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INSIDE

Non-hospice patients receive more aggressive end-of-life care

Lack of reimbursement for advance care planning is obstacle

Patients who do not enroll in hospice are more likely to receive aggressive cancer care at the end of life, according to a recent study.[1]

Researchers at Brigham and Women's Hospital in Boston analyzed health care utilization and costs in 18,165 elderly Medicare patients with advanced cancer who enrolled in hospice before death, and compared them to 18,165 similar patients who died without hospice care. Some key findings include:

• Most non-hospice patients (74%) died in hospitals and nursing facilities, compared to only 14% percent of hospice patients.

• Hospice care was associated with significantly lower rates of both health care utilization and total costs during the last year of life.

"We were interested in the kind of care people get after they are diagnosed with certain bad cancers," says **Ziad Obermeyer**, MD, MPhil, the study's lead author and an assistant professor of healthcare policy at Harvard Medical School in Boston. "We were specifically interested in what happened when these people enrolled in hospice care at the end of their lives, and what

EXECUTIVE SUMMARY

Hospice care was associated with significantly lower rates of both healthcare utilization and total costs during the last year of life, according to a recent study.

- Non-hospice patients were five times as likely to die in hospitals or nursing homes.
- Hospice patients had fewer invasive procedures and less time in hospitals and intensive care units.
- Time and poor communication are common barriers to goals of care conversations.

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happened to their care."

The researchers compared people who chose hospice before they died to those who didn't. "We were especially careful to make sure we were comparing people with equally aggressive disease, with the same amount of time from being first diagnosed with cancer to death," says Obermeyer. "What we found was really interesting."

Non-hospice patients were five times as likely to die in hospitals or nursing homes; they also achieved the same length of survival with fewer invasive procedures and less time in hospitals and intensive care units (ICUs). Non-hospice patients "cycled in and out of the hospital," says Obermeyer. "They got twice as many procedures and ICU stays — mostly for infections and strokes and heart attacks that had nothing to do with treating their cancer."

Costs "diverged sharply"

The costs of care for hospice and non-hospice patients were not significantly different before hospice care began, according to the study. "However, costs diverged sharply thereafter. This contributed to a statistically significant difference in total costs of $8,697 over the last year of life," says **Anjana Ranganathan**, MD, assistant professor of clinical medicine at the Hospital of the University of Pennsylvania's Division of Medical Oncology and Palliative Medicine.

Ranganathan says it's important to note that decreased health care utilization and lower cost of care were not a direct result of the reduction in use of expensive anti-cancer interventions. The study specifically excluded 11% of non-hospice and 1% of hospice patients who had cancer-directed therapy after exposure, demonstrating that this was not the driver of cost savings.

"Hopefully, this formal demonstration of decreased health care utilization and lower health care costs highlights the significant impact that hospice care can have for patients with poor prognosis cancer," she says.

The study's authors cite the following factors to explain the trend toward increased intensity of care at the end of life and decreased length of hospice enrollment:

- a high degree of scrutiny and prosecution of hospice companies that have inappropriately long hospice stays;
- lack of physician reimbursement for goals-of-care conversations;
- requirements that patients enrolling in hospice renounce disease-directed therapy.

"There is increasing urgency for a change in our health care system to reduce the overall cost of care," notes Ranganathan. "This significant cost savings demonstrated in this study suggests that [current] standards be reconsidered."

The study demonstrated an overall increased cost in the last year of life for those patients enrolled in hospice for over 52 weeks. However, this group comprised only 2% of the hospice cohort, with care costing about $7,000 more in the last year of life. In comparison, $12,000 to $18,000 was saved for patients enrolled in hospice for four to 26 weeks.

"Perhaps less scrutiny should be placed on hospice agencies attempting to provide patient-centered care that has a high potential to reduce health care costs

and improve the quality of end-of-life care," says Ranganathan.

Multiple barriers to hospice care

Multiple systems barriers currently prevent some patients from accessing hospice care. "Hospice is not for everyone," says Obermeyer. "But it's an ethical issue that those who want it should know about it and enroll in it."

Some insurance companies — and Medicare itself — are experimenting with "open access" hospice programs. These don't require patients to give up curative care. "There has been some hesitation about this because of concerns that it might drive up costs," notes Obermeyer. "But having more choices would give patients more freedom to choose the care they want." Such programs could also encourage patients and doctors to talk about end-of-life issues earlier than a few days before death, he says.

Honest goals-of-care discussion

Obermeyer says the data suggest that getting patients with poor-prognosis cancers into hospice earlier is unlikely to increase costs. "It's far more likely that giving patients what they want will reduce costs instead," he says. "More choice, and more patient-centered care, that also happens to cost less? That seems like an easy decision."

The study's findings underscore the importance of honest discussions between doctors and patients about goals of care at the end of life, says Obermeyer. Providers aren't currently reimbursed for advance care planning. "We pay doctors to perform invasive procedures and give chemotherapy. Why wouldn't we pay them to discuss what patients actually want at the end of life?" he asks.

Treatment of patients with advanced or metastatic cancer should prioritize early discussions of advance care planning to ensure high-quality end-of-life care, according to a 2014 review article.[2]

> "THERE IS INCREASING URGENCY FOR A CHANGE IN OUR HEALTH CARE SYSTEM TO REDUCE THE OVERALL COST OF CARE."

"With hospice care, providers are more likely to discover that patients, in fact, do not want to undergo invasive, intensive, and expensive interventions at the end-of-life, but would rather remain comfortably in their own homes," says Ranganathan, the article's lead author.

Lack of physician reimbursement for goals-of-care conversations is clearly one obstacle to more patients enrolling in hospice services. "This is unfortunate," says Ranganathan. "Goals-of-care conversations are crucial to providing high-quality, patient-centered care, but are also extremely time-consuming."

As physicians are pushed to maintain a certain level of fiscal productivity, these lengthy conversations are often abbreviated or neglected. "In order to prioritize high-quality patient care, health care reimbursement must shift toward patient-centered quality metrics," says Ranganathan.

The requirement that most disease-directed therapies be stopped at the time of hospice enrollment prevents many patients from electing hospice care. Given the significant reduction in health care utilization and costs at the end of life, "consideration should be given to time-limited trials of disease-directed therapies concurrent with hospice support, to allow time to demonstrate the clinical trajectory to the patient, family, and providers," says Ranganathan.

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Survey identifies key ethical dilemmas encountered by nurses

Ethical issues went unresolved in one-third of cases

The Hospice and Palliative Nurses Association (HPNA) conducted a survey of 129 of its members to identify ethical dilemmas encountered by hospice and palliative nurses.[1] Nurses reported these issues related to ethical dilemmas: inadequate communication, provision of non-beneficial care, patient autonomy usurped or threatened, issues with symptom management and the use of opioids, issues related to decision-making, and issues related to discontinuation of life-prolonging therapies. "The findings were not surprising," says **Sally Welsh**, MSN, RN, NEA-BC, HPNA's CEO, pointing to the following factors:

• There are multiple disciplines involved in the patient's care.

• Advanced technology is often used that can prolong life or prolong the dying process.

• There is often inadequate training around goal-of-care discussions.

• The patient's care is often transitioning from life-prolonging to a focus on promoting comfort and quality of life.

• There is inadequate institutional support in many settings for nurses.

"The inability to solve or at least address ethical issues can have a very negative impact on patients and families, as well as nurses, physicians, and other members of the team," says Welsh.

Approximately two-thirds of the nurses used educational and other clinical resources to resolve ethical issues, according to the survey. These included formal ethics consultations, involvement of the palliative/hospice team, consulting with a health care professional or clergy, and team meetings.[1]

One-third of nurses reported that institutional or personal barriers prevented the ethical dilemma from being resolved. "The quality and type of resources available to nurses and other staff varied," notes **Jooyoung Cheon**, MSN, RN, the study's lead author. The nurses reported that the following factors were related with an inability to resolve ethical issues:

• the family's insistence on non-beneficial interventions;

• concerns about drug-seeking behaviors;

• family avoidance of family meetings and other communication issues;

• disagreements among team members;

• lack of a palliative care consult or inability of a nurse to request a consult;

• staff inexperienced in end-of-life issues;

• too little time to help the family process what was happening;

• the family's difficulty in accepting the inevitability of death;

• the family's financial problems;

• cases with pediatric patients.

Welsh recommends these approaches to assist nurses in dealing with ethical issues:

• Providing nurses with education on bioethical issues and resolution, including models for evaluating ethical issues. "Discussion of ethical issues can be included in all clinical case presentations," says Welsh.

• Discussing ethical issues during clinical case presentations.

• Ensuring nurses have access to clinical and administrative policies and procedures, and resources such as ethics committees or consultations.

"The availability of a formal process or method to review bioethical issues is very beneficial in assisting nurses to work through bioethical issues," says Welsh.

• Including nurses as members of ethics committees and ethics consult teams.

• Giving nurses the autonomy to request ethics consults within their organizations. "The availability of a formal process or method to review bioethical issues is very beneficial in assisting nurses to work through

EXECUTIVE SUMMARY

Hospice and palliative care nurses reported inadequate communication, provision of non-beneficial care, and discontinuation of life-prolonging therapies as some of the factors contributing to ethical issues, according to a recent survey. Some recommended the following strategies:

• Use role-playing exercises to teach nurses to voice concerns on end-of-life care.

• Include nursing in patient care discussions.

• Mandate nursing presence on bioethics committees.

bioethical issues," says Welsh.

Nurses are often not included in discussions about end-of-life care because they are often not seen as full partners in patient care, says **Margaret Quinn Rosenzweig**, PhD, FNP-BC, AOCNP, FAAN, associate professor at University of Pittsburgh's School of Medicine. "Nurses often undervalue their contribution to health care," she adds. Therefore, nurses don't always speak up regarding things they have observed during their patient care and interactions with the patient and family, she says.

"Including nursing really opens the discussion of end-of-life care to a more holistic approach," says Rosenzweig. "End-of-life care and decision-making should not be based solely on a medical/disease model." She recommends that bioethicists utilize these approaches:

• Provide education to nurses regarding end-of-life care and the role of palliative care in life-ending illness. "Role-play or model ways in which nurses could add to the conversation regarding end-of-life care through case vignettes," says Rosenzweig. "This allows nursing to practice adding their voice during family meetings or discussions."

• Make an effort to include nursing in patient care discussions. "If bioethicists who are involved in the clinical care of patients embrace nursing, the contribution of nursing will be more highly valued," says Rosenzweig.

• Mandate nursing presence on bioethics committees, family meetings regarding care planning, and cases involving surrogacy decisions. "In this manner, nursing will be automatically included in vital discussions," says Rosenzweig. "Nurses will contribute an important viewpoint in end-of-life care."

Nurses uninformed about plan of care

Some physicians believe nurses need to know only what's necessary to provide bedside care. This means nurses aren't always informed of the plan of care.

"Nurses not infrequently will request an ethics consultation because they are concerned when it appears an aggressive intervention is being continued, seemingly with no clear goals or end point," says **Lucia D. Wocial**, RN, PhD, nurse ethicist and program leader at Indiana University Health's Charles Warren Fairbanks Center for Medical Ethics in Indianapolis.

This arises, for example, if a patient's surrogate makes a comment to the nurse that suggests they are unaware of the risks or burdens of ongoing aggressive treatment. "On the face of it, it may look like the patient's surrogate has not received all the information necessary to make an informed choice, and that doesn't seem right," says Wocial.

When physicians clearly explain the plan and their efforts to inform the patient's surrogate, whether verbally or in their notes, nurses can support the plan. "They often help to reinforce the information shared by the physician," says Wocial.

Address moral distress

Both nurses and physicians experience genuine distress over not being able to restore a patient to his or her previous level of functioning or a health status that the patient would find valuable, says Wocial. "Many don't know how to communicate that to a family member who is in shock, grieving, and angry," she says. "These are hard conversations. Nobody looks forward to them."

More than 80% of clinicians interviewed by Wocial for a quality monitoring evaluation of ethics consults reported that they experienced moral distress when caring for a patient who was the focus of the ethics consultation request. Many reported that the ethics consult gave them confidence in the overall plan of care, she says. One respondent stated, "If I hadn't participated in the consult, I still would think what we did was wrong."

Physicians don't always verbally convey to nurses how the goals of care conversation went, she says. Such information is often absent from the chart. "Often, physicians don't have time to document details of the discussion," says Wocial. Sparse documentation such as, "Spoke with the family about prognosis" leaves others, including nurses, in the dark about the goals of care.

"My question is always, 'And? How did it go?'" says Wocial. Ideally, documentation would include how the patient responded, what other caregivers need to reinforce, and what the next meeting or decision point is, she says.

"Everybody needs to know what others are doing, in order to work together to achieve the patient's goals," says Wocial.

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Commission calls for integration of ethics into public health response

Ethics should "not be an add-on or an obstacle"

The federal government has both a prudential and a moral responsibility to actively participate in coordinated global responses to public health emergencies wherever they arise, according to a February 2015 report, titled *Ethics and Ebola: Public Health Planning and Response*, from the Presidential Commission for the Study of Bioethical Issues.[1]

"The Commission feels strongly that in the midst of this very challenging epidemic, while attention is being paid to public health and the ethics of our response, we ought to look at how to plan and prepare for the next one," says **Lisa M. Lee**, PhD, MA, MS, the commission's executive director. The report recommends that a single U.S. health official should be accountable for ethics integration. Other key recommendations include the following:

• That ethical principles be integrated into "timely and agile" public health decision-making processes employed in response to rapidly unfolding epidemics.

Many scientists report that they feel ill-equipped to face ethically challenging situations, notes Lee. "During the Ebola epidemic, one thing that people really struggled with was who should get a limited supply of an effective treatment should one become available," she says. "That's something that makes public health officials feel uncomfortable."

A related issue involved what level of supportive care is ethical; interventions such as dialysis are not sustainable in certain locations. "That decision will have implications for what happens when the epidemic is over," says Lee. "There are ethical questions about introducing something that you know you can't sustain."

Ethics should be involved "early and explicitly," says Lee — both in public health research and also in practice. "In addition to that, we have to consider the longer-term ethical and societal implications of the work we are doing," she adds. "If we decide that we ought to treat at an effective — but unsustainable — level, what do we do when we go home and have to take that treatment with us?"

• That qualified public health ethics expertise be readily available to identify ethical considerations relevant to public health emergencies and responses, in light of real-time available evidence.

"In order to do this, we need people whose focus is on identifying ethical considerations and implementing a solution," says Lee. "They can help teams anticipate ethical concerns, so we don't find ourselves in situations where something went wrong and we are reacting to it."

The report recommends that "timely and agile" ethics expertise be available to planning and response personnel. The commission didn't delineate specifically what the structure should look like — whether it should consist of a consultation service, for example, or an advisory body of several people. "There are many models," says Lee. "But the efforts should be integrated, with accessible, knowledgeable ethicists who are trained in science."

High-quality service on public advisory committees and well-argued, evidence-based writing on public health ethics topics are the best markers of public health ethics expertise, says **Steven Joffe**, MD, MPH, Emanuel and Robert Hart associate professor of medical ethics and health policy and vice chair of the Department of Medical Ethics and Health Policy at the University of Pennsylvania's Perelman School of Medicine.

"In my view, there's value to constituting ethics advisory groups for major organizations with a public

health function," he adds.

The Presidential Commission for the Study of Bioethical Issues plays a critical public health advisory role to the federal government, notes Joffe. "In this light, it's disappointing that in April 2013, the Advisory Committee to the Director of the CDC [Centers for Disease Control and Prevention] voted to disband its Ethics Subcommittee," he says.[2]

Bioethics, as a discipline, "hasn't paid nearly enough attention to public health," says Joffe. "As important as clinical and research ethics are, public health ethics is just as important — and deserves equal attention from our field."

Many public health decisions involve a complex weighing of the interests of groups and populations against the interests and rights of individuals. This often occurs in situations of considerable uncertainty. "Recent debates about the freedom of movement of people who had had potential Ebola exposures were one prominent example," says Joffe.

The commission's overarching goal is for ethics to be included in the multidisciplinary approach to public health. "Medical practice and science are becoming incredibly multidisciplinary; one of those disciplines has to be ethics," says Lee. "Ethics should not be an add-on or an obstacle."

Ethics principles should always be an integral part of the decision-making process at all levels of public health, says **Piero Olliaro**, MD, PhD, Newton-Abraham visiting professor at United Kingdom's University of Oxford and a senior research manager at the WHO-based Special Programme for Research and Training in Tropical Diseases. "But while they are highly regulated in certain areas — clinical trials — they are remarkably opaque in others," he says.

There has been a concerning trend all over the world toward public health decisions being increasingly dictated by efficiency and cost-saving, and less so by basic rights to health, says Olliaro, pointing to decisions not to invest in health systems, surveillance and reporting, and international aid. "There are publicly available damning figures to show how slow the response to Ebola has been, both at the country and international levels," he says.

If all people have a right to health, then this right "must be part and parcel of decisions which will, one way or another, determine whether one will live a healthy life or not, if illnesses will be prevented, and if ill, whether one will receive adequate treatment," says Olliaro. "One will have to accept that the separation between ethics and rights will become increasingly tenuous."

Role of NGOs

George J. Annas, JD, MPH, William Fairfield Warren Distinguished Professor and chair of the Department of Health Law, Bioethics & Human Rights at Boston University, says the commission's report "voided almost all of the important issues of public health ethics by ignoring human rights," and thus missed the opportunity to deal with international human rights in a public health crisis, he says.

"Medical ethics is primarily about physicians and patients or research subjects; human rights is about the obligations governments have to their citizens — including, but in no way limited to, protecting their health," says Annas. In the Ebola crisis, which involved more than one country, issues of the role of the United Nations (UN) and the World Health Organization (WHO) needed to be "much more front and center," says Annas, as did the question of when, if ever, it is consistent with human rights to use military power to intervene in another country for health reasons.

"Finally, there is virtually nothing about the role (and ethics) of [nongovernmental organizations] in epidemics, although MSF [Medicins Sans Frontieres, also called Doctors Without Borders] did virtually all of the response for the first six months in all three affected countries," says Annas.

MSF's philosophy of a "duty to interfere" to help alleviate human suffering cries out for ethical and human rights analysis, says Annas, "especially since the UN has been trying to answer the question of

EXECUTIVE SUMMARY

A February 2015 report from the Presidential Commission for the Study of Bioethical Issues explores ethical issues involving the Ebola epidemic and public health planning and response. Some key recommendations include:

- that ethical principles be integrated into public health decision-making processes in response to rapidly unfolding epidemics;
- that a single U.S. health official be accountable for ethics integration;
- that qualified public health ethics expertise is readily available to identify ethical considerations.

when it might to appropriate for the UN to intervene in a country for humanitarian reasons without that country's permission."

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Measles outbreak puts spotlight on vaccine refusers: Providers need ethical responses

Clash between public health and individual autonomy

Ninety-three percent of pediatricians and family physicians reported that, in a typical month, some parents of children younger than two ask to spread out vaccines; most agree to do so either often/always (37%) or sometimes (37%), according to a recent study.[1] However, the majority (87%) said such delays put children at risk for contracting vaccine-preventable diseases. A previous study reported that about 10% of physicians "often" or "always" dismiss families from their practice if they refuse vaccines entirely.[2]

"This is a very complex and difficult subject," says **Alexander A. Kon**, MD, FAAP, FCCM, clinical professor of pediatrics at University of California San Diego School of Medicine. He notes that much of the distrust of immunizations arose from a discredited 1998 study that suggested a link between the Measles, Mumps and Rubella (MMR) vaccine and autism.

"In fact, every study looking at a potential link between immunizations and autism — and there have now been many — has not shown any such link," says Kon. "Yet there remain lingering fears among parents who are misinformed by celebrities and others."

A recent measles outbreak stirred public debate over vaccine refusers. "Those of us caring for sick children, however, never lose sight of this problem," says Kon. Last year, Kon cared for a child who was admitted with a severe lung infection. He was infected with strep pneumonia — a very dangerous bacterium against which most children are immunized. "This child nearly died because his parents chose to withhold immunizations — a decision they made based on a false belief that immunization might cause autism," says Kon.

The American Academy of Pediatrics recommends that physicians discharging patients from their practices solely because a parent refuses to immunize a child should be left for unusual cases, only after attempts have been made to work with the family.[3]

"That being said, many pediatricians do discharge patients from their practice if parents refuse immunizations," says Kon. "They believe strongly that failure to immunize a child is so counter to the child's best interest that they cannot be involved in what they view as medical neglect."

For this reason, some pediatricians and ethicists support mandated universal immunizations. "In the United States, such policies are at odds with our strong support for individual autonomy and parents' rights to raise their children as they see fit," says Kon.

Under such programs, immunizations are given to children without parental consent. Only when the physician determines that immunizations are not indicated for the child, such as if the child is severely immunocompromised, can the physician withhold immunizations.

"The state may indeed have a responsibility to mandate immunizations, both for the public good and to safeguard the best interest of individual children," Kon says.

Douglas S. Diekema, MD, MPH, attending physician and director of education at the Treuman Katz Center for Pediatric Bioethics at

Seattle Children's Hospital, is seeing more parents seeking at least an altered vaccine schedule, if not a full exemption. Both scenarios present ethical challenges for pediatricians.

School exemptions mean other children are exposed to unvaccinated children. "Delaying vaccines for completely non-scientific reasons means children remain unprotected at a fairly vulnerable time," adds Diekema. He notes that in the past decade, there have been significant efforts in several states to eliminate or reduce vaccine requirements for school attendance.

Some states, however, have made vaccine exemptions more difficult to obtain. "How easy it is to get an exemption is probably the most important variable related to vaccination rates," he says. "The easier the exemption is to obtain, the higher the exemption rate."

Diekema says the majority of people see vaccines as a good thing without question, and a very small percentage are anti-vaccine and can't be convinced. "Then there is a middle group, the vaccine-hesitant, who are worried about what they've read or heard," he says. "This group comprises 20 to 30% of the population, and is the group that's most amenable to education."

There is growing public concern that vaccine exemptions are putting other children at risk. According to a recent Pew Research Center report, 68% of U.S. adults say childhood vaccinations should be required.[4] "I wish legislatures would pay more attention to this sizable majority," says Diekema. "The problem is that the people lobbying are the ones who don't want vaccines to be required for school attendance."

Diekema says an increasing number of physicians are discharging vaccine-refusers from their practices. Such families require time-consuming education; the eight to 10 minutes typically allotted per visit doesn't allow for a lengthy discussion on vaccines, he says.

"From a public health perspective, I think refusing to see families who have chosen not to vaccinate their children is a worthless tactic," says Diekema. "The families just end up somewhere else." Providers lose the opportunity to convince them that vaccination is the right choice.

"I have some ethical concerns about turning away these families solely on the basis of their decision about vaccination," adds Diekema. Physicians have an ethical obligation to their patients — in this case, a child whose parents have made a decision that you disagree with.

"It's extraordinarily frustrating to have families rejecting what may be one of the most powerful tools we have to keep children safe," Diekema says. "But while they may not be convinced at the first or second visit, the goal is to get the child vaccinated over time."

Bioethicists should consider contributing editorials to newspapers or doing radio interviews on the topic of vaccine refusal, says Diekema.

"The academic literature has covered this pretty well," he says. "But bioethicists and physicians have a responsibility to bring messages like this out to the general population."

EXECUTIVE SUMMARY

An increasing number of pediatricians are encountering families requesting an altered vaccine schedule or refusing vaccines altogether; some are responding by dismissing families from their practices, according to a study.

- Some states have made it easier to obtain vaccine exemptions.
- There is growing concern about unvaccinated children putting themselves and others at risk.
- Bioethicists can voice concerns publicly about vaccine refusers, experts say.

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Network of bioethicists gives guidance to investigators with research ethics issues

Group complements the work of IRBs

Institutional review boards (IRBs) typically give guidance to researchers only during the pre-study regulatory review process, but investigators also struggle with ethical questions that arise during research. "For years, this has been done informally," says **Benjamin Wilfond**, MD, director of the Treuman Katz Center for Pediatric Bioethics at Seattle Children's Research Institute.

When facing an unexpected ethical issue, researchers sometimes seek advice from ethics consultants at their institutions; the final recommendation is often to discuss any proposed change in protocol with the IRB. "IRBs have varying degrees of expertise and comfort with more complex ethical issues," notes Wilfond. "Some of these are hard cases."

Increasingly, investigators are anticipating ethical issues in advance of conducting their projects and seeking advice, says **Mildred Cho**, PhD, associate director at the Stanford (CA) Center for Biomedical Ethics. "In addition, investigators also have been working with ethicists to publish co-authored articles about ethical issues they identified, and strategies they developed to address the issues," she notes.

Wilfond founded the Clinical Research Ethics Consultation Collaborative, a group of 40 bioethicists at 30 institutions, as a resource to help investigators resolve ethical issues that arise during research.[1]

"In building this collaborative, we want to be very clear that we need to supplement, not replace, the IRB," he says. Wilfond co-authored a 2009 paper that examined how a research ethics consultation service may differ from and complement the role of an IRB.[2]

"Ethics consult services have varying degrees of success," adds Wilfond. "Often, it's a combination of the overall institutional enthusiasm and the people running the program."

Communication of findings

Many ethical issues confronted by researchers involve communication of findings to study participants. "There may not necessarily be a plan to return the findings of laboratory or clinical evaluations to individual participants. But suddenly, the information seems important to convey," says Wilfond.

This issue arose during a study in which participants were given the option of knowing results of genetic testing, Wilfond says. Two siblings participated; one was sick and one was healthy. The healthy sibling said he didn't want to know the results.

"The researchers ended up having findings that suggested he had the same condition as the sibling, but decided not to tell him because those were his wishes," says Wilfond. However, the investigators then learned that the man was scheduled to be a bone marrow donor for his sibling. "This raised the question of whether the researchers should tell him against his stated wishes," says Wilfond. The group considered that he was also committed to the health of his sister, and the information was disclosed.

In another study, a member of a family tested positive for the BRCA1 gene, but wanted to keep it confidential; in fact, the man lied about the result to his relatives, which had implications for their own health. "He told all his family members he was negative, including his adult children, in front of the investigators," says Wilfond. The group considered that maintaining a therapeutic relationship with the subject was the best way to encourage him to tell the truth.

Another frequent ethical issue involves incidental findings. For example, investigators donated a DNA sample so other researchers could study a rare disease, Cho says.

EXECUTIVE SUMMARY

The Clinical Research Ethics Consultation, a group of 40 bioethicists at 30 institutions, helps investigators resolve ethical issues that arise during research.

- Investigators want help in real time with ethical issues they're confronting.
- Some participants are willing to consult with investigators from other institutions.
- Bioethicists use conference calls to present a range of opinions.

As part of the analysis, the researchers found in one of the samples from the normal healthy control population a variant in one of the genes they were studying that is associated with that disease. "People with this disease are often asymptomatic until they die suddenly," says Cho, a member of the Clinical Research Ethics Consultation Collaborative.

The question was whether the researchers had an obligation to tell this individual about their finding, even if the consent form said that no such results would be returned. The researchers were advised to first confirm the finding in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory. "As it turned out, the presence of a disease-associated variant was not confirmed," says Cho. "This highlighted the need for clinical-grade tests for any results that are reported to individuals."

Range of views

The Clinical Research Ethics Consultation Collaborative is currently developing a website to allow investigators to learn about the members and the service. "Some are willing to do consults for people who are from other institutions," notes Wilfond. "Not everybody has access to groups like this."

Recently, a dozen ethicists participated on a conference call with an investigator faced with a difficult ethical issue. "This consult focused on research studies that provide more frequent standard clinical data for which the clinical meaning is not clear, and could result in unnecessary subsequent clinical interventions," says Wilfond.

This allowed the investigator to hear a wide range of views. Some thought disclosure was necessary, while others thought it was problematic. "There were a number of people throwing out ideas that I hadn't thought of," says Wilfond. "We've only done this twice now, but I think it's a new, interesting way of trying to help investigators."

Since 2012, the group has recorded the cases from 10 institutions in a database. "Our fantasy at the time was for people to use the database to get immediate advice. It turns out that people would rather have a listserv," says Wilfond. Researchers prefer to consult with someone who can tell them right away what they think about the particular issue the researcher is dealing with, he says.

"We are in the process of creating opportunities, when we do a complicated consult, to get input from other people," says Wilfond. Another possibility is for a group of ethicists to be invited to call in at a certain time, if available, to address a particular question.

"People often try to resolve this on their own. Most things never get to an outside consultant for advice — it's only when people are really, really stuck," says Wilfond. "We can provide greater clarity of thinking."

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CME OBJECTIVES

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

1. Discuss new developments in regulation and health care system approaches to bioethical issues applicable to specific health care systems;
2. Explain the implications for new developments in bioethics as it relates to all aspects of patient care and health care delivery in institutional settings;
3. Discuss the effect of bioethics on patients, their families, physicians, and society.

COMING IN FUTURE MONTHS

- New research identifies barriers to goals-of-care conversations
- Ethical approaches to address problems with disruptive clinicians
- Identify unethical practices with disclosure of medical mistakes
- Surprising new data on code status discussions for psychiatric admissions

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To earn credit for this activity, please follow these instructions:

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CME QUESTIONS

1. Which is true regarding end-of-life care received by patients with advanced cancer, according to a *JAMA* study?

A. Patients who enrolled in hospice before death received more aggressive care at the end of life.
B. Hospice care didn't affect the likelihood of patients dying in hospitals and nursing facilities.
C. Hospice care was associated with significantly lower rates of both health care utilization and total costs during the last year of life.
D. Non-hospice patients had significantly fewer intensive care unit stays.

2. Which is true regarding ethical dilemmas encountered by hospice and palliative care nurses, according to a recent survey?

A. None of the ethical issues involved advanced technology that prolongs the dying process.
B. None of the nurses reported inadequate training or institutional support.
C. Inability to resolve ethical issues was linked to advanced technology used to prolong life.
D. Virtually all respondents did not want nursing presence mandated on bioethics committees.

3. Which is the most ethical response for pediatricians regarding vaccine refusals, according to Douglas S. Diekema, MD, MPH?

A. Providers should discharge families who request an altered vaccine schedule from their practices.
B. Under no circumstances should providers discharge families who refuse vaccines from their practices.
C. Providers should not engage in time-consuming discussions educating reluctant families about vaccines.
D. Pediatricians have an ethical obligation to children whose parents have made a decision with which the physician disagrees.

4. Which is true regarding ethical issues that arise during research, according to Benjamin Wilfond, MD?

A. Ethics consultation services should replace the role of Institutional Review Boards (IRBs).
B. IRBs, not ethics consultation services, should be the sole resource used to help investigators resolve ethical issues.
C. If consent forms state that no such results will be returned, findings may not be communicated to study participants.
D. Investigators can benefit from hearing a wide range of views when facing a difficult ethical issue.