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INSIDE

AHC Media

'Betraying Trust' of Subjects is Ethical Concern of Unpublished Clinical Trial Data

"Clearly an ethical obligation" for researchers

About a third of all clinical trials conducted in the United States go unpublished, a recent study reported.[1] This is a serious ethical issue, according to **Joseph Solomon Ross**, MD, MHS, one of the study's authors. Ross is associate professor of medicine at Yale School of Medicine's Institute for Social and Policy Studies in New Haven, CT.

One problem is that participants exposed themselves to potential risks, at least in part, so everyone might benefit in the future. "The researchers are betraying the trust of the individuals who volunteered to participate in the trials," Ross says.

Researchers analyzed 4,347 trials at 51 major research centers, which were completed in 2007 to 2010. Just 29% had been published two years after completion, and only 13% of the results had been submitted to ClinicalTrials.gov. As of July 2014, only 66.5% had either been published or reported on ClinicalTrials.gov.

EXECUTIVE SUMMARY

A growing body of research demonstrates that many completed clinical trials are not published. Ethicists call for research funders to require publication of all completed trials, or to make study data publicly available to other investigators. Ethical concerns include the following:

- Study participants are needlessly exposed to potential harm.
- The resulting knowledge can't benefit future patients.
- Trials with favorable results are more likely to be published.

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Previous research uncovered similar poor dissemination rates. Less than half (46%) of 635 National Institutes of Health (NIH)-funded trials were published in a peer-reviewed biomedical journal within 30 months of completion, found one study.[2] Another study found no results published in journals for 29% of nearly 600 trials registered on ClinicalTrials.gov.[3] The study looked at only very large clinical trials. "This shows that the problem of non-publication is not just limited to small pilot studies, but affects even large-scale, resource-intensive trials," says lead author **Christopher Jones**, MD. Jones, head of the division of clinical research in the department of emergency medicine at Cooper University Hospital in Camden, NJ, argues, "There is clearly an ethical obligation to make clinical trial results publicly available."

Another recent study looked at publication rates of studies which enrolled children. The findings were in line with the previous research on adult trials.[4] "This may speak to how commonplace discontinuation and non-publication are in medical research in general," says co-author **Natalie Pica**, MD, PhD, a resident at Boston Children's Hospital.

Researchers found that 19% of trials started in 2008 to 2010 that recruited children were not completed. Often, this was because researchers weren't able to recruit enough volunteers. Of the 455 trials that were completed, 19% were discontinued early. About one-third (30%) remained unpublished in the medical literature several years later. "We believe that researchers have an ethical obligation to publish the findings of completed trials, regardless of the study findings," says Pica.

Overall, more than 8,000 children were enrolled in trials that were never completed. Over 69,000 children were enrolled in completed trials that were never published.

Senior investigator **Florence Bourgeois**, MD, MPH, an assistant professor of pediatrics and emergency medicine at Boston Children's, says, "We need to make sure that when children participate in clinical trials, their efforts are contributing to broader scientific knowledge."

The following are ethical concerns of completed trials going unpublished:

• Part of the reason patients choose to participate in clinical research is because they hope it will improve care for future patients.

This expectation is often explicitly included during the informed consent process. "When trial results are not publicly disseminated, this knowledge cannot be used by clinicians and researchers to help improve the care of other patients," says Jones.

• Study participants can be subjected to potential risks, inconveniences, costs, and occasional true harms.

"When investigators fail to make trial results publicly available, these consequences are not balanced by the opportunity to help improve the care of future patients," says Jones.

• Trials which reflect positively on a particular intervention are more likely to be published than trials which are not favorable.

"This publication bias can lead patients and clinicians to make medical decisions which result in wasted time and money, as well as poor health outcomes," says Jones.

Ideally, treatment recommendations are based on a comprehensive understanding of the existing medical research.

"When trial results are not publicly disseminated, this becomes impossible," says Jones.

• Future progress in medical research depends on the reliability of previous studies.

"When researchers do not have access to all of this foundational work, substantial time and money can be wasted pursuing research which is based on flawed assumptions," says Jones.

Future Developments

The growing body of research on unpublished clinical trials is raising awareness of the importance of disseminating research findings, Ross says. "The question is no longer whether it's okay for researchers not to disseminate their results, but what should be done about it," he says. The following are some recent developments in the area and possible solutions:

• Many major pharmaceutical companies have enacted policies promoting the publication of all clinical research they fund.

"I think the next step is for other large funders to follow suit, and establish requirements that researchers publish findings from all completed clinical trials," says Ross. This includes the NIH, CDC, and the U.S. Department of Veterans Affairs, he says.

• ClinicalTrials.gov enabled the medical community to detect and quantify the problem of non-publication.

"Unfortunately, the problem still persists," says Jones.

• A number of regulatory agencies and funding organizations have policies on using trial registries to ensure that results are consistently publicly disseminated.

"Enforcement of these policies has been inconsistent," notes Jones.

• The International Committee of Medical Journal Editors and the NIH continue to push for improved ways of disseminating research results.[5,6]

• The World Health Organization's recent position statement calls for prompt reporting and public disclosure of interventional clinical trial results.[7]

"Continued progress will likely depend on more consistent enforcement of existing policies," Jones says.

• The Restoring Invisible and Abandoned Trials (RIAT) initiative invites researchers with unpublished trials to either commit to publish within a year, or provide public access to their data.

This allows independent investigators to step in and become "restorative authors." Pica acknowledges that it's hard to reanalyze others' data, "but this may be a useful mechanism to make sure that findings from completed trials are disseminated in the medical literature."

• Groups such as AllTrials have called the public's attention to the issue.

"As this awareness continues to grow, investigators and study sponsors will face increasing pressure to consistently release trial results," says Jones. ■

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Is Hospital Keeping Spiritual Care Promises In Mission Statement?

Ethicists and chaplains 'occupy a strategic position'

Most health systems' mission statements promise to care for patients' spiritual health, to respect their values, or address the needs of the "whole person."

"However, many fall short of meeting this obligation," says **J. Vincent Guss, Jr.**, DMin, BCC, a clinical ethicist and bioethics professor at Georgetown University School of Medicine in Washington, DC. In Guss' view, this is because there is no one specifically charged with seeing to it.

"Ethicists and chaplains occupy a strategic position in helping to assure that clinicians, administrators, and allied health professionals maintain faithfulness to these values," says Guss. He recommends the following approaches:

- remind hospital staff that spiritual health affects the physical and emotional aspects of healing,
- meet with senior administrative staff on a regular basis to monitor the attention given to the spirituality of both patients and staff, and
- ask clinically trained, board-certified chaplains to help develop mission statements. "They are sensitive to the values that different groups of people have, depending upon their religious, ethnic, and philosophical backgrounds," explains Guss.

Vance Goodman, a chaplain in the cardiac ICU at Children's Health-Children's Medical Center in Dallas, says, "If a health system's mission and values include 'the total well-being' of patients, then spiritual health cannot be overlooked." Chaplains can communicate the religious and cultural needs of patients and their families to the clinical team.

"Chaplains can be advocates and champions for a person's religious traditions, spiritual beliefs, and cultural customs," says Goodman. "We help to integrate those things into a treatment plan or daily routine."

The Joint Commission requires all healthcare organizations to provide adequate care for patients' spiritual, religious, and cultural needs in conjunction with the medical care they receive. These expectations can be found in the "Ethics, Rights and Responsibilities" section of the standards.

"Beyond that provision, the standards are relatively vague when looking at the 'Elements of Performance' to measure or prove that needs are being met," says Guss.

Regarding metrics for evaluating whether the care is being offered, it is stated that the healthcare organization simply has to set forth its own measurements on how the care is being provided. The Joint Commission doesn't specify credentials or training that are required. "Nor does it make any statement regarding the kind of support healthcare organizations need to give pastoral care and ethics departments to assure effectiveness," says Guss.

Clinically trained chaplains and professional ethicists often attempt to fill this role. "But they are often hampered by the place to which they are often relegated in the administrative charts," says Guss.

Many chaplains who had been department directors have been made managers or coordinators, or staff chaplains, notes Guss. "This reduces or eliminates departmental status," he says. This leaves many professional chaplains without a significant place at the table when decisions are being made.

Regarding The Joint Commission's requirements to meet spiritual health needs, Guss urges ethicists to "remind people that lack of [meeting spiritual needs] could result in a citation jeopardizing the organization's certification."

Guss says compliance means more than just giving patients ready access

EXECUTIVE SUMMARY

Ethicists and chaplains can hold health systems accountable for mission statements referencing "whole person" care and spiritual health. Some approaches to that include the following:

- Hospitals can ask clinically trained, board-certified chaplains to help develop mission statements.
- Ethicists can meet with senior administrative staff to monitor the attention given to spirituality.
- Chaplains can communicate patients' spiritual needs to clinicians.

to pastors, priests, rabbis, and imams. "A board-certified, clinically trained chaplain is equipped to identify the spiritual needs of patients that untrained clergy or other healthcare practitioners may miss," he explains.

F. Keith Stirewalt, PA, MBA, MDiv, chaplain for clinical engagement at Wake Forest Baptist Medical Center in Winston-Salem, NC, cautions against having a "checkbox mentality" when considering The Joint Commission spiritual health requirements. "Healthcare systems should place this expectation set into context for every major decision and critical process review," he says.

At many smaller hospitals, ethics issues are addressed by multidisciplinary or community committees. Many members have not received any formal— or even informal — training or mentoring.

"This situation exists because of the constant financial pressures on healthcare organizations," says Guss. "Pastoral care departments and ethics services are seen as non-revenue-producing costs centers." This makes them easy targets for budget cuts.

Guss argues that it's counterproductive to cut disciplines charged primarily with promoting cultural and spiritual sensitivity. "Research demonstrates that adequate, competent, professional, and consistent attention to the values and spiritual dynamics of patients improves patient care," he says.

Stirewalt says that rapidly shifting reimbursement policies put healthcare systems on "a never-ending journey of trying to assist margins through expense reduction. Sadly, professional chaplains and reimbursed ethicist positions are attractive targets for expense reductions," he says.

"While neither discipline directly generates revenue, their worth to the health of patients, families, staff, and the overall institution is significant," says Stirewalt.

Rev. **Barbara Patten**, MDiv, BCC, a staff chaplain at Memorial Hospital of Carbondale (IL), says the discipline of chaplaincy's code of ethics empowers the board-certified chaplain to become "a voice at the ethics table."

This is only possible if the chaplain's professional skill set is recognized and valued by the health system, however. "Basic professional trust and respect among the disciplines determines how ethical policies and practices are shaped," says Patten.

Patten says chaplains have something unique to contribute: They can see the "whole scenario." This comes into play if staff experience moral distress due to disagreement on the plan of care.

"Another discipline might choose to dismiss the moral distress, focus on the rights of the durable power of attorney, and interpret that an ethics consult is not necessary," says Patten.

A chaplain could invite staff to discuss their feelings of moral distress. "This becomes a learning moment for all disciplines involved — to return to the health systems' mission and values statement as the foundation of the ethical process," says Patten.

While frequently involving prayer, Stirewalt notes that healthcare chaplaincy focuses on healing. This is done through conversation, presence, and exploring values.

"Some healthcare institutions ... see chaplains as theological cuckoo clocks, coming out to pray when the time calls," says Stirewalt. He sees the chaplain's role as assisting the health system in respecting patients' spiritual needs.

"Chaplains and bioethicists have a duty to maintain an ethical voice in the institution, if for no other reason than to remind our institutions of why we do what we do," says Stirewalt. He recommends the following to bioethicists and chaplains:

- participate in many hospital committees, especially ones involving patient rights, safety, or the development of new service lines,
- reinforce holistic, culturally sensitive treatment of individual patients,
- use their observations and experiences to keep the healthcare institution focused on spiritual health, and
- "maintain a vigilant lens" on groups who might be marginalized.

"If hospital chaplains are not involved in anything other than occasionally praying for patients, you're not asking them to do enough — or you have the wrong chaplains," says Stirewalt. ■

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Getting Buy-in For Including Cost in Decision-making is Uphill Battle

Public remains wary of 'rationing' of care

Any talk of considering costs in treatment decisions usually triggers an immediate outcry against "rationing" of care, experts say.

"It will always be challenging to obtain public buy-in for making cost of care a factor in medical decision-making," says **Nancy S. Jecker**, PhD, a professor in the Department of Bioethics and Humanities at Seattle-based University of Washington. She offers the following approaches to make cost considerations more "palatable to the public":

• Separate medical and societal decision-making.

This takes physicians out of the role of rationing healthcare, she says. "Physicians are obligated to distribute limited treatments on the basis of potential medical benefits, without regard to nonmedical factors," explains Jecker. This means not taking the patient's social worth, ability to pay, or lifestyle choices into consideration.

"By contrast, society is responsible for establishing policies that allocate scarce healthcare resources based on both medical and nonmedical factors," says Jecker.

Faced with limited resources, society may choose to invest more on lower-cost preventive care that benefits a large number of people, for instance, and less on high-cost care that benefits a relatively small number of individuals.

• Make cost-effective analyses transparent and publicly accountable.

A life-year gained by a healthcare intervention might be assigned a value of $50,000. "This benchmark is then used to make comparative assessments of what represents a reasonable healthcare investment," says Jecker.

This is one example of a transparent and systematic way of setting healthcare priorities. "It benefits everyone when there are fair and explicit procedures for allocating healthcare that are consistently applied and publicly accountable," says Jecker.

Is it Reasonable?

"Rationing" of healthcare, referring to the denial of beneficial treatments under conditions of fiscal scarcity, raises justice considerations. The ethical issue is what constitutes a fair share of healthcare services when there is not enough to provide services to everyone who stands to benefit, she says.

"Even when interventions offer a reasonable likelihood and quality of benefit to the patient, patients may be denied treatment in order to ensure a just distribution of scarce healthcare resources for all," says Jecker.

In Jecker's view, the probability of medical success is a major factor that should be taken into account in patient care. She says that if care is of little value and there is not a reasonable prospect of benefitting the patient, interventions should not be used — even if they are inexpensive and readily available.

"What constitutes a 'reasonable' prospect of benefit can be determined by appealing to the idea of the 'quantitative futility,'" says Jecker. This is the same threshold that is already used in the statistical evaluation of clinical trials. If an intervention produces its desired effect in only 1 in 100 cases, this is not considered significant, because it occurs so infrequently that it may be due to chance. "Likewise, if the likelihood of medical benefit from a particular intervention is just 1 in 100, that is not considered significant and qualifies as quantitatively futile," says Jecker.

Aging Populations

One increasingly important trend is the aging of populations around the globe. "This will raise new questions about the fair allocation of healthcare, and what constitutes a just allocation of healthcare between young and old," says Jecker.

People 65 and older are among the heaviest users of healthcare services. Also, diseases affecting older people tend to be chronic, progressive, and disabling. Thus, healthcare systems will need to place greater emphasis on out-of-hospital caregiving services. "This is necessary to ensure that people suffering from chronic progressive disease have the capability to perform basic activities of daily living," says Jecker. ■

SOURCE

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Data On 2,000 Patients Gives Visual of Final Year of Life

Nick Stepro, senior director of product management at Burlington, MA-based Arcadia Healthcare Solutions, used data on 2,398 patients from EHRs and insurance claims to create a visual graphic of the last year of life.

The graphic shows that most patients died either at home or at the hospital. "We are often over-treated in a sterile hospital environment, when we could spend our last days more peacefully with the right care in a different setting," says Stepro.

While not the primary goal of the analysis, the graphic revealed massive cost differences when patients died in hospitals as opposed to home. These costs are not necessarily tied to a better quality of life in one's final days.

"This graphic does not tell a new story to the thousands of nurses and physicians that deal with this on a daily basis. It confirms what they know," says Stepro — namely, that there can be huge differences in cost and quality of life depending on decisions made by the patient.

Stepro says he's continually surprised at how difficult it is to know when, where, and how individuals die. "The documentation is simply not there in any standardized, reliable way," he says. "This limits our ability to analyze death and provide guidance."

Given the complex nature of healthcare data, differentiating between home deaths, hospital deaths, and hospice deaths can be difficult.

"We know, for example, that many more people die in hospice than is represented in this graph," says Stepro. "But given the data provided, it is difficult to separate out those individuals from those that died at home." *(The graphic can be viewed at: http://bit.ly/2aMMJEE.)*

'Eleventh Hour' Discussions

Daniel B. Hinshaw, MD, FACS, director of the palliative care program at VA Ann Arbor (MI) Health Care System, says it's still unusual to introduce advance care planning discussions at the time of diagnosis of a life-threatening illness.

"Most physicians think of such discussions as primarily addressing specific interventions at the actual end of life," he explains. Physicians don't always take the opportunity to start a dialogue about the treatment plan for the life-threatening illness. "This takes into consideration the patient's goals of care and values from the very beginning," says Hinshaw.

Clinicians usually assume that patients will want "everything" done in terms of aggressive disease-modifying treatment, he says. "This assumption leads down a path that becomes increasingly difficult to reverse or modify as the disease progresses," warns Hinshaw.

Thus, patients with serious life-threatening illnesses often have an ICU admission prior to death — even if the patient later dies at home. "Discussions about hospice-type care typically occur at the eleventh hour," says Hinshaw.

Even if the patient chooses hospice, the length of service is often of very short duration. "With the increased use of hospice home care, there has not been the corresponding decrease in hospital — including ICU — care in the last weeks and months of life that was expected," says Hinshaw.

Hinshaw urges bioethicists to advocate for a broader definition of advance care planning. This includes in-depth goals of care discussions between patients and their healthcare providers at the time of diagnosis of a serious life-threatening illness.

"This initial discussion should also represent the beginning of a conversation that is revisited frequently during the course of treatment," adds Hinshaw. ■

SOURCE

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EXECUTIVE SUMMARY

Advance planning discussions rarely occur at the time of a life-threatening diagnosis. This, in part, is responsible for the large number of in-hospital deaths depicted by a new visual graphic on the last year of life.

- Most patients died either at home or at the hospital.
- Increased costs don't always indicate a better quality of life in one's final days.
- Bioethicists can advocate for a broader definition of advance care planning to include in-depth goals of care discussions.

Report: Proposed Common Rule Revisions Should be Withdrawn

Existing framework more than 40 years old

The Notice of Proposed Rulemaking (NPRM) to Revise the "Common Rule," (formally known as the Federal Policy for Protection of Human Subjects), should be withdrawn, according to a new report from the National Academies of Science, Engineering, and Medicine.[1]

"One of the important areas of government regulation is of human subjects research and human subjects protections," says **Steven Joffe**, MD, MPH, a member of the committee that developed the report. Joffe is vice-chair of the Department of Medical Ethics and Health Policy at University of Pennsylvania's Perelman School of Medicine.

The report says an independent national commission is needed to make recommendations on how the ethical principles governing human subjects research should be applied to unresolved questions and new research contexts. Examples include the following:

- research involving genomic datasets,
- research within learning healthcare systems,
- research using "big data" from electronic health records, administrative data from health systems and other settings, sensors, and wearables,
- emergency research with no possibility of consent,
- research involving biospecimens, and
- research involving adults with reduced decision-making capacity.

The report covers a wide range of issues affecting the partnership between the federal government and the academic research community.

"Its basic conclusions are that the increasing profusion of regulations, and the duplications and lack of harmonization among them, are compromising the ability of academic research to fulfill its mission," says Joffe. This mission is to produce science and scholarship that benefits the nation. To do this effectively, he says, the regulation and oversight of human subjects research needs updating.

"We recognized that the basic framework that underlies our regulations is almost 40 years old," says Joffe.

There are numerous unresolved questions that could not have been anticipated in the 1970s, given enormous growth in technologies and capabilities.

"We judged it was time to take a systematic, multi-stakeholder, independent look at the numerous questions that confront the enterprise, as well as the basic structures for research oversight, to bring them into the 21st century," says Joffe.

Many important questions go unaddressed in the NPRM, he says. "Recognizing the controversy that surrounds it, we recommended that it be withdrawn so the commission can do its work with an open field," says Joffe.

Ruth Macklin, PhD, distinguished university professor emerita in the Department of Epidemiology and Population Health at Albert Einstein College of Medicine in Bronx, NY, sees de-identified human specimens as one of the central ethical concerns.

According to the current regulations, researchers may use human biological materials from which personal identifiers have been removed without obtaining consent from the individuals from whom the specimens were taken.

"The current regulations do not consider this as 'human subjects research,'" says Macklin. The proposed change would require that individuals provide "broad" consent for any future use of de-identified specimens.

"This would not only be burdensome on researchers — it

EXECUTIVE SUMMARY

The Notice of Proposed Rulemaking to Revise the Common Rule should be withdrawn, according to a report from the National Academies of Science, Engineering and Medicine. Some recommendations include the following:

- an independent national commission is needed,
- guidance is needed on how to apply ethical principles to "big data" and genomics, and
- unresolved questions involving new technologies need to be addressed.

could also thwart progress in important research ongoing today," Macklin adds.

Research involving human specimens and other novel techniques is beyond the scope of the current regulations. "An independent, multidisciplinary, high-level national commission is the most appropriate way to ensure that scientific progress continues, while at the same time protecting the rights and welfare of human participants," says Macklin. ■

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When Should a Threatening Patient be Reported?

Recent amendments to HIPAA give new allowance for clinicians to report patients with mental health issues to the National Instant Criminal Background Check System. However, these shouldn't be misinterpreted.

"The amendments to the HIPAA rules do not create a duty to report — they only give permission to report," says **Thaddeus Mason Pope**, JD, PhD, director of the Health Law Institute and professor of law at Mitchell Hamline School of Law in Saint Paul, MN.

Clinicians must still comply with state law, which may not permit such reporting. "Therefore, clinicians should consult with their legal counsel before making reports," says Pope.

Does a clinician know of a patient who poses an imminent and serious risk to an innocent third party and fail to report it? In this scenario, Pope says the main ethical risk is that serious and probable harm is not avoided or mitigated. "Reporting might permit implementation of risk avoidance or protective measures," he explains.

Pope sees two main ethical risks involving over-reporting. "First, patient confidentiality is breached without sufficient justification. Second, the patient's liberty may be limited without sufficient warrant," he says.

Pope says that the clinician's legal duties are strongly weighted in favor of reporting. "There is normally little risk from over-reporting, but there is risk from under-reporting," he explains. "Ethics consultants and ethics committees can help clinicians assess whether a particular case may be or must be reported."

Unlike other mandatory reporting duties, such as with child abuse or elder abuse, the trigger for breaching confidentiality and reporting mental health threats is usually higher than "mere suspicion." "Consequently, the risk of unnecessarily disrupting a patient's liberty and privacy is lower," says Pope.

The obligation to report is often known as "Tarasoff" duties, referring to the California case that originally articulated the duty to report.

"Other states have articulated the duty in different ways and through different cases and statutes," says Pope. "Bioethicists should be sure to know the rule in their own state."

EXECUTIVE SUMMARY

Recent amendments to federal patient privacy regulations give clinicians new allowance to report patients with mental health issues, but state laws may differ. Ethicists can do the following:

- help clinicians assess if a particular case may be, or must be, reported,
- refer clinicians to the appropriate resource, such as security, and
- de-escalate conflicts between a patient's family and the clinical team.

Not Domain Of Ethics

Mathew David Pauley, JD, MA, MDR, regional ethicist at Kaiser Permanente Northern California in Oakland, has seen ethics consults called because clinicians were alarmed at a patient's documented history of violence. Other times, ethicists were called when a patient

or family member became violent in the hospital setting. "There is a loss of control when someone you love is sick or injured," says Pauley. "Sometimes, people respond aggressively."

In Pauley's experience, ethicists have gotten involved with incidents involving violent or threatening family members more often than for out-of-control patients. Sometimes, the decision-maker is making a decision that another family member finds alarming.

"A lot of people have very poor coping mechanisms, especially when they're experiencing life-changing events like the loss of a loved one," Pauley says.

Ethicists are often called because of an escalating conflict between family and clinicians. For instance, a family member may reject the physician's assertion that their loved one is brain-dead.

"Often, when there is threatening behavior, we bring somebody in to say, 'We can't tolerate this behavior,'" says Pauley.

Meeting with the ethicist one-on-one allows that person to be heard. "By diminishing their frustrations, with concerns put on the table, that hopefully will de-escalate the conflict," Pauley says.

Ethicists set ground rules before any sort of conversation occurs. "That sets the tone for the entire conversation," says Pauley. For instance, people agree not to raise their voices or interrupt others.

"If things are getting loud, we can stop the conversation and say, 'You agreed to not raise your voice.' When you put the limits on beforehand, it can sometimes prevent abuses," says Pauley.

At times, ethicists are called for issues that aren't under the purview of ethics. "We tend to get calls for everything. We've gotten numerous consults for sexual harassment, which is not clinical ethics," says Pauley.

Neither is a violent patient or family member. "What we struggle with is that everything can be framed as an ethics issue," Pauley says. "If a family member is threatening someone, is it bioethics? No, it's a security issue."

When clinicians see a conflict, their first reaction is call a person that they know addresses conflict in their everyday duties — an ethicist. "This raises the issue that the ethicist needs to know when to delegate something, or defer someone to the appropriate resource," says Pauley. This might be security, the manager of the unit, or the on-call administrator.

"The role for the ethicist would be more at the 10,000-foot level — that is, how do we as an institution work with people who are historically and repetitively violent?" says Pauley. The following are some ethical concerns:

- avoiding stigmatizing individuals with a history of violence,
- ensuring that patients' individual rights are maintained, and
- asking the question, 'Why is this person being violent?'" It could be that patients or family are left feeling unheard and powerless.

"It could be that the healthcare system is driving them crazy," says Pauley. "If we are somewhat complicit in it, we should recognize that." ■

SOURCES

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Undergrads See Real-Life Ethics by Shadowing Clinicians

If asked to name the main target audience for bioethics education, you'd probably think of either practicing clinicians, or medical and nursing students.

"There is little emphasis on deep medical ethics education for undergraduates," says **Margaret R. McLean**, PhD, associate director of the Markkula Center for Applied Ethics at Santa Clara (CA) University.

Research suggests, however, that medical schools can neither improve ethical inclinations, nor guarantee progress in moral reasoning for students who lack well-developed moral motivation and moral sensitivity when starting such training.[1]

McLean sees undergraduate students as more open to ethics education than clinicians. "The packed curriculum in professional schools often does not allow students to reflect on many important ethical issues they will face in practice," she

adds.

The Markkula Center for Applied Ethics developed a program in ethics education for undergraduates. Participants spend the academic year shadowing health professionals at local hospitals and clinics. "Students observe clinicians' everyday work," says McLean. "They are directly exposed to ethical issues arising in the healthcare setting."

The Health Care Ethics Internship consists of clinical rotations, reflection sessions, and ethics lectures. With more than 190 alumni since the program began in 2001, the current class is composed of 16 junior and senior undergraduates.

"Students develop a deep understanding of current ethical issues in healthcare, strong critical thinking skills, and compassion," says McLean.

Santa Clara University does not have a medical or nursing school, or any programs in the health professions. Thus, great effort is put into building relationships with the local hospitals and clinics that host and mentor students.

"We work one-on-one with hospital administrators and unit managers to develop rotations in both inpatient and outpatient settings, from the ICU to the pharmacy," says McLean.

Students are paired with a mentor such as a nurse, physician, social worker, or chaplain. "We're always a phone call away, should questions arise," says McLean.

Interns are held accountable for physician/provider confidentiality by the hospitals and by the university. "At the university, the students attend multiple orientation sessions at which confidentiality is discussed," says McLean.

The students all sign contracts agreeing to adhere to confidentiality standards established by the university and the hospitals, and to comply with federal privacy and security regulations, California patient privacy laws, and The Joint Commission's patient confidentiality standards.

The students also must complete hospital-specific training. "This includes an onsite educational session on patient privacy regulations, and online training in confidentiality and corporate compliance," says McLean.

More Ethical Awareness

Recently, the students' mentors completed a survey to ascertain the effect of the Health Care Ethics Internship on themselves and their organization. "We are looking at the impact that the ethics interns have on the ethical awareness of their mentors," McLean explains.

The survey included questions on how participation in the internship influences the individual's ethics awareness in the workplace and in everyday life. "We have gathered over 30 responses from a variety of healthcare professionals who serve as mentors for the student interns, and/or help coordinate the program within the organizations," says McLean.

Students are also surveyed on their experience. One commented, "That year, I experienced my first case of child physical abuse. I watched a physician break the news to a young adult that her athletic career was over, and a physician hold the hands of family members while their father was taken off life support."

"Our experience demonstrates that undergraduate medical ethics education aids in the development of critical ethical reflection skills," says McLean. "These carry over into professional schools and careers."

One graduate stated, "I have used [the ethics knowledge gained in the internship] in numerous decisions that I have faced in the hospital working as a nurse." Another student wrote, "The social work rotation was immersed in ethical issues surrounding racial and ethnic disparities, and inspired my future interests."

While the program's focus is on bioethics education, the students also explore their vocational commitments. A few decided that a career in healthcare was not right for them. "Better to come to this realization as an undergrad than in the third year of medical school," says McLean. ■

REFERENCE

1. Morton KR, Worthley JS, Testerman JK, et al. Defining features of moral sensitivity and moral motivation: Pathways to moral reasoning in medical students. *Journal of Moral Education* 35(3); 2006:387-406.

SOURCE

- **Margaret R. McLean**, PhD, Associate Director, Markkula Center for Applied Ethics, Santa Clara (CA) University. Email: mmclean@scu.edu.

COMING IN FUTURE MONTHS

- Ethics concerns if hospitals won't hire obese employees
- Update on new guidance on ethics of telemedicine
- Unproven stem cell treatments stir ethical controversy
- Ethical issues when cancer drugs are "overhyped"

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CME/CE QUESTIONS

1. Which is true regarding publication of completed clinical trials, according to recent research?

A. Researchers with unpublished trials are currently barred from providing public access to their data.
B. A significant percentage of results go unpublished for completed clinical trials.
C. Study participants are generally told that the study's findings may not be published, as part of the informed consent process.
D. Trials which reflect unfavorably on a particular intervention are just as likely to be published as those which reflect favorably.

2. Which does The Joint Commission require healthcare organizations to do?

A. Provide adequate care for patients' spiritual, religious, and cultural needs in conjunction with the medical care they receive.
B. Provide patients with board-certified clinically trained chaplains.
C. Allocate sufficient resources to pastoral care.
D. Utilize specific metrics to track effectiveness of pastoral care.

3. Which is recommended to obtain public buy-in regarding including the cost of care in medical decision-making, according to Nancy S. Jecker, PhD?

A. Give physicians a more visible role in rationing healthcare.
B. Limit the public's access to data on cost-effective analyses.
C. Make it clear that any intervention that offers any benefit to a patient will always be provided to everyone.
D. Separate medical and societal decision-making.

4. Which is true regarding reporting patients with mental health issues under HIPAA?

A. Recent amendments create a duty for clinicians to report.
B. A "mere suspicion" threshold is typically all that's required to allow clinicians to breach confidentiality and report mental health threats.
C. Clinicians have new allowance to report patients with mental health issues.
D. Clinicians' legal duties are strongly weighted in favor of protecting patients' confidentiality from being breached without sufficient justification.