliance in the nursing profession and healthcare organizations," Stokes says.

Overall, clinicians must acknowledge slow codes do occur. "We can no longer ignore that this happens," Stokes says. "We must accept that it occurs to better understand the motivation and strive for a solution." ■

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COMING IN FUTURE MONTHS

- Ethical worries if participants withdraw from clinical trial
- IRBs turn to outside experts for health-related AI research
- Ethical oversight of citizen science projects
- Implications for IRBs if clinical trial results go unreported

Infectious Complications Carry Ethical Implications for End-of-Life Care

End-of-life decision-making often is a complex process, even more so if patients develop an infection.

To learn how infectious complications affect goals-of-care decision-making, researchers reviewed 232 trauma patients without advance directives who were labeled "comfort measures only."[1] Of this group, 72 developed an infection (most commonly, pneumonia).

"It seemed to us that many people think that infections are always curable with the help of antibiotics," says **Stephanie Lueckel**, MD, ScM, FACS, one of the study's authors and section chief of trauma at Rhode Island Hospital.

Lueckel and colleagues wanted to know if people considered infections as a serious enough setback, it would speed their decision to withdraw life-sustaining treatment. They did find this to be the case.

"Our results speak to the fact that infections may not be viewed as a significant complication," says **Elizabeth Tindal**, MD, MPH, BA, the study's lead author and a surgical resident at Rhode Island Hospital's division of surgical research.

People often assume antibiotics are a simple solution to infectious complications, which is not always the case.

"As providers, this may reflect on how we counsel patients and family members on the clinical significance of infections and how they relate to injury severity and a patient's baseline health status," Tindal says.

Clinicians "really need to explain the downstream effects of traumatic injuries and ICU care to families in detail so they can see how each bump in the road will affect the patient," Lueckel says.

Contracting pneumonia is one thing; treating pneumonia in a patient with rib fractures, pelvic fractures, traumatic brain injury, and hemorrhagic shock is another.

"This concept is difficult for families to understand," says Lueckel, associate professor of surgery at Warren Alpert Medical School at Brown University

Clinicians can prevent end-of-life conflicts with goals-of-care discussions shortly after high-risk patients are admitted. This way, a plan of care is established in line with the patient's wishes from the beginning, and providers can set expectations for curveballs such as infections.

Still, some people will reject withdrawal of life-sustaining treatments regardless of the clinical situation.

"Provider counseling needs to be tailored to their perspectives and values," Tindal offers.

Infections are common among ED patients and often affect end-of-life decision-making. "Some infections are easily treated, and treatment may result in comfort and dignity," says **Catherine A. Marco**, MD, FACEP, a professor in the department of emergency medicine at Wright State University in Kettering, OH.

Examples might include patients with a urinary tract infection or cellulitis. However, more invasive or complex infections might require invasive or painful interventions, such as bilateral pneumonia with respiratory failure, requiring intubation and ventilatory support.

"In cases where aggressive interventions are not in accordance with patient wishes, comfort measures should be provided, including pain control, noninvasive respiratory support, and social and religious support," Marco says. ■

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Medical Residents Know Little About Surrogate Decision-Making Laws

Healthcare proxies and surrogates can ensure incapacitated patients receive treatment in accordance with their wishes. Unfortunately, identifying the correct decision-maker can prove quite challenging. "Surrogacy laws differ substantially between states, and house officers rarely receive sufficient training on the subject," explains **Jacob M. Appel**, MD, JD, MPH, HEC-C, director of ethics education in psychiatry at Icahn School of Medicine at Mount Sinai.

Thus, physicians often are uncertain about the appropriate decision-maker, what the basis of their decisions should be, and how much effort must be rendered to identify the correct person.

"Sometimes, proxies or surrogates aren't aware of their role in advance. Some may even refuse to serve because of mistaken beliefs regarding liability," adds Appel, attending physician at Mount Sinai Health System.

Some proxies even fear that if they have not made decisions as the patient would have wanted (despite acting in good faith), they could be sued for mistakenly disregarding the patient's wishes. Ethics consults often are called because of problems like these, with many cases centering on difficulty identifying the correct surrogate.

"It is a frequent occurrence in the hospital, and a question that arises on a regular basis," Appel reports.

Even family members may disagree about the correct decision-maker. "Another related question may arise if there are suspicions that the surrogate is not acting in good faith, or is not trying to effectuate the patient's prior wishes," Appel notes.

Medical residents know little about surrogate consent laws, according to the results of a recent study.[1] Researchers surveyed 35 medical residents in Indiana hospitals in 2018. Only 22.9% knew the default state law did not create a hierarchy for settling disputes. All reported "little" or "some" knowledge of laws on surrogate decision-making. Only 43% recalled receiving some relevant training during their residency.

> ETHICISTS CAN PLAY AN IMPORTANT ROLE IN EDUCATING CLINICIANS ABOUT HOW TO IDENTIFY APPROPRIATE DECISION-MAKERS.

"Every medical school and residency program should train students and house officers on the basics of capacity and third-party decision-making," Appel suggests.

Ethicists can play an important role in educating clinicians about how to identify appropriate decision-makers and the roles proxies and surrogates ought to play in patient care. "Correctly identifying the appropriate decision-maker can prevent patients from having their values undermined," Appel says.

Equally important is ensuring providers know where to go for help if such questions arise. "Depending on the nature of the concern, clinicians may wish to turn to hospital ethicists, ethics committees, legal teams — or all three — to resolve questions around third-party decision-making," Appel says.

Ignorance of surrogate decision-making laws persists despite decades of education, according to **Kenneth W. Goodman**, PhD, FACMI, FACE, director of the University of Miami Miller School of Medicine Institute for Bioethics and Health Policy. "Reminders and updates are essential to ensure that clinicians know the responsibilities of surrogates and proxies and the differences between them," Goodman says.

Too often, clinicians misunderstand what it means to be a legally authorized representative.

"Family member" can be a meaningless label when there are several present. "We err when we appoint the oldest — or loudest — adult child, for instance, as proxy," Goodman shares.

Most troublesome is clinicians' insistence that surrogates or proxies must "make a decision."

"In fact, there is no decision to make," Goodman explains. "Surrogates and proxies must signal what the patient would want if capacitated, and such preferences do not include the right to demand nonbeneficial treatment." ■

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Remote Consults Expand Reach of Ethics, But Complex Cases Remain Challenging

Many ethics services are using remote approaches to communicate with clinicians, colleagues, patients, or family members. The extent to which they do so varies widely.

"Tele-ethics makes ethics consultation more available and provides a level of expertise that is simply not otherwise available," says **Gretchen M. Spars**, MA, MDiv, HEC-C, co-director of ethics programming and Certificate in Bioethics coordinator at the University of South Dakota Sanford School of Medicine.

A virtual format "stands in the gap and shortens the distance," says Spars, who co-authored a recent paper on this topic.[1] Tele-ethics has made many conversations possible that would not have occurred. This has been the case for many years.

"However, the [COVID-19] pandemic has prompted even more innovative methods of connecting with healthcare workers, patients, and families for ethical deliberation," Spars notes.

For other ethics services, remote approaches have not proven feasible for several reasons. "We are really not doing many tele-ethics consults," reports **Ian Wolfe**, PhD, MA, RN, CCRN, HEC-C, a clinical ethicist at Children's Minnesota.

During the height of the pandemic, ethicists at Children's Minnesota used some virtual platforms and devices to attend care conferences and talk with parents. "Overall, it has proven quite difficult to really engage in difficult conversations virtually," Wolfe laments.

Remote ethics consults helped families with non-acute decision-making, provided guidance for medical teams, and offered other institutions second opinions.

"It does not work well for complex cases where there are many specialties, particularly when there is an in-person provider team meeting. It becomes too difficult to mediate and facilitate if you are not in the room," Wolfe shares.

Additionally, it is "near impossible" to collect data from nursing and other staff members in a virtual consultation.

"Overall, there is so much involved in orchestrating the social structure around these cases that tele-ethics is just not sufficient enough to provide any help, outside of simple ethical questions where there is no conflict," Wolfe concludes. ■

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Most PICU Clinicians Report Moral Distress During COVID-19 Pandemic

About 85% of pediatric critical care clinicians reported some degree of moral distress, according to a April to May 2020 survey of 337 pediatric critical care professionals.[1]

"At the start of the pandemic, the world's attention was, rightfully so, on the adult ICUs caring for the critically ill adult patient populations," says **Tessy A. Thomas**, DO, MBE, one of the study's authors and an assistant professor of pediatrics and bioethics at the Center for Translational Bioethics and Health Care Policy. Thomas and colleagues studied whether pediatric critical care clinicians were experiencing anticipatory active moral distress. "It would be only a matter of time before we would possibly be in the same distressing situations as they were," says Thomas, pediatric intensivist in the division of critical care medicine at Janet Weis Children's Hospital at Geisinger Medical Center in Danville, PA.

Were providers distressed out of anticipation of what might be coming during the pandemic, or was it because of known professional challenges that existed before? These challenges included scarce resources, inadequate staffing, supervisors asking staff to handle duties outside professional training, family or patient choices, institutional policies, conflicting opinions about care, miscommunication among team members, and power differentials. Many of these trying situations have existed for years.

"The acute pressure of the pandemic quickly brought to light numerous chronic vulnerabilities of our fragile healthcare systems and workforce," Thomas notes.

The researchers also wanted to know if the pediatric critical care clinicians were preparing to remain resilient in the midst of these challenges.

"Our findings indicate that despite the challenges, healthcare providers remain resilient," Thomas reports.

Notably, about the same number of providers who reported moral distress indicated lingering distress continued to weigh them down after an ethically complex case.

"Moral distress is a universal phenomenon that is inherent within healthcare. We need to acknowledge that it is not a one-time phenomenon that simply goes away," Thomas says. "Being afraid to discuss distress or feeling silenced is not the answer."

Thomas suggests ethicists join rounds on various units, routinely conduct multiprofessional team debriefing sessions within departments and units, and offer educational workshops on ethical frameworks.

"Allow employees to be part of the solution and be participants in brainstorming ideas to address everyday problems at the bedside," Thomas advises.

For example, engaging in frequent informal "check-ins" with staff helps ethicists develop strong relationships.

"To create flourishing professions, we have to equip bedside healthcare providers with the knowledge, skills, attitudes, voices, and moral characteristics needed to compassionately care for vulnerable populations within complex sociotechnical systems," Thomas says. ■

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CME/CE INSTRUCTIONS

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CME/CE OBJECTIVES

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

- Discuss new developments in clinical ethics and research regulation and their implications in healthcare systems for patient care, healthcare delivery, and research;
- Discuss the implications of developments in clinical ethics for patients, families, physicians, other healthcare professionals, and society;
- Review and apply principles of human subject protection in clinical trial programs, including compliance with mandated regulatory safeguards and educational requirements for human subject research.

CME/CE QUESTIONS

1. **Which is recommended regarding research exclusion for serious mental illness?**

   a. Chronic pain rehabilitation programs refusing any patients with schizophrenia
   b. Excluding individuals with serious mental illness from research as standard practice
   c. Explicitly excluding serious mental illness for any study involving substance use disorders or chronic pain
   d. Basing exclusion on ability to consent and follow study directions

2. **Which is a likely result if patients or family members request ethics consults?**

   a. Better shared decision-making
   b. An impaired patient/physician relationship
   c. Higher out-of-pocket costs for uninsured patients
   d. Increased risks of lawsuits and regulatory complaints against the hospital

3. **Which did a recent study reveal regarding informed consent for high-risk surgery?**

   a. Surgeons were overly focused on the harm it might inflict on patients' daily lives in discussions.
   b. Patients were highly distressed due to lack of informed consent for organ transplant surgery.
   c. Surgeons described the nature of the illness, the operation, and potential complications most frequently.
   d. If patients deferred a final decision on treatment, surgeons were less likely to discuss treatment alternatives.

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4. **Which did a recent study reveal regarding IRB violations?**

   a. Neglecting to maintain project records rarely occurred.
   b. Problems with data storage was viewed as a relatively serious violation.
   c. Perceived prevalence of IRB violations differed widely across the social, natural, and applied sciences.
   d. Data archiving services made it less likely researchers would meet IRB requirements.

5. **Which is recommended regarding eligibility criteria for clinical trial participation?**

   a. Participants should not be offered payment or any incentives to cause them to want to meet the criteria to enroll in the trial.
   b. Study protocols should specify participants will not be given specifics on eligibility criteria ahead of time.
   c. Researchers should expand eligibility criteria to increase generalizability.
   d. Researchers should strongly consider adding additional screening tests, even if the tests produce many false-negative results.

6. **Which did a recent study reveal as a current concern regarding single IRB review?**

   a. Liability exposure, considering recent successful lawsuits against hospitals
   b. Insufficient communication
   c. Lack of simplification
   d. Major problems with consistency

7. **A recent study on emergency research revealed:**

   a. overly long timeframes to notification only for cardiac arrest patients.
   b. traumatic injury patients notified at a point when patients still lacked decision-making capacity.
   c. wide variation in time-to-notification.
   d. too many cardiac arrest patients withdrawing from studies after notification.

8. **Which did a recent study reveal regarding current practices for "slow codes?"**

   a. In some cases, nurses conduct limited resuscitation efforts with direction from physicians.
   b. A growing number of families are suing hospitals because limited resuscitation efforts occurred without their knowledge.
   c. Nurses uniformly understood the term "slow code" to mean CPR performed slowly with the possibility the patient will survive.
   d. Most nurses felt comfortable refusing non-beneficial or harmful CPR demanded by families.

9. **Which did a recent study reveal regarding end-of-life decision-making?**

   a. People often assumed anti-biotics are a simple solution to infectious complications.
   b. Too many patients were with-drawing life-sustaining treatment due to easily treatable urinary tract infections.
   c. Patients were switching to "comfort measures only" before learning enough information on their clinical situation.
   d. Unfounded fears of infectious complications caused many pa-tients to reject life-saving surgery.