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INSIDE

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The Evolving Ethics of Researching Illegal Substances

By Stacey Kusterbeck

Interest in clinical research on cannabis and psilocybin (a psychedelic compound found in many fungi species) is soaring.[1-4] However, current barriers to studying these controlled substances raise ethical questions.

"These drugs, particularly psychedelics, show incredible early potential for treating a number of disorders. There is a real ethical issue with not conducting cautious research to explore that therapeutic potential," says **Matthew W. Johnson**, PhD, associate director of the Johns Hopkins Center for Psychedelic & Consciousness Research and lead investigator in multiple psilocybin studies.[5,6]

Many psilocybin clinical trials are underway, including a randomized study of the drug's effect on 100 participants with depression.[7] Psilocybin was effective for treatment-resistant depression, according to a recently published study.[8] **David Nutt**, DM, FRCP, FRCPsych, FSB, FMedSci, one of the study's authors, sees no significant ethical issues with studying cannabis and psilocybin. "There is lots of evidence of safety. But for other more harmful drugs, like fentanyl or synthetic cannabis receptor agonists, there may be issues."

Under federal law, using and possessing cannabis is illegal. However, state laws have evolved significantly over the past decade. Depending on the state, cannabis might be legal for medicinal or recreational purposes (or both). Meanwhile, laws on psilocybin remain strict across the board, although some cities are beginning to loosen restriction. Regardless, regulatory hassles can add significant costs to research in these areas.

"There is an emerging realization that the banning of these drugs was politically driven, not by true health concerns," says Nutt, deputy head of the Centre for Psychedelic Research and the Edmund J. Safra Professor of Neuropsychopharmacology Imperial College London.

The extra hurdles for these particular drugs, says Nutt, are "a waste of time and money. It also slows research that could help people with significant

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mental health issues that current therapies don't help."

If studies do reveal benefit, substances remain unavailable to many patients, including the clinical trial participants themselves. "Some people respond, then relapse. They can't re-access the treatment that they know helped them, as the license is just for research on psychedelic-naïve patients," Nutt explains.

When access to cannabis and/or psilocybin is unequal, that "could be framed as an issue of justice," says **Daniel J. Hurst**, PhD, ThM, MSc, director of medical professionalism, ethics, and humanities at Rowan University School of Osteopathic Medicine in Stratford, NJ.

Society's changing views on various controlled substances can facilitate research, or it can add obstacles. Stigma around medical marijuana use is evaporating.[9,10] "But it's a different story with mushrooms. People are not as prepared for that to be brought to mass market use," Hurst says.

Some convincing evidence could change that, in light of increased awareness of the need for better mental health treatments. "Give it some good data, with grassroots advocates, and we very well may see increasing acceptance of it," Hurst offers.

For now, federal agencies remain reluctant to fund such studies.[11] "From my point of view, psilocybin still carries significant stigma. This is a significant barrier to overcome for clinical application," Hurst laments.

Yet in the financial world, investors appear eager to fund research on psychedelics.[12] "This surely coincides with the lessening of stigma in society associated with mental health issues," Hurst suggests.

Patient safety always is top of mind with informed consent for clinical trials. In the case of controlled substances, there are some extra hurdles. Participants likely will have to agree not to drive a car or operate machinery for specific periods. "Researchers have a moral onus to ensure, to the best of their ability, that participants will abide by safety precautions," Hurst stresses.

Where psychedelics are concerned, the research likely will be conducted at inpatient facilities. "This would mitigate many risks and would allow for researchers to monitor vitals and how the body responds," Hurst says.

When studying drugs that carry abuse potential, appropriate safety mechanisms are paramount. "There is both a risk of undertreating people and also a risk of using treatments prematurely in the practice of medicine," Johnson says.

Elsewhere, pain management professionals are pushing for more research on controlled substances. For example, vaporized cannabis is a safe, potentially effective treatment for chronic pain caused by sickle cell disease.[13] Participants reported that pain interfered less with activities as the five-day study progressed. This particular study, unlike others, was a crossover, randomized, double-blind, placebo-controlled investigation. "You have to do a very well-validated study; otherwise, we cannot draw any relevant conclusions. It has to be double-blind to prevent bias," says **Kalpna Gupta**, PhD, one of the study's senior authors.

With cannabis research in particular, the question of exactly what is under investigation becomes crucial.

"The problem is that there are so many cannabis products available through dispensaries and other sources, but none of them are controlled for under any regulatory

compliance," says Gupta, professor of medicine in the University of California, Irvine division of hematology/oncology.

The ethical concern is patients with chronic pain will obtain cannabis products expecting to experience the same benefits identified by a study, when the product is not the same as what was studied.

"What is the difference between one product and all of the other products being sold? To find out, we would have to test each of them pharmacologically and in clinical trials," Gupta explains.

Cannabinoids obtained at dispensaries often do not contain what they claim and may even contain harmful ingredients. [14-16] To obtain valid results, "the product, the amount, the route all has to be determined in a case-by-case, disease-by-disease basis," Gupta says.

Another issue is some confuse studies on vaporized cannabis with vaping. Because of possible confusion on this point, "there is potential for cannabinoids to be used inappropriately," Gupta notes.

As for funding, regulatory bodies might agree to fund cannabis studies initially, but there are subsequent roadblocks. Sometimes, says Gupta, "it goes to peer review and it gets shot down." One potential solution is for regulatory bodies to, instead, allocate a set amount of funding specifically for cannabis research and find ways to complete those studies.

But on top of all this, recruitment also is challenging for cannabis studies. For instance, many forms of cannabis products already are available without constraints; there is no need to participate in a study to obtain them. Also, inpatient admission is needed, as with the participants in the sickle cell disease trial, to ensure participants use only the drug tested and are monitored for safety. "Larger studies with more participants are needed to give more information on the benefits of cannabis," Gupta says.

Some previous cannabis studies showed benefits but the authors could not recruit the number of participants needed to achieve statistical significance. In that case, researchers might need to secure permission from the funding agency to continue recruitment for a longer period.

"We should be identifying a problem we are trying to solve, instead of going by a specific deadline where you are done no matter what you have," Gupta argues.

Overall, says Gupta, "the problem is that the literature on cannabis is promising, but it's not very well-proven scientifically, to withstand the need for validated clinical use in the majority of cases." ■

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Many Ethical Considerations for MDs if Patient Is Unvaccinated

By Stacey Kusterbeck

Some clinicians wonder whether they are ethically obligated to treat unvaccinated patients. "This is a serious concern among many doctors. I suspect that sooner rather than later, some physicians will start avoiding unvaccinated patients in the outpatient setting," says **Jacob M. Appel**, MD, JD, MPH, HEC-C, director of ethics education in psychiatry at Icahn School of Medicine at Mount Sinai.

A solid understanding of ethical obligations is essential in this tricky situation.

"Ethicists should certainly have a seat at the table when hospitals and policymakers formulate rules in this area," says Appel, an attending physician at Mount Sinai Health System in New York City.

The rules governing dismissal of patients who are unvaccinated against COVID-19 are basically the same as for other patients, according to Appel. In the hospital, physicians generally cannot refuse to treat patients.

"Specific religious or medical concerns may arise that merit consideration for exceptions," Appel explains. For instance, physicians who cannot be vaccinated for medical reasons might ask not to be assigned to COVID-19-positive patients.

Did the patient willfully refuse vaccination? Or is the issue that the patient cannot be vaccinated for medical reasons? From an ethical point of view, it probably matters. "Many ethicists would be deeply troubled by a provider discontinuing care with a long-term patient who could not be vaccinated because of past anaphylaxis to vaccine ingredients," Appel notes.

Physicians are ethically responsible for incurring some risk as part of their jobs. At the same time, hospitals are ethically obligated to minimize risk to clinicians. "That might mean shifting the care of certain patients away from immunocompromised providers, at their request, as long as patient care wasn't significantly impaired," Appel says.

Unlike in the inpatient setting, outpatient providers generally can "fire" patients for reasons such as frequent no-shows or nonadherence — or unvaccinated status. The caveat is the "fired" patient must be able to access another provider. Usually, that means giving patients enough time to find another doctor. "The only exceptions might be if religion or disability was the cause of the patient's nonvaccinated status," Appel says.

Physicians refusing to take on a new patient simply because they are unvaccinated is ethically questionable, according to **Trevor M. Bibler**, PhD. If the same provider refused to care for smokers or people with unhealthy diets, "it would be seen as a breach of good medicine, based either in stigma or an unacceptable amount of caution and self-preservation," says Bibler, assistant professor of medicine at the Baylor College of Medicine Center for Medical Ethics and Health Policy.

Where vaccination is concerned, the provider would have been expected to care for the patient before the vaccine was available. The fact the vaccine is widely available now does not change that ethical obligation, says Bibler — even if the provider's risk would be lower if the patient became vaccinated.

Bibler says requiring unvaccinated patients to engage physicians only through virtual visits also is ethically problematic, unless physicians are at higher risk for some reason.

"But even then, their reasoning should apply to all of those with communicable diseases, not just those who have refused the COVID-19 vaccine," says Bibler, who argues vaccination status simply should not play a role in the distribution of resources. "One might view the decision unwise or selfish. But medicine deals with patients who refuse recommended interventions constantly."

A patient might refuse to take their blood pressure medication and have a heart attack or a stroke as a result. "Part of the challenge of being a healthcare professional is working with people who make decisions we might view as ill-advised or deleterious to their own interests," Bibler says.

The health risk to vaccinated medical staff treating unvaccinated patients in person today is "much smaller than it was during the earlier pandemic, when we lacked experience with treating COVID and lacked a vaccine," says **Olivia Schuman**, PhD, a clinical ethics fellow at Baylor College of Medicine Center for Medical Ethics and Health Policy.

The ethical concern is refusal to treat unvaccinated patients seems rooted in a negative bias toward those patients. "We need to leave moral judgments out of medicine. Given their fiduciary responsibilities to their patients, clinicians shouldn't refuse care on these grounds any more than on the grounds that they don't like a patient's political views, profession, or criminal record," Schuman says.

Unvaccinated patients could pose a risk to others who are immunocompromised. "But we have to be cautious

about treating COVID as morally exceptional," Schuman says.

Regardless of vaccination status, patients and medical staff may be carriers of any number of infections that can harm others. "That's just the reality of putting all the sick people into one building. What we need is evidence-based ways of maintaining the safety of these spaces, rather than excluding some patients from accessing care," Schuman suggests.

Providers may offer many compelling reasons for wishing to avoid unvaccinated patients: protecting themselves, their families, staff, and other patients.

"Some may simply wish to make a moral statement that they object to the behavior of individuals who are endangering the public health by refusing to get vaccinated," says Appel, who compares this to a psychiatrist who refuses to treat a patient who continues to drive intoxicated.

On the other hand, providers should factor in legitimate reasons for vaccine hesitancy, such as minorities' historical reasons for distrusting medicine. "No one wants to deny care to individuals who have already been short-changed by the healthcare system," Appel says. Once a provider-patient relationship is built, state medical boards have established rules on patient abandonment. "These require that the patient receive adequate notice and, in some cases, be transferred to another provider to prevent gaps in treatment," says **Stacie Kershner**, JD, associate director for the Center for Law, Health & Society at Georgia State University College of Law.

Generally, providers in outpatient settings can decline to treat people who choose to not be vaccinated if they are new patients. "However, that does not mean that this is ethically a good practice," Kershner says.

For one thing, refusing to treat unvaccinated patients is unlikely to convince anyone to take the vaccine. "Rather, it reduces the opportunity for pro-vaccine providers to try to sway vaccine-hesitant patients to accept the vaccine through providing trustworthy information," Kershner observes.

People with long-standing relationships with clinicians are more likely to take the flu shot.[1] Refusing to treat unvaccinated patients might serve only to increase distrust of medical providers. It limits access to care if people cannot find other providers. "These patients may cluster with specific doctors who are willing to treat them, rather than being spread out across multiple providers, potentially increasing risk of disease spread at these offices," Kershner says.

Telehealth might be a viable alternative for some patients, but health plans do not always cover it. "There may be concerns about access to care," Kershner adds.

Do patients have a right to request vaccinated doctors and nurses? "I imagine educated patients will start making such requests," Appel predicts. "This has implications beyond ethics, in areas related to hospital logistics, employee privacy, and even equity."

It is possible if patients start making such requests, especially regarding elective procedures, hospitals will strive to meet the demand. "It is conceivable that hospitals and clinics will even advertise having all-vaccinated care teams," Appel says. ■

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Complicated Ethics of Adolescent Children Self-Consenting for Vaccines

By Stacey Kusterbeck

In response to Washington, DC's newly passed law allowing minors to consent for vaccines, even over parents' religious objections, some have sued.[1] The well-publicized lawsuit centers on a timely topic, but the conflict over adolescent consent is nothing new. "The COVID vaccine is just bringing this issue to the surface. It is a long-standing issue in pediatric medical ethics," says **Kyle Brothers**, MD, PhD FAAP, a member of the American Academy of Pediatrics' section on bioethics executive committee and an associate professor in University of Louisville's department of pediatrics.

Parental rights issues often are asserted, but at the same time, society has a stake in protecting children from harm, including medical neglect.

"Parental rights are important, but there are limits," says **Gregory D. Zimet**, PhD, HSPP, a clinical psychologist and professor at Indiana University's department of pediatrics.

Adolescent children also have rights to make certain decisions about their health.

"COVID-19 vaccination has, unfortunately, become a high-profile, divisive issue, which is probably why the issue of adolescent consent has been so prominent," Zimet says.

"The question in terms of giving adolescents the ability to consent to their own COVID-19 vaccine, or any other vaccine, is: Is there a good reason to break from the law's defaults?" Brothers asks. "There are already exceptions."

State laws allow adolescents to make healthcare decisions for services they probably would not seek without confidentiality (e.g., substance abuse, STIs, and birth control). Emancipated minors have the legal rights of adults in terms of medical decision-making. Some states have enacted a "mature minor" doctrine, allowing minors to consent if they are deemed sufficiently mature to understand the risks and benefits of treatment. "The fundamental idea is children don't have their 18th birthday and suddenly change in terms of their ability to make decisions. The law has only imperfect solutions for respecting that continuous process of development," Brothers observes.

Brothers says a strong ethical case could be made for a blanket policy for adolescents to consent to any approved vaccine without parental consent. "It's clear that older adolescents, and maybe even younger adolescents, are frequently mature enough to make a decision like this," Brothers offers.

Even before the COVID-19 pandemic, there were problematic cases. Some adolescents needed vaccination to attend college, for instance, but parents were not available or refused to consent. "We do see situations where parents and kids are not on the same page," Brothers reports.

In those cases, says Brothers, pediatricians use a shared decision-making approach. Even if the vaccine disagreement is not resolved during the office visit, it is a chance for pediatricians to model good medical decision-making. "It's part of the role of parents, and also pediatricians, not just to give children the best possible medical care, but also to prepare them to make decisions as they get older," Brothers says.

If parents still will not consent to vaccines, though, adolescents can circumvent this only if they are emancipated minors, turn 18, or take the rare step of obtaining a court order. "We do have kids in difficult situations where they are trying to get medical care, but the people who have the right to make decisions [on their behalf] are not available or willing. There is not a great solution for this under the law," Brothers laments.

Adolescents do have the capacity to make a thoughtful, informed decision about vaccinations, according to Zimet. "It would be great if policymakers used this moment to consider allowing minor adolescents to consent to vaccination. However, I do not have a lot of confidence in this happening," he says.

Zimet says it is ethical for adolescents to decide to vaccinate themselves against a clear health threat, such as COVID-19 or HPV. "Healthcare providers are certainly faced with a dilemma when an adolescent directly asks for the vaccine when parents do not consent," Zimet says. "However, I think this dilemma is a legal and logistical one, not an ethical one."

In fact, Zimet argues it is ethically questionable if a parent denies COVID-19 vaccination when the adolescent wants the shot. "An argument could be made that the parent's behavior in this circumstance is unethical, comparable to medical neglect," Zimet says.

Parents usually are the best advocates and prioritize the teen's interest, says **Dorit Rubinstein Reiss**, PhD, professor of law at UC Hastings College of the Law in San Francisco. "But parental rights are not absolute and do not always match the teen's interests. At the end of the day, parents have a duty to the teen and are trustees, not owners," she says.

Since the risks of COVID-19 vaccines are small in general, and are smaller than the risk of not vaccinating, "there are good grounds to let teens get access to vaccines without parental consent," Reiss says.

Older children, and especially adolescents, often are capable of ethically valid informed consent, says **Mark C. Navin**, PhD, HEC-C, a clinical ethicist at Beaumont Health and chair of philosophy at Oakland University in Michigan. That counts in favor of allowing such children to choose to be vaccinated. "However, parents also have moral responsibilities to make good choices for children," Navin notes. "Since vaccination is almost always in a child's interests, the moral case for parental refusal of vaccines for their children is not good."

Physicians should bear in mind their primary responsibility is to their patient, says **Georges C. Benjamin**, MD, executive director of the American Public Health Association. State laws concerning the age of maturity for decision-making and particular situations (e.g., emancipated minors, homelessness, minors who are not living with their parents, or married minors) also are considerations. "There are also situations where engaging the parents becomes a real challenge because it's not in the child's best interest," Benjamin says.

In cases of abuse or domestic violence, providers often work with local authorities to override parental consent requirements. "The other thing is that you can have a conflict where the child's best interest collides with the parent's views," Benjamin reports.

In extreme cases, providers can secure a court order to override parents' decisions. "These are generally not things that happen each and every day.

What happens much more frequently is that the adolescent wants to get their care confidentially," Benjamin explains.

This often happens with treatment for STIs or substance abuse, but it also could happen with vaccinations. "In those situations, the physician has an obligation to try to reconcile that situation the best that they can," Benjamin says.

The physician must maintain the trust between the child and parents and not undermine it, to the extent possible. "It's important that the physician evaluates the request and the context for that request," Benjamin stresses.

The physician should try to learn why the child is reluctant to engage their parents and correct misconceptions. Even if the state has carved out certain healthcare services that do not require parental consent, that does not mean parents will not find out about it through insurance claims or medical records.

"If the child is uncomfortable talking to their parents but has not really thought it through, physicians can let them know that parents can find out about these things," Benjamin suggests.

This can be a jumping-off point to encourage the child to allow the provider to engage their parents in the situation. The issue of potential harm to others has to be factored in, too. If it is a live vaccine at issue, and a family member is immunocompromised, the child taking the vaccine could harm that family member. "Or, one could argue, in the case of COVID, that not vaccinating their child could put somebody else at risk," Benjamin offers.

Some parents are vaccinated themselves but weigh the risk/benefit analysis differently for their children. "They are not quite sure of the long-term risks for their children and they know that studies are still ongoing in kids. We have to be knowledgeable about that and not just make the assumption that parents don't want to vaccinate their kids for some crazy reason," Benjamin says.

The complexities of the COVID-19 vaccine consent issue underscore the importance of a good patient/physician relationship. "At the end of the day, this is why it's important to have every patient linked to a primary care practice. Trust doesn't get built overnight, either with the patient or with their families," Benjamin observes.

Providers should supply minors with age-appropriate information about the benefits and risks of vaccination and should rely on their state's mature minor standard to determine competency.[2] Some vaccine-hesitant parents perceive expanded autonomy to minors as a threat to their authority, acknowledges **Larissa Morgan**, JD, MBE. "But minors of vaccine-hesitant parents should not be placed at an increased risk of contracting COVID-19 based on their parents' own uncertainty. Indeed, some minors might possess a greater understanding of the benefits of vaccination than their parents," Morgan says.

Competency determinations must balance the interests of parents with the autonomy of minors. "The burden to vaccine-hesitant parents' interests by allowing minors to consent independently does not outweigh the significant individual and public health benefits of increased vaccination rates," Morgan says. ■

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Survey: More Education Could Boost COVID-19 Vaccination Rates Among Youth

By Stacey Kusterbeck

Adolescents and their parents are interested in taking the COVID-19 vaccine; more education and other developments could sway even more, according to the results of a survey.[1]

Researchers surveyed 985 adolescents age 13 to 17 years and 1,022 parents of children age 12 to 17 years. Among surveyed parents, 55.5% said they would "definitely" or "probably" take their adolescent to receive a COVID-19 shot. Among unvaccinated adolescents, 51.7% reported they would "definitely" or "probably" receive the vaccine.

Notably, respondents indicated more information on safety and efficacy for adolescents was one of the top factors that would increase the likelihood of taking the vaccine. They also said primary care providers and health officials were their most trusted sources for vaccine information.

Researchers conducted this survey in mid-April, about one month before the FDA expanded its emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine to include adolescents age 12 to 15 years.[2] Later in May, the Advisory Committee on Immunization Practices issued interim recommendations for the vaccine among this cohort.[3] As of press time, the FDA appeared on the verge of moving beyond the EUA to give the Pfizer solution full agency approval.

These three events might give uncertain respondents from the April survey more confidence in changing their minds, but that remains to be seen. As of Aug. 17, the CDC reported 6.8 million people age 12 to 15 years and 4.1 million people age 16 to 17 years had received at least one COVID-19 vaccine shot. At least 4.9 million people age 12 to 15 years and 3.2 million people age 16 to 17 years are fully vaccinated.[4] The results of the April survey could serve as a preview of future trends. For example, the survey revealed significant differences among parents from various demographic groups. Parents who identified as female or with education lower than a bachelor's degree expressed significantly lower adolescent COVID-19 vaccine uptake and intentions. Fewer non-white parents reported vaccination uptake. Parents living in the Midwest and South were not as eager about the shot. "Interestingly, we found no significant differences across demographic groups for adolescents," says **Aaron Scherer**, PhD, the study's lead author and an assistant professor in the department of internal medicine at the University of Iowa.

Scherer and colleagues did find a difference in demographic moderator results between parents and adolescents. This finding was surprising. "These results would suggest that inequities may manifest when parents are the primary decision-makers for adolescent COVID-19 vaccination, but these inequities may not emerge when adolescents are the primary decision-makers," Scherer says.

Scherer provides a word of caution about interpreting data, considering the information reported about COVID-19 vaccine uptake might not be complete. That presents a challenge to creating a general strategy to promote adolescent vaccination equity. "Instead, plans to address inequities will need to be developed and implemented at the community or state level, as opposed to a one-size-fits-all federal-level approach," Scherer suggests. ■

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Informed Consent, Payment Are Ethical Concerns with Egg Donation

By Stacey Kusterbeck

In a survey of 375 current and former egg donors, 55.2% said they believed they were poorly informed on potential long-term risks.[1] In contrast, 64.8% believed they had been well-informed on possible short-term risks.

"With lack of longitudinal research, it's impossible to know potential long-term consequences, both emotionally and physically," says **Diane Tober**, PhD, the study's lead author and an associate professor in the University of Alabama department of anthropology.

Most donors said the clinic indicated there was no evidence of long-term risk. Donors took that to mean egg donation has been studied and found to be safe. In reality, there is no evidence because the studies have not been conducted. "It's misleading. Informed consent discussion should make it clear that the impact of the egg donation process on women's health has not been studied, so risks are unknown," says Tober, adding that more needs to happen to track donor health over time. Undue inducement caused by high compensation is another concern. A total of 86.1% of the egg donor survey respondents received compen-

sation beyond direct reimbursement. The consensus is egg donor fees should be enough to provide reasonable compensation, but not so high it leads to "undue inducement."

"The thinking here is that financial precarity and promise of large sums of money could lead a person to make a medical decision they would not otherwise make," Tober explains. Financial compensation of women donating oocytes is ethically justified and should "acknowledge the time, inconvenience, and discomfort associated with screening, ovarian stimulation, oocyte retrieval, and postretrieval recovery and not vary according to the planned use of the oocytes or the number or quality of oocytes retrieved," according to an updated policy statement from the American Society for Reproductive Medicine (ASRM).[2]

The other ethical challenge concerns the fact some people are compensated far more than others. "There is a tiered market in human eggs that breaks down by race, class, and education," Tober notes.[3] In the United States, there is no system to track donor cycles, making it possible for donors to undergo more than the number (six) recommended by ASRM.[4] "Those who do so are highly motivated by increased compensation on subsequent cycles. Knowing another $10,000 to $15,000 or more could be just a few weeks away is hard for many people to say no to," Tober observes.

Efforts also are underway to enable donors and donor-conceived people to find each other down the road if they so choose. As donor-conceived people are reaching adulthood, some have voiced their own desires to be connected with their biological donors.[5] "Many intended parents also want contact with donors. Things are definitely opening up on this front," Tober says. ■

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Framework for Developing Health Research Ethics Competencies

By Stacey Kusterbeck

Ethicists at the Johns Hopkins Berman Institute of Bioethics collaborated with the University of Malaya in Kuala Lumpur to develop a new master's program in health research ethics.

"When we were developing the curriculum and seeking to rigorously evaluate the program, we were unable to find an existing framework delineating the competencies our graduates should have," says **Sean Tackett**, MD, MPH, an associate professor of medicine at Johns Hopkins.

Tackett and colleagues created a framework to define expected outcomes for participants and programs.[1] The first graduates of the MOHRE (Master of Health Research Ethics Program) initiative are working in research ethics committees, government, and academia. The second cohort of students is nearing the end of the program. A third cohort will begin in the fall. "Without a clear statement of the outcomes expected of advanced degree programs in research ethics, it is challenging to measure a program's effectiveness and if there is a favorable return on investment in supporting these programs," Tackett says.

Tackett's team was surprised that despite ongoing efforts to develop research ethics programs over many years in the United States and internationally, there was no published competency framework to follow. "We were also surprised that there wasn't a standard approach to creating competencies in this context," he adds.

This, despite the fact competencies have been used for education in business, medicine, and elsewhere for more than 50 years. In hospital settings, "our work could be useful to bioethicists where research is being conducted, perhaps if they serve on institutional

review boards or are involved with developing hospital policies related to research," says **Jeremy Sugarman**, MD, MPH, MA, deputy director for medicine at the Johns Hopkins Berman Institute of Bioethics. For example, IRBs might want to assess whether its members have the necessary competencies to conduct meaningful ethics oversight of research.

Biomedical and behavioral scientists need awareness of ethical, legal, and social implications that come up in day-to-day research environments, says **Camille Nebeker**, EdD, MS, the director of the Research Center for Optimal Digital Ethics Health (ReCODE Health) at the University of California, San Diego. Nebeker suggests courses cover bias, research subject protections, mentor/mentee roles, collaboration, authorship, and data management. IRBs should increase awareness of human research protection ethics by pointing out if research protocols are ethically problematic in some way.

Additionally, IRBs should connect regulatory requirements with the ethical principles of The Belmont Report, a summary of basic ethical principles for research involving human subjects.[2] "This is one way an IRB could educate in tandem with the role of regulatory compliance," Nebeker offers. Finally, IRBs should involve ethicists, whether that means providing guidance on a specific question or considering ethical issues for all phases of a study. "ReCODE Health provides ethics consultation and education and conducts research focusing on digital health research ethics," Nebeker reports.

If research ethics training is inadequate, "it raises both ethical and legal concerns," says **Stephanie Solomon Cargill**, PhD, MSPH, associate professor of healthcare ethics at Saint Louis University.

The highly regulated research environment includes many requirements for training, documentation, and surveillance. "If researchers and clinicians are unaware of these expectations, they are likely to violate them and incur penalties," Cargill cautions. IRBs should play a key role in research ethics education, says Cargill, "since IRBs sit at the junction between ethics and compliance."

Research ethicists sometimes provide this education. "But unless they are aware of how their content intersects with the IRB practices at their institution, researchers and clinicians may be led astray," Cargill notes.

Concurrently, IRBs' educational focus is more on compliance than ethics. "Thus, IRBs should not be the sole provider of ethics education, at risk of reducing the ethical questions of research to the technical questions of compliance," Cargill says.

Ethicists can determine how researchers can assess for coercion and power dynamics, mitigate vulnerabilities in patient populations, and inform diverse patient populations adequately of what they are asked to do and why. "Without research ethics training, many people tend to conflate the practices of clinical care and research, to the detriment of both," Cargill says. ■

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Chaplains Play Unique Role in Advance Care Planning

By Stacey Kusterbeck

Chaplains are integrally involved in advance care planning, according to the authors of a study.[1]

"We recognized a gap in the literature in this space and recognized the importance of shining a light on the often behind-the-scenes role chaplains play," says the Rev. **Brian Hughes**, MDiv, MS, BCC, study author and director of programs and services for the New York City-based HealthCare Chaplaincy Network. Hughes and colleagues surveyed 585 board-certified healthcare chaplains on their role in advance care planning. Ninety percent said advance care planning is important to their work, 70% regularly help patients complete paperwork after discussions, 90% facilitate discussions with patients about their preferences, and 45% reported they were not consistently included in team discussions on decision-making.

Some clinicians do not realize advance care planning is part of the chaplain's role. Even if they do, logistics can block the way if conversations are not scheduled early. "It then falls to whomever is within arms' reach at the moment," Hughes notes. If chaplains are not involved, advance care planning documents can

be completed — but there might not be anyone who really understands the patient's values.

"Many ethical dilemmas arise when the paperwork is clear, but it is untethered from the clear articulation of the patient's values," Hughes explains.

An advance directive is clear: The patient does not want to be put on a ventilator. The problem is no one on the clinical team knows how to interpret this preference. The patient probably never considered an acute clinical crisis the medical team believes could be remedied with a ventilator, with strong confidence in eventual and successful extubation.

"If the ventilator is the means to the end of healing, then a values discussion becomes paramount," Hughes says.

Hopefully, it is clear enough to inform the plan of care in real time as new options arise.

"Ideally, the chaplain would continue to be involved, to unpack the real-world implications of the patient's stated values on the potential plans of care," Hughes notes.

Clinicians should be able to answer the question: Is the care consistent not just with prescribed clinical boundaries but also with the patient's expressed values? "This values discussion underlying the advance care planning process is one where chaplains excel, and can be of unique benefit," Hughes offers.

Chaplains connect with patients and families by acknowledging the stress and fear associated with serious illness. "In doing so, they are often able to facilitate conversations that explore a patient's values," says **Ann L. Jennerich**, MD, MS, assistant professor of medicine in the division of pulmonary, critical care, and sleep medicine at University of Washington. Chaplains cannot be involved in every advance care planning discussion; there just are not enough of them. "We just don't have the number of chaplains necessary to meet the needs of our patients, family members, and healthcare providers," Jennerich laments.

Chaplains' documentation can help clinicians, but a direct conversation is ideal.

"Patients might describe concerns to the chaplain that they don't share with the remainder of the medical team," Jennerich observes. "Sometimes, it is hard to convey that information in writing." ■

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Hybrid ED/ICU Setting Cuts Critical Care Admission Rates

By Stacey Kusterbeck

As the percentage of the U.S. population older than age 65 years expands, "the need for palliative medicine is likely to continue to increase," says **Nathan Haas**, MD, clinical assistant professor in the department of emergency medicine at the University of Michigan.

However, palliative interventions in the ED often prove challenging. Barriers include limited time, pressure to maintain patient throughput, and competing clinical demands. This frequently results in patients near the end of life moving from the ED to the ICU.

In the ICU, says Haas, "goals of care conversations often result in treatment focused on palliation rather than life extension."

In 2015, the University of Michigan opened the Emergency Critical Care Center, an ED-based ICU. If ED patients near the end of life receive care in this setting, some ICU admissions can be prevented.[1] Of 218 patients near the end of life treated in the ED-ICU from December 2015 to March 2020, only two were admitted to the ICU, and 22 were discharged home from the ED-ICU. "In the absence of the ED-ICU, it is likely that the majority — or all — of these patients would have been admitted to the ICU," Haas says. For patients and families, the ED-ICU means avoiding costly ICU admissions that do not align with care goals. For health systems, it means alleviating ICU capacity strain.

"This study adds to the growing body of literature that palliative interventions can be effectively delivered in the ED setting, to best provide care in line with patients' goals of care, and to reduce downstream resource utilization," Haas says. ■

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Observational Study Highlights Differences in IRB Start-Up Times

By Sue Coons, MA

The results of a recent observational study revealed a significant difference in start-up times for large cardiovascular trials in North America, highlighting changes needed for trials to become more efficient and feasible.[1]

This objective was to "measure the start-up times needed to reach prespecified milestones across sites in large cardiovascular RCTs [randomized clinical trials] in North America and to evaluate how these metrics vary by time and type of regulatory review process."

Researchers studied nine trials conducted from July 13, 2004, to Feb. 1, 2017. The trials were coordinated by the Duke Clinical Research Institute.

Investigators found the overall site start-up time was almost nine months, although the top 10% of performing sites completed their start-up in less than four months.

The study authors cited problems for IRBs, including resources spent on the contractual process, protocols changing and requiring additional review, and centers with large portfolios deciding how to allocate resources.

"There was a significant but modest improvement in this metric when comparing early to contemporary trials, possibly related to the outpatient setting in which these later trials were conducted," the researchers wrote.

"Contemporary trials more frequently used a central IRB and had faster times to regulatory approval when compared with earlier trials and sites using a local IRB. To our knowledge, this study for the first time quantitatively characterizes these performance metrics and provides insight into target areas for improvement."[1]

"We were not terribly surprised by these results, having run clinical trials over the last 20 years in the United States," says study co-author **William Schuyler Jones**, MD, an interventional cardiologist and associate professor at the Duke University School of Medicine and a member of the Duke Clinical Research Institute. "Ultimately, it placed a focus on the ability to start up and complete clinical studies, but it was an observational study."

The data revealed using central IRBs can improve overall efficiency. The rationale for multiple sites reviewing clinical trial protocols through individual IRBs should be reconsidered. "Such multicenter clinical trial protocols are often reviewed by several independent parties, including academic leaders, data monitoring committees, and regulatory agencies," the researchers wrote.

"It's very clear that some of the top centers can start studies and enroll in studies in an efficient manner," Jones says. "When we think of thousands of sites doing this work, central IRB is probably a key solution. But sites still can improve how they perform studies overall."

"The use of central IRBs may enhance RCT start-up efficiency," the authors concluded, "but more work is needed to ensure the timely implementation of a research protocol while protecting the interests of various stakeholders."

A Harvard cardiologist found the results of this study "eye-opening."

"I knew that IRB start-up times varied, but was surprised by the degree of variation," says **Deepak L. Bhatt**, MD, MPH, professor at Harvard and executive director of Interventional Cardiovascular Programs at Brigham and Women's Hospital. In a commentary on the study, Bhatt noted the cardiovascular clinical trial enterprise is in "disarray globally," and the issues have been made more evident by the COVID-19 pandemic. "However, the crumbling clinical trial infrastructure, leading to inefficient trial execution, has been evident in the U.S. for a much longer time," he wrote.[2]

For many reasons "spanning legal, regulatory, and cultural domains," RCT enrollment in the United States remains "suboptimal," with high costs per each patient enrolled, Bhatt noted. This potentially leads to a lack of generalizability of findings from international RCTs to patients in this country. "Over time, it will also lead to continued outsourcing of RCTs to other regions of the world and eventual loss of U.S. leadership in RCTs," he wrote.[2]

In the most notable result, the start-up times of the top 10% of sites were less than half the other sites, Bhatt said. It is not a sustainable model for sites to take about three-quarters of a year from the time of study protocol delivery to enrolling their first patient. "No intelligent, fiscally responsible industry sponsor or not-for-profit organization would invest in such an enterprise if there were feasible alternatives available elsewhere in the world," Bhatt wrote.[2]

Regulatory approval, contract execution, and site activation all are

factors in slowing RCTs in the United States. "The parts that really slow things down are contracting and IRB approval," Bhatt tells *Medical Ethics Advisor*.

Bhatt and the study authors agreed broader adoption of master service agreements between trial sponsors and sites could help streamline processes. "[H]aving master contracts between companies and institutions could help so that each trial contract doesn't require the same wrangling back and forth about issues such as intellectual property," he says.

It also might be more efficient to concentrate on high-performing sites. "This, of course, is dependent on these sites also being able to enroll a large number of patients, to provide thorough follow-up, and to maintain good adherence to the study protocol," Bhatt wrote in his commentary. The more efficient sites also can share best practices with the slower sites.

The use of central IRBs also would "greatly enhance trial start up times in a way that would not compromise patient safety, and may even enhance it," Bhatt tells *Medical Ethics Advisor*.

"As the saying among trialists goes, once you have seen one local IRB, you have seen one local IRB," he wrote. "To a given trial protocol, there tend to be several idiosyncratic responses from individual well-intentioned IRBs, with one IRB finding a particular issue, and another finding a totally different one."

IRB approval can be made more uniform and conducted by experts who have the time to devote to the task, but many hospitals do not have the resources to staff the IRB appropriately. Large academic centers might not want to cede authority to a central IRB.

"I understand that local IRBs work hard, try to do the right thing, and are proud of the work they do," Bhatt tells *Medical Ethics Advisor*. "But the truth is that there is an enormous amount of variability in IRB skill sets and turnaround times. It is not clear to me that local IRBs generally add much in the way of patient protection for multicenter trials that have typically undergone several layers of regulatory and ethical board review. Central IRBs seem to handle multicenter trials much more efficiently, without any downside that I have seen to date." He points out that local IRBs bring value in other situations, such as handling local single-site studies.

Bhatt says he has received an enormous amount of positive feedback about his editorial. "I can say that 100% of the clinical researchers I know agree with the points the authors made and that I made," he notes.

Most of the reaction Jones received from his research contrasts with the findings from traditional studies to the ADAPTABLE (Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-Term Effectiveness) study. "It was a pragmatic, virtual clinical trial that used some of the newer methods," he says.

In ADAPTABLE, patients with established atherosclerotic cardiovascular disease were randomly assigned to either 81 mg or 325 mg of aspirin per day. The study revealed substantial dose-switching to 81 mg of daily aspirin. The researchers did not find significant differences in cardiovascular events or major bleeding in patients assigned to 81 mg and those assigned to 325 mg.[3]

In this pragmatic trial, Jones and colleagues used "innovative and low-cost methods to simplify the identification, recruitment, and follow-up of patients."

This included using algorithms in electronic health record data to identify eligible patients within the National Patient-Centered Clinical Research Network, providing web portal access for patients to give informed consent and obtain information on their aspirin regimen, and conducting trial visits via video chat or phone.

The author of a recent editorial called ADAPTABLE a "major achievement" because it provided a method of conducting efficient, low-cost trials in the United States that can be adapted quickly and used more widely. "This should allow many more clinical questions to be answered, with obvious benefits to healthcare consumers," the author wrote.[4]

The observational study about cardiovascular trial start-up times highlights multiple key factors that are problematic for traditional clinical trials in the United States, Jones says.

"As clinical trials shift to a more patient-centered focus and a more pragmatic operational approach, we hope that people will be able to minimize start-up times and reduce the overall burden that's required to conduct studies." ■

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Interdisciplinary Teams Collaborate on Disaster Research

By Sue Coons, MA

Social scientists provide invaluable data for disaster and hazard research as they study human predictability, risk, and the consequences of such events. However, social scientists are not the only ones researching natural or man-made disasters. Disaster research also can include teams of engineers, urban planners, risk analysts, and public health administrators.

The National Institute of Standards and Technology (NIST) has recognized the importance of interdisciplinary teams working together in disaster and hazard research. A recent project began with a five-year grant NIST awarded in 2015 that established the Center for Risk-Based Community Resilience Planning: A NIST-Funded Center of Excellence (NIST-CoE). Creating this interdisciplinary research team involved writing IRB authorization agreements (IAAs) through a central IRB and approving a core research protocol.

NIST-CoE researchers noted different modes of research: unidisciplinarity, multidisciplinarity, interdisciplinarity, and transdisciplinarity. Interdiscipinarity research integrates information, data, methods, tools, concepts, and/or theories from two or more disciplines focused on a complex question. "The key defining concept of interdisciplinarity is integration, a blending of diverse inputs that differs from and is more than the sum of the parts," the researchers wrote. *(Read more here: https://bit.ly/2XicxGl.)*

NIST-CoE, headquartered at Colorado State University (CSU), includes "more than 120 researchers and students across 15 universities and spans multiple disciplines within engineering, urban planning, and the social, behavioral, and economic sciences." *(Read more: https://bit.ly/3iD2zHY.)* Its primary goal is to advance community resilience by "creating a decision support system that facilitates community planning and the adoption of best practices."

This system is embedded in a state-of-the-art computational environment, called IN-CORE (the Interdependent Networked Community Resilience Modeling Environment). IN-CORE uses modeling to create scenarios of various infrastructure exposed to different hazards and intensities. It also uses data-based models of socio-economic networks and resilience-based performance criteria and metrics. The NIST grant was renewed in 2020 and will continue through 2025.

To simplify the process, the CSU IRB was chosen as the IRB of record for the protocol reviews under the award. A second IRB protocol and consent form were required from the academic institution that did not cede oversight. **John W. van de Lindt**, PhD, F ASCE, F SEI, co-director of the Center for Risk-Based Community Resilience Planning, participated in the research. He recommends setting up a meeting with the staff of the reviewing IRB to become more familiar with its process.

As the research became interdisciplinary, some teams possessed little or no experience working with human subjects and had to complete IRB process training. Before joining a NIST-CoE-funded field study, all members of the team who expected "to collect data from human subjects, view or analyze the identifiable data collected, or supervise a student in analyzing identifiable data" were required to complete CITI training and submit their course certificates to their home academic institution and the IRB research coordinators.

When establishing an interdisciplinary team and task leadership, it is important to create clear leadership structures. "We started by trying to understand vocabulary and terminology differences," van de Lindt says. "The most important aspect is respect of one another's methods and approaches across disciplines. No one discipline is superior to another simply because it may be quantitative vs. qualitative."

To ensure broad representation, the initial field study team included two sociologists, two engineers, and two urban planners. Asking team members from at least two disciplines to conduct interviews and/or damage assessments allows cross-fertilization of methods and techniques, van de Lindt says. This team was given five primary responsibilities:

- serve as primary points of contact for communication with the CSU IRB, NIST, and partner institutions;
- educate researchers about the importance of IRB oversight and research ethics;
- encourage ethics training and ensure all CITI certificates are up to date and in compliance;
- create rigorous research designs and submit updated protocols and research instruments to the IRB;
- ensure compliance with the IAA process. The leadership team met monthly to review progress, track researcher status, and develop research protocols.

The broader field study teams included researchers from NIST and

11 of the 15 academic institutions involved in the NIST-CoE. The number of researchers depends on the project and the needs of the researchers/team, van de Lindt says. "If the scope is big, then a small team wouldn't be able to get it completed, so you may have to 'go all in' right away," he notes.

The leadership team in this project also found it needed to educate the researchers about the IRB and IAA requirements. The team discussed this through semi-annual in-person meetings, phone calls, and emails with the team leads at each institution.

Knowing the IRB could take weeks or months to approve a submitted protocol, the team created a NIST-CoE "core research protocol" that could be amended with information from a specific disaster research event. The core protocol was designed using the CSU IRB form and required supplemental documents, including recruitment scripts, interview guides, and a survey instrument. "The protocol and associated research documents used placeholder text that could be amended to specify the exact location of the study, number of participants, specific research questions, and any updated forms or instruments based on the intent of the study and actual disaster context," researchers wrote.

The core protocol underwent a full board review at CSU. During this review, the IRB asked clarifying questions and allowed the team members to respond verbally. Written revisions were made based on the IRB recommendations. The CSU IRB committee agreed to review and approve or deny any disaster amendments to this core protocol within 48 hours. "The approved IRB protocol states that access to primary data collected in the field is limited to investigators who have completed the CITI training and whose universities have signed the IAA agreement." The core protocol is available to view here: https://bit.ly/3s8oUQM.

In late fall 2016, van de Lindt participated in a flood disaster that tested the core protocol process. When Hurricane Matthew dumped 15-18 inches of rain onto Lumberton, NC, the soil already was saturated. At the time, there were 22,000 residents in Lumberton, a racially and ethnically diverse community with higher-than-average poverty and unemployment rates. The hurricane caused the Lumber River to flood the town, displacing residents, disrupting utility services, and closing schools.

NIST-CoE teamed with researchers from NIST's Engineering Laboratory to conduct a field study focused on the effects of the flooding. Researchers noted two major objectives for the initial data collection:

- to document conditions after the flood to study the town's recovery, with a focus on improving flood damage and population dislocation models;
- to develop a multidisciplinary protocol with a quantitative link between engineering-based flood damage assessments and social science-based interviews to capture socioeconomic conditions (e.g., social vulnerabilities related to race, ethnicity, income, tenancy status, and education levels; *Read more: https://bit.ly/3Azc1SP*).

Each interdisciplinary team included at least one engineer and one social scientist. Before deployment, team members participated in the field survey training session and completed IRB training. All universities involved in the study signed an IAA with CSU.

Hurricane Matthew made landfall in South Carolina on Oct. 8, 2016. On Nov. 16, the field team submitted a study amendment to the CSU IRB. The IRB responded within two days with requested revisions. The revised amendment was approved on Nov. 23, and the team entered the field four days later. "IRB approval can take weeks or even longer, but it is critical following a disaster to get the teams into the field once emergency management activities have been completed," van de Lindt says. "Having the protocol essentially preapproved with only a modification required is optimal for these types of events."

Preliminary findings showed dislocation probabilities were driven primarily by flooding damage. Dislocation also varied significantly among Lumberton's racial/ethnic populations and by tenure. The field study team continued to track Lumberton's community recovery and resilience through multiple trips to the town several years after the event. The CITI ethics training expires after three years, so any members still operating in the field or working with study data were required to retake the ethics training. The IRB also requires an annual update on information such as number of study participants, the number of field studies to be completed, and updated plans for data analysis, management, and publication. The review form is approved by the CSU IRB, and all associated documents and approval forms are submitted to the institutions covered under the IAA.

Van de Lindt says he hopes this process is changing the way teams can gather data to affect real change to communities over the long term, and to better understand how communities recover following an event such as a flood or hurricane. "Historically, disaster and hazards research has been studied in or at least near disciplinary silos, but interdisciplinary is to hazards science as diversity is to society," he says. "It improves us as a whole. For hazards specifically, [it improves] the thought process for data collection and studying events, and ultimately creates better methodologies and solutions for at-risk communities." ■

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CME/CE QUESTIONS

1. **Which is true regarding research on controlled substances?**

   a. Stigma around cannabis use continues to increase.
   b. Psilocybin still carries significant stigma, which is a significant barrier to overcome for clinical application.
   c. Investors are increasingly reluctant to fund psychedelics research.
   d. Regulators require cannabis research to be conducted at outpatient facilities.

2. **Which is true regarding physicians' obligations to unvaccinated patients?**

   a. In the hospital, physicians generally cannot refuse to treat patients, although specific religious or medical concerns may arise that merit consideration for exceptions.
   b. Hospitals are not ethically obligated to minimize risk to providers.
   c. Outpatient providers cannot refuse to see patients over vaccination status, even if those patients can access other providers.
   d. Refusal to treat unvaccinated patients is a proven approach to convince patients to take the vaccine.

3. **Which is true regarding adolescents self-consenting for vaccinations?**

   a. Most "mature minor" doctrines allowing young people to consent for healthcare specifically exclude vaccination.
   b. Most states allow minor adolescents to consent to vaccination.
   c. There is clear evidence showing most older adolescents are incapable of ethically valid informed consent.
   d. Competency determinations must balance the interests of parents with the autonomy of minors.

4. **Which is an ethical concern regarding egg donation?**

   a. Overemphasis on potential short-term risks when such risks are quite minimal
   b. Lack of information on potential long-term risks
   c. Most donors receiving no compensation beyond direct reimbursement
   d. Overly restrictive requirements limiting the number of cycles donors can undergo

5. **What do many researchers suggest will improve IRB startup times for cardiovascular trials?**

   a. Adoption of best practices
   b. Use of a central IRB
   c. Increased federal funding
   d. Master service agreements between sites and IRBs

6. **What step in the interdisciplinary process saves the most time in helping research teams respond after a disaster happens?**

   a. Ethics training with the Collaborative Institutional Training Initiative
   b. IRB authorization agreements
   c. Pre-approval of a core protocol
   d. Use of a central IRB