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INSIDE

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Study: Research on Dying ICU Patients Is Ethically Feasible

Researchers encountered "hesitation and discomfort"

When a group of researchers first proposed to study dying patients during the process of withdrawal of life-sustaining therapies and after death, they met with a fair amount of resistance.

"Initially, there was some hesitation and discomfort from the intensive care research community," reports **Amanda van Beinum**, MSc, a researcher at Canada's Children's Hospital of Eastern Ontario.

Many experienced researchers thought that the design of the Determination of Death Practices in Intensive Care Units study might not be acceptable to research ethics boards, ICU staff, or families of dying patients.

Regardless, the pilot study went forward, with a requirement that written consent be obtained from families prospectively. It was approved by institutional review boards at all five participating sites, with minimal requested revisions to consent forms.

> "THAT IT ACHIEVED A 95% CONSENT RATE FOR APPROACHED FAMILIES WAS, INDEED, SURPRISING TO MANY IN THE CRITICAL CARE RESEARCH COMMUNITY."

"That it achieved a 95% consent rate for approached families was, indeed, surprising to many in the critical care research community," says van Beinum, lead author of a paper about the study's experiences with consent and feasibility.[1]

The study demonstrates that prospective, observational research can be ethically conducted even in critically ill, imminently dying populations.

"We can get consent to do research

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from the families of comatose, dying patients at the end of life," says van Beinum. "This area of ICU care has been somewhat neglected by researchers due to hesitation to intrude on a sensitive time."

This information is important when making policy recommendations about quality end-of-life care in ICU and about organ donation practices. **Tia Powell**, MD, director of the Montefiore Einstein Center for Bioethics in Bronx, NY, says, "It is not only permissible to do research on patients dying in the ICU — it is required if we hope to improve the circumstances of the deaths of these many thousands of patients."

Judith Gedney Baggs, PhD, RN, Elizabeth N. Gray distinguished professor at Oregon Health & Science University's School of Nursing in Portland, has studied end-of-life decision-making in multiple ICUs.[2] "We, too, found that families were, in general, willing to consent and to participate," she says. Baggs heard similar concerns from institutional review boards, which underscored the importance of sensitive wording to avoid upsetting family members.

"When I studied end-of-life decision-making, both nursing and medical staff understood the importance of knowledge to be gained," adds Baggs. Clinicians enthusiastically offered their assistance and support.

Baggs says the ethical implications of studying dying ICU patients are actually similar to any study involving human subjects. There are obligations to not interfere with care, to explain your purpose, and to inform all involved of what the study entails. Researchers need to do these things, says Baggs: "Assure consenters that they can refuse to answer any questions or withdraw from the study, that patient care will not be affected in any event, and that you recognize the difficult situation they are facing."

The majority of ICU patients are likely too ill to give consent for research. Therefore, Powell would limit research to those who clearly have decision-making capacity, or have a surrogate who can consent on their behalf.

"Patients in the ICU are extremely vulnerable," adds Powell. "Research should be of minimal to no risk for patients and families, including emotionally."

It would still be possible to conduct important research, for instance, by interviewing families after the fact about whether the circumstances of the patient's death were consistent with his or her values. Powell says the following

EXECUTIVE SUMMARY

Research on critically ill, dying ICU patients is ethically feasible, found a recent study which achieved a 95% consent rate for approached families. Some ethical considerations include the following:

- Patients and family members may lack decision-making capacity due to illness or extreme stress.
- Avoiding research on this patient population means patients and families cannot benefit from attempts to improve care.
- Researchers must consider how to approach patients regaining decisional capacity during the study.

two questions could be looked at prospectively:

• Was pain adequately controlled, from the perspective of both clinicians and family?

• Did the family feel communications with staff were timely, compassionate, and sufficiently informative?

Critically ill patients may lack decision-making capacity regarding participation in research. Family members may be unable to give consent due to extreme distress over a loved one's critical illness. "It is ethically important that research in this context protect patients and their family members," says **J. Randall Curtis**, MD, MPH, director of Cambia Palliative Care Center of Excellence at UW Medicine in Seattle.

Since critically ill patients often lack the capacity to make decisions about participation in research, researchers often turn to surrogate decision-makers. "If patients regain decisional capacity during the study, it is important to consider whether and how researchers will approach patients to confirm their consent to participate in the research," notes Curtis.

Anna Nolan, MD, MS, assistant professor of medicine and environmental medicine at NYU School of Medicine in New York City, says a central ethical concern with ICU research is that surrogates' decisions may be based on views that differ from the patient's. "Surrogates may not know the subject's values or preferences in the specific situation being studied," she adds.[3]

Curtis says similar principles apply to the conduct of ethical research on critically ill patients, as for research on other serious medical illnesses: "We need to understand and incorporate the vulnerabilities of patients and their family members to coercion." Avoiding such research simply because it's a stressful time is not the answer, says Curtis. "This is unethical because it means that patients and their families cannot benefit from attempts to improve the provision of critical care." ■

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New Report on Research Integrity: Institutions Also Play a Role

It's not just individual researchers who need to support scientific integrity. Institutions and environments also play important roles, says a new report from the National Academies of Sciences, Engineering, and Medicine.[1] The report, "Fostering Integrity in Research," says that detrimental research practices should be understood to include not only actions of individual researchers, but also irresponsible actions by research institutions and journals.

The report recommends the following:

• research institutions go beyond simple compliance with federal regulations;

• senior leaders at each institution — the president, other senior

executives, and faculty leaders — should be actively engaged in these tasks;

• whistleblowers who raise concerns about the integrity of research are protected, and their concerns addressed in a fair, thorough, and timely manner;

• institutions encourage routine disclosure of all results, including negative findings.

C.K. Gunsalus, a member of the committee which developed the report, doesn't expect any of these recommendations to elicit controversy. "The recommendations are generally evidence-based and make sense in the environments in which we operate," she says.

Gunsalus, director of the National Center for Professional and Research Ethics at University of Illinois Urbana-Champaign, adds, "The central observation that we must look at environments as well as people, and assess them, is a central finding I hope gets traction."

National Focus Needed

The report recommends that a Research Integrity Advisory Board be established. Gunsalus says this will take time and work to accomplish. "It's been recommended before, and has so much to offer. I hope that it gets off the ground this time," she says.

The report notes that no such platform exists currently to foster research integrity at a national level. **Barbara Redman**, PhD, RN, an associate of the Division of Medical Ethics at NYU School of Medicine, says, "I am hopeful that this time, such a board will be established, and can vigorously work through current problems with research integrity."

More information is needed on environmental pressures that could lead to detrimental research practices. "We have to learn more, and apply what we learn to improving the 'nudges' our environments provide to make good choices," Gunsalus says.

Redman, an external reviewer for the report, notes that the current situation is referred to as "a serious threat" to the scientific enterprise. "I was heartened to see the scientific community coming to grips with its problems in quality of science," Redman says. However, she says, there is a "long road of work ahead" to determine the following:

• the level of reproducibility that should be expected;

• how common standards of quality can be extended across the commercial and academic settings, regardless of funding source;

• whether it's misguided to believe that whistleblowers are sufficient to detect research misconduct despite strong incentives against speaking out;

• how research integrity requires reforms across the entire system of science (institutions, publishers, funders, as well as individual scientists);

• the degree to which science can be self-correcting, or requires different or more rigorous regulation.

"It is important to note that this is an international problem," says Redman. "Countries vary widely regarding the attention they are giving to the cluster of issues under the umbrella of research integrity."

Institutions Also to Blame

Zubin Master, PhD, associate professor at Albany (NY) Medical College's Alden March Bioethics Institute, says the old way of thinking is that a morally corrupt individual was solely to blame for research misconduct such as fabrication, falsification, or plagiarism.

"People have now started to move away from that," says Master. "Of course the individual has responsibility, but research institutions are also accountable." In Master's view, this includes not just the academic institutions where the researchers are actually housed, but also major research funders like the National Institutes of Health (NIH).

"The institutions to some degree are influencing the research environment and how scientists conduct their business," says Master. "They are either promoting, or not, a culture of research integrity."

Many researchers are under a great deal of pressure to secure external grant funding to pay part or all of their salaries. Research

EXECUTIVE SUMMARY

Institutions and environments — not only individual researchers — play an important role in supporting scientific integrity, stresses a new report from the National Academies of Sciences, Engineering, and Medicine. The report recommends that:

- an independent, nonprofit Research Integrity Advisory Board be established;
- all results are routinely disclosed, including negative findings;
- research institutions go beyond simple compliance with federal regulations;
- whistleblowers' concerns are addressed in a fair, thorough, and timely manner.

institutions benefit from the indirect costs from these grants — and from cheaper trainee labor. "We are in a hypercompetitive environment. Trainees find it difficult to find faculty appointments, and scientists have a very low success of getting NIH grants right now," Master explains.

Many research institutions have had recent scandals involving research misconduct, with considerable repercussions including damaged reputations.

"Some research institutions are very good at handling issues, while others are not," says Master. Some take action only after a particularly egregious incident gets headlines. "They don't want embarrassment. The typical approach has been to eject the bad apple — firing or severely reprimanding the researcher," says Master.

Tools Are Available

Institutions historically have lacked well-studied tools to assess the research environment. A recently developed tool, the Survey of Organizational Research Climate (SORC), evaluates researchers' views on a range of issues involving their institutional climate.[2]

While SORC is a relatively new tool, says Gunsalus, "it's been used at a number of large universities across the U.S., including several Big 10 universities, and in a nationwide study in the VA research service."

It's problematic that some institutions provide minimal education on research integrity, says Master. "We need to shift our mentality away from compliance, and actually promote a culture of research integrity," he says.

Other institutions invest a great deal of educational resources in the hopes of preventing misconduct. "Whether education influences ethical behavior, we really don't know," says Master. "The instruments to actually test whether people are behaving ethically are only also starting to be built and used."

In his own research, Master is focusing on the effect authorship misallocation has on other, possibly more egregious, research misbehaviors. "In the work we've done, we're seeing that authorship might have a bigger impact than we realized. People who were slighted when it came to authorship may be more inclined to cut corners or seek retribution in the future," says Master.

Master says that much more information is needed. While the NIH funds bioethics research involving human subjects or genomics, there is no dedicated funding available for studies looking at the research integrity climate.

"The NIH should be funding research on research integrity," says Master. "They don't have any funding devoted to that, and they should make such funding available for this important research." ■

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Are Hospital Billing Practices Unethical? Chargemaster Still Used To Boost Revenue

U.S. hospitals still are using chargemaster markups to maximize revenues, a recent study found.[1]

"The findings are contrary to a common argument that chargemaster prices are innocuous and inconsequential," says **Ge Bai**, PhD, CPA, the study's lead author and assistant professor at The Johns Hopkins Carey Business School in Washington, DC.

The researchers analyzed data from the chargemasters — the prices hospitals set for services before discounts — of more than 2,400 hospitals. In another paper, they compiled a list of the 50 U.S. hospitals with the highest markups over their actual costs.[2]

"When hospitals set their

chargemaster prices, they need to consider the financial and ethical implications of high charges for uninsured, out-of-network patients, and other patients who are liable to the chargemaster price," says Bai.

Transparency Is Growing

Tim K. Mackey, MAS, PhD, associate director of the Joint Masters Program in Health Policy and Law at the University of California, San Diego, sees similarities in the growing concern over pricing transparency in the hospital setting and the recent public uproar over prescription drug pricing. He points to the recent controversy around the price of Mylan's EpiPen.

"This stems from a few factors, including the fact that Medicare is barred from negotiating pricing with drug companies," says Mackey. There is little transparency despite wide variations in drug pricing, largely depending on the individual's insurance status.

"This lack of pricing regulation and wide variation in cost is analogous to hospital charges," says Mackey. Another factor is the cost used to market drugs, either by direct-to-consumer advertising or marketing to physicians, which ultimately is passed on to consumers.

"In this area, efforts have been made through Sunshine laws, first enacted by states and later as part of the ACA," notes Mackey. These require drug manufacturers to report all payments made to physicians, which is then publicly reported.

"Similar efforts are emerging to encourage transparency and disclosure of hospital charges and provider payments," says Mackey. He points to the Centers for Medicare & Medicaid Services (CMS)'s 2013 release of data on charges for the 100 most common inpatient services and 30 common outpatient services nationally. These showed wide variation across states.

"Whether CMS or the federal government will ever require more robust transparency and public disclosure of hospital charges remains unknown," says Mackey, adding that he expects states to lead the way.

According to the National Conference of State Legislatures, more than 30 states require hospitals to report select charges and reimbursement rates. "Some states run their own public health price information disclosure websites," adds Mackey.

Data on charges, coupled with quality and patient satisfaction data, helps consumers make more informed healthcare decisions. "These initiatives, coupled with the changing physician-patient relationship and digitization of healthcare data and services, will likely lead to the further 'consumerization' of healthcare," notes Mackey. "That has its own benefits and costs."

EXECUTIVE SUMMARY

U.S. hospitals still are using chargemaster markups to maximize revenues, found a recent study. Some ethical considerations include the following:

- Some patients pay more for care to compensate for unreimbursed care.
- Hospitals are legally obligated to provide care to people unable to pay.
- Patients may be unable to make rational decisions about the cost of care due to illness or emotional stress.

Some Charged More

Matthew Wynia, MD, MPH, FACP, professor of medicine and director of the Center for Bioethics and Humanities at University of Colorado Anschutz Medical Campus in Aurora, says the central ethical question is, "What comprises a 'fair' charge for services and goods provided by a hospital?"

"The answer to that will depend on the extent to which you think hospitals should be allowed to make a profit, and if you think they should be allowed to charge more to some people to make up for the others who don't have insurance — or who have bad insurance — and can't pay their bills," says Wynia.

If hospitals operated like most for-profit businesses, they would simply charge whatever the market will bear. Some believe competition is enough to keep prices down. As for whether it's acceptable to charge some patients more to compensate for unreimbursed care, Wynia says this is a difficult question.

"By law, many hospitals can't just turn people away," he notes. "So they are forced to provide care, at least in emergencies, to lots of people who won't be able to pay their bills." Once a physician has taken on a patient's care, he or she is ethically obliged not to abandon that patient. This creates some responsibilities for the hospitals where physicians work.

Some hospitals actually must charge more to some in order to cover the costs of others, says Wynia. "Because some people can't pay their bills when they get sick, hospitals — who are required to provide care to these folks — are required to behave a bit like health insurance plans," he says. Hospitals charge everyone more to cover the cost of those who can't afford care.

"If hospitals can't charge extra to their paying customers to make up for this, then they will lose money on these nonpaying patients. Eventually, they will go out of business," says Wynia. Most hospitals operate on very thin margins, making this a very real possibility — especially for smaller, rural facilities.

Since insurance plans regularly negotiate discounts on the chargemaster prices, this puts pressure on the hospital to start out with a high baseline structure as a starting point. "Of course, if you are just one person, not a health plan, it's practically impossible for you to negotiate a better price," says Wynia.

The result of this dynamic is that well-insured people, who usually are better off financially, end up paying less for the same care compared to uninsured people, who generally are poor.

"Many people see that as fundamentally unfair. It's one of the reasons for the Affordable Care Act: If everyone has insurance, then everyone has a group that can help negotiate on their behalf," says Wynia.

Wynia says hospitals should include costs, when possible, as part of the informed consent process. "'Free market' healthcare solutions often assume that if people have better information, they will make wiser healthcare choices," says Wynia. "And sometimes that's true. But I also wonder how often someone who's a patient in a hospital can really act like a rational consumer of the hospital's services." Patients may be fearful, in pain, or incapacitated or unconscious when confronted with these decisions.

Another issue is the collections practices of hospitals, and how aggressive they should be when individuals can't or won't pay their bills. Wynia says the following are difficult, but important, questions:

- Should hospitals put patients and their families into collections?
- If the bill is much higher than it would have been if the patient had been insured, should hospitals just seek to recoup what the charges would have been if the patient had been insured — or should they try to collect the higher amount?
- What will be the effects of being put into collections on the patient's eventual ability to pay, and on his or her health?

While these questions are best addressed on a case-by-case basis, says Wynia, "they can be guided by ethical principles and practices — which should be based on the organizations' core values." ■

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Very Few Patients Address ICDs in Advance Care Planning

Very few people have thought about what to do with their ICDs in an end-of-life situation.

In one small study, only 15% of patients with an ICD or cardiac resynchronization therapy with defibrillator had thought about device deactivation if they were to develop a serious illness from which they were not expected to recover.[1] Of the study participants, 53% had advance directives, but only one mentioned what to do with the device.

In Canada, nearly 200,000 patients have an implantable cardiac device (ICD).[2] "In the U.S., that number is over a million. These numbers are growing with our aging population," says **Blair Henry**, BSc, MTS, a senior ethicist at Sunnybrook Health Sciences Centre and assistant professor at the University of Toronto in Ontario.

"It is argued that the implantable device has become part of the patient, and should not be deactivated any

more than a transplanted organ should be deactivated," says **James N. Kirkpatrick**, MD, one of the study's authors.

Ethical Justification

Significant minorities of clinicians and patients either believe deactivation to be unethical, or are unsure of the ethical and legal permissibility of deactivation.

"Deactivation of an implantable device has been equated with physician-assisted suicide," says Kirkpatrick, adjunct assistant professor in the Department of Bioethics & Humanities at University of Washington Medical Center in Seattle. Kirkpatrick also is director of UW's Echocardiography Laboratory.

A 2011 study found patients viewed deactivation of ICDs as morally different from withdrawal of other life-sustaining therapies such as mechanical ventilation and dialysis.[3]

"Despite persisting concerns about the morality and legality of deactivation of implanted cardiac devices, the bulk of the discourse in the ethics literature has maintained that the intra-body location of a device should not be a determining factor as to whether the device can be deactivated," notes Kirkpatrick.

Deactivating a pacemaker isn't necessarily any different than removing a patient from a ventilator or stopping dialysis. "These are all measures which artificially prolong life, and are not incorporated into the patient's physiology or anatomy the way that a transplanted organ is," says Kirkpatrick. The interventions generally are dependent on power sources to maintain function, can be externally manipulated, and have limited ability to respond to physiological alterations.

"Of course, in the future, they are likely to function more autonomously, with automatic adjustments to meet physiological changes, so these arguments will no longer apply," adds Kirkpatrick.

As it stands now, the devices all have "off" switches — an indication they are intended to be deactivated should burdens outweigh benefits. "Perhaps that is part of the ethical justification," says Kirkpatrick. "They are inherently and intentionally supportive. Ultimately, they are temporary — not intrinsically constitutive."

Ethicists Are Needed

Ethicists can navigate difficult questions involving ICDs for clinicians, patients, and families — but only if they're very familiar with how the devices function. "There may be significant misunderstandings about what the device is actually doing," says Kirkpatrick.

For instance, unless a patient is experiencing active lethal arrhythmias, or is at risk for developing them in the setting of electrolyte disturbances, deactivating a defibrillator may have little or no effect. "Pacemaker deactivation may not lead to death, but simply reduced quality of life," notes Kirkpatrick. For instance, a patient may become lightheaded and fatigued.

The informed consent process for turning off a device also needs to be considered, Henry says. "You need to know what will happen when a device is deactivated. What will be the new symptom burden for the patient when death is not imminent?"

Close collaboration with cardiologists and electrophysiologists is needed to understand how a deactivated device is likely to affect a particular patient. "Even patients with left ventricular assist devices may not die right away after deactivation, depending on how much residual native cardiac function they possess," Kirkpatrick explains. Ethicists can assist with the following:

• Ensure proper palliative care is given during deactivation.

"There are specific issues pertaining to device patients," notes Kirkpatrick.

For example, reduction in cardiac output following deactivation of a left ventricular assist device or cardiac resynchronization device may reduce the ability of the heart to circulate morphine and other palliative or sedative medications at the end of life. "These should be given and titrated well before the device is deactivated," says Kirkpatrick.

EXECUTIVE SUMMARY

Some clinicians and patients view deactivation of implantable cardiac devices (ICDs) as morally different from the withdrawal of other life-sustaining interventions, yet very few people address this in advance care planning. Ethicists can assist in the following:

- Prompt patients to consider what to do at end of life with implanted devices at the time of implant, and include this in advance care planning.
- Help to develop appropriate responses if clinicians are conscientious objectors.
- Ensure appropriate palliative care is provided during deactivation.

• Prompt patients and clinicians to include devices in advance care planning.

Ideally, this should occur at the time the device is implanted. "We, and others, have shown that patients can have complicated relationships with their devices," says Kirkpatrick. "Some evince anthropomorphic gratitude and see them as friends or family members and even give them names."

Others see devices as a constant reminder of morbidity and mortality, and resent the intrusiveness. "This has important implications for advance care planning concerning devices," says Kirkpatrick.

Decision-making related to ICDs includes the following scenarios, notes Henry:

-whether to have an ICD implanted;

-refusing a device exchange when the battery life is ending or in rare instances where the device itself fails;

-requests for deactivation for patients who are not otherwise dying, and also for terminally ill patients.[1]

• Proactively address appropriate responses to conscientious objectors.

A capable patient, or surrogate if the patient is incapable, has the right to decide to withhold and withdraw any and all therapies — including ICDs.[4] "This fact does not detract from the distress frequently noted by physicians and front-line staff involved in this practice. Ongoing support and education is needed," says Henry.

Kirkpatrick says that deactivating a device, especially in an awake patient, "can still feel like turning off an organ for clinicians and patients and families."

Physicians were consistently less comfortable discussing cessation of pacemakers and ICDs compared to other life-sustaining therapies, found a 2010 study.[5] Henry has found it helpful for clinicians to ask themselves, "Is the ICD prolonging life or prolonging death?" He adds, "The underlying disease — not the removal of an ICD — is the actual cause of death."

The person who "turns off" the ICD is usually the nurse practitioner along with a technician from the cardiac electrophysiology clinic. In some cases, a representative from the ICD supplier is involved. "They will need support when undertaking this task, before and after deactivation," says Henry.

> "WE, AND OTHERS, HAVE SHOWN THAT PATIENTS CAN HAVE COMPLICATED RELATIONSHIPS WITH THEIR DEVICES."

Ethicists can help the institution to set expectations for the role of individuals working in a cardiac electrophysiology department, and address how to respond if a clinician conscientiously objects to deactivation of an ICD.

"It would never be acceptable to force a healthcare practitioner to act against their deeply held values," says Henry. "But it may need to be a consideration for the future hiring practices of clinicians." ■

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Impossible-to-comprehend Forms 'Make a Sham Of Informed Consent'

Many participants don't understand what they're signing

A researcher places a 20-page form full of "legalese" in front of a potential study participant, gives a brief explanation, and hands over a pen.

"The average research subject doesn't even read the form. It makes a sham of informed consent, which is a real shame," says **Tim Lahey**, MD, MMSc, chair of the clinical ethics committee at Dartmouth-Hitchcock Medical Center in Lebanon, NH.

Long sentences, large paragraphs, technical language, and multisyllabic words all contribute to reading and comprehension difficulties, found a recent study.[1]

"Forms prone to these problems include those involving areas of high-tech clinical research, such as artificial intelligence and deep learning, robotics, genetics, artificial organs, and imaging," says **Katrina A. Bramstedt**, PhD, senior ethics officer at Philips Research Eindhoven and adjunct professor at Bond University School of Medicine in Queensland, Australia.

People may feel that reading the entire form will waste the researcher's time, and perhaps even jeopardize their opportunity for study participation. "They might feel uncomfortable admitting they do not understand the content of the form, and be embarrassed to ask questions," adds Bramstedt. Research ethics committees can play an important role in educating research teams to produce consent forms that use lay language and facilitate the informed consent process, she says.

Kavita Shah Arora, MD, MBE, assistant professor of reproductive biology and bioethics at Case Western Reserve University in Cleveland, has seen one informed consent form, in particular, that is difficult to understand: the federally mandated Title XIX sterilization consent form. This is required to be signed by all patients on Medicaid or Medicare prior to receiving a sterilization procedure. "When evaluated for readability and comprehension, this form has scored poorly," says Arora.

After signing the form, some patients are still unaware that sterilization is permanent, or that nonpermanent contraceptive options as effective as sterilization are available. "Revised versions of the forms that have been tested in research settings that are shorter and easier to read have led to additional understanding about the nature of sterilization," says Arora.

Ann Munro Heesters, director of bioethics at University Health Network in Toronto, Canada, says the length of forms is only part of the problem: The words used, and the order they're in, also are problematic. "Consent forms typically address questions that no one would ever ask," she explains. "They fail to clarify exactly what is being offered, and why a participant should consider the offer being made to them."

'Great Vulnerability'

In research encounters, participants are like "strangers in a strange land," says Heesters. "They are in a position of great vulnerability. The customs are different. The language is foreign." Some are suffering and in great need of care.

Participants may fail to understand the very nature of research: That it tries to answer unanswered questions. "Enrollment in a clinical trial may make them worse off, because we simply don't know which treatments or interventions will be better for people like them," explains Heesters.

There are important tradeoffs to be weighed: Improvement in one set of symptoms may come at the cost of an increase in others. Trial participation also may involve significant time.

"Participants often conflate research and clinical care," adds Heesters. Based on the assumption that the researcher's job is to act in participants' best interests, people overlook the fact that research participation has the potential to make conditions worse.

Including all the required information in a succinct way is quite a challenge, says Heesters, "especially when study designs are complex, potential side effects are many, and multiple procedures and data points are involved."

Out-of-the-box Ideas

If a form is incomprehensible to participants, "the consent they provide can no longer be considered 'informed.' At that point, the informed consent process is actually obfuscating its own purpose," says **Tamar Krishnamurti,** PhD, assistant research professor of engineering and public policy at Carnegie Mellon University in Pittsburgh.

Shortening consent documents makes no significant difference to how well potential research participants understand a clinical trial, found a recent study.[2] "If documents are too long or dense, there is a risk that people may skim them or fail to read them at all," says Krishnamurti. This could result in someone unwittingly taking a risk that they would otherwise find unacceptable. There also is a risk to scientific integrity. "Enrolling uninformed participants may increase their likelihood of dropping out of research studies, causing unnecessary attrition problems," says Krishnamurti.

Lahey says the traditional approach to informed consent undermines the ability to obtain real informed consent. "We need to come up with pithier, non-legalistic ways of connecting potential research subjects to the information they need to make informed decisions," says Lahey. "This will require creative, out-of-the-box thinking." The following are suggested approaches:

• Add short, one-page summaries to overly legalistic forms.

"In time, these one-pagers should replace the legal malarkey of these longer forms," says Lahey.

• Use a "teach back" process.

Simply put, the researcher explains the study to a potential participant, who then explains it to the researcher. "That way, it is clear, not what from the subject signed or what words were said near them by the researcher, but actually what we care about: what the subject understood," says Lahey.

• Ask patients what information they think they need to make a decision.

Krishnamurti and a colleague developed a methodology for creating a shorter, patient-centered informed consent document.[3]

Researchers gave potential study participants a lengthy consent form, and asked them to extract only the information pertinent to their decision-making. "We then created a shorter form that met normative standards for good clinical practice, but did not contain information that wasn't relevant to participants' informed decision-making," says Krishnamurti.

The findings: Providing concise informed consent content, systematically developed from patients' self-reported information needs, may be more effective at informing participants than the traditional consent approach. There was no detriment to comprehension, risk assessment, or enrollment.

"Even potential participants with high levels of technical understanding and reading comprehension levels will benefit from easy-to-read forms," notes Krishnamurti.

• Include pictures, videos, or online pop-up windows defining unfamiliar terms.

"One form used pictorial representations that were more meaningful to patients with aphasia than printed words," recalls Heesters.

As an institutional review board chair, Heesters acknowledges that board members occasionally can be taken off-guard by unusual consent strategies. "These unconventional approaches, however, may be precisely what we should endorse if we are to better meet the needs of our participants," says Heesters.

Regardless of what type of form is utilized, enough time is needed for meaningful discussions. "Participants should be able to focus on the aspects of the trial that concern them most," says Heesters. "And research coordinators should have the time to assess the understanding of those they enroll." ■

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CME/CE QUESTIONS

1. **Which is true regarding research on critically ill ICU patients, according to J. Randall Curtis, MD, MPH?**

   a. Such research is unethical if dying patients lack decision-making capacity, even if surrogates consent.
   b. The risks of harming family members in extreme distress outweigh the benefits of potential improvements in care that could result from such research.
   c. Such research is not feasible due to consistently low consent rates from families.
   d. If patients regain decisional capacity during the study, it is important to consider whether and how researchers will approach patients to confirm their consent to participate in the research.

2. **Which is recommended by a report on research integrity from the National Academies of Sciences, Engineering, and Medicine?**

   a. Individual researchers are solely responsible for their own misconduct, and institutions have no culpability for their role.
   b. Research institutions should go beyond compliance requirements when providing education on research integrity.
   c. Executives at academic research institutions should decline involvement in development of approaches to prevent misconduct, since misconduct is a character defect that cannot be prevented.
   d. Negative findings should not be disclosed unless there is a risk patients will be harmed by non-publication, since routine disclosure of all results is overly burdensome.

3. **Which is true regarding hospital billing practices, according to a recent study?**

   a. U.S. hospitals continue to use chargemaster markups to maximize revenues.
   b. Prices have dropped significantly due to Medicare's efforts in negotiating pricing with drug companies.
   c. Pharmaceutical companies can no longer pass on to consumers the costs of marketing drugs to physicians.
   d. Hospitals are legally barred from charging some patients more in order to compensate for unreimbursed care.

4. **Which is a finding in a recent study regarding deactivation of implantable cardiac devices (ICDs)?**

   a. Few patients had considered device deactivation in an end-of-life situation.
   b. Advance directives are required to specifically address what to do with devices.
   c. Clinicians feel that discussing deactivation with a patient at the time of implant is unethical because it results in unnecessary emotional distress.
   d. Patients view deactivation of ICDs as no different from withdrawal of other interventions.