MEDICAL ETHICS ADVISOR

YOUR PRACTICAL GUIDE TO ETHICS DECISION-MAKING AND INSTITUTIONAL REVIEW BOARD MANAGEMENT

NOVEMBER 2021 Vol. 37, No. 11; p. 133-148

INSIDE

Relias Media

From Relias

IRBs Now Expect More Diversity in Research Trials

Multiple 2021 studies demonstrate the long-standing problem of certain groups remaining underrepresented in clinical trials.[1-3] IRBs are demanding much more of researchers in this regard. "It is a topic on the minds of PIs [principal investigators] and IRBs lately," says **Lucas Sikorski**, BA, CIP, senior IRB analyst at Northwestern University.

Current regulations that govern IRB review of human subjects research require equitable selection.[4] "But the regulations don't have any more specific way of attesting this or determining this. It is kind of vague about how it should be assessed," Sikorski explains.

Researchers typically recruited the people they saw in the course of their clinical practice.

"Historically, we have accepted that PIs recruit from their clinical population, and this was considered an acceptable population source," Sikorski notes.

Northwestern's IRB has been encouraging investigators to go beyond this, and consider if they are meeting the intent of the regulatory criteria for equitable selection.

"There's definitely a push to be cognizant of the potential participant pool that may be eligible for the study," Sikorski reports.

IRBs want to see investigators recruit outside their clinics if the people they see regularly do not include underrepresented groups. This might be the case with community-centered studies or investigations of a specific population that is not necessarily treated in a clinic (e.g., a specific LGBTQ+ population). Overall, IRBs want to see researchers conduct more community outreach, with an eye toward including diverse participants.

"That takes more resources, but we are seeing more expectations for that kind of outreach," Sikorski says. "Having a diverse data pool will lead to more accurate results. It makes for better science."

Previously, the status quo was for protocols to exclude non-English speakers, and IRBs usually accepted this. "But now we don't accept that as a de facto exclusion criterion out of convenience," Sikorski says.

If a protocol excludes non-English speakers, the IRB will want to know

Financial Disclosure: None of the planners or authors for this educational activity have relevant financial relationships to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

MEDICAL ETHICS ADVISOR®

Medical Ethics Advisor®, ISSN 0886-0653, is published monthly by Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468. Periodicals postage paid at Morrisville, NC, and additional mailing offices. POSTMASTER: Send address changes to *Medical Ethics Advisor*, Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468.

GST Registration Number: R128870672.

SUBSCRIBER INFORMATION
(800) 688-2421
customerservice@reliasmedia.com
ReliasMedia.com

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, Relias LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

The Relias LLC designates this enduring material for a maximum of 2 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

2 ANCC contact hours will be awarded to participants who meet the criteria for successful completion.

This activity is intended for acute care physicians, chiefs of medicine, hospital administrators, nurse managers, physician assistants, nurse practitioners, social workers, chaplains, and clinical trial research physicians and nurses.

This activity is in effect for 36 months from the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

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

why. "We might still accept a lack of resources as a justification. It would depend on the study, the target population, and the size of the enrollment goal," Sikorski explains. "It may be harder to justify if it's a wide-ranging and large target population."

To meet IRB approval, Sikorski says researchers should include people fluent in non-English languages on the study team, or otherwise be able to access non-English speakers. Also, he says to create plans for translating all subject-facing documents and to make non-English study staff available as part of recruitment, consent, and study visits.

Researchers might initially use the short consent form process for a non-English speaking participant. However, after encountering several such cases, the team would translate the consent form.

"Informed consent is all about communication and understanding," Sikorski observes. "If you don't have the tools or the resources to make sure that communication is transparent and understandable, it's a problem."

Existing guidance has focused mainly on detecting and preventing exploitation and coercion of research participants.[5]

"But that focus has evolved and expanded. The growing emphasis on including those underrepresented in clinical research is shared by IRBs," says **Madelon V. Baranoski**, PhD, chair of the IRB at Yale Medical School.

Increasingly, IRBs view the equitable selection of participants as a responsibility of investigators. "The expanding concerns reflect the evolving appreciation of the ethical principle of justice," Baranoski says. All in a community have the right to know about the research conducted and to be able to participate. Reliable and generalizable research results require full representation.

"The obligation of the research institution, therefore, is to remove barriers to participation," Baranoski says.

For IRBs, this means identifying specific barriers in protocols and exploring ways to mitigate them. "Language can be a barrier to including people from different backgrounds," Baranoski says.

IRBs may require materials be translated into a language that is common to a significant segment of the community. The IRB also may require making translation services available during the study visits. "The cost of travel and parking may be prohibitive to persons with low income," Baranoski notes.

If so, reimbursement for cost or providing a free parking area would make research more accessible. Likewise, providing evening and weekend times for study visits can reduce the burden of participants who would have to lose a workday to enroll.

Traditionally, researchers relied on notices or brochures in physicians' offices to alert people about clinical trials. "To reach a broader population, however, recruitment, education, and a two-way discussion of the research is best accomplished by going into the community to invite citizens to engage with the researchers," Baranoski offers.

The issue is not just about recruitment. "Equitable, diverse, inclusive, and just participation in research begins long before recruitment of subjects," notes **Linda Coleman**, JD, CIP, CHC, CHRC, CCEP-I,, director of the Yale University Human Research Protection Programs. Groups

underrepresented in research must be involved in research design, methods, the consenting process, and in formulating the research questions. "Science, medical care, investigators, and communities will all benefit," Coleman says.

To address obstacles that interfere with equitable recruitment of participants, the Yale IRB requires investigators to gather input from the Cultural Ambassador Program. This group "educates investigators about the community and educates the community about research," Coleman explains.

The IRB and study investigators have benefitted from the ambassadors' consultation in several ways. Previously, the prevailing attitude was that underrepresentation in research stemmed from community resistance. The ambassadors gave feedback, suggesting the onus is on researchers to build trust in the community. Today, investigators present protocols at churches, mosques, synagogues, high schools, nursing homes, and community groups.

Additionally, investigators have made changes to reduce the effect of missing a workday to participate in studies. Researchers offer evening and weekend hours; telehealth visits; and reimbursement for parking, transportation, and child care.

Despite these positive changes, obstacles to accessibility remain. "There are economic, practical, and regulatory limits on what IRBs can require," Coleman laments.

Equitable selection is not the responsibility of investigators alone. "Promoting equitable participation must not be at the cost of impeding research," Coleman stresses. "Within an ethical framework beyond regulations, however, IRBs are evolving to address and accelerate equitable inclusion in research." ■

REFERENCES

1. Flores LE, Frontera WR, Andrasik MP, et al. Assessment of the inclusion of racial/ethnic minority, female, and older individuals in vaccine clinical trials. *JAMA Netw Open* 2021;4:e2037640
2. Nguyen HT, Zheng A, Gugel A, Kistin CJ. Asians and Asian subgroups are underrepresented in medical research studies published in high-impact generalist journals. *J Immigr Minor Health* 2021;23: 646-649.
3. Tharakan S, Zhong X, Galsky MD. The impact of the globalization of cancer clinical trials on the enrollment of black patients. *Cancer* 2021;127:2294-2301.
4. 45 CFR Code of Federal Regulations 46.111. Criteria for IRB approval of research. https://bit.ly/3lnGtdG
5. HHS.gov. Approval of research with conditions: OHRP guidance. Nov. 10, 2010. https://bit.ly/30dOqu9

Report: Still Not Enough Women Included in Cardiovascular Research

Despite many years of efforts to include more women in cardiovascular studies, there still are not enough women represented in these investigations, according to a recent report from the American College of Cardiology Cardiovascular Disease in Women Committee.[1] "We've made some progress, but, unfortunately, we've been kind of stuck. Most trials continue to have low participation of women," says **Leslie Cho**, MD, FACC, lead author of the report.

Currently, women represent more than 51% of the U.S. population, and cardiovascular disease continues to be their No. 1 killer. Still, women only comprise approximately 38% of cardiovascular clinical trial participants.[1] For many years, data on male participants mostly were extrapolated to women, despite evidence indicating women respond differently to drug therapies than men.[2] "Physicians and regulatory bodies need to really make this a priority. Until we make it a priority, nothing is going to happen," says Cho, director of the Women's Cardiovascular Center at the Cleveland Clinic.

Cho and colleagues offered some reasons why this problem persists:

• **Participants in cardiovascular trials still are usually recruited only at large centers.** "Unfortunately, the status quo of having the same centers enrolling the same population is going nowhere," Cho says. "Women are less likely to be referred. Minority women are even less likely to be referred."

Typically, patients at smaller community hospitals cannot access cardiovascular clinical trial enrollment. Most never even hear about the studies. "Most patients receive their care in community centers, where they are unaware of trials. But every patient who goes there should still have the ability to get into a trial if they fit the criteria," Cho offers.

One way to accomplish that is by advertising cardiovascular clinical trials in community hospitals. Clinicians can refer their patients to the investigators. "If it's only being done in large centers, then

people who never make it to those centers never get access," Cho explains. "It should be a priority for pharmaceutical companies, regulators, and insurers to mandate that these trials be advertised and widely available to everyone."

Some investigators have created referral networks to include more women and minorities in the whole process. Other researchers have solicited participants for studies (or asked for input on design of research studies) at neighborhood barbershops.[3] "That kind of novel thinking is really important," Cho adds.

• Many people do not understand the benefits of participating in cardiovascular clinical trials, misunderstand the risks. Cho says it is understandable that minorities may be wary of researchers' motives or even express the attitude, "I don't want people to experiment on me."

"We have to acknowledge that there is an unfortunate, horrible history with African Americans and clinical trials," Cho notes. "But we need to acknowledge that is no longer the case, and then move forward."

There is some evidence indicating people who enroll in cardiovascular clinical trials experience better clinical outcomes, regardless of whether they receive the active drug.[4] "In part, that's because there is closer follow-up. If they have a question, people will answer them right away," Cho observes.

More diversity in cardiovascular trials is even good for pharmaceutical and device companies. "I don't think they are malintentioned. They are just used to doing things the same way," Cho suggests.

Demonstrating that there are no adverse events in women could increase profits for drugmakers. Otherwise, drug manufacturers might find out later that women are experiencing more adverse events than expected, and then retrospectively have to change the recommended dosage or put warning labels on the medication. "It's good for everybody. There's nobody who doesn't benefit," Cho adds.

It is critically important that women "are participating in all aspects of research, from basic to clinical to epidemiological," says **Jennifer H. Mieres**, MD, FACC, MASNC, FAHA, senior vice president of the Northwell Health Center for Equity of Care.

Almost 30 years ago, the NIH Revitalization Act of 1993 established guidelines for the inclusion of women and minorities. "We still have a lot of catching up to do," Mieres notes.

Most cardiovascular studies require physical access to centers participating in trials for enrollment. That means participants need transportation, time off work, and child care. "One can think of IRBs as partners with clinical researchers in ensuring the inclusion and safety of diverse patients in clinical trials," Mieres says.

The American Heart Association (AHA) Go Red for Women initiative engages women in the research process by using technology. "Women don't even have to leave their homes to contribute to research through this initiative," Mieres says.

Also, the AHA launched a Strategically Focused Research Network on Diversity in Clinical Trials. "The goal is to engage underrepresented groups in clinical trials to align with the diversity of our communities," Mieres says.

There is "an unfortunate, and false, perception that women are more difficult to recruit, and may be more difficult study participants. That may also deter efforts," says **Rita F. Redberg**, MD, MSc, FACC, a professor of medicine and Araxe Vilensky Endowed Chair in Cardiology at the University of California, San Francisco.

The fact that most principal investigators for cardiovascular clinical trials are men could lead to lower enrollment rates for women.[5] "Gender parity in inclusion should be required for FDA approvals of new drugs and devices," Redberg argues. "We have had many years of recommendations, and women remain underrepresented in cardiovascular clinical trials."

To augment the enrollment of women in cardiovascular trials, researchers must build awareness of cardiovascular risk factors and foster trust among women. Redberg suggests increasing the percentage of women who lead clinical trials, modifying inclusion and exclusion criteria, and advertising the risks and benefits of participation to the general population.

"Most importantly, if we hope to make measurable, lasting change, organizations, including the FDA, must statutorily require sex-based analyses and gender parity in trial data reporting," Redberg says.

Additionally, Redberg says IRBs should require the presentation of specific sex-based analysis data for all clinical trials. In trial design, researchers should specify concrete steps that will be taken to maximize gender representation by disease prevalence, particularly in interventional and procedural specialties. Finally, medical journals should make sex-based analyses data available for published trials. "Sex-based analyses would benefit from the development of a standardized system of reporting for all sexes and genders, including transgender and nonbinary genders," Redberg adds. ■

REFERENCES

1. Cho L, Vest AR, O'Donoghue ML, et al. Increasing participation of women in cardiovascular trials: JACC Council Perspectives. *J Am Coll Cardiol* 2021;78:737-751.
2. Zucker I, Prendergast BJ. Sex differences in pharmacokinetics predict adverse drug reactions in women. *Biol Sex Differ* 2020;11:32.
3. Balls-Berry J, Watson C, Kadimpati S, et al. Black men's perceptions and knowledge of diabetes: A church-affiliated barbershop focus group study. *J Racial Ethn Health Disparities* 2015;2:465-472.
4. Majumdar SR, Roe MT, Peterson ED, et al. Better outcomes for patients treated at hospitals that participate in clinical trials. *Arch Intern Med* 2008;168:657-662.
5. Wang TY, DesJardin JT. Time to end "manels" in clinical trial leadership. *JAMA Intern Med* 2020;180:1383-84.

Some Researchers Turn to Social Media Influencers for Help with Recruitment

A small but growing number of researchers are turning to a controversial approach to recruit hard-to-reach populations. They are contacting social media influencers with thousands of followers to help spread the word about clinical trials. "These are people who have a standing in the social media space who can help you connect with the population you are trying to study," says **Katherine Wentzell**, PhD, PNP, pediatric nurse practitioner at Joslin Diabetes Center in Boston.

Wentzell and colleagues outlined steps for researchers to follow, including IRB approval and engaging with influencers.[1] "All of the authors have been successful [when] recruiting for our studies using this method. It is new and innovative, so there are not a lot of details out there," Wentzell reports.

When recruiting for a diabetes study, Wentzell contacted about 20 influencers. Eight of them agreed to partner with her to recruit. "Though my study was an anonymous survey, I did ask how participants found out about my survey," Wentzell explains.

About 150 participants (more than half the sample) reported learning about the survey through a post by a person or hashtag they followed on Instagram. After successfully using social media influencers to recruit, the authors realized many other investigators probably were interested in this approach. However, there was no clear guidance on ethical considerations and IRB issues. "We felt like we were reinventing the wheel each time. After doing that work, we felt that we should share what we learned," Wentzell says.

Many researchers struggle to recruit hard-to-reach populations. During the COVID-19 pandemic, it became even more difficult since researchers could not recruit in clinics. "We decided to write a 'how to' paper on how to interact in the social media world as a researcher, and to reach people who you would not be able to reach otherwise," Wentzell says.

A good example is when researchers recruit young adults with type 1 diabetes. "We often lose that population to follow-up during the transition from pediatric care to adult care. It is so hard to find ways to recruit them in clinical spaces," Wentzell explains.

Other researchers struggled to recruit racially diverse, older adults with type 2 diabetes. Those patients tend to seek care in many different places; some go to primary care physicians, and others see endocrinologists. "There are all these people out there, but they don't necessarily have one clinical home where we can find them," Wentzell observes.

Other populations are even harder for researchers to reach. When investigators partner with a social influencer to recruit their followers, it effectively adds a third party to the recruitment process. "You are recruiting twice," Wentzell says.

First, researchers have to convince the social media influencer to partner with them. Next, investigators have to follow up with potential participants who found out about the study through the influencer. "The power of influencer culture is that followers look to the influencer for advance or word-of-mouth information, as we've seen in marketing," Wentzell notes.

In the same way, when the influencer posts about a research study, it confers legitimacy to the people who follow that influencer. "It's a different way to connect with your study population," Wentzell says.

To do this effectively, researchers must become familiar with the social media environment relevant to their study population, find the right influencers, and contact those people. Wentzell started with hashtags that represented the study population. Next, she saw which people were using those hashtags, learned who

had accumulated many followers, and who posted content that connected with the study population of interest.

Wentzell only sought out influencers who disclosed they were living with diabetes and posted about their condition. "This is one of the limitations of this recruitment approach, because we know that not all young people disclose their diagnosis on social media," Wentzell says.

For researchers who lack social media know-how, the first step is creating accounts themselves. "It might be necessary to create an Instagram account when they normally wouldn't have one," Wentzell offers.

It is necessary to learn how to connect with their study population. Concurrently, researchers have to keep the IRB's perspective in mind every step of the way.

"One of the big things we recommend is building a rapport with the IRB. We have found it does take some time for IRBs to get comfortable with this innovative approach," Wentzell says.

Probably the biggest hurdle is lack of control over what people are going to post about the study. Usually, IRBs want to approve the precise language and images used. When researchers are approaching someone else (i.e., social media influencers) to recruit, it is another story. The language is going to be more conversational, and communication happens informally through private messages or public comments. "You can't just send them a form letter," Wentzell says.

Once the influencer agrees to post something about the study, researchers can offer suggested wording, but it will not be followed word-for-word. For example, an influencer might share stories of feeling overwhelmed living with diabetes. Then, the influencer would post, "I am partnering with a researcher [and include @username for transparency] to recruit for a study. Please see the approved language in the comments."

At that point, Wentzell would post the IRB-approved language: "Help us understand what it feels like to live with T1D as a young adult! And get a chance to win 1 of 5 $100 Amazon gift cards. All young adults (ages 18-30) with T1D are eligible. Tag your friends! Click the link in bio."

What makes the influencer appealing to the followers is his or her unique style. "The power of influencers is in their brand, so the images and text should be the influencer's own creative content," Wentzell says. "The IRB can get a little fussy about that."

IRBs will ask, "What is the influencer going to say about the study?" Researchers cannot answer that. "As researchers, our role is to be cautious about editing or revising what the influencer is saying," Wentzell cautions.

IRBs are accustomed to approving the exact language used to promote the study. "Though some IRBs may ultimately require this, it is important to note that this may make the influencer partnership less effective," Wentzell stresses.

IRBs often want to hear the researcher will write the influencer's post in its entirety. Researchers cannot give those assurances because the influencer's authentic voice is how he or she connects with followers. "The IRBs are not used to hearing that someone who is not research-trained is promoting the study," Wentzell observes.

IRBs also will want to know how the research team is going to monitor comments made by other people about the original post. "It's important to let the IRB know you will be following the post, looking at comments, and keeping a log documenting all the communications," Wentzell says.

Researchers can assure IRBs they have a plan to track comments. If any comments are incorrect or unsafe, researchers can ask the post be taken down or comments turned off, and the IRB will be notified. "But it is out there in the world. You do have less control over that," Wentzell says.

For investigators, "the important thing is to emphasize that the influencer's creative content is simply the flashing lights, and is just to get people interested. It is not the recruitment language, which is separate, and is IRB-approved," Wentzell says.

It is not unlike placing recruitment posters on brightly colored paper in an attention-getting spot. After reading an influencer's post, anyone interested in participating still has to click on a link, call a number, or receive email correspondence. At that point, the researcher will use only IRB-approved language and IRB-approved consent processes.

Another ethical concern is researchers must be transparent about who they are and their intentions when engaging with people on social media. The same always was true for in-person interactions. "But the risk with social media is that there is something in between you," Wentzell says.

To mitigate this, researchers use clear language on social media profiles used for their research, such as "I am a scientist interested in diabetes research."

Above all, researchers interested in social media recruitment via influencers must be proactive in building a rapport with the IRB even before submitting protocols.

"Start the conversation," Wentzell offers. "Find out what the IRB is most worried about." ■

REFERENCE

1. Wentzell K, Walker HR, Hughes AS, Vessey JA. Engaging social media influencers to recruit hard-to-reach populations. *Nurs Res* 2021; Jul 30. [Online ahead of print].

Bioethics Field Lacks Standardized Competencies for Trainees

Residency and fellowship programs are accredited through the Accreditation Council for Graduate Medical Education (ACGME), which sets requirements for the measurement of progress. "As part of that requirement, they have, over time, developed tools like milestones for programs to use," says **Douglas S. Diekema**, MD, PHP.

Ethics programs, on the other hand, are comparatively new. "There is, at present, no central accrediting body to establish standards. Each individual ethics program more or less decides whether to evaluate fellows and how to do it," says Diekema, director of education at the Treuman Katz Center for Pediatric Bioethics in Seattle.

The Pediatric Emergency Medicine Fellowship at the University of Washington and the Pediatric Residency Program at Seattle Children's are accredited by the ACGME, which has published competencies and milestones that have been developed for each accredited residency. "The expectation is that each training program use these to map the progress of their residents and fellows as they move through the program," says Diekema, who is affiliated with both programs.

In contrast, there are no competencies for bioethics training programs to track progress. Diekema and colleagues set out to develop milestones based on the American Society of Bioethics and Humanities Core Competencies for Healthcare Ethics Consultation, along with the Pediatrics Milestones Project, a joint venture by the ACGME and American Board of Pediatrics.[1] "My primary purpose was to have an implementable standard that we could use locally in judging the progress of our fellows and the adequacy of their training," Diekema says.

It turned out to be a bigger project than expected — and one that would benefit from multiple perspectives. The primary team included a prospective fellow, a fellow, and the bioethics program director. "We then sought input from all faculty in our own fellowship program," Diekema explains. "We realized that there was value in sharing this work with others."

The goal was to move toward a standard approach among training programs in bioethics. "As it currently stands, bioethics programs span a huge range in terms of training, experience, time commitment, and competency at completion," Diekema reports.

Without some standardization, it is difficult for anyone seeking to hire someone into a bioethics job to know if the candidate has achieved an adequate level of competency in the field. In bioethics, hiring occurs in academic settings for jobs that include ethics consultation or research in ethics. It also occurs in hospital systems that are looking for a clinical ethicist. In either setting, says Diekema, "they have little to evaluate, other than looking at what kind of training in ethics someone has had and any publications" for which they might have written.

The newly developed standards give more information, according to Diekema, and can be adapted for specific needs. Programs may train students to be ethics consultants, academic bioethicists, or both. "Some of our milestones and competencies are more appropriate for one goal or the other," Diekema notes.

The hope is that training programs will find a way to evaluate not only trainees' progress, but also the adequacy of their programs in training people to work in the field of bioethics. "There's been a lot of interest in professionalizing at least some aspect of bioethics," Diekema says.

The problem is there is no agreed-upon standard for what kind of training someone working in bioethics requires. Nor is there a standard that must be met to market a program as a bioethics training program.

"Our article was an attempt to provide one step toward the goal of setting minimal standards for training programs," Diekema offers.

The hope is training programs will use some version of the milestones and competencies to evaluate fellows. "Eventually, there may be some attempt to have an accreditation process for fellowship programs," Diekema says.

This would include a requirement for evaluation of the fellows and the program. "Until then, institutions hiring fellowship graduates face

wide variation in terms of the skill and competencies coming out of fellowship programs around the country," Diekema says. ■

REFERENCE

1. Sawyer KE, Dundas N, Snyder A, Diekema DS. Competencies and milestones for bioethics trainees: Beyond ASBH's Healthcare Ethics Certification and Core Competencies. *J Clin Ethics* 2021;32:127-148.

Patients, Family, Clinicians All Misunderstand Chaplains' Role

After the Duke Outpatient Clinic in Durham, NC, added a chaplain intern in 2019, clinicians wanted to effectively integrate this role in the outpatient setting. "In the outpatient setting, patients regularly face challenging decisions in their healthcare and spiritual distress related to grief and trauma," says **Alissa Stavig**, MD, a resident physician in internal medicine/psychiatry at Duke University Health System.

Some organizations, like the Veterans Health Administration, incorporate chaplains into outpatient care.[1] However, chaplains typically work in the inpatient setting. Stavig and colleagues were curious what patients and staff in the outpatient setting actually knew about the role of hospital chaplains.[2]

To find out, they surveyed 78 patients, 10 caregivers (who were accompanying the patients), and 74 providers and staff at an outpatient clinic. They found a few knowledge gaps. Most respondents wrongly believed church approval is all chaplains need to begin their work. Both staff and patients were mostly unaware of the standardized training requirements for chaplains. Few respondents realized chaplains can respond to patient's needs from any religious background. Finally, most patients incorrectly thought part of chaplains' role is to teach religious practices and principles.

Many respondents correctly reported that chaplains' general role was to support patients at the end of life and that chaplains were there to help patients who are struggling for any reason. "Notably, a better understanding of the role and training of chaplains correlated to an increased desire for chaplain services," Stavig reports.

Those who understood the role of chaplains were more likely to want their help. "It stands to reason that education could result in increased utilization of chaplains," Stavig offers.

One way to help, according to Stavig, is providing patients and providers with background information on chaplains, with an emphasis on the fact chaplains are certified professionals who are specifically trained to provide patient-focused spiritual care to all people, regardless of belief system. "Efforts designed to clarify and validate the chaplain's role and expertise can contribute to ethical patient care in both the outpatient and inpatient setting," Stavig says.

At Ascension St. Vincent Hospital — Indianapolis, the hospital board asked the spiritual care department for data on what Indiana recipients of care wanted from chaplains. The board asked for data specific to the population St. Vincent serves all over Indiana, as opposed to relying on research literature or information from other markets.

"[Patients] think we are an angel of death or a prayer dispenser. Our research reinforced that chaplains are more than that," says **Beth L. Muehlhausen**, PhD, MDiv, BCC, LCSW, researcher for spiritual care and mission integration for at St. Louis-based Ascension.

Muehlhausen and colleagues interviewed 452 hospitalized patients and their loved ones at 16 Ascension hospitals in Indiana.[3] Of this group, 93% said they wanted at least one chaplain visit. The number was so high that the peer reviewers for the journal that eventually published this work questioned the findings. Two-thirds of participants expected a chaplain visit without having to request one. Participants thought chaplains would just show up, much like a nurse or respiratory therapist who they do not specifically ask to see. In reality, someone has to put in a request for a chaplain. "The days of having enough human resources to meet and greet every single patient are gone," Muehlhausen laments.

Participants were asked what religion they identified with, including "none." Interestingly, many non-religious patients also wanted a chaplain visit. "Despite stereotypes, I think people know a chaplain is someone they can confide in, share their concerns with, and will receive care and emotional support," Muehlhausen says.

Chaplains can meet the needs of patients from all religious faiths (including none). Chaplains can offer non-religious patients all kinds of help. It might be advocacy, someone to listen, or simply a reminder that they are not alone in what they are going through.

Recently, a chaplain had to advocate not to allow a dying patient's family to baptize a patient once the patient slipped into a coma. The chaplain supported the patient's desires; in this case, the fact the patient did not share their family's deep beliefs. "The chaplain protected the patient's right to self-determination," Muehlhausen reports. Another interesting finding: "Participants' top reasons for wanting a chaplain visit centered around emotional issues," Muehlhausen says. Patients wanted "someone to listen to me" and "be there for my loved ones."

"In an increasingly secular society, it was interesting to find that patients and loved ones value emotional support followed by more traditional spiritual or religious support," Muehlhausen observes.

For clinicians and ethicists, the findings emphasize the importance of screening patients for spiritual distress (with referral to a chaplain if a patient feels hopeless, despondent, lonely, scared, or struggling to make meaning out of their medical diagnosis.

Involve a chaplain in the interdisciplinary team to mitigate clinicians' anxiety and emotional stress. As a chaplain, Muehlhausen spoke with family members about hospice care, knowing the medical team had ordered palliative care. "I spoke quite highly of hospice, and the family seemed relieved. Afterward, the medical residents thanked me profusely, as they were anxious about bringing up the topic of hospice with the family," Muehlhausen shares.

Include a chaplain in plan of care conversations, ethical dilemmas, or conversations about palliative care. The Ascension St. Vincent ICU rotates physician teams every Monday. Muehlhausen was called to provide prayer for a patient where mechanical ventilation was going to be withdrawn, as the patient was not expected to be able to survive without it. "As I was speaking with the patient's sister, the new doctor entered the room, mentioning new drugs that the team could try," Muehlhausen says.

The sister was confused. Muehlhausen explained the plan to withdraw life support to the physician and asked if his suggestions were simply going to prolong the inevitable. At that point, the physician understood the situation and reassured the sister that withdrawing life support was the appropriate step.

Medical teams often use terminology that is unfamiliar to families. Chaplains consider what the medical team is saying, while also remaining highly sensitive to patients' and family members' ability to comprehend it.

"This can help bridge the divide that is often felt between patients and loved ones and the medical team," Muehlhausen says. ■

REFERENCES

1. Earl BSW, Klee A, Cooke JD, Edens EL. Beyond the 12 steps: Integrating chaplaincy services into Veteran Affairs substance use specialty care. *Subst Abus* 2019;40:444-452.
2. Stavig A, Bowlby LA, Oliver JP, et al. Patients', staff, and providers' factual knowledge about hospital chaplains and association with desire for chaplain services. *J Gen Intern Med* 2021; Jan 22. doi: 10.1007/s11606-020-06388-8. [Online ahead of print].
3. Muehlhausen BL, Foster T, Smith AH, Fitchett G. Patients' and loved ones' expectations of chaplain services. *J Health Care Chaplain* 2021;April 21:1-15.

Study: More Than Half of DNR ED Patients Resuscitated Against Their Wishes

If ED patients are resuscitated despite the existence of a valid DNR order, it is a serious ethical concern. However, this happens more often than one might believe.[1] "Performing a medical intervention, such as CPR, on a patient who did not wish to be resuscitated violates a patient's autonomy," says **Danielle Turrin**, DO, assistant professor of medicine at Hofstra/Northwell in Hempstead, NY.

Of 419 cardiac arrest patients, 65 were DNR status. Of this group of DNR patients, 38 were resuscitated against their wishes. "Not adhering to a patient's wishes not only violates their autonomy, but it is arguably not acting in the patient's best interest — and may in fact be causing them suffering or harm," Turrin says.

Additionally, when patients are resuscitated against their wishes, it means many other medical resources are used, such as ventilators and ICU beds. "This may make [resources] unavailable or difficult to procure for the patients who do desire them," Turrin offers.

Unwanted CPR happened for several reasons. Some DNR orders were not documented; other valid orders were documented, but clinicians did not realize it. Certain patients had only non-actionable advance directives to convey their wishes.

"When it comes to CPR and end-of-life care, physicians should be having these difficult and sensitive conversations with patients early in the course of an illness and with any change in their health status," Turrin emphasizes.

Physicians should ensure their patients' wishes are documented as medical orders. "These need to be displayed or stored in a way that are easily accessible and can be honored and upheld by other medical professionals, such as EMS," Turrin stresses.

Family members should be included so they can honor and respect their loved one's decisions, too.

"Obviously, the most concerning implications of ignoring or misunderstanding a patient's goals of care is the irreversible lack of resuscitation or the irreversible resuscitation," says **Jay M. Brenner**, MD, FACEP, medical director of the ED at Upstate University Hospital's Community Campus in Syracuse, NY.

There also can be reversible intubations onto ventilators. In Brenner's experience, poor agreement on goals of care between patients and ED physicians happens for these reasons:

• **The patient has not defined his or her goals of care beyond "feeling better."** "Nobody has taken the time to discuss their prognosis and offer palliative care," Brenner notes.

• **The ED physician does not know the patient's goals of care.** "It is critically important that ED physicians ask patients what their goals of care are at the earliest opportunity before irreversible decisions have to be made," Brenner stresses.

• **The ED physician disagrees with the patient's goals of care.** This is uncommon, but some physicians may question the patient's decision-making capacity to choose comfort care. In rare cases, the physician might even believe it is not best for the patient.

"The ED physician should prioritize the patient's preferences over their own. If the patient does lack decision-making capacity, reach out to an appropriate surrogate decision-maker," Brenner says. ■

REFERENCE

1. Haddad G, Li T, Turrin D, et al. A descriptive analysis of obstacles to fulfilling the end of life care goals among cardiac arrest patients. *Resusc Plus* 2021;8:100160.

Ethics Service Uses Relative Value Units to Quantify the Work of Consultants

Unlike clinical areas, ethics services have no consistent way to measure their work. The lack of quantifiable data makes it hard for hospital leadership to comprehend. "Hospital administrators live in the world of productivity measures. They don't fully understand what the world of clinical ethics is doing," says **Joseph Sayegh**, MBA, administrator of the Baylor College of Medicine Center for Medical Ethics and Health Policy in Houston.

A group of ethicists at Baylor wanted to quantify the work of clinical ethics consultants.

"Our goal was to try and standardize how we define and report consultation activities at different hospitals, to better understand what our consultants do, communicate what we do to our stakeholders, and use data to identify trends in the services," Sayegh says.

The first step was to define an ethics consult; there is no standardized definition. To some, it means a formal process where all stakeholders are interviewed in multiple meetings. To others, it includes informal discussions, such as an ethicist moving into the hallway to answer a question.

In networking with peers at ethics conferences, Sayegh hears a wide range of opinions on how to define an ethics consult. Baylor's ethicists identified five core activities that constitute an ethics consult: The initiation portion (which includes information-gathering to find out what is going on), the interaction portion (which includes clinicians meeting with family and/or the patient), a closeout (which includes making recommendations), follow-up to learn whether the recommendations were followed, and documenting in the patient's chart.

At first, the group quantified the work of ethics consults using time, looking at how long it took consultants to complete these five activities. "But we found that basing it on time penalizes experts in the field," Sayegh reports.

A highly efficient ethicist with many years' experience completes these tasks faster than a trainee. This made it appear the more experienced consultants spent less time (and performed less work), which was misleading.

Instead, the group decided to try a new approach — to quantify ethics work using relative value units (RVUs). Using RVUs, if a fellow takes 30 minutes to gather information from the family but a faculty member takes half that time, the work is quantified in the same way. "We use a process called an RVU crosswalk to identify corresponding CPT codes that can be tied to the activity the consultant is doing to develop a framework to assign an RVU value," Sayegh explains.

Family medicine or clinics can control how many RVUs they generate based on how many patients they see. This makes it possible to link reimbursement to RVUs. In contrast,

clinical ethics cannot anticipate volume.

"I look at clinical ethics much more like an emergency physician. There is zero control over who comes through the door and what encounters you have," Sayegh observes.

This makes using RVUs to determine reimbursement a tricky proposition in the ethics field. "We don't have any control over what comes through the pipeline," Sayegh says. "If it's a quiet night in the ER, it's not like we are not going to compensate providers."

Also, RVUs reflect only part of the ethics consultant's work; it only includes what the consultant is doing within the clinical ethics consult service. RVUs do not include important, valued activities like institutional grand rounds, policy development and review, or education. "Those other pieces aren't really accounted for. This is just a slice of the pie," Sayegh says.

In fact, if ethicists are doing a really good job with education, consult volume might decrease. "People can deal with simple, straightforward ethical questions that come up," Sayegh says. The ethics service has gathered some preliminary data on the RVU model. "We did a three-month pilot to validate the model, and currently we have about nine months of data collected in our current iteration of the database. The next big challenge is how we can benchmark against that," Sayegh says.

If necessary, the data can be presented to hospital leaders to justify the ethics service. "It can ensure staffing is correct and help identify potential burnout. It helps our fellows in their training, and gives them data they can take to the job market," Sayegh adds.

Ethicists studied a few other clinical service lines that, like the ethics service, are low-volume but high-contact. One example is genetic counseling. "They don't have a lot of volume. But with the volume that they do have, there's a lot of contact with the patient," Sayegh says.

The ethics service has not presented the data to hospital administrators. There are no immediate plans to use the data to request additional funding. For now, the RVUs are simply a way to measure the work of ethics consultants. Standardizing the definition of ethics consults would allow different institutions to compare their ethics services. RVUs could help determine if additional ethicists are needed. It also could show how ethics consults affect closely tracked hospital metrics, such as length of stay.

"Others have tried to do that and have not been able to really nail it down. That is a super-complicated problem," Sayegh laments.

Regardless, the RVU model has opened the door to more effective communication with hospital administrators. "Right now, it's hard to make the case that you need more money for the ethics program if you present it in an abstract way and not in the same 'language' as hospital leadership uses," Sayegh says.

For ethics, there is tremendous value in talking in terms administrators understand.

"When we meet with hospital leadership, I have gotten the question 'How does this translate to RVUs?' several times," Sayegh adds. ■

Ethics of 10-Year Research Agenda for Dementia, Alzheimer's Studies

The next decade's research agenda for dementia and Alzheimer's disease is outlined in a recent report from The National Academies of Sciences, Engineering, and Medicine.[1]

One of the central ethical issues is the vast majority of NIH funding related to dementia has gone to research looking for a cure, according to the report. "We get why people would want to do that. There really are no medications to effectively treat dementia," says **Tia Powell**, MD, chair of the report writing committee and director of the Montefiore Einstein Center for Bioethics in New York City.

The problem is the failure to find a cure despite decades of effort has come at a cost to other research areas. "For people who actually have dementia, there is very little research on how we can support them or make their lives more comfortable," Powell says.

There is a pressing need for more research on non-cure-based treatments for people living with dementia. "Millions of people actually need our help with things right now that are unrelated to a cure. That gap in our research is a real ethical concern," Powell says.

It is not only medical treatments that are needed. "Even if they find a cure tomorrow, that's not going to be beneficial to people with more advanced dementia," Powell notes.

Social-behavioral research can help family members who are struggling to figure out where the loved one with dementia is going to live. "Research would be useful that helps us clarify how to balance respecting the values and preferences of a person living with dementia while still meeting obligations to keep vulnerable people safe," Powell offers.

Critical questions about capacity makes important decisions (e.g., where to live and how to manage money)

complex and troubling. "People living with dementia and their caregivers could use more support with these issues," Powell observes.

Many people do not want their family members to go to a nursing home. "Nursing homes are super-expensive, and it's hard to provide high-quality care there. But can you keep somebody at home safely? How do you keep a job and feed your family?" Powell asks.

Some patients with many needs cannot be remain at home, even though older spouses and others may try to continue caring for loved ones there. Data can help with the decision-making process. "It's important for people to know: 'What can we reasonably do?'" Powell says. "We do have an obligation to answer that with research."

Investigators already struggle to find enough people with dementia (and their caregivers) to participate in studies. Ensuring study participants are sufficiently diverse is an additional challenge.

The report by Powell and colleagues calls for more research to determine the best ways to engage different communities. "We are not sure we are actually doing it well," Powell acknowledges.

Traditional practice is to recruit dementia patients from academic physicians working at large medical centers. "Not everybody has the means to get care at a big, fancy medical center," Powell admits.

Some researchers are connecting with study participants at faith-based settings; others are using new technology (e.g., Apple watches that gather data on cognitive function). "Approaches that work with community-based organizations and advocacy groups may be helpful in increasing diversity among research participants," Powell suggests.

Informed consent is an inherent problem in studying dementia, since the illness causes people to lose decision-making capacity. This is less of an issue with low-risk interventions, such as what kind of leisure activities are satisfying for those with early-stage dementia.

Another approach to boost research participation is to enroll people when they still have decision-making capacity, and identify someone who can consent on the person's behalf going forward. Researchers also need to study caregivers' stress levels. "That's a really important area that needs study, and we are encouraging people to look at," Powell reports. "In some communities, the level of stress experienced by dementia caregivers is quite high."

An older study revealed African American caregivers are not as depressed as white caregivers.[2]

"Is that something we can capture and help other people with? What are they doing right?" Powell asks. "It's not about having more resources or more money. It's something else that we don't understand."

Answers to questions of what kind of help people need at different stages of the illness also are needed. If someone is diagnosed at an early stage, that person might need financial advice, such as how to go about securing their bank accounts to protect funds from scammers. Someone at the end stages of the illness will need different help. "Dementia is a fatal illness, and those in the late phases will require end-of-life care," Powell says.

This includes palliative care and hospice that is tailored to meet the needs of someone who is cognitively impaired.

"We really encourage researchers to reach out to people living with dementia and their caregivers and ask them, 'Please collaborate with us. What is it that's hard for you? Where could we help you?'" Powell says. ■

REFERENCES

1. National Academies of Sciences, Engineering, and Medicine. *Reducing the Impact of Dementia in America: A Decadal Survey of the Behavioral and Social Sciences.* https://bit.ly/3AD66fe
2. Pinquart M, Sörensen S. Ethnic differences in stressors, resources, and psychological outcomes of family caregiving: A meta-analysis. *Gerontologist* 2005;45:90-106.

The Earlier, the Better for Formal Ethics Training

Senior medical students at the University of Michigan Medical School now can become trained clinical ethics consultants early in their careers, instead of waiting until after completing a graduate degree. Six students have completed a pre-doctoral clinical ethics fellowship program to date."We were motivated by an opportunity to re-envision how to train the next generation of physician-ethicists, given changes to the medical school curriculum allowing more flexible and self-directed scheduling that availed a chance to pilot a novel program," says **Andrew G. Shuman**, MD, FACS, HEC-C, co-chief of the clinical ethics service at University of Michigan Medical School Center for Bioethics and Social Sciences in Medicine.

Students spend about 40 hours a week on ethics service for at least six months and conduct at least 50 formal consults. Two faculty ethicists recently rated fellows' consultation notes before and after the program,

using the Ethics Consultation Quality Assessment Tool, and found scores improved.[1] For physicians anticipating prolonged post-graduate training, a key advantage of this program is it happens concurrently with the medical school curriculum. "This means that the pre-doctoral fellow will not need to delay graduation," Shuman says.

There were some logistical challenges with program implementation. "These were ameliorated by a supportive medical school administration and overwhelming enthusiasm of the students and involved faculty and staff," Shuman reports.

The results demonstrated that a predoctoral fellowship in ethics can improve senior medical students' knowledge, experience, and application of clinical ethics. "Their involvement facilitated the productivity of the service, contributed to patient care, and demonstrates the program's ability to produce trainees that effectively incorporate ethics into clinical care," Shuman says. ■

REFERENCE

1. Feder KJ, Chao SK, Vercler CJ, et al. A pre-doctoral clinical ethics fellowship for medical students. *J Clin Ethics* 2021;32:165-172.

IRBs Face Unique Ethical Questions About Disaster Research

Some IRBs are reviewing many more disaster studies, given the rapid expansion of the field since Hurricane Katrina in 2005.

"It is clear that the field is expanding, especially in the last decade. As the frequency and intensity of disasters increase, there are more scholars doing research, which is good," says **Alice Fothergill**, PhD, professor in the department of sociology at the University of Vermont.

However, there is a lack of guidance for IRBs to consider human research protection issues with disaster research, according to a recent paper.[1] "It's a little overwhelming for human subjects boards to know how to respond to the requests and for researchers new to disaster work to know how to work with IRBs," says Fothergill, one of the authors.

In a previous paper, researchers and practitioners from many disciplines came up with some recommendations for IRB review of disaster research.[2] "It was so well-received that we were asked to develop the thinking further," Fothergill notes. An ethical issue is that often, researchers enter the field suddenly, without advance preparation. Researchers might decide to conduct the study right there since the disaster poses a unique and valuable research opportunity. "If researchers do not move quickly and get into the field, the data they want to collect may be gone. That urgency poses an additional challenge," Fothergill observes. During two decades of disaster research, Fothergill has found most scholars are careful and thoughtful about how they conduct their work. "But there is a lot of debate around the ethics of disaster research," Fothergill explains. "Debate is healthy for the disaster field, and there are many strong viewpoints."

One controversy is over whether disaster survivors should be studied (i.e., ask them questions or take medical samples) right after a disaster has happened. "Most disaster researchers are sensitive to this. Most research is not too distressing for the participants," Fothergill reports.

Participants in social science research often report that talking about the experience with a compassionate researcher was helpful. But Fothergill says other important questions remain:

- Are there some times when people are too distressed to give informed consent?
- Should participants be compensated?
- Do participants understand the role of the researcher, or do they assume the researcher is affiliated with relief agencies or the media?
- Is disaster research different than other circumstances in which research is conducted on populations under a lot of stress caused by poverty, violence, or homelessness?
- Do participants have any physical or mental health needs that should be addressed before they participate in the study?
- Is there a way to maintain privacy and confidentiality during the data collection, even in shelters?
- Are some survivors studied by multiple groups of researchers, putting them at risk for too much burden?
- Do researchers know enough about the local cultural context?

"People who just lost their homes and are in a mass shelter may be taking care of a child with a disability, without medications they need, and don't speak the language being spoken by officials in the shelter. They may be elderly and disoriented by the rushed evacuation," Fothergill says.

IRBs must consider the value of the research to advance science and reduce suffering. At the same time, IRBs must consider the potential for harm based on the unique vulnerabilities of disaster survivors in the aftermath. "Education, flexibility, collaboration,

and compassion are critical as we move forward," Fothergill says. ■

REFERENCES

1. Packenham JP, Rosselli R, Fothergill A, et al. Institutional review board preparedness for disaster research: A practical approach. *Curr Environ Health Rep* 2021;8:127-137.
2. Packenham JP, Rosselli RT, Ramsey SK, et al. Conducting science in disasters: Recommendations from the NIEHS working group for special IRB considerations in the review of disaster related research. *Environ Health Perspect* 2017;125:094503.

Protocols for Scarce Resources Draw on Ethical Principles, Empirical Data

When COVID-19 cases filled ICUs to capacity in 2020, hospitals needed to determine the criteria used to allocate scarce resources. Ethicists were asked to develop crisis standards of care; now, some are scrutinizing those criteria. "Many of us were tasked with writing these plans. We thought some data on the ethical consequences of each of these plans would be incredibly useful," says **William F. Parker**, MD, PhD, assistant director of the University of Chicago MacLean Center for Clinical Medical Ethics.

In the wake of shocking disasters, such as Hurricane Katrina in 2005, and the 2009-2010 H1N1 influenza pandemic, the Institute of Medicine produced a series of workshops about providing healthcare in worst-case scenarios.[1] "They coined the term 'crisis standards of care.' But in practice, few states had well-developed crisis standards of care," Parker says.

When COVID-19 case counts skyrocketed in spring 2020, states and individual hospitals scrambled to come up with their own specific plans.[2] Even if hospitals started with the same set of agreed-upon ethical principles, they still created different protocols to achieve those ethical principles. "The protocol can be more or less successful in doing it. Even if you can agree on the ethics, the protocol still needs testing and refinement," Parker notes.

Parker and colleagues recently compared survival to hospital discharge rates of four triage strategies used during the pandemic: lottery, youngest-first, Sequential Organ Failure Assessment (SOFA) scores only, and "multiprinciple" (SOFA scores and severe comorbidities).[3] The authors simulated a ventilator shortage in 998 critically ill patients with COVID-19 who were receiving mechanical ventilation. The sample was about one-third Black, one-third Hispanic, and one-third white, which was fairly representative of COVID-19 patients in the Chicago area. Researchers picked two patients randomly from the group and determined who would go on the ventilator based on each protocol. "Until you actually simulate it, you don't know if the protocol will achieve the ethical framework that was written down," Parker explains. Some key findings:

- The youngest-first protocol saved more lives than the SOFA-only protocol, but it led to significantly lower survival and allocation in the oldest patients.
- The SOFA-only protocol and the multiprinciple protocol saved more lives than allocating ventilators randomly with a lottery.
- The lottery system/random assignment of ventilators saved the fewest lives, but it produced equal survival rates by race/ethnicity.
- Black patients were less likely to survive with protocols that used SOFA scores, but were equally likely to survive with a lottery system.
- Critically ill Black and Hispanic patients were younger than white patients, and were most likely to be allocated ventilators with the youngest-first system.

"The question is: What do we want to have happen, based on our ethical framework? We then need to determine if it actually did happen," Parker says. "You can't answer this question without empirical data."

Some ethicists have suggested subtracting points on SOFA scores for patients who live in certain ZIP codes to combat disparities.[4] But exactly how many points should one subtract?

"Ethics, in general, needs a lot more empiricism," Parker offers. "We should move beyond well-intentioned people writing down a score that seems OK to something that's actually providing a mathematical realization of an ethical framework."

Ethical principles and empirical data are needed, and not just in cases of scarce resource allocation. More routinely, empirical data and ethics are used to address questions on risks and benefits of a procedure.

"This type of work could be extended to any scarce resource, and should be," Parker says. "To just ignore resource scarcity or cost — all the things that ethicists like to

conveniently forget exist — you can't do that anymore."

Crisis standards of care were used to make difficult tradeoffs during the pandemic. "But it's a mistake to say that nothing like this has ever happened in the history of bioethics," Parker argues.

One example is the ongoing debate on how to take ethical principles and translate them into a ranking system for allocation of organs. "The marriage of ethical principles and empirical data is really important. The protocol doesn't get derived just from ethical principles. You need to reference empirical data," Parker says. "If you are the empiricist developing the protocol, you need to understand the ethics."

The same is true for efforts to address inequities. It is one thing to say SOFA-based systems will disadvantage Black patients who tend to produce higher SOFA scores. "But it's another thing to prove that with data," Parker says. "To really put the meat on the bone with inequities, you need empirical data." ■

REFERENCES

1. Institute of Medicine of the National Academies. *Crisis Standards of Care: Summary of a Workshop Series*. 2010. https://bit.ly/3BzWVx3
2. Piscitello GM, Kapania EM, Miller WD, et al. Variation in ventilator allocation guidelines by US state during the coronavirus disease 2019 pandemic: A systematic review. *JAMA Netw Open* 2020;3:e2012606.
3. Bhavani SV, Luo Y, Miller WD, et al. Simulation of ventilator allocation in critically ill patients with COVID-19. *Am J Respir Crit Care* Med 2021; Sep 9. doi: 10.1164/rccm.202106-1453LE.
4. White DB, Lo B. Mitigating inequities and saving lives with ICU triage during the COVID-19 pandemic. *Am J Respir Crit Care Med* 2021;203: 287-295.

CME/CE QUESTIONS

1. Which is true regarding IRB expectations for underrepresented groups in clinical trials?

a. No current regulations that govern IRB review of human subjects research require equitable selection.
b. IRBs are discouraging researchers from conducting extensive community outreach due to growing concerns about the cost.
c. IRBs want to see investigators recruit outside their clinics if the people they see regularly do not include underrepresented groups.
d. IRBs still accept default exclusion of non-English speakers.

2. Which is true regarding women in cardiovascular clinical trials?

a. Despite efforts to include more women in cardiovascular studies, women remain underrepresented.
b. Most cardiovascular trial participants, both men and women, are recruited at small community hospitals.
c. Minority women are most likely to be referred if trials recruit at large centers.
d. Women who enroll in cardiovascular clinical trials generally experience poorer clinical outcomes vs. women who are not enrolled.

3. If researchers use social media influencers for recruitment, which is recommended?

a. Build a rapport with the IRB before protocols are submitted to learn concerns in advance.
b. Ensure the IRB that social media posts will use IRB-approved language.
c. Assure the IRB that no communication will be conducted through private messages or public comments.
d. Acknowledge it is unrealistic to monitor comments made by other people about the original post.

4. Which did a study reveal about hospitalized patients and chaplains?

a. The vast majority wanted at least one chaplain visit.
b. People were dissatisfied because chaplains showed up without request.
c. Non-religious patients rejected chaplain visits.
d. Religious conflict was the top reason for patients wanting a chaplain visit.

5. Which is true regarding ED patients?

a. Scarce ICU beds made it less likely patients underwent CPR, even for those without a DNR order.
b. Most DNR patients were resuscitated against their wishes.
c. Resuscitating patients with a valid DNR order was more likely if ICU beds were available.
d. Non-actionable advance directives caused clinicians not to resuscitate some patients who indicated they wanted CPR. ethics consult.

MEDICAL ETHICS ADVISOR®

DocuSign Envelope ID: FC606685-AC2F-4CE8-9584-8BFF7230C6F8

Statement of Ownership, Management, and Circulation
(All Periodicals Publications Except Requester Publications)

1. Publication Title	2. Publication Number	3. Filing Date
Medical Ethics Advisor	0 8 8 6 – 0 6 5 3	10/1/2021
4. Issue Frequency	5. Number of Issues Published Annually	6. Annual Subscription Price
Monthly	12	$299

7. Complete Mailing Address of Known Office of Publication *(Not printer) (Street, city, county, state, and ZIP+4®)* — Contact Person: Sabrina Johnson
1010 Sync St., Ste.100, Morrisville, NC 27560-5468. — (919) 459-9495

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not printer)*
1010 Sync St., Ste.100, Morrisville, NC 27560-5468.

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do not leave blank)*

Publisher *(Name and complete mailing address)*
Relias LLC, 1010 Sync St., Ste.100, Morrisville, NC 27560-5468.

Editor *(Name and complete mailing address)*
Jonathan Springston

Managing Editor *(Name and complete mailing address)*
Leslie Coplin

10. Owner *(Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual owner. If the publication is published by a nonprofit organization, give its name and address.)*

Full Name	Complete Mailing Address
Relias LLC	1010 Sync St., Ste.100, Morrisville, NC 27560-5468.
Bertelsmann Learning LLC	1745 Broadway, New York, NY 10019

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box → ☑ None

Full Name	Complete Mailing Address

12. Tax Status *(For completion by nonprofit organizations authorized to mail at nonprofit rates) (Check one)*
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☑ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months *(Publisher must submit explanation of change with this statement)*

PS Form **3526**, July 2014 *[Page 1 of 4 (see instructions page 4)]* PSN: 7530-01-000-9931 **PRIVACY NOTICE:** See our privacy policy on *www.usps.com*.

DocuSign Envelope ID: FC606685-AC2F-4CE8-9584-8BFF7230C6F8

13. Publication Title: Medical Ethics Advisor
14. Issue Date for Circulation Data Below: September 2021

15. Extent and Nature of Circulation			Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a. Total Number of Copies *(Net press run)*			50	91
b. Paid Circulation *(By Mail and Outside the Mail)*	(1)	Mailed Outside-County Paid Subscriptions Stated on PS Form 3541 (Include paid distribution above nominal rate, advertiser's proof copies, and exchange copies)	35	77
	(2)	Mailed In-County Paid Subscriptions Stated on PS Form 3541 *(Include paid distribution above nominal rate, advertiser's proof copies, and exchange copies)*	0	0
	(3)	Paid Distribution Outside the Mails Including Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Paid Distribution Outside USPS®	1	1
	(4)	Paid Distribution by Other Classes of Mail Through the USPS (e.g., First-Class Mail®)	5	7
c. Total Paid Distribution *[Sum of 15b (1), (2), (3), and (4)]* ▶			41	85
d. Free or Nominal Rate Distribution *(By Mail and Outside the Mail)*	(1)	Free or Nominal Rate Outside-County Copies included on PS Form 3541	0	0
	(2)	Free or Nominal Rate In-County Copies Included on PS Form 3541	0	0
	(3)	Free or Nominal Rate Copies Mailed at Other Classes Through the USPS (e.g., First-Class Mail)	0	0
	(4)	Free or Nominal Rate Distribution Outside the Mail *(Carriers or other means)*	2	2
e. Total Free or Nominal Rate Distribution *(Sum of 15d (1), (2), (3) and (4))*			2	2
f. Total Distribution *(Sum of 15c and 15e)* ▶			43	87
g. Copies not Distributed *(See Instructions to Publishers #4 (page #3))* ▶			7	4
h. Total *(Sum of 15f and g)*			50	91
i. Percent Paid *(15c divided by 15f times 100)* ▶			95%	98%

* If you are claiming electronic copies, go to line 16 on page 3. If you are not claiming electronic copies, skip to line 17 on page 3.

DocuSign Envelope ID: FC606685-AC2F-4CE8-9584-8BFF7230C6F8

Statement of Ownership, Management, and Circulation
(All Periodicals Publications Except Requester Publications)

16. Electronic Copy Circulation	Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a. Paid Electronic Copies ▶		
b. Total Paid Print Copies (Line 15c) + Paid Electronic Copies (Line 16a) ▶		
c. Total Print Distribution (Line 15f) + Paid Electronic Copies (Line 16a) ▶		
d. Percent Paid (Both Print & Electronic Copies) (16b divided by 16c × 100) ▶		

☐ **I certify that 50% of all my distributed copies (electronic and print) are paid above a nominal price.**

17. Publication of Statement of Ownership

☑ If the publication is a general publication, publication of this statement is required. Will be printed in the November issue of this publication. ☐ Publication not required.

18. Signature and Title of Editor, Publisher, Business Manager, or Owner	Date
DocuSigned by: kay kraft 4007ADA3CF8246E... Chief Executive Officer	29-Sep-2021

I certify that all information furnished on this form is true and complete. I understand that anyone who furnishes false or misleading information on this form or who omits material or information requested on the form may be subject to criminal sanctions (including fines and imprisonment) and/or civil sanctions (including civil penalties).