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INSIDE

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IRBs Facing Ethically Controversial Questions on Brain Research

The field of brain research sounds a lot like science fiction, but human neural organoids, human neural transplants, and human-animal chimeras all are imminent realities. IRBs are going to be facing some difficult decisions on whether this research can proceed. The authors of a recent report examined these issues.[1]

"The National Institutes of Health is the major funder of cutting-edge brain research in the U.S. The Dana Foundation has led the way in advancing public understanding of the brain," says **Bernard Lo**, MD, co-chair of the study committee that wrote the report.

Leaders of the two organizations asked the National Academies of Science, Engineering, and Medicine to review the emerging areas of human neural organoids, transplants, and chimeras. "These are exciting models that provide new ways to analyze the human brain," says Lo, president emeritus at The Greenwall Foundation.

Lo and colleagues were charged with examining ethical issues raised by emerging brain research and considering oversight mechanisms that might be appropriate. The committee was instructed to issue only findings, not to make recommendations. New models for studying the human brain show great promise for laying the groundwork for new therapeutic approaches to brain diseases that have so far proved hard to treat.

"However, this promise must be carefully weighed against the ethical concerns that such models raise," says **Joshua Sanes**, PhD, co-chair of the study committee and Paul J. Finnegan Family Director of Harvard's Center for Brain Science.

One ethical concern is whether previously collected and deidentified biological materials should be used for this research, without the specific consent of the people who originally donated the tissues. There also are some major ethical concerns related to animal welfare. "As transplantation and chimeric models of human brain diseases become better able to model key disease features, it is likely that research animals will show behaviors that resemble distressing human symptoms," Sanes says.

If host animals develop altered behaviors, such as new forms of problem-solving or complex social interactions, objections to such research likely will flare up. "These concerns would be greater if nonhuman primates are used as hosts," Sanes says. The research raises moral, ethical, and religious concerns regarding

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mixing of humans and other animals. "For example, animals might acquire attributes that could be viewed as distinctively human or as threats to human dignity," Lo says.

Another ethical concern is that neural organoids could possess consciousness, feel emotions, or experience pain. "The committee reviewed the scientific evidence and concluded that this is extremely unlikely in the foreseeable future," Sanes reports.

Neural organoids (3D cell aggregates grown from human stem cells in the laboratory) currently do not reach the levels of complexity, connectivity, or maturity believed to be necessary for higher cognition, pain, or consciousness, according to Sanes.

Engaging the broader public in discussions would offer many benefits, the report authors wrote. "In a pluralistic society, the diversity of religious and secular views on these issues must be respected," says Lo, adding the United States currently lacks mechanisms to facilitate this kind of public engagement.

There is a real need to help the public understand the research, identify public concerns, facilitate informed public discussion, and influence science policy. "Ongoing, respectful dialogues between religious, secular, and scientific perspectives, and among different viewpoints regarding biotechnology research, are important," Sanes says.

For now, ethical concerns on neural organoid, transplant, and chimera research are addressed by current oversight mechanisms. These include IRBs and institutional animal care and use committees. These bodies might need additional expertise in evaluating the behavior of transplanted or chimeric animals in the near future. Scientists familiar with animal behavior in natural settings could be important contributors. "Oversight will need to be reassessed as the science develops," Lo says. "Members of IRBs might start to educate themselves about these developing areas of science and the ethical and oversight issues they raise."

Meanwhile, technologies are advancing rapidly. "Areas that are not of immediate concern may become concerning in the future," Lo adds. "The committee, therefore, finds that periodic re-examination of these areas will be needed." ■

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To Eliminate Race-Based Disparities, Start by Asking Questions

For more than five decades, **Vernellia R. Randall**, JD, MSN, BSN, professor emerita at the University of Dayton School of Law, has focused on disparities in healthcare for minorities and the poor. She also is the founder and editor of Race, Racism, and the Law (www.racism.org). In this Q&A, which has been lightly edited for length and clarity, Randall discusses how ethicists can play a crucial role in eliminating disparities.

MEA: What is the bioethics role in eliminating disparities in healthcare?

Randall: Traditional bioethics limits itself to individual problems and individual issues. Consequently, [bioethics] doesn't deal with the needs of the community, particularly the African American community. That's a flaw in how bioethics thinks. That's a major issue that they have to deal with. There is no way to eliminate racial health disparities without focusing on the community. For instance, as a public health nurse, I understood that if I want to improve the health of the community, I have to look beyond the health of the individual. Bioethics has to do the same.

MEA: How can the ethics service start?

Randall: By asking questions of the hospital. Bioethicists can say, "We in bioethics are really concerned and want to ensure that this hospital isn't systemically racist, because that is a bioethics issue. We need data on what you are doing. We need to be able to assess and recommend things to you." Dealing with individual problems will only take us so far. I think a bioethics committee could legitimately ask for more information from the hospital. Before you start cleaning the community, you need to clean your own house. Ask questions like, "Are there more complaints from patients of color? What is the nature of those complaints? Is it something we as a committee can deal with?"

As soon as you begin to ask those questions and ask for information about your own institution, your institution will start to change. I wholeheartedly believe that is the lowest level of change that a person on the bioethics committee on a hospital can do. It may not go anywhere initially. A law school just ... adopted a model I recommended 20 years ago. Those things get pushed into the institutional memory. At some point, it may have an impact that you may not even know about. Just asking for the information will prompt changes. This comes from my belief about lawsuits. Lawsuits are effective because nobody wants to be sued. As soon as you have a lawsuit about something, the system changes.

All discrimination in this country is not illegal. Negligent discrimination is not illegal. It's up to the bioethics committee to say, "This may not be illegal, but it's still unacceptable."

MEA: What else can bioethicists do in the hospital setting to drive change?

Randall: The bioethicists could be the lead on training hospitals on what disparities in social determinants of health exist in the African American community and why it's important to eliminate those.

That might be something hard to get their head around, because bioethicists deal with issues of the individual patient. But it's unethical to sit in an institution where there's disparities. If you're a bioethicist and you don't know whether disparities exist, you're being willfully blind. If you find out ... there is a disparity, then you would be obligated to do something about it as a bioethical issue.

Make sure that the African American community is represented on the hospital's patient advisory committee. Are they represented in sufficient numbers, where one person doesn't end up having to be the only voice for a whole community, or get drowned out because there are only one or two people? The patient advisory committees often function in such a way that they are sort of like grand juries. They kind of deal with whatever the hospital brings in front of them. The bioethicist can sit in the meeting and ask questions that you know is going to stir up stuff — not only in the minds of the people who are leading the hospital, but also the other people on the committee. It says to them: You have a right to ask for a lot more.

MEA: How can bioethicists be most effective in examining clinical practices at their own institutions, in areas where research has shown racial disparities?

Randall: You've got to arm yourself with all the ethical arguments and be ready to make a case for why.

Disparity in pain management is an ethical issue. Bioethicists can ask for data on what's happening based on race in the institution, in terms of pain management. Bioethicists can also ask to see all the data on restraints. You can set up a subcommittee whose only issue is going to be looking at the records produced regarding restraint — who's being restrained, for how long, and how it's being carried out.

It can be a real substantive evaluation of one issue. That kind of approach will bleed into other areas. The hospital will say, "If they are going to start wanting this kind of information, we need to look at other areas as well."

If not the bioethicist, who else in the hospital system is going to be responsible for checking to make sure that systemic racism isn't occurring within the hospital? To me, bioethics has an interest, because of the ethical principle of justice, in making sure that the community is treated appropriately.

If the response is going to be, "We don't collect that kind of data," that in itself is a problem. The only reason not to collect race-based data, in this day and age, is because you don't want to have to analyze it. The bioethics committee should not accept that the data are not collected. If you are asking for any demographic information other than date of birth, then you need to collect race and ethnicity data. If the response is, "People don't like to give that data," that is a problem. You can

always put that someone preferred not to answer, and then that's part of the analysis. You can look at how many people preferred not to answer and [if] that group [is] different in any way. As a member of the ethics committee, it is not your responsibility to do all of this. It's the hospital's responsibility. You are not collecting or analyzing the data. You are just asking questions. You're a bioethicist. Asking questions is what you can do. ■

IRBs Use Inconsistent Processes for Informed Consent with Non-English Speakers

IRB policies are inconsistent for obtaining informed consent from non-English speaking research participants, according to a comparison of guidelines of the top 21 recipients of National Institutes of Health funding in 2018.[1]

"I thought I would find well thought-out documents that were consistent, logical, and tied to sound ethical reasoning. Most of all, I expected similarity across the board," says **Gianna McMillan**, DBe, the study's author and program administrator at the Bioethics Institute at Loyola Marymount University.

Instead, the results showed much disparity. "Just over 25% of them had what I would call sound policies. Another 25% did not do a good job at all. Those in the middle were all over the place," McMillan reports.

The criteria for "sound policies" were based on identifying actions that directly affected the consent process in a positive way. Best practices included reference to federal regulations, minimal use of short form consent, definitions of key terms, standards for interpretation and translation, no use of family members as interpreters, and ethical discussion about language use. Some institutions used all of these; some used only a few.

"Every potential subject deserves a full explanation of the study before they make a decision, and ethical practice demands that a consent form be understandable to the potential subject," McMillan says.

Translations, interpretation services, and other necessary accommodations for non-English speakers need to be built into study budgets, McMillan argues. "Those 21 institutions received $3 billion that year. That seems like enough money to come up with sound and consistent policy that supports a full explanation of a study in the language the subject actually speaks," McMillan says. ■

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Ethical Concerns on Conscience Clauses in Genetic Counseling

Oklahoma, Nebraska, and Virginia have put in place genetic counseling "conscience clauses," allowing healthcare providers to refuse to counsel patients about abortions based on moral or ethical objections. Investigators studied genetic counselors' awareness of these laws. *(Learn more here: https://bit.ly/3DB802o.)*

Of 274 genetic counselors surveyed, 90% were not even aware the conscience clauses existed. On the issue of whether genetic counselors had the right to use a conscience clause, responses were mixed: 24% said yes, 31% said no, and 45% were unsure. Ninety percent of respondents agreed counselors were ethically obligated to refer a patient to another provider if using a conscience clause.

The 274 counselors also were asked about attitudes on whether conscience clause laws align with the National Society of Genetic Counseling Code of Ethics. Forty-five percent said neither supersedes the other, 31% said the code supersedes, 8% said conscience clauses supersede, and 16% were unsure.

"I was surprised by the overall lack of consensus on many of the questions," says **Shea Bonine**, MS, LCGC, the study's lead author and a licensed certified genetic counselor at Sioux Falls, SD-based Sanford Health. Only one genetic counselor reported actually using a conscience clause in practice. Still, about one-third believe the clauses granted some extra legal protection and wanted additional information to understand how it affects their practice.

The genetic counseling field is evolving in many ways, in light of preimplantation genetic diagnosis used with in vitro fertilization, gene therapy used for select genetic conditions, and polygenic risk scores.

"The field is rapidly changing because genetic technology, knowledge, and accessibility is rapidly increasing," Bonine observes.

In addition to those changes presenting some new ethical questions, Bonine says ethicists also should be aware of state conscience clause laws. "All genetic counselors receive some level of ethics training during their program, but this really highlights the need for clarification," Bonine says. ■

IRBs Scrutinizing Recruitment of Adolescents via Social Media

Increasingly, IRBs are seeing researchers recruiting adolescent participants through social media, according to **Rachel Reynolds**, MPH, senior IRB analyst for social and behavioral research at Northwestern University.

Researchers have evaluated study protocols for privacy concerns, transparency on the part of the investigator, and terms of services (e.g., whether an online forum is private vs. public). "One ethical concern we've seen a lot lately is when participants share comments on a recruitment post," Reynolds says.

Some posts make false claims of efficacy (e.g., participating in the trial cured a medical condition). "Participants — adolescents, particularly — shouldn't be taking part in the recruitment process," Reynolds cautions. IRBs expect investigators to follow a process to monitor comments regularly and turn off comments and/or prevent sharing of posts if it becomes necessary during the study.

Parental consent for online recruitment of teens is another problem. Investigators must consider consent carefully. "Challenges related to consent are often the most difficult for researchers to address online," Reynolds explains. "But there really has to be a method of parental permission, even with online studies."

Consent can be handled verbally, but some researchers email parents the permission form. After sending the form, the child is cleared to assent and complete the survey. Recently, a PI surveying adolescents asked for a waiver of parental permission after arguing the process was too time-consuming. The IRB did not grant the waiver. "We did not feel it was too difficult because we have seen other researchers do it," Reynolds says.

If researchers want to waive parental consent, there has to be a valid reason. Investigators reviewed a recent study involving LGBTQ+ youth participating in online focus groups. The researchers requested a waiver of parental permission, which was granted. Everyone agreed the study posed some unique risks for participants. "The investigators had done research with the LGBTQ+ population before, and knew not all the participants had come out to their parents," Reynolds explains.

There is no hard-and-fast rule when it comes to waiving parental permission. "We are happy to help investigators if questions do arise," Reynolds offers.

Reynolds suggests that when recruiting adolescents online, investigators think about how they would proceed if recruitment was conducted in person. For instance, recruitment ads posted on a bulletin board raise the same issues as ads posted on websites. "The recruitment method and materials cannot create undue influence. Also, recruitment language cannot contain misleading statements or exculpatory language," Reynolds notes.

Likewise, researchers would not be able to barge into an in-person group meeting without an invitation, just as they cannot post in a private Facebook group without the moderator's permission. "As the online world is changing, we have to adapt with it and look at all the ethical considerations," Reynolds says.

Guardian permission is a significant barrier to adolescent involvement in sexual health research, according to **Celia B. Fisher**, PhD, director of Fordham University's Center for Ethics Education. Thus, the minority of adolescent girls who are willing to participate in studies requiring guardian permission are not representative of the larger population. "This skews study findings in ways that can lead to poorly conceived interventions by healthcare providers," Fisher laments.

This issue arose during the design of research looking to understand associations between sexting behaviors and risks to mental and sexual health among adolescent girls.[1] "We found there is a paucity of studies on the consequences of sexting among younger adolescents," Fisher reports.

Typically, IRBs determine such research requires guardian permission, based on the assumption that answering such questions may cause teens to experience worse discomfort than what they deal with in everyday life.

In another study, the authors sought data to inform future IRB decision-making regarding guardian consent.[2] Girls' comfort with sexting research participation was compared to their attitudes toward sharing such information with doctors, parents, and teachers in everyday life and during routine medical examinations. "We

were surprised to find that adolescent girls were more comfortable reporting on their sexting and sexual behaviors in anonymous online surveys than discussing such topics with their parents, practitioners, and teachers," says **Xiangyu Tao**, MA, the study's lead author and a doctoral student in the Fordham University Applied Developmental Psychology program.

IRBs have been reluctant to waive guardian permission for sexual health-related research based in part on the opposite assumption, that it presents a greater probability of discomfort than girls might experience during routine medical exams or in everyday life. "Our findings suggest that anonymous online sexting studies can be classified as minimal risk for adolescent girls and provide empirical support for IRB decisions to waive guardian permission for participation in such studies," Tao says. ■

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Minority Residents' Palliative Care Training Quality Trails Other Medical Education

Internal medicine and family medicine residents at two medical schools at a historically Black college and a historically Black university (Morehouse College and Howard University) see palliative care as important. However, most residents believe the quality of their palliative care education was not as good as their other medical training.[1]

"Black medical schools are the leaders in training underrepresented minorities to become physicians," says **Robert M. Arnold**, MD, one of the study's authors and section chief of palliative care and medical ethics at the University of Pittsburgh. "If we are going to integrate palliative care broadly, and if we want to make sure that Black physicians have the skill set to take care of their patients, then we have opportunities."

The 91 residents surveyed reported receiving less training on palliative care than they did on sepsis management. "They get very good training. But they felt less well-trained in palliative care than in many other areas of their training," Arnold reports.

Half the residents reported receiving negative messages about palliative care. Two-thirds said they considered care for dying patients to be depressing.

"As we are worrying about ensuring that all patients have access to the best possible care, we need to make sure palliative care is integrated into all medical students' curriculum," Arnold offers.

Medical schools with the highest Black enrollment were less likely to offer palliative care rotations in family medicine or internal medicine residency training vs. schools with the lowest Black enrollment.[2]

"We wanted to understand the role that the medical education system might play in the lack of workforce diversity and health disparities that exist in palliative care," says **Lindsay Bell**, MPH, the study's lead author.

Bell and colleagues were surprised to learn that among historically Black colleges and universities with medical schools, none offered palliative care training during medical school or residency.

"National palliative care organizations that are committed to addressing this issue should look for opportunities to work with these institutions to enhance exposure and training for students and to support faculty with incorporating palliative care education into the curricula," says Bell, research project coordinator for the University of Pittsburgh's Palliative Research Center.

Palliative care skills are important to a cardiologist, an oncologist, or anyone who takes care of seriously ill patients. There also is the hope that more minority residents will choose to go into the palliative care field. There are ongoing concerns about a shortage of palliative care clinicians generally.[3] "There is clearly not enough diversity in palliative care clinicians so that we look like the population of America," Arnold says.[4]

Evidence suggests doctor-patient race concordance, particularly for minority patients, results in better care.[5] "This is why having so few physicians of color in palliative care is such a problem," Arnold explains. "We need to make sure our workforce represents the patients that we are caring for, as much as we can." ■

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Quality Improvement Project Reveals Reasons for Long IRB Approval Process

A recent quality improvement project identified reasons for long delays in the IRB approval of clinical research. Project leaders offered some tactics to streamline the process.[1]

"It is very important that the conduct of research be safe and ethical, but also that the appropriate review of the protocols be as expeditious and timely as possible," says **Elaine Larson**, PhD, RN, FAAN, CIC, one of the paper's authors and professor emerita and special lecturer at the Columbia University School of Nursing.

Larson and colleagues analyzed minutes of IRB meetings for 33 protocols that were approved in 2019. All 33 protocols required at least two full board reviews before approval. They also evaluated 244 protocols that were reviewed faster.

"The majority of delays in IRB approval relate to the fact that researchers submit protocols that do not adequately describe the research," Larson explains.

Some consent documents are incomprehensible to people without medical backgrounds. Safety risks, duration, and allocation of cost sometimes are unclear. All this requires feedback from the IRB, to which researchers need to respond.

"All of this could be prevented if researchers took the time to seriously review their own protocols before submitting them for IRB approval," says **Emily Rodriguez**, MS, the paper's lead author and an intern with Columbia University Irving Medical Center's Human Research Protection Office.

These factors were linked to long delays in IRB review: researchers' conflict of interest; the need for radiation safety evaluation; protocols that also were clinical trials; consent forms using too much technical jargon; inadequate description of data security; protocol design that insufficiently protected participants' safety; and lack of clarity on either participant compensation, payment, or study duration.

Clinical trials and protocols with demonstrable conflicts of interest require additional review. It makes sense the review process will be extended somewhat for those studies.

Additionally, investigators found not all problems came from researchers. Correspondence from IRBs to researchers could be difficult to decipher. Some IRB reviewers identified issues in the second or third return of a protocol they did not catch the first time.

"Our paper doesn't suggest a complete transformation of the review process," Rodriguez notes. "It just identifies a number of small inefficiencies that can pile up." ■

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COMING IN FUTURE MONTHS

- IRBs want to see efforts to reach underrepresented groups
- Ethics of privacy protection in psychology research
- Standardizing competencies for bioethics trainees
- Social media influencers and clinical trial recruitment

Needlessly Delayed IRB Approval Raises Ethical Concerns

Delayed study startup times obstruct the enrollment process for prospective participants in clinical trials with a therapeutic intent. That is an ethical concern. "There are patients waiting to start on these studies. Delays in IRB approval will delay the patient obtaining access to research procedures that are integrated with their clinical care," says **Nathalia Henry Whitely**, MS, CHRC, CIP, executive director of the IRB office at Northwestern University.

Delays in IRB approval hinder enrollment, data collection and analysis, and submissions to regulatory oversight agencies. It takes longer to learn if new therapies are effective and safe. Updated product labeling and product approvals are held up. "In the long term, it means delays in those discoveries being available to patients at the bedside," Whitely says.

Some multicenter, industry-sponsored studies include specific enrollment time frames. Delayed IRB approval might mean the enrollment window closes. "The institution misses the opportunity to conduct the study. Patients affiliated with that institution miss the opportunity to participate in the research," Whitely says.

There are a few reasons for delays in the IRB approval process:

• IRBs and research teams might be challenged by the sheer volume of studies that need preparation, submission, and review. "Due to human research portfolio growth and expansion, institutions face increases in the influx of studies coming down the pike. That is a good problem to have," Whitely says.

However, many institutions are finding their human research portfolios are growing at a much faster pace than their human research protection program (HRPP) infrastructure. To keep up, HRPPs, IRBs, faculty, and support teams must be adequately staffed. It is a challenge. "Research teams are constantly laboring to find and retain qualified research personnel with the appropriate level of expertise," Whitely says.

• Certain studies require review by an ancillary committee before the IRB can give final approval. The scientific review committee might need to review oncology studies, or an investigation might need conflict of interest review. "To prevent delays, it is important for the principal investigator [PI] and the research teams to know which ancillary reviews must occur prior to or in parallel with IRB review," Whitely says.

• Regulatory bodies, such as the FDA, might need to provide additional oversight. For studies in this category, the PI and/or the industry sponsor might need to obtain a determination from the regulatory body (e.g., obtaining an investigational new drug or an investigational device exemption from the FDA) before the study can begin.

• Poorly written protocols raise additional questions. "IRBs work with PIs to iron out protocol discrepancies and bolster protocol content that adds the clarity needed for the IRB to perform a thorough review and appropriate risk determination. That takes time," Whitely notes.

If any component of a protocol is unclear, such as research procedures, risk mitigation plans, participant eligibility criteria, recruitment plans, or participant compensation, PIs will field multiple clarification requests from the IRB to adjust the protocol. "If an IRB notes an issue with a protocol, the IRB will send the protocol back to the PI for clarification and resolution of the issues," Whitely says.

For industry-sponsored studies, the sponsor must approve any protocol changes that result from an IRB's questions. "Therefore, during the IRB process, there are blocks of time where the study may be sitting with other parties outside of the IRB who need to take an action, such as the PI or industry sponsor," Whitely observes.

It is critical for PIs to maintain close oversight of their teams. "PIs must ensure research staff have the appropriate expertise and receive adequate training to adhere to detailed instructions provided by the IRB and regulatory bodies," Whitely says.

At the University of Texas at El Paso, many IRB review delays happen because of a lack of clarity about risks and benefits. "These include lack of congruency and researchers not responding to requested modifications in a timely manner," says **M. Lorraine Torres**, EdD, MT(ASCP), clinical laboratory sciences program director.

Some protocols describe procedures in which participants would be partaking, but it is not consistent with what the consent form says. Many researchers ask participants for sensitive information, such as criminal activity, drug use, or sexual behaviors. "This could compromise participant privacy and confidentiality, thus affecting their employability, insurability, and overall reputation if a breach were to occur," Torres cautions.

For social-behavioral projects deemed as "clinical trials," the IRB

advocates for preparation meetings with the researcher before submission. This promotes open discussion so issues can be ironed out proactively. Recently, the IRB raised the question of whether identifiers were absolutely necessary in a study. The IRB recommended excluding identifiers to minimize potential risk to the participant. Whatever the issue, "the office can assist the researcher in finding solutions that are allowable within the regulations and acceptable to the IRB committee," Torres says.

Ryan Spellecy, PhD, views lengthy delays of IRB review as interfering with the ethical principle of beneficence. "We ultimately delay the opportunity for individuals and society at large to benefit from research," explains Spellecy, chair in bioethics at the Medical College of Wisconsin.

Life-saving or life-improving treatments could be delayed. "Even the clinical trials that fail are important as we [can] learn from them," Spellecy notes.

One might assume long turnaround time happens because of understaffed, overworked IRBs. This can be the case, but delays also can happen when investigators take too long to respond to IRB requests. Clearly written protocols can prevent too much back-and-forth between the IRB and the PI.

"IRBs and study teams need to work together to identify the causes of delays at their institutions and collaboratively design solutions," Spellecy says. ■

Data on Ethics Programs Fill Knowledge Gap

Hospital-based healthcare ethics programs vary in scope, activities, workload, financial compensation, and staffing. Researchers recently surveyed 600 hospitals to learn more.[1]

"National data regarding ethics programs can provide valuable input to national leaders in the field of bioethics," says **Marion Danis**, MD, the study's lead author and head of the section on ethics and health policy at the National Institutes of Health Clinical Center.

Data on the role of ethicists in hospitals and the financing of their work, "fills a knowledge vacuum," Danis says. "These data are important on a long-term basis for sustaining and building the field." Ninety-seven percent of hospitals had established a healthcare ethics program (defined as "an officially sanctioned entity within a hospital that supports healthcare ethics by providing ethics-related services such as ethics policy development or ethics education.") In 97% of hospitals with healthcare ethics programs, the program's scope included clinical ethics functions.

Some ethics programs included additional functions: Ethical leadership (35.7%), regulatory compliance (29%), business ethics (26.2%), and research ethics (12.6%)

"These data are likely to be particularly important when institutions are under financial stress, budgets are tight, institutional demands are high, and various programs are under threat, as they are now during the pandemic," Danis says. Other findings:

- 77% of programs were responsible for providing ongoing ethics education to all staff.
- Ethics program staff review existing policies more commonly than they are involved in developing new policies.
- In 80.5% of hospitals, there is an ethics representative in executive leadership, while there are ethics representatives on other committees in 40.7% of programs.
- 17.7% lead large-scale quality improvement ethics initiatives.
- There are more individuals performing ethics program work (and more are paid specifically for that work) at urban hospitals, larger

hospitals, and academically affiliated hospitals.

• The average total number of FTEs provided specifically for ethics program work was 0.3.

• 76.3% of hospitals provided zero FTEs in specific financial support for ethics program staff.

"It is surprising that designated funding for ethics program personnel is so limited. This poses a challenge to the development of the field of bioethics," Danis says.

Bioethics training program leaders might struggle to place their trainees in financially well-supported programs, despite the fact hospitals seem to maintain substantial ethics programs.

• Large hospitals (500 or more beds), major teaching hospitals, and urban hospitals were most likely to list resource shortages (e.g., time, money, staff, and training) as the greatest challenge facing their ethics programs.

• The smallest institutions (fewer than 100 beds) were more likely to list underuse of their services (staff were unaware of the service, did not understand the role of the service, did not appreciate its possible benefits, or did not identify a need for the service) as their ethics program's greatest challenge.

"The other challenges they faced were lack of clarity of their programs, lack of leadership support, and lack of understanding of their role by healthcare providers," Danis says. ■

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Qualitative Methods Give Unique Insights on Ethics Consult Standards

At Michigan Medicine, surveys were the main way ethics consult quality was evaluated. Participants rated how satisfied they were on a 5-point scale with the consult outcome, timeliness of response, professionalism of the consultant, and usefulness of recommendations.

"But this results in 'thin' information that is of limited usefulness," says **Janice Firn**, PhD, MSW, HEC-C, a clinical ethicist at the Center for Bioethics and Social Sciences in Medicine at the University of Michigan.

Just asking if people are satisfied with an ethics consult only raises more questions. A participant might be very satisfied, but only because of a hoped-for outcome — for instance, a specific family member was identified as the appropriate surrogate decision-maker. Conversely, someone might rate satisfaction as very low just because they did not like the case outcome. This misconstrues the purpose of an ethics consult. "The process of a consult creates space for appreciating other people's perspectives. It facilitates dialogue between all the stakeholders," Firn says.

After participating in an ethics consult, clinicians ideally understand why multiple options can be ethically justifiable. Survey data alone do not reveal those nuances. It also is hard to compare results between institutions. "There aren't standardized, validated surveys for ethics," Firn says. "A more robust evaluation of services, through qualitative methods, may provide greater understanding of the value and quality of ethics consultation."

To address this, Firn and colleagues interviewed 14 healthcare professionals who requested ethics consults in 2020.[1] "We wanted to do a more robust exploration of quality, particularly as it related to the intensity of the initial phase of the pandemic," Firn explains.

To encourage busy clinicians to commit, researchers offered flexible interview times in person, by phone, and virtually. The interviews revealed nuanced information on how participants really felt about the ethics consult process. Clinicians, in general, said the ethics consultant was approachable, responsive, and respectful. Participants offered these additional specifics:

• Participants talked about how the clinical ethics service fills a gap that otherwise would not be filled. One noted there are clear clinical guidelines for treatment of conditions, such as atrial fibrillation, but nothing comparable for how to resolve a complex ethical dilemma.

• Participants said involvement in the consult enhanced their own skills in handling difficult conversations.

• A few participants admitted to concerns about stigma associated with consulting ethics. These clinicians observed others on the team might interpret consults as something that are "policed" for bad behavior.

• Clinicians expressed the need for greater visibility of ethics services.

• Participants perceived the value of consults as creating "moral space" for analyzing and reflecting on ethical problems.

This concept has been described in the literature.[2] "But little has been

done to demonstrate it empirically. It was gratifying to see empirical evidence of 'moral space' in our data," Firn shares.

Participants talked about the chance to slow down in a fast-paced care setting to clarify points of medical and ethical uncertainty, and to confirm the right course of action.

Last year, ethicists at UC San Diego Health developed a new system to gather ongoing feedback on consults. "When we complete a consult, we have an automated system that sends the requestor a questionnaire," says **Lynette Cederquist**, MD, director of clinical ethics and chair of the hospital ethics committee.

The survey asks the requestor to rate on a 1 to 5 scale (ranging from "poor" to "excellent") whether the ethicists made the requestor feel at ease, respected the requestor's opinions, gave useful information, explained details well, clarified decisions that had to be made, specified the right person to make decisions, described possible options, resolved disagreements, was easy to contact, and was timely. "In the past year, we have received 31 follow-up survey responses out of 197 consults and advisory calls. It's about a 15% response rate," Cederquist reports.

Most responses rated ethics as "good" or "excellent." Only four out of the 31 responses included some "fair" or "poor" ratings. "We have been mostly reassured by all of the positive feedback," Cederquist says.

One clinician commented: "At times, it would be helpful to have ongoing daily input from ethics, rather than more of a one-shot deal." Another clinician noted that talking through a case and hearing immediate feedback was what was really needed most. "About half of our calls end up being advisory, without proceeding to a formal consult," Cederquist shares.

One respondent indicated a desire for more follow-up on cases after the initial consult. The ethics service deliberated on whether this would be possible. In the end, it was not feasible. "We do try to check in on active cases," Cederquist notes. "But we do not feel we are adequately staffed to provide a lot of ongoing follow-up on a regular basis."

There is much debate over the best way to assess the quality of ethics consultation. "There is a bit more agreement than in the 1980s when clinical ethics really began to get off the ground. But the field of clinical ethics is not unified," says **Stuart G. Finder**, PhD, MA, director of the Center for Healthcare Ethics at Cedars-Sinai in Los Angeles.

This remains the case, despite movement toward certification of ethics consultants. "The field is still quite young, and the internal norms are yet to be finalized," Finder observes. In other healthcare fields, outcomes are more clear-cut. Quality is measured by whether a stroke patient received medication in a specific time frame, or whether a patient was discharged to an appropriate setting.

"In contrast, ethics consultation is concerned with addressing the full range of moral dynamics encountered in taking care of patients. This is not easily reduced to simplistic metrics," Finder laments.

Some ethicists believe numbers are what matters most. They focus on how many consultations are conducted annually. Other ethicists are more concerned with outcomes, satisfaction scores, or the diversity of stakeholders served. "Data can be created about almost anything. It's easy to slip into quantitative thinking, especially when there are real financial matters at stake," Finder offers.

Many clinical ethicists must demonstrate to hospital leadership that their work produces a worthwhile return on investment. "Literally, next year's funding for ethics may depend upon showing data that argue for continued financial support," Finder says.

However, using qualitative methods can reveal how nurses, physicians, social workers, directors, and administrators view the ethics service. For instance, follow-up questionnaires with open-ended

questions can be sent to participants in ethics consults (both clinicians and patients or their families).

"These insights can then help shape practical agendas for education, institutional engagement, and allocation of resources," Finder explains. ■

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Inconsistent Ethics Training in Undergraduate Radiologic Technology Programs

Ethics training in undergraduate radiologic technology programs varies depending on the level of degree offered and on the education of the instructor.[1] "The motivation for the study was to address an alarming and sharp rise in ethical violations among registered radiologic technologists," says **Candace Ayars**, PhD, assistant professor in the College of Graduate Health Studies at A.T. Still University in Kirksville, MO.

In 2020, 1,837 alleged ethics violations were investigated, with 18 cases resulting in revocation of certification.[2] Violations include altering credential identification cards, forged patient records, patient privacy violations, practicing with an expired license, and falsifications of mammography quality control data. "This suggested that ethical training in radiologic technologist programs was not optimal," Ayars says.

It was unknown exactly what ethical content the programs were teaching and how they were assessing student understanding, if at all. To find out more, Ayars and a colleague surveyed 226 faculty members. Most relied on lectures based on the American Registry of Radiologic Technologists Standards of Ethics and used tests to assess student understanding. "Standardizing ethics curricula within undergraduate radiologic technology programs is an important step in decreasing the number of ethical violations being committed," says **Janyce Prier**, DHEd, MSRS, RT(R)(CT)(ARRT), adjunct instructor of radiologic sciences at ECPI University in Virginia Beach.

Few programs used case-based studies and group discussions. "Programs are not using currently established best practices," Ayars says.

Incorporating case-based instruction gives students the opportunity to recognize, analyze, and understand ethical dilemmas. This would allow educators to evaluate how students apply their learning in the professional setting. "A case-based curriculum moves away from traditional lecture-based instruction and test-taking evaluation by putting students in scenarios they are likely to encounter in the workplace," Prier says. ■

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Many Nurses Hesitate to Ask for Ethics Consult

Some nurses mistakenly believe only the attending physician can request ethics consults. Others do not even know their institution offers an active ethics consultation service. Still others worry about retaliation.

Nurses usually give one of these three reasons when asked why they never request ethics consults, according to **Claudia R. Sotomayor**, MD, DBe, chief of the clinical ethics consultation service at Georgetown University's Pellegrino Center for Clinical Bioethics. Ethicists have made a concerted effort to encourage nurses to be comfortable with requesting consults. "When rounding, we talk to the charge nurse directly to make sure they know how to contact us if needed," Sotomayor says.

Ethicists remind nurses anyone involved in the case can request an ethics consult. "When someone has retaliation concerns, we take the

consult on an anonymous basis," Sotomayor adds.

These approaches have produced results. In 2020, nurses requested 41% of ethics consults. Only 26% came from physicians. At MedStar Georgetown University Hospital, most consults nurses requested involved uncertainties about the plan of care for a patient. "Typically, these are the cases of patients at the end of life where the goals of care are not well-defined. These uncertainties trigger moral distress as well," Sotomayor says.

Other nurse-requested consults were related to advance directives. Sometimes, there was confusion about the appropriate surrogate decision-maker. In 2021, so far, equal numbers of nurses and physicians have requested consults.

It makes sense nurses would be the ones requesting ethics consults as the provider who spends the most time at the bedside. However, nurses requested an ethics consult less frequently than other providers.[1] Researchers surveyed 150 physicians, 35 advanced practice providers, and 109 nurses. Thirty-five percent of these nurses had ever requested an ethics consult vs. 51% of physicians and 63% of advanced practice providers.

"Many have questioned why the statistics on referrals to ethics has been traditionally lower with nurses," says **Blair Henry**, D. Bioethics, a former senior ethicist at Toronto's Health Ethics Alliance. Targeted education to nursing units on how to make an ethics consult request is helpful. "However, there may be a more complicated dynamic at play, which acts as a gatekeeper to getting ethics involved," Henry says.

Ethicists should offer debriefing sessions on difficult cases as a teachable moment to show nurses how ethicists can help with future cases. Assign unit-based nursing ethics champions and document ethics involvement in the medical record so nurses can review what was covered. "Shift work means a constant rotation of care providers. The notes are a great way to reach all staff," Henry offers.

Marcia Bosek, DNSc, RN, says nurses often ask questions on end-of-life decision-making and the doctrine of double effect (actions that cause harm as a result of promoting something beneficial, such as relieving pain and at the same time hastening the person's death).[2] Bosek says the best approach is to "become known by nurses and establish professional relationships with nurses."

As a clinical ethicist, Bosek participated on morning rounds on the ICU and transplant units. It was a chance to engage in real-time ethical problem-solving conversations. "Nurses should request ethics consultation when faced with ethical questions regarding nursing care," according to Bosek, an associate professor at the University of Vermont department of nursing.

Nurses question how to respond when a patient consistently refuses bathing, turning, and incontinence care, or when a patient demands no nursing personnel enter the room. "In addition, the nurse should seek out ethics consultation when experiencing moral distress," Bosek says.

The ethics committee at UConn School of Medicine in Farmington provides many education sessions. "The ones that have produced the most bang for our buck have been sessions during National Nurses' Week," says **Zita Lazzarini**, JD, MPH, director of the division of public health law and bioethics.

Recently, nurses attended a session about the work of ethics committees. "Nurses are a very important constituency that didn't necessarily realize that they had the option to reach out to ethics. Nor did they feel comfortable talking about ethics," Lazzarini says.

Nurses also acted as an ethics committee, with a case presented and discussed. "That was really well-received," Lazzarini reports. "After that, we got more requests for consults from nurses." ■

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For Most Patients on Dialysis, Religious/Spiritual Beliefs Are Important

Most patients receiving dialysis said their religious or spiritual beliefs were important to them, which affected their care preferences.[1]

Researchers surveyed 937 patients receiving dialysis at 31 facilities in Nashville and Seattle from 2015 to 2018. Those for whom religious or spiritual beliefs were more important were more likely to favor a shared decision-making role, more likely to favor resuscitation and mechanical

ventilation, and less likely to have considered stopping dialysis.

"We chose to look at this question because we often see how spirituality influences a patient's approach to serious illness and their end-of-life care preferences," says **Jennifer S. Scherer**, MD, the study's lead author and assistant professor in the divisions of palliative care and nephrology at NYU Grossman School of Medicine.

Despite the importance of spirituality to so many, there is not much research that included dialysis patients. A lot of healthcare providers feel uncomfortable discussing spiritual beliefs.

"This may be a missed opportunity to understand our patients better and to help them make important decisions about their care," Scherer offers.

Scherer and colleagues were surprised that patients who found spirituality important were no less likely than those who did not to have unmet palliative care needs, and were more likely to report needs related to peer support, pain management, finding hope, and learning about treatment options for the future. They also were no less likely to have engaged in advance care planning. This could mean patients who find spirituality important need assistance in important domains of their care and coping with serious illness. "It suggests that incorporating their spiritual beliefs into our approach to their care may help us, as providers, better meet the needs of our patients," Scherer says. ■

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Medical Organizations' Ethics Statements Are Inconsistent

A Texas-based radiologist noticed strong disagreements among well-meaning physicians on many ethical issues. These included physician-assisted suicide, abortion, contraceptives, and cosmetic surgery.

"I hypothesized that if medicine lacked a unified mission, then that may be the cause of our internal disagreement," says **Christopher Lisanti**, MD.

Lisanti and a colleague found the ethics statements of various U.S. medical organizations are inconsistent regarding the direct goals of medicine.[1] They analyzed the ethics statements of 22 organizations and characterized each as traditional (18%), relational (9%), or social constructionist (73%).

Overall, there was significant inconsistency and lack of clarity on the direct goals of medicine. The study showed 33% to 53% of direct statements regarding the goals of medicine contained a fundamental philosophical disagreement.

"This leads to sometimes-conflicting concepts of physicians' duties, the goals of medicine, and the patient/physician relationship," Lisanti says.

Concurrently, many physicians are struggling with a changing physician-patient relationship. "More and more, physicians feel that they are no longer trusted health consultants, but merely drug or medical procedure vending machines for patients," Lisanti argues, adding bioethicists "will likely face physicians and patients increasingly at odds with each other, since they do not agree on the purpose or goals of medicine."

Ethicists can guide physicians to verbalize the philosophical assumptions driving opposing, sometimes heated, viewpoints.

"This will promote mutual understanding," Lisanti offers. "Hopefully, it will promote unity in an agreed-upon course of action for our patients." ■

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Nurses Appreciate Training on End-of-Life Care

Few nurses receive formal training on end-of-life care, and many would like more expertise in this area. "Within our practice, and within our years of teaching undergraduate students, we continually noted knowledge deficits of individuals caring for patients with poor prognosis and/or actively dying," says **Shelly Orr**, PhD, RN, CNE, research operations program director for Virginia Commonwealth University

(VCU) Health System. Orr and colleagues studied the benefits of targeted education on principles of end-of-life care, with two workshops provided to 19 nursing students and 24 practicing nurses.[1]

Using the End-of-Life Nursing Education Consortium (ELNEC) Knowledge Assessment Test, Orr and colleagues found the initiative was beneficial and feasible.

"The goal of ELNEC is to get training on end-of-life care principles, and then teach the principles to others to spread the knowledge," Orr explains.

Two workshops were provided. The first was in person, but because of COVID-19 restrictions, the group was forced to offer the second workshop remotely.

"We were surprised to find there were not differences in learning between the face-to-face and virtual learners," Orr reports.

Communication with patients and their families tends to be the No. 1 issue for which nurses indicate they are unprepared. Most undergraduate nursing programs provide little to no formal training regarding palliative care principles, including communication.

"Mostly, nurses feel unprepared when put in a situation that warrants a difficult conversation with patients and/or their family about a patient's declining status," Orr laments.

It is difficult for nurses to remain hopeful and honest when caring for someone at the end of life.

"Caring for the family of a dying patient can be just as important, yet demanding, as caring for the dying patient," Orr notes.

Families need physical, psychological, and spiritual care, too, that nurses must be adept in providing. "Formal training and experiential learning are needed," Orr stresses. Nursing education programs need to value end-of-life and palliative care as a part of their formal curriculum, according to Orr. "Everyone dies," she says. "Shouldn't all nurses be prepared to deliver the best end-of-life care based on sound evidence-based principles?" ■

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CME/CE INSTRUCTIONS

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CME/CE QUESTIONS

1. **Which did a committee find regarding ethics of emerging brain research?**

   a. Consent is not legally or ethically required for previously collected biological materials, even if not de-identified.
   b. It is established that neural organoids could possess consciousness and/or experience pain.
   c. Diverse views on moral, ethical, and religious concerns regarding mixing of humans and other animals must be respected.
   d. Overengagement of the public to identify concerns and influence science policy is a central ethical concern.

2. **Which is true regarding recruitment of adolescents on social media?**

   a. Participants sharing misleading statements on a recruitment post is outside the scope of an IRB review.
   b. Principal investigators are not obligated to address false claims of efficacy made by trial participants.
   c. IRBs expect investigators to use a process to monitor comments regularly.
   d. Generally, IRBs waive parental permission for online studies because it is overly burdensome.

3. **Which is true regarding palliative care training received by residents at medical schools at a historically Black college and a historically Black university?**

   a. Residents received more training on palliative care than sepsis management.
   b. Most residents believed the quality of their palliative care education was not as good as

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training they received in other areas of medicine.
c. Residents reported receiving a plethora of positive messages about palliative care from faculty.
d. Palliative care electives are more prevalent at schools with higher percentages of minority students.

4. **Which factors did researchers learn are linked to lengthy delays in the IRB review process?**

a. Researcher conflict of interest
b. Overly simplistic descriptions used in consent forms
c. Too-stringent requirements for data security
d. Unrealistically short study durations

5. **Which did a study reveal on healthcare ethics programs?**

a. Virtually all programs included ethics representatives on hospital committees.
b. Ethics staff are involved in the development of new policies far more commonly than reviewing existing policies.
c. The largest institutions faced resource shortages of time, money, staff, and training.
d. Overuse of ethics services was the biggest challenge reported by the smallest institutions.

6. **Which did a qualitative study on requestors of ethics consults reveal?**

a. Participants rated satisfaction as very low because they did not like the case outcome.
b. Participants disagreed with the concept of multiple options as ethically justifiable.
c. Involvement in the ethics consult enhanced participants' own skills in handling difficult conversations.
d. There was a consensus that the ethics service was setting up unrealistic expectations.

7. **Which is true regarding ethics education in radiologic technology programs?**

a. Training did not affect the frequency of ethics violations.
b. Most programs based lectures on the American Registry of Radiologic Technologists Standard of Ethics.
c. Programs used strictly case-based learning.
d. Training programs attempted to cover ethical content that was too broad in scope to be of real-life use to students.

CME/CE OBJECTIVES

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

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