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INSIDE

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Lack of Basic Knowledge on Clinical Trials Makes Study Recruitment Harder

When people are deciding whether to participate in a study, most consider the possible risks, the amount of time involved, and possible compensation. How much they know about trials also comes into play.

Aisha T. Langford, PhD, MPH, studies reasons why people choose to participate in clinical trials, and was interested in exploring general knowledge of trials among U.S. adults. Using the National Cancer Institute Health Information National Trends Survey data, Langford and colleagues analyzed 2,648 responses on clinical trial knowledge.[1]

More than one-third (37.4%) of respondents said they "don't know anything" about clinical trials. Most (62.6%) knew either "a little bit" or "a lot" about clinical trials. The study team only evaluated self-reported knowledge on trials, as opposed to the ability to gauge understanding of the purpose of informed consent or the phases of clinical trials.

Based on the responses, "several factors affect knowledge of clinical trials," Langford says. Respondents with a history of cancer and those who have heard of ClinicalTrials.gov knew more about trials. Such knowledge also was more abundant among college graduates and those who had been asked to participate in a trial.

Participants were asked if they had used a computer, smartphone, or other electronic means to look for health information for themselves in the last 12 months. Those who did so knew more about clinical trials. "This finding is consistent with general calls to make information about clinical trials more accessible on the internet vs. relying mainly on in-clinic conversations about clinical trials," says Langford, assistant professor of population health and co-director of CTSI Recruitment and Retention Core at NYU Grossman School of Medicine.

Lacking basic knowledge of how clinical trials work can impede study participation. "We have a large oncology

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clinical research unit in our center. We felt it would be interesting to see what will help motivate participation in a trial amongst our patients," says **Ravit Geva**, MD, deputy director of the division of oncology at Tel Aviv Sourasky Medical Center in Israel.

Geva and colleagues surveyed 200 patients receiving cancer treatment to evaluate their attitude toward clinical trials and gauge their basic knowledge of how clinical trials work.[2] People with sufficient basic knowledge of clinical trials were significantly more likely to participate in research.

"Knowledge is known to reduce concerns in many aspects in life. As we described in our study, this applies also to clinical trials," Geva explains.

Patients who knew more about the aim of a clinical trial, and how the trial was conducted, were less afraid of participating in one. Geva says these findings underscore the duty of researchers to inform patients on what a clinical trial is and its importance.

"This will reduce misconceptions, such as the patient is a 'lab rat,' and explain that patients are actively treated under strict ethical and medical guidelines," Geva says.

People with deep-seated distrust of research probably will not agree to participate. "Most people who sign informed consent are eager to participate — or at least are not distrustful. But there are some elements of distrust that can come up," says **Mary McDermott**, MD, professor of medicine at the Northwestern University Feinberg School of Medicine.

Occasionally, research participants develop adverse effects on therapies, which could be either a placebo or an active drug. Naturally, these patients are going to ask questions. It is rarer for an enrolled participant to express second thoughts about signing up for research, but it does happen. In those cases, McDermott, as the principal investigator, typically speaks to the participant and reminds him or her it is their prerogative to not participate in any parts of the research they distrust.

In some cases, someone signs up for research willingly, but a family member objects. In those cases, with the participant's permission, McDermott offers to speak directly with the family member about their concerns.

"Investigators can dispel distrust by being open, transparent, and honest — and by being available to address questions and concerns," McDermott observes.

Some people assume clinical trials must be safe simply because their healthcare provider is offering the option. Others believe trials always are unsafe for participants. "The truth is more nuanced and somewhere in between," says **Tricia Teoh**, MD, MPH, IRB medical chair at WCG IRB.

Potential risks and benefits of any trial are based on scientific knowledge to date, but ultimately are unknown. "If there are misunderstandings or misconceptions, the ethical concerns are that people are not giving a fully informed consent," Teoh explains.

Researchers may find it difficult to recruit participants who have no concept of how trials are designed. Trust in the study investigator may be broken if it turns out there is no clinical benefit when the participant expected this, or if something unexpected happens during the study.

"The informed consent process should start with study investigators finding out how much people know about clinical trials," Teoh says.

Investigators could start with an open-ended question such as: "I think there is a clinical trial you may be interested in. Can you tell me what you know or have heard about clinical trials?"

"This gives investigators and potential participants a common foundation before discussing details of a specific clinical trial," Teoh concludes. ■

REFERENCES

1. Langford AT, Orellana KT, Buderer N. Correlates of knowledge of clinical trials among U.S. adults: Findings from the 2020 Health Information National Trends Survey. *Contemp Clin Trials* 2022;114:106676.
2. Asher N, Raphael A, Wolf I, et al. Oncologic patients' misconceptions may impede enrollment into clinical trials: A cross-sectional study. *BMC Med Res Methodol* 2022;22:5.

Analyses: Older Patients Excluded from Many Research Studies

Geriatric patients often are excluded from clinical trials due to age-based exclusion criteria.[1,2] Researchers recently analyzed 302 trials with 262,354 participants. They found the median age of trial participants was a mean 6.49 years younger than the median age of the population.[3]

Age disparities were worse for industry-funded trials; for trials with enrollment criteria restrictions based on age cutoffs or performance status; for trials that evaluated a targeted, systemic therapy; and for lung cancer trials, according to another group of researchers.[4] Their analysis of 847 trials on ClinicalTrials.gov revealed older adults were likely to be excluded from more than 50% of COVID-19 clinical trials and 100% of vaccine trials. "Most academic papers and news articles are limited to reporting the problem instead of directly addressing it. What's missing are solutions," says **Anh Ninh**, PhD, an associate professor of computational operations research at William & Mary in Williamsburg, VA.

Ninh and colleagues analyzed data on ClinicalTrials.gov regarding cardiovascular diseases, cancer, and type 2 diabetes studies conducted from 2010-2021. They investigated relevant factors that could be contributing to the exclusion of elderly people from trials.[5] "As people age, they are usually subject to concomitant drug treatment, comorbidities, and worsening levels of organ functioning," Ninh observes.

Cancer trials recorded the lowest percentage of age-capped enrollment, while type 2 diabetes trials were most likely to be age-capped. Cardiovascular trials were more likely to be age-capped than cancer trials. "The results obtained from clinical trials are based on a certain demographic, and they should only be applied confidently to that same group of individuals," Ninh says.

Researchers also studied whether the funding mechanism (public vs. private) affected the proportion of people excluded from studies. NIH-funded trials include fewer age caps, historically, than trials funded from sources other than NIH. There were no significant changes in the percentage of trials with upper age limits before or after the 2019 NIH Inclusion Across the Lifespan policy was enacted. "Apparently, guidelines are not effective in preventing age exclusion since this issue is still going on," Ninh notes.

Notably, this work was hindered somewhat by lack of detailed data. "Companies do not report the number of patients in certain age groups," Ninh explains.

The only available information on ClinicalTrials.gov is the age cap for trials. Adverse events reported by age group after drugs are approved should be collected and made available on ClinicalTrials.gov, according to Ninh. "Only with more detailed data can we investigate this problem more deeply and come up with better solutions," Ninh offers. ■

REFERENCES

1. van Marum RJ. Underrepresentation of the elderly in clinical trials, time for action. *Br J Clin Pharmacol* 2020;86:2014-2016.
2. Sedrak MS, Freedman RA, Cohen HJ, et al. Older adult participation in cancer clinical trials: A systematic review of barriers and interventions. *CA Cancer J Clin* 2021;71:78-92.
3. Ludmir EB, Mainwaring W, Lin TA, et al. Factors associated with age disparities among cancer clinical trial participants. *JAMA Oncol* 2019;5:1769-1773.
4. Helfand BKI, Webb M, Gartaganis SL, et al. The exclusion of older persons from vaccine and treatment trials for coronavirus disease 2019 - Missing the target. *JAMA Intern Med* 2020;180:1546-1549.
5. Nguyen D, Mika G, Ninh A. Age-based exclusions in clinical trials: A review and new perspectives. *Contemp Clin Trials* 2022;114:106683.

Preventing Age Disparities in Cancer Trials

A clinician researcher at the University of Texas MD Anderson Cancer Center, **Ethan Ludmir**, MD, who has studied age disparities in cancer trials extensively, recently spoke with *Medical Ethics Advisor* about efforts to address this persistent issue. *(Editor's Note: This transcript has been lightly edited for length and clarity.)*

MEA: Why should age disparities in clinical cancer trials concern the research community?

Ludmir: The top priority from the medical side is generalizability. When you get a trial result that says Therapy A is better than Therapy B, the question is: Are these results applicable to the general population? What if you run a clinical trial where the average age is 15 years younger than the general population in the real world that would be exposed to the therapy? If participants in a lung cancer trial had a median age of 55, and [the results show] that Drug A is better than Drug B, is that result generalizable for the 80-year-old patient sitting in your clinic?

The other dimension to this is one of equity. Patients should have equity with regard to their ability to access clinical trials, to the greatest extent reasonably possible.

MEA: Is the problem becoming better or worse?

Ludmir: Our data suggest that age disparities are worsening over time. Other data suggest that at the very least, age disparities are not getting better over time. Either way, it is still a persistent problem.

However, I remain optimistic. The geriatric oncology community has been advocating quite effectively to have this issue be investigated and addressed. The FDA recently issued a guidance encouraging older patient enrollment in cancer clinical trials — specifically, those sponsored by the biopharmaceutical industry.[1] We know that in cancer at least, the vast majority of late-phase clinical trials — about 85% or so — are sponsored by the pharmaceutical industry. In many ways, effective engagement with the pharmaceutical industry is a critical path toward ameliorating these disparities.

Not only have we seen this regulatory push by the FDA, but there are also several investigators and research groups, including our own, trying to identify actionable and meaningful changes that could help push the needle in the right direction.

MEA: What are the most promising developments?

Ludmir: The rates of studies explicitly excluding patients based on age alone is very uncommon. Only about 10% of cancer trials exclude patients based on age alone.[2] That is a rare phenomenon, and it is getting rarer.

MEA: Why do researchers tend to include stringent exclusion criteria in study protocols? Wouldn't they want to include more people in the study?

Ludmir: If you're running a clinical trial, in an ideal world, you'd fill all the spots as quickly as possible. The caveat is, if you're the sponsor of that trial, if you're taking everyone who could possibly be on that trial, and there's a lot of heterogeneity of who you're enrolling, then your signal may get lost in the noise. It's not by definition an ethical problem. Some may feel otherwise, but I don't necessarily think it's an issue if you say upfront, "There are certain patients who have this disease who are not going to be eligible for this trial."

Maybe it's increased risk of side effects, or maybe the biology of the disease is different, so they don't really fit the parameters of the trial. There are legitimate reasons to try and look for some homogeneity in the clinical trial population without having it cross an ethical line.

On the other hand, that's not the real world. In the real world, people are older and sicker, and have had previous cancers. If healthy 50-year-olds in the study do better on three drugs than two, does that conclusion apply to frail 80-year-olds? Or would it do more harm than good? With a more homogenous population, we get the clearest possible signal. However, maybe patients over 80 do better with one drug instead of two.

Randomized, controlled trials, ideally, would be able to inform differential treatment options for healthy 50-year-olds and frailer 85-year-olds who have the same condition. A lot of times, that's something we have as an ideal. The issue is that a randomized, controlled trial is an incredibly ambitious undertaking. Forgetting the finances for a moment, the sheer effort and coordination required to make one happen is impossible to understate, and very often trials may not [be] complete[d] due to incomplete accrual. They take years to run. Often, in the time between when you start and end them, the whole landscape of the disease has changed.

Many people have run trials specifically for geriatric patients, or for older and sicker patients.[3-5] That is also a very impressive thing we have seen more of in the last several years, running trials specifically targeted at those populations.

MEA: What can IRBs do?

Ludmir: IRBs, which tend to be judicious by nature, have the ability to critically examine inclusion and

exclusion criteria in clinical trials. In general, it's become harder to reasonably and scientifically justify an explicit cutoff based on age alone. But there are still exclusion criteria based on renal function, hepatic function, blood counts — which we know change naturally and physiologically with age. Those criteria can disproportionately skew enrollment away from older patients unnecessarily.

We recently found there is an independent association with prior malignancy exclusion criteria and age disparities.[6] Very often, investigators will exclude patients who have had a previous cancer from participating in a current cancer trial. Participants with a previous cancer could certainly complicate the trial results.

If a patient is being treated for cancer A in a clinical trial, and had another known cancer B — and dies of cancer B — it may limit your information from the trial about optimal treatment for cancer A. As older patients are more likely to have had previous malignancies, these exclusion criteria may disproportionately impact older patients.

Our data show trials with prior malignancy exclusion criteria tend to suffer from wider age disparities. This allows for reasonable consideration by trialists, investigators, and sponsors to potentially omit or tighten prior malignancy exclusion criteria in order to reduce age disparities. These potentially actionable changes in trial design, including eligibility criteria, are only one piece of the puzzle in addressing age disparities. Ultimately, the onus is on the investigators to be more thoughtful, and perhaps more relaxed, about who participates in clinical trials. ■

REFERENCES

1. 87 FR 11718. Inclusion of older adults in cancer clinical trials; Guidance for industry; Availability. *Federal Register*. March 2, 2022. https://bit.ly/3tJ0gas
2. Ludmir EB, Subbiah IM, Mainwaring W, et al. Decreasing incidence of upper age restriction enrollment criteria among cancer clinical trials. *J Geriatr Oncol* 2020;11:451-454.
3. Muss HB, Berry DA, Cirrincione CT, et al. Adjuvant chemotherapy in older women with early-stage breast cancer. *N Engl J Med* 2009;360: 2055-2065.
4. Pfreundschuh M, Schubert J, Ziepert M, et al. Six versus eight cycles of bi-weekly CHOP-14 with or without rituximab in elderly patients with aggressive CD20+ B-cell lymphomas: A randomised controlled trial (RICOVER-60). *Lancet Oncol* 2008;9:105-116.
5. Perry JR, Laperriere N, O'Callaghan CJ, et al. Short-course radiation plus temozolomide in elderly patients with glioblastoma. *N Engl J Med* 2017;376:1027-1037.
6. Patel RR, Parisi R, Verma V, et al. Association between prior malignancy exclusion criteria and age disparities in cancer clinical trials. *Cancers (Basel)* 2022;14:1048.

IRBs Strive to Improve Consistency of Study Protocol Decisions

Is a study protocol OK to go forward? Or are many changes needed for recruitment, consent, or other processes? IRB decisions often are inconsistent on these points — even at the same institution, and sometimes at the same IRB. "Different IRBs have different people on them with different opinions," explains **Andrew Hedrick**, MPA, CIP, senior IRB protocol analyst at The Ohio State University.

A common example is the language used in informed consent documents. "Some IRBs will look at a consent document and say, 'This is fine.' A week later, another IRB member may say, 'This isn't detailed enough. We want more,'" Hedrick reports.

IRB members might take contrary views on criteria for waiving consent for records review studies, or on research that involves deception of some kind. Some IRBs just look strictly at the criteria and grant a waiver as long as the study protocol meets the bare minimum. Other IRB members push back, challenging researchers on why they really need a consent waiver. "If a needed waiver is not granted, it's sometimes only an inconvenience. But other times it can affect how a [principal investigator] wants to do their study," Hedrick says.

Some IRB decisions made years earlier may no longer reflect current realities. "Technology is ever-evolving. Things that we don't worry about now might be a big deal five years from now," Hedrick observes.

Confidentiality and data are good examples. Certain IRB members consider data "anonymous" since no names or addresses are involved, even though other demographic information is involved. For example,

in the context of a national survey of hospital patients conducted online, the IRB might consider the information to be anonymous if the only demographics collected are age, gender, ethnicity, and number of children.

"However, if you added something like a ZIP code into that same list, anonymity may go out the window for a lot of respondents, depending on how diverse the population is in a ZIP code and how many people live there. More savvy IRB reviewers would say it's absolutely identifiable," Hedrick says.

Studies involving children also tend to provoke strong opinions on subjective issues, regardless of whether regulatory criteria are met. "The IRB will ask: 'Is it appropriate? Is it ethical? Should parents be involved?'" Hedrick says.

There can be heated discussion on all those questions. "You can never eliminate inconsistency completely, even within the same IRB," Hedrick says.

Still, IRBs should monitor for inconsistent decisions. It is troublesome if IRBs decide on a study protocol without realizing the same issue arose previously and the panel made a different decision. Usually, investigators will alert IRB staff to the issue. Researchers will complain (perhaps heatedly) if the IRB asks for major changes the board did not request with a previous similar study (either their own or one by a colleague).

"In some cases, investigators are doing very similar types of research, but the devil is in the details," Hedrick says.

In that situation, this gives the IRB a chance to explain to the researcher the two studies were not the same.

Hedrick tries to offer researchers guidance on how to comply with IRB requests so their work can go forward. "Ultimately, we want to promote research. We try to be researcher-focused and customer service-oriented to help the researchers do the research they want to do while keeping them inside the lines, so to speak, of regulatory frameworks. That's the reason we're all here," Hedrick says.

Ohio State's IRB Policy Committee (IPC) serves as a forum for deciding how boards will approach various issues. Occasionally, inconsistent decisions are a topic of discussion.

"If we notice widespread inconsistencies, we put it on the agenda so the committee can decide how to address this going forward," Hedrick reports.

If one IRB approves a study with no questions asked, but another board asks for many changes, it raises some important questions. "Do we have one IRB approving research that's riskier than we should be approving?" Hedrick asks. "It means there's a difference of opinion. That's something we definitely want to look at."

Using templates with language that investigators use for consent forms, instead of creating a unique consent form for every study, is one way to avoid issues. "To the extent you can standardize things, there is less guesswork for the IRB," Hedrick says.

At the University of Pennsylvania, the Consortium to Advance Effective Research Ethics Oversight (AEREO) conducted a pilot project to understand whether IRB decisions could be summarized in a way that would allow them to be used as precedent for future decisions.[1] "We were motivated by the analogies between IRB decisions and judicial decisions," says **Holly Fernandez Lynch**, JD, MBe, co-chair of AEREO.

Courts are expected to rely on previous rulings to inform current decisions, and justices write opinions summarizing the rationales for their key opinions. In contrast, IRBs often rely on institutional memory to make decisions. "IRBs strive for consistency. But formal approaches to looking back at previous decisions are rare," Fernandez Lynch explains.

IRBs lack a mechanism to index and search those prior decisions in a systematic way. "That's what we were looking to address. IRB precedent has been discussed before, but we wanted to see what it would take to do in practice," Fernandez Lynch explains.

AEREO members started by focusing on protocols and decisions for comparative effectiveness research. The team developed and tested several methods of summarizing prior IRB decisions on protocols. "We assessed the summaries on the basis of whether they were efficient to produce, valid, searchable, and comprehensive," Fernandez Lynch reports.

Ultimately, none of the methods tested satisfied all these criteria. This led the team to identify a new approach. "We learned that for this to work, we need to find a way to support IRB decision summaries being written up in real time as protocols are reviewed," Fernandez Lynch says.

This approach is more likely to be efficient and accurate since decision summaries can be produced as IRBs are reviewing them.

The team's next step will be to test the feasibility of this prospective approach, a project on which they are about to embark. Once AEREO identifies mechanisms of developing IRB precedent, the next step is finding ways to make those precedents searchable so they can be used as a routine part of board deliberation. "In the future, we hope

institutions will consider sharing these decision summaries with each other to improve learning more broadly," Fernandez Lynch says.

For researchers, the benefit of a more systematic approach to using IRB precedent will be greater predictability and consistency. "Hopefully, there will be more clarity around how IRBs will interpret discretionary regulatory and ethical standards," Fernandez Lynch says. ■

REFERENCE

1. Seykora A, Coleman C, Rosenfeld SJ, et al. Steps toward a system of IRB precedent: Piloting approaches to summarizing IRB decisions for future use. *Ethics Hum Res* 2021;43:2-18.

Too Many Scientific Articles End Up Retracted

The number of scientific publications has increased exponentially over the past 50 years. Unfortunately, too many of those articles end up retracted. "This topic has remained under-recognized by the scientific community for a long time, despite the detrimental impact it has on the generation of evidence-based knowledge," says **Mario F.L. Gaudino**, MD, an attending cardiac surgeon at Weill Cornell Medicine.

Gaudino and colleagues analyzed trends and characteristics of articles retracted from 1971-2020.[1] "While analyses of retractions in non-biomedical fields have been published, a comprehensive analysis of retractions in the biomedical literature did not exist," Gaudino explains.

Gaudino and colleagues sought to identify characteristics of retracted articles on which the peer review process should focus. In the five decades studied, more than 5,000 papers were retracted. Almost 9% of the retractions were meta-analyses or reviews. "This raises some concerns, as these study designs are in a high position on the level of evidence pyramid," Gaudino offers.

Guidelines only represented a small percentage of total retractions (0.3%). Scientific misconduct (including data fabrication, plagiarism, and duplication) was found in 62.3% of retracted studies. The number of retractions and misconducts increased from 1980 to 2014, but declined after 2015. The median time from publication to retraction significantly decreased over the study period. The median impact factor of the journals that published retracted articles decreased as well. "This may be the result of increased efficacy of the peer review process," Gaudino suggests.

Each retraction was cited nine times on average. A few retractions were cited more than 100 times. "More attention while indexing the retraction notices is necessary to avoid this dangerous issue," Gaudino says.

Retractions of problematic manuscripts aim to preserve the integrity of the scientific literature. However, retractions rarely receive as much coverage as the initial publication. Problematic data might be included in subsequent meta-analyses and reviews. "This is particularly concerning in the biomedical field in which unreliable studies may have a negative effect on patients' care," Gaudino warns.

The fact there are fewer retractions in recent years, and shorter time frames between publication and retraction, and less impact factor in journals that publish retracted articles is "encouraging," according to **Katia Audisio**, MD, another of the study's authors and a fellow in the department of cardiothoracic surgery at Weill Cornell. "This improvement is likely multifactorial and related to an increased attention on this subject."

The Committee on Publication Ethics presented recommendations to editors on how to deal with unreliable studies. Committees such as the European Science Foundation and the U.S. Office of Research Integrity are scrutinizing published evidence. Editors and reviewers are improving the quality of the peer review process. "While this is promising, the number of citations of retracted articles is still too high," Audisio says.

The authors want to see standardized processes after retraction, and proactive approaches to prevent errors that lead to retraction. "Incentives to report misconduct and standardize the process to detect incorrect data should be adopted to prevent future erroneous and potentially harmful findings," Audisio argues.

The rapid and extensive dissemination of information online has dramatically affected the progress of scientific research, with findings readily available on virtually any topic almost instantaneously — even prior to peer review, says **Paul A. Kurlansky**, MD, another of the study's authors and associate director of the Columbia University Center for Innovation and Outcomes Research.

Research findings that are questionable or false may have slipped into the scientific literature. "It can be extremely difficult to detect data that have been manufactured or manipulated. Occasionally, a percentage — we can never know

how great a percentage — of these reports are identified and result in article retraction," Kurlansky laments.

However, those problematic articles might have been referenced in other papers or included in meta-analyses. "Vigilance and critical thinking on the part of researchers is the key to maintaining scientific integrity," Kurlansky says.

Consider two key questions: Are data consistent with what has been shown elsewhere? Did a laboratory or clinician report a high volume of findings that appear to be unique and/or not reproducible?

"When performing literature reviews and/or meta-analyses, a paper or series of papers that appear to be in contrast with the rest may need to be checked for possible retraction or questionable results," Kurlansky advises.

Studies are retracted for all kinds of reasons. "However, two main buckets the reasons can be placed in are honest error and fraud or misconduct," says **Hallie Kassan**, MS, CIP, director of the IRB at the Feinstein Institutes for Medical Research in Manhasset, NY.

Examples of misconduct that can lead to retraction include fake peer review, fake data, or image manipulation. Before approving a study, IRBs must determine if risks to subjects are minimized by use of procedures consistent with sound scientific design. When reviewing studies, IRBs should assess protocols to assure their eligibility criteria are reasonable, and that protocols are designed in a way to collect the data needed to answer the research question. Finally, IRBs can use a biostatistician as a reviewer.

"This assures the statistical analysis plan is designed to support the hypothesis to assure sound scientific design," Kassan adds. ■

REFERENCE

1. Gaudino M, Robinson NB, Audisio K, et al. Trends and characteristics of retracted articles in the biomedical literature, 1971 to 2020. *JAMA Intern Med* 2021;181:1118-1121.

Ethicists Become Involved in Managing Aggressive, Violent Patients

Ethicists at the University of Vermont Medical Center are increasingly called on to help clinicians manage verbal and even physical conflicts with patients. "When clinicians try to help aggressive — or, frankly, violent — patients, it pits respect for patient autonomy [against] clinician self-interest and institutional duty to provide a safe work environment," says **Tim Lahey**, MD, MMSc, director of clinical ethics.

In response to an uptick in these cases, ethicists created behavior response teams to support clinicians. "The pattern of increasing frequency of consultation led us to conclude there was a preventive ethics interest in developing better plans of response," Lahey explains. "Either our teams could be more expert at de-escalation, or better at knowing when to say enough was enough." Ethics could not manage those situations on their own. "We had to catalyze a multidisciplinary collaboration of relevant parties," Lahey explains.

The behavior response teams resulted from that teamwork, with ethicists playing a major role in collaboration with other hospital leaders. The teams are led by a psychologist working with ethics, security, and other stakeholders. "We devise the right approach to a given patient's situation. Sometimes, we save the life of a combative patient and put risk mitigation measures in place," Lahey reports.

An example would be a confused, demented patient with a life-threatening illness who could be sedated; later, a 1:1 security posting could be placed bedside. "We can treat their mortal illness and keep staff safer," Lahey says.

In some cases, the team notifies a patient his or her behavior is unacceptable. If unchanged, such behavior will lead to loss of non-life-saving care. "When we make boundaries like that, perhaps with a combative patient whose care would ideally happen in the hospital but who ends up being notified their care will be outpatient if they don't shape up, sometimes they do change their behavior out of self-interest," Lahey says.

Other times, patients leave the hospital angry. "We hope these preventive ethics interventions help us make wise decisions in the moment while ameliorating the twin risks of bias or clinician physical or moral injury," Lahey offers.

In situations like these, the nature of the patient-clinician interaction could be contributing to the patient's behavior.

"Maybe they're afraid and not expressing it productively. More reassuring communications can help them calm down," Lahey suggests.

In certain situations, clinicians cannot understand what is driving the patient's anger. "Clinicians from one cultural background might perceive vehement, emotional behavior on the part of a patient from a different background who has no threatening intent," Lahey says.

Ethicists can help clarify those cultural differences so patients and clinicians can meet each other halfway. "The chosen multidisciplinary solution differs substantially from case to case depending on the facts behind the worrisome behavior," Lahey explains.

In some cases, clinicians are turning to behavior contracts, which were typically used to encourage patients to adhere to treatment plans. "Physicians and other staff members sometimes gravitate toward behavior contracts as a means to end destructive interactions or undesirable conduct," reports **Autumn Fiester**, PhD, director of the Penn Program in Clinical Conflict Management.

Recently, Fiester co-authored a paper highlighting ethical concerns in the use of behavior contracts.[1] "It is understandable that, under very trying circumstances, providers reach for this tool. But in my view, behavior contracts are not ethically justifiable," Fiester says.

Behavior contracts can be effective in stopping disruptive behavior. "Patients in need of care may modulate their behavior in order to safeguard their ability to access the care they need. But that doesn't make the tool ethical," Fiester says.

Behavior contracts might simply coerce patient or family compliance without solving the conflict's cause. The ethical concern is the potential damage inflicted on the doctor-patient relationship and in the trust in the institution. Instead of using behavior contracts, Fiester suggests healthcare systems focus on providing effective skills to manage interpersonal conflict. "Mediators and conflict management experts have tools to enable providers to prevent conflicts from occurring and to troubleshoot them when they do," Fiester says.

Healthcare institutions can identify staff members who already possess this expertise, or train staff with the potential to function as mediators in these circumstances. "Those techniques get to the root of the conflict so they can be solved at their source," Fiester explains. ■

REFERENCE

1. Fiester A, Yuan C. Ethical issues in using behavior contracts to manage the "difficult" patient and family. *Am J Bioeth* 2021;Sep 30:1-11.

Updated Guidance on Informed Consent in Stroke Management

There is a rapidly evolving repertoire of treatments that are highly effective in preserving brain function after stroke, "but only if administered quickly, during a time when patients often are unable to make decisions for themselves, and those who could make decisions for them may be unavailable," says **Justin A. Sattin**, MD, professor at the University of Wisconsin (UW) School of Medicine and Public Health and medical director of the UW Health Comprehensive Stroke Program.

A 2022 position statement from the American Academy of Neurology, American Neurologic Association, and Child Neurology Society offers guidance for this ethically complex situation.[1] "The position statement aims to help neurologists provide the highest quality patient care for ischemic stroke by providing ethical guidance on how to navigate the decision-making process for stroke patients who may have difficulty providing consent," reports Sattin, lead author of the position statement.

Strokes affect the faculties patients require to make informed decisions for themselves — speech, comprehension, and reasoning. "At the same time, advances in stroke treatment demand careful consideration of many clinical and scientific facts in conjunction with patients' values and preferences in order to arrive at an optimal treatment plan," Sattin observes.

Ethical challenges arise when patients' understanding, reasoning, and values cannot be discerned while there is great time pressure to render treatments when they are most likely to be effective. Some recommendations in the position statement:

• A surrogate decision-maker may not be adequately prepared to represent a stroke patient's wishes, in which case neurologists may need to guide the decision-maker. Neurologists should prioritize the patient's preferences if those are documented. If nothing has been documented, the goal is to decide based on the patient's beliefs. If those are unknown, decisions should be made based on the person's best interests.

• If there is a generally accepted treatment (e.g., a clot-busting drug), neurologists can proceed

on the presumption of consent, if necessary. In some cases of acute stroke, in which the patient lacks decisional capacity and no advance directives or surrogates are available, consent to treatment may be presumed. "When a lawful surrogate is available, consideration must be given to preferences previously expressed by the patient. In cases of stroke, such statements are usually lacking. Surrogates must consider what the patients would choose if they could speak for themselves," Sattin says.

Some treatments involve a more complex risk-benefit analysis (e.g., endovascular treatments to remove clots). If the neurologist must treat on the presumption of consent, the main consideration is whether the facts of the case are such that most neurologists would offer treatment and most patients would accept it. In other words, does the case align with currently accepted practices and guidelines? "The further a case falls outside of these, the less justification there would be for treatment on the basis of presumed consent," Sattin says.

The most difficult cases do not fall squarely within or outside of current guidelines, where the patient lacks decisional capacity and a lawful surrogate, and where the neurologist must determine whether treatment based on presumed consent is warranted. "There are many 'relative' contraindications to alteplase treatment, for example. The position statement can't provide guidance for every nuance in the complex field of cerebrovascular disease," Sattin notes.

Neurologists must determine how closely the facts of such cases match current practices and guidelines, and use that determination to guide treatment.

Significant ethical issues involving informed consent in the care of stroke patients include whether the patient still possesses decisional capacity. If not, who will make decisions on the patient's behalf? Since stroke occurs on a spectrum of severity, one should not assume the patient lacks capacity to give informed consent to care and treatment.

"In cases of mild or less severe stroke, careful examination of the patient's cognitive capacity is called for," says **Robert S. Olick**, JD, PhD, associate professor emeritus of bioethics and humanities at Upstate Medical University in Syracuse, NY.

Patients need the ability to understand and reason about the nature of their condition and the risks and benefits of the proposed treatment and treatment options. "It may be advisable to involve a stroke specialist and/or psychiatry in this process," Olick suggests.

The healthcare team should be mindful that some patients can make some decisions, but not others. Sometimes, patients with impaired capacity can choose a family member to act as their surrogate, but may not be able to make a specific treatment decision. "Some patients may regain cognitive capacity with treatment and time for recovery," Olick says.

Olick has responded to several ethics consult requests involving stroke patients' capacity to give consent. Ethics consultants do not make formal determinations of capacity. "Ethicists can, however, clarify the parameters of informed consent and capacity, the meaning of the patient's stated wishes, and who is the appropriate surrogate decision-maker if the patient is determined to lack capacity," Olick explains.

In cases of serious stroke, loss of decisional capacity may be evident and possibly permanent.

Consequently, a healthcare proxy, spouse, or family member must be identified to assume the responsibilities of making decisions on behalf of the patient. "Family members may struggle with the trauma of sudden loss, the uncertainty of prognosis, and the burdens of decision," Olick says.

Ethics can help with this situation, particularly if there is disagreement among the proxy, family, physician, or others directly involved in the stroke patient's care. "Ethics consultants often provide support and assistance in understanding the patient's wishes, determining who is the appropriate decision-maker, and resolving disagreements," Olick says. Still, it is important to bear in mind that ethics consultants serve as a supportive and advisory role. "They do not make decisions," Olick cautions. "The right and responsibility for treatment decisions rests within the patient-family-physician relationship." ■

REFERENCE

1. Sattin JA, Chiong W, Bonnie RJ, et al. Consent issues in the management of acute ischemic stroke. AAN Position Statement. *Neurology* 2022;98:73-79.

Tips for Researchers Looking to Recruit More Pregnant Black Women

When conducting research on understanding and mitigating health inequities specific to Black families during pregnancy, recruitment and retention can be especially challenging. A group of Michigan-based researchers have conducted several studies that only include Black women.

"Through our experience, we feel that we have gained knowledge on successful recruitment and retention [tactics]. It is important to share these [tactics] with others in order to continue to include people of color in research and make research more generalizable and representative of different populations," says **Sarah Vaughan**, PhD, MPH, a research associate in the department of epidemiology and biostatistics at Michigan State University College of Human Medicine.

Recently, Vaughan and colleagues authored a paper outlining effective approaches to recruit and retain pregnant Black women for a study of preterm birth.[1]

They reported tactics that worked on the participant level (matching recruiters by gender and race when possible), the clinical level (prioritizing clinical care over research activities), and protocol level (maintaining a wide enrollment window and compensating participants for their time).

In addition to their primary function of making sure the proposed research is safe and ethical, IRBs should consider how the research affects the community with which investigators want to engage.

"It is important that the research portrays positive feelings within and about the community, rather than negative attitudes. This is especially important for pregnant participants, as there is often 'mother blaming' when there are complications with a pregnancy," Vaughan says.

Overall, the research should be positive for the community participating. Vaughan says investigators should think about the questions they are asking and to whom those questions apply.

"For example, we don't include white women in our studies because it is well-documented that health disparities surrounding pregnancy exist between white women and women of color," Vaughan explains. "We want to know what is affecting birth outcomes specifically in the Black community because that's where the interventions will need to be implemented in order to improve outcomes."

Additionally, the aim of the research should appeal to the engaged population.

"The research should address issues that are important, on a personal level, to the population being studied," Vaughan says.

One of the most successful tools to recruit African American women in clinical trials is "visiting minority communities, speaking with community leaders, and building relationships," according to **Christina Brennan**, MD, vice president of clinical research at the Feinstein Institutes for Medical Research in Manhasset, NY.

Working with churches or attending community events can build trust within the neighborhood. "As researchers and clinicians, we need to show our commitment to these communities," Brennan says. "Being visible, sharing educational materials, and being a part of our neighbors' everyday lives is key."

Translating study materials, advertisements, and brochures into the predominant languages in the community is helpful.

"One other often-overlooked approach to reach diverse communities is to deploy culturally concordant staff — for example, Hispanic staff in Hispanic-dominant communities," Brennan says.

Researchers also must address financial assistance. "This has demonstrated the ability to improve trial equity and participation," Brennan says.

When designing trials, investigators should select trial sites based on the geographical distribution of ethnic/racial minority patients and physicians.

"It all goes back to trust, communication, education, and building a presence within the community," Brennan says. ■

REFERENCE

1. Vaughan SE, Misra DP, Wong AC, et al. Successful recruitment strategies for engaging pregnant African American women in research. *West J Nurs Res* 2022;44:94-100.

Uncertainties on Future Use of Study Participants' Data

Patients may agree to donate a biosample (e.g., blood, urine, saliva, or tissue from biopsies or surgeries) for their physician's clinical study, but potential future uses of that sample raise complex ethical issues.

Under the Common Rule, investigators can obtain broad consent for future use of identifiable samples, notes **Sharona Hoffman**, JD, co-director of the Law-Medicine Center at Case Western Reserve University in Cleveland. Therefore, if a patient whose sample will be used for a colon cancer study provides broad consent for the future use of the sample, a different researcher could use the sample for an Alzheimer's disease study without notifying the patient.

"One problem is a lot of study participants may provide broad consent but not understand what that really means, and they won't think to ask probing questions about it," Hoffman says.

The average patient has no medical, academic, or scientific background. Average patients are unlikely to ask questions such as "What types of studies might my sample be used for in the future?" or "How long will the sample be retained?" Thus, for researchers, what is there to say about it? "Do you raise that concern for patients very explicitly, or more subtly?" Hoffman asks.

It might be better if investigators ask patients to agree for a sample to be used for a specific study and then for that sample to be destroyed. Sometimes, researchers want to keep the sample indefinitely, but that conversation is more complicated. "You don't know what technologies or capabilities will develop," Hoffman notes.

No one can really predict how others will use the sample in the future. "The fact that samples will be retained for future studies does have to be disclosed in the consent documents, but those are typically really long. Chances are the patient is not reading it carefully," Hoffman says.

Some patients might not want their sample used for certain kinds of research, such as studies on reproductive technology or on genes that are associated with violence. "If something is being done that is controversial, it should absolutely be discussed with the patient," Hoffman asserts.

If the patient objects for religious or other reasons or because of concerns about stigmatization, the researcher should address that concern.

"Doctors don't want to discuss things in scary ways that are going to turn off prospective research participants. Not all doctors are highly skilled in communication or psychology, and they have limited time to do one-on-one discussions," Hoffman observes.

Often, nurses or research staff are the ones who engage in consent discussions, closely following scripted language.

Recontacting every person who donated a sample is not feasible. "People might suggest we contact everyone anytime the sample is used for a new study instead of obtaining broad consent. But if it's 1,000 people, and many of them have moved, you can't do it," Hoffman says.

Since samples often are de-identified, investigators cannot know the patient's identity. "Research with de-identified samples is not covered by the Common Rule, so no consent needs to be obtained for any research with those samples," Hoffman explains.

If the sample cannot be connected with the patient, investigators never have to obtain permission from patients, regardless

of the nature of the project. If researchers need to ask questions about the adequacy of broad consent or de-identification, they can refer to the IRB for consultation.

"While doing research without specific consent from patients might seem distasteful, it is vitally important to facilitate research that can lead to medical advances that will benefit all of us," Hoffman says.

Some researchers seek explicit consent. This means participants' data are used for a specific study. "This model differs from broad consent, which permits researchers to use data for future, unspecific purposes and is often pursued in the context of biobank research," says **Vasiliki Nataly Rahimzadeh**, PhD, a postdoctoral fellow at Stanford Center for Biomedical Ethics.

Generally, the informed consent process needs improvement, particularly when it comes to explaining to participants what data will be used and how, according to Rahimzadeh.

"Responsible data-sharing rests on making quality data accessible to authorized researchers to meaningfully advance science while respecting participant values," she says.

Participants may perceive some types of data as more sensitive than others, such as genomic information. "To enhance transparency, there have been proposals, at least among some teaching hospitals, to notify patients that their data may be used for research," Rahimzadeh says.

The concept of a learning health system depends on treating the patient encounter as an opportunity to improve care delivery through research. "Innovations in health information exchange platforms using blockchain technology, for example, may soon enable participants to exercise greater control over the data they share for research that advances their values and interests," Rahimzadeh predicts.

Rebecca D. Pentz, PhD, professor of research ethics at Winship Cancer Institute at Emory School of Medicine in Atlanta, makes it clear to participants that no research on their samples can be conducted without IRB approval.

"Explaining the regulatory process that makes sure only ethical research is conducted is important," Pentz says. For example, research using any personal identifiers must justify the use and explain in detail how the information will be protected.

Pentz and colleagues recently explored whether face-to-face or electronic informed consent was more effective for participants in biobank research.[1] They analyzed 501 patients at two U.S. biobanks, finding no differences in understanding between the two methods.

Electronic consent may lead to better understanding for non-Hispanic patients of higher socioeconomic status. Face-to-face consent may lead to better understanding and higher enrollment of Hispanic patients and those of lower socioeconomic status. Researchers should consider maintaining a face-to-face consent process to better address the needs of some populations.

"In all cases, the consent should be conducted by a well-trained person who will interact with the potential participant respectfully and ask for any concerns that person may have. Then, address each concern," Pentz says.

Some study participants worry genetic information might be used in a way that would stigmatize a racial or ethnic group. "We recommend being up front about past research abuses in certain communities and the protections we now have," Pentz says. "With the new awareness of the importance of diversity, we are now even more careful. Journals are more careful about publishing discriminatory articles."

Other candidates might ask questions about sharing samples with other countries. "During informed consent, the researchers should be up front and transparent about whom

will have access to the biorepository's samples and data," Pentz says.

Specifically, researchers should disclose if the samples will be shared internationally, which countries will have access, and if samples will be shared with for-profit companies.

"If none of these are true, it can simply be stated that the samples will be shared within the institution and ... with other academic health centers," Pentz says.

Recruiters should convey how important biosamples are in the search for new treatments to cure diseases. In two previous studies, Pentz and colleagues found most potential participants were quite willing to participate.[2,3] This was true even at an inner city hospital whose patients were the underserved.

"We make it clear that you can always opt out at any time, though samples already given to researchers cannot be returned," Pentz says.

Jeffrey R. Botkin, MD, MPH, says his impression is research participants do not ask questions about this issue because most people do not understand what research entails.

"We all know that the informed consent process is largely ineffectual in promoting a thorough understanding of the facts and implications of the proposed research," says Botkin, professor emeritus of pediatrics at the University of Utah S.J. Quinney College of Law.

Most participants do not know enough about secondary uses to ask questions. In a focus group, Botkin and colleagues found the lay public does not know clinical data or tissues can be used for research without their permission.[4] However, when the process and protections were discussed, most participants were comfortable with the system and supported an opt-out approach to consent.

"It would be ideal to have a more effective consent process to more fully inform participants about this and other issues," Botkin offers.

Sometimes, candidates want to know if a company will make a profit off their data. The answer probably is yes.

"This is a turnoff for many potential participants. Yet we all know pharmaceutical companies, for example, expect to make a profit," says **Elizabeth Eisenhauer**, PhD, RN, assistant professor at the Oakland University School of Nursing in Rochester, MI.

Other candidates ask if their sample could be used for cloning research. "However, I'd say the majority of potential participants simply don't have sufficient genetic or scientific literacy to ask these questions at all," Eisenhauer says.

That means people are making important decisions without sufficient knowledge. "In other words, they are making uninformed decisions. It is not ethical for researchers to obtain consent from individuals who don't understand what they are agreeing to," Eisenhauer says.

Eisenhauer sees a need for legislation that requires researchers to provide explicit examples during the informed consent process of the types of research that may be conducted with personal information or biospecimens.

"We need not just beneficial, life-saving research examples, but examples of controversial research, too," Eisenhauer says.

This information should be provided even if the candidate does not know to ask for it. A tiered approach to informed consent is a possible solution. For example, individuals may agree to provide a biospecimen, but not provide access to their medical records. "The current status of informed consent for biospecimen and data research is greatly flawed," Eisenhauer says.

Currently, if data or biospecimen are "nonidentified," it may not even be considered human subjects research, even though the data or biospecimen certainly came from a human. In the case of biospecimen research, deleting someone's name may not remove the feeling of complicity in various types of biomedical research some find unethical.

"Just because a researcher removes a name from a biospecimen doesn't make it OK for them to do whatever they please with it," Eisenhauer concludes. ■

REFERENCES

1. Simon CM, Wang K, Shinkunas LA, et al. Communicating with diverse patients about participating in a biobank: A randomized multisite study comparing electronic and face-to-face informed consent processes. *J Empir Res Hum Res Ethics* 2022;17:144-166.
2. Warner TD, Weil CJ, Andry C, et al. Broad consent for research on biospecimens: The views of actual donors at four U.S. medical centers. *J Empir Res Hum Res Ethics* 2018;13:115-124.
3. Pentz RD, Billot L, Wendler D. Research on stored biological samples: Views of African American and White American cancer patients. *Am J Med Genet A* 2006;140: 733-739.
4. Botkin JR, Rothwell E, Anderson R, et al. Public attitudes regarding the use of electronic health information and residual clinical tissues for research. *J Community Genet* 2014;5:205-213.

Many Parkinson's Research Participants Cannot Recall Study Risks

Over the last decade, more studies have included neurosurgical patients as human subjects. "These studies utilize the intraoperative neurosurgical setting to conduct research to advance basic science," explains **Anna Wexler**, PhD, a neuroethicist and assistant professor in the department of medical ethics and health policy at the University of Pennsylvania Perelman School of Medicine.

Such patients already are undergoing procedures to implant electrodes in their brains for clinical purposes. For researchers, this is a unique opportunity to obtain valuable data. "Scholars had begun to discuss some of the unique ethical issues that arise in these types of the studies. But there had been no empirical examination of these concerns among research participants," Wexler says.

Wexler and colleagues surveyed 22 patients with Parkinson's disease who had agreed to participate in research during surgery to learn more about the effectiveness of the informed consent process.[1] "None of the research participants had a therapeutic misconception," Wexler says.

In other words, all participants correctly understood the research had no possibility of direct therapeutic benefit to them. However, just one week after the informed consent discussion had taken place, only 23% of the patients could recall either of the two risks that had been conveyed to them — higher risk of infection and possible loss of confidentiality caused by researchers sharing their data.

This raised the question of how the informed consent process could have been handled differently so participants would recall the risks about which they were informed. For example, rather than consenting the individual in the office during the presurgical visit, at a time when the patient was already receiving a large amount of information, the outreach could be conducted by phone later. This would give the subject time to carefully review the study materials. "More attention is needed to consider how the informed consent process for these studies is conducted," Wexler says. ■

REFERENCE

1. Wexler A, Choi RJ, Ramayya AG, et al. Ethical issues in intraoperative neuroscience research: Assessing subjects' recall of informed consent and motivations for participation. *AJOB Empir Bioeth* 2022;13:57-66.

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

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

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- Concerns about rapid sharing of research results
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CME/CE QUESTIONS

1. **What did the authors of a recent study find regarding participation in clinical trials?**
   a. Those who understand the purpose of informed consent are less likely to participate.
   b. People with sufficient basic knowledge of clinical trials are significantly more likely to participate.
   c. Patients who know less about the specific aim of a clinical trial were more likely to participate.
   d. Those who fully understand how clinical trials are conducted were more afraid of participating.

2. **Which did the authors of a recent study find regarding age disparities in clinical trials?**
   a. The median age of trial participants closely mirrored the median age of the population.
   b. Age disparities were more of a problem for lung cancer trials.
   c. There have never been reported age disparities for industry-funded trials.
   d. NIH-funded trials set more age caps than trials funded from other sources.

3. **Which did the authors of a recent study find regarding retracted studies?**
   a. Most retracted studies do not involve scientific misconduct.
   b. There are longer time frames between publication and retraction.
   c. Most retractions were meta-analyses or reviews.
   d. Guidelines represented less than 1% of total retractions.

4. **Which does a new position statement on informed consent in management of acute ischemic stroke recommend?**
   a. Neurologists should not guide surrogate decision-makers, even if the decision-maker is not adequately prepared to represent a stroke patient's wishes.
   b. Neurologists can proceed on the presumption of consent for treatments with complex risk-benefit analysis.
   c. For some cases of acute stroke, in which the patient lacks decisional capacity and no information about patient preferences from advance directives or surrogates is available, consent to a generally accepted treatment (considering inclusion and exclusion criteria) may be presumed.
   d. If a case aligns with currently accepted practices and guidelines, there is less justification for treatment based on presumed consent.

5. **What worked for researchers regarding recruiting and retaining pregnant Black women for study participation?**
   a. Prioritizing research activities over clinical care
   b. Matching recruiters by gender and race, when possible
   c. Narrowing the enrollment window
   d. Ending financial compensation for participants.

6. **Which is true regarding use of study participants' data?**
   a. Regulations require researchers to obtain consent for every future use of even de-identified samples.
   b. Researchers can obtain broad consent for future use of identifiable samples.
   c. The fact samples will be retained for future studies does not have to be disclosed in the consent documents.
   d. Most people are aware samples can be used for future research without their permission.