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What do you know about effectiveness of ethics consults? Data are often lacking

Good outcomes aren't enough

In order to demonstrate the effectiveness of clinical ethics consultations, it's not enough to show good outcomes — for example, that patients and staff are satisfied. "You have to show that the outcome was better than it would have been without the ethics consultation," says Ellen Fox, MD, director of the National Center for Ethics in Health Care for the Department of Veterans Affairs (VA).

This requires comparing groups that received an ethics consultation with similar groups that did not. "You also have to figure out ways to control for other factors that could affect the outcomes," says Fox. "This sort of study requires a lot of expertise, a lot of money, and a very large volume of consultations."

What to measure

There have been several empirical studies of ethics consultation and how it is practiced, including a large national study of ethics consultation in U.S. hospitals.[1]

However, none of the studies demonstrated effectiveness. "To demonstrate effectiveness, you need to measure outcomes," says Fox.

EXECUTIVE SUMMARY

To demonstrate the effectiveness of clinical ethics consultations, organizations need to show that the outcome was better than it would have been without the ethics consultation, but these data are often lacking. Bioethicists at the Department of Veterans Affairs use these approaches:

- Asking for feedback from everyone who was involved in a consultation;
- Documenting consults in a standardized way;
- Utilizing a tool to evaluate the quality of ethics consultations based on written consult records.

The American Society for Bioethics and Humanities' 2010 Core Competencies for Health Care Ethics Consultation includes a section on evaluation. Fox co-authored an article on what outcomes should be measured to demonstrate that ethics consultation is effective.[2]

"First and foremost, an effective ethics consultation service should improve patient care by ensuring that the health care organization and its staff are consistently adhering to the highest standards for ethical practice," says Fox.

For example, ethics consultations should ensure that patients' preferences for life-sustaining treatment are appropriately and sensitively discussed, documented, and honored.

Ethics consultation should increase patients' and families' satisfaction with their health care experience, adds Fox, and reduce moral distress and employee burnout.

"Unfortunately, however, this sort of effectiveness research on ethics consultation has been limited," she says. "Evaluating ethics consultation quality is a lot easier than demonstrating effectiveness."

Determining how ethics service affects patient care is a challenge, says **Blair Henry**, an ethicist at Sunnybrook Health Sciences Centre in Toronto, Ontario, Canada. There are many confounding factors that could influence such an evaluation, given the complexity of care environments.

Many ethics consult services send a quick survey to the involved clinicians after a consultation, with open-ended questions asking for feedback. "This may get at elements of process quality, but not outcomes," says Henry. "A more robust evaluation process is needed to properly illustrate the impact of ethics consultations on patient care."

Some have suggested that a randomized, controlled trial design is required, says Henry, but "the uncertainty of which tools might be used to measure outcomes, and the impossibility of using a non-intervention, or even a placebo arm, make this methodology problematic."[3]

Clear standards needed

It may be premature to try to demonstrate the effectiveness of an intervention, says Fox, before there are clear standards on how the intervention should be performed. "That's why we have been focusing our efforts on establishing standards and measures for ethics consultation quality," she says.

The VA uses these approaches:

- The ethics consultation services ask for feedback from those involved in a consultation.

Each of the VA's health care facilities has an ethics consultation service, with about 2,000 consults each year. "We receive feedback on about a third of those consults, which is a number we're very proud of," says Fox.

- Ethics consultants document consults in a standardized way.

The VA uses an internally developed web-based database called ECWeb. This system captures information on who is requesting ethics consults; how often ethics consultants visit the patient; and what percentage of consults are about surrogate decision making.

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EDITORIAL QUESTIONS

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"Data like these help us target activities toward high-priority issues," says Fox.

• The National Center for Ethics is developing a tool to evaluate the quality of ethics consultations based on written consult records.

Once this tool is validated, it will be posted on the VA's website for others to use.

"Tools like this will enable us to relate ethics consultation to a number of important outcomes such as ethical practices, patient satisfaction, and employee morale," says Fox. "Ultimately, we hope to demonstrate the effectiveness of ethics consultation with respect to all of these outcomes."

"Separate, elitist world"

An ethics committee in the field of health care can be said to have reached maturity when it becomes a necessary piece in the organizational chart of a medical institution, according to **Rogelio Altisent**, chair of professionalism and clinical ethics at the University of Zaragoza in Spain.

"For this to occur, the label that it is only a group of ethics enthusiasts must be eliminated," he says.

Bioethics is still seen by many clinicians as a "separate, elitist world that is interested in philosophy and in 'splitting hairs,'" adds Altisent. "This is probably because most health care professionals have received little academic training in this field."

Clinical bioethics should not be used only for cases with very complex ethical problems, argues Altisent.

"Ethics should also be the engine that drives us to dedicate the necessary time to each patient — to treat seemingly unpleasant patients with patience; to make an effort to give elderly, deaf, or psychiatric patients information they understand; to analyze treatments from the perspective of efficiency; and to avoid criticizing colleagues in front of patients," he says.

The classic functions of ethics committees are receiving queries about cases with ethical problems, providing ethical recommendations, and providing bioethical education. "I believe there should be a fourth function — that of promoting research aimed at understanding the real needs of their field of action," he says.

Ethics committees should play an active role outside the walls of meeting rooms, says Altisent, in determining what really concerns professionals and patients from an ethical perspective.

The efficiency of ethics committees must be evaluated the same way as other services, adds Altisent, utilizing a qualitative methodology. "Otherwise, ethics committees can become distorted by their members' own interests," he says. ■

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• **Blair Henry**, Ethicist, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada. Phone: (416) 480-6100, ext. 7178. E-mail: Blair.henry@sunnybrook.ca.
• The VA designed an Ethics Consultation Service Proficiency Assessment Tool that enables leaders of ethics consult services to evaluate the collective competencies of their service and identify opportunities to improve the service. The tool is available at http://1.usa.gov/1jF5KsW. A standardized Ethics Consultation Feedback Tool is also available at http://1.usa.gov/1bxkRB8.

Bioethicists "ideally qualified" to help address disruptive behavior

Basic ethics are central to policy development, education

"The problem isn't really that serious." "Some people are just being overly sensitive." "The physician is close to retirement, so there is no need for formal intervention."

Responses such as these serve to deny or rationalize disruptive behavior by physicians who are rude, condescending, or abusive, says ethics consultant and former hospital CEO **Paul Hofmann**, DrPH, FACHE. Hofmann is president of Hofmann Healthcare Group in Moraga, CA.

"When staff members are intimidated by physicians or others who exhibit threatening behavior, a

severe impact on both patient care and staff morale is unavoidable," says Hofmann. He says that hospital leaders must:

- provide training programs concerning this critical topic;
- perform periodic surveys of staff members regarding satisfaction with their working environment;
- monitor compliance with codes of conduct, as well as disruptive behavior policies and procedures;
- address areas of noncompliance;
- have simple, confidential, and convenient means for reporting concerns;
- investigate all allegations promptly and thoroughly;
- give timely feedback on all complaints submitted.

"Having appropriate policies and procedures is obviously not enough," says Hofmann.

Disruptive physician behavior has been the subject of medical staff investigations and sanctions for decades, and hospitals are required by The Joint Commission and other regulatory agencies to address the issue.[1,2]

Many leaders don't have the courage or know-how to deal with disruptive doctors, however, says **John D. Banja**, PhD, a medical ethicist at the Center for Ethics at Emory University in Atlanta, GA.

"In many instances, the disruptive doctor knows that his or her clinical skills are valuable to the organization — 'Dr. X is the only neurosurgeon for 100 miles around and we must keep him.' So he gets away with just about anything," says Banja.

Involvement of bioethicists

While most bioethicists lack the requisite training for intervening with disruptive doctors directly, says Banja, they can point out that such disruptiveness is not conducive to organizational goals; can harm employees and even patients; and degrades employee morale.

"The primary reason that disruptive doctors are disruptive is because they are allowed to be disruptive," says Banja. He says the best intervention is an empathic one in which the disruptive doctor is made aware of the consequences of his or her behavior and, it is hoped, becomes impressed with the need to change.

"Bioethicists can and should support efforts to reduce disruptive behavior," according to Hofmann. Bioethicists are certainly well trained in dealing with sensitive issues, including conflict resolution, he adds, so they can make particularly important contributions in policy development and staff education.

"Bioethicists may not have been involved in the past, because many have focused almost exclusively on clinical ethics and devoted less attention to organizational ethics," Hofmann says. "But this subject clearly overlaps both arenas."

Bioethicists underutilized

Hofmann has found that bioethicists are often underutilized in addressing challenges associated with organizational ethics, including disruptive behavior.

Some executives are hesitant to invite input from bioethicists in administrative matters, such as developing a policy on the solicitation of donations from high net worth patients by their physicians or contributing to the revision of a community benefit plan to reduce health care disparities due to racial, ethnic, and socioeconomic factors.

"By demonstrating organizational insight and credibility when making presentations to employees, physicians, and board members, bioethicists can be increasingly viewed as valuable participants in management and business discussions that have ethical implications," says Hofmann.

However, senior managers don't always recognize when issues have significant ethical dimensions. Hofmann suggests that bioethicists review the American College of Healthcare Executives' Ethics Self-Assessment Survey to familiarize themselves with topics identified as ones requiring attention.

In Hofmann's view, bioethicists are "ideally qualified" to help with policy development and education regarding disruptive behavior because the subject involves many basic ethical principles.

"Concerns related to confidentiality, competing values, avoiding a rush to judgment, the influence of organizational power on reporting problems, and procedural fairness and justice are examples of matters very familiar to bioethicists," he says. ■

EXECUTIVE SUMMARY

Bioethicists are well-qualified to help address disruptive behavior by physicians, but often aren't involved in this process. Involved parties often deny or rationalize disruptive behavior. Bioethicists can:

- Underscore that disruptiveness is not conducive to organizational goals;
- Remind hospital leaders that disruptive behavior can harm employees and patients;
- Help with policy development and education in this area.

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Microbiome research poses some unique ethical issues

"Do-it-yourself" community raises ethical concerns

Just as companies are offering whole genome sequencing to individuals, companies are offering to sequence their microbiomes and determine how they compare to others.

There has been a lot of controversy recently about direct-to-consumer genetic testing, notes **Amy L. McGuire**, JD, PhD, Leon Jaworski Professor of Biomedical Ethics and director of the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, TX.

"The FDA [Food and Drug Administration] recently sent a stern warning letter to 23andMe, one of the most well-known direct-to-consumer genetic testing companies," she says. The letter reiterated that the test kit is a medical device under the jurisdiction of the FDA to regulate, expressed concerns with the clinical validity and safety of the test, and reminded the company that it must comply with FDA requirements for regulatory oversight. (To view the letter, go to http://1.usa.gov/1crGLGd.)

In addition, a class action lawsuit filed against 23andMe alleges that the company has made false and misleading claims about the clinical validity of the test.

The direct-to-consumer sale of human microbiome analyses faces the same risk of being classified as a medical device subject to FDA regulation, especially as evidence of its health implications grows, says McGuire.

"There is a 'do-it-yourself' community that's developed around this. People with certain diseases see a lot of potential for benefit from the science, and are understandably desperate for treatment," says **Jean E. McEwen**, JD, PhD, program director of the Ethical, Legal, and Social Implications Program at the National Institutes of Health (NIH)'s National Human Genome Research Institute.

Explain limitations of science

A related development is an attempt to "crowdfund" microbiome research projects over the Internet. "In some ways, it's an interesting new model, but it also raises all sort of potential ethical issues," says McEwen.

A key concern involves uncertainty about what the science means, and the likelihood that some people will misinterpret information about their microbiomes.

"It is very, very early. One of the risks is that people will attach more certainty to the science than is warranted," says McEwen. "Bioethicists can play a role in explaining the limitations of the science."

There are also ethical issues related to probiotic treatments making claims based on microbiome research, says McGuire, especially the regulation of probiotics like yogurts being marketed as providing benefits for digestive health.

It is important that the public is educated about the current state of microbiome research; what it can and cannot tell us about the role of bacteria on health and disease at this point; and the risks and benefits of different pharmaceuticals, probiotic foods, and supplements, she underscores.

"This area of research is relatively new. Although there have been some exciting advances, we still have a lot to learn," says McGuire.

EXECUTIVE SUMMARY

Microbiome research poses many of the same ethical concerns as genetic testing, and also some unique ethical considerations. Here are three key concerns:
• People may misinterpret information due to the direct-to-consumer sale of human microbiome analyses.
• There is a need to ensure the information generated can't be tied to a particular person.
• People might be stigmatized either at the individual or group level.

Unique ethical issues

The NIH program has received funding specifically to look at ethical issues of microbiome research. "Some of these are pretty similar to the issues we've all been hearing about for a long time with genetics more generally, but some are unique to microbiome research," says McEwen.

Privacy is a major ethical concern with microbiome research, in terms of how to ensure the information generated in the research can't be tied to a particular person. "It's hard to get a sample that doesn't also include some human DNA," explains McEwen. In addition, some preliminary research suggests that individuals may actually have unique microbiome signatures.

"This raises a whole new set of possible ways that somebody could be tied back to a particular sample," says McEwen. There are potentially some forensic applications, such as law enforcement using microbiomes to track someone's whereabouts. "Some of that, at this point, may seem a little bit farfetched — but maybe not," says McEwen.

There is also a concern that people might be stigmatized somehow based on their microbiomes, either at the individual or group level. For example, research may suggest that particular patterns are found more frequently in some racial or ethnic groups than others.

"We don't know where the research is heading, but some researchers are already suggesting that there may be certain differences among populations," says McEwen.

People may make negative associations about certain individuals or groups, whether they are warranted or not. "Given the historical association between microbes and contamination, there is the potential of negative reactions in people's minds that don't exist as much with other types of research," says McEwen.

Concerns about informed consent are mainly due to safety risks being largely unknown at this point. "It's hard to consent people in a way that is informed when we don't even know what the potential risks are, because the science is so new," says McEwen. ■

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High spiritual support linked to more aggressive end-of-life care

Patients with high spiritual support were less likely to receive hospice care, and more likely to receive aggressive end-of-life medical treatment, according to a recent study.[1]

However, **George Handzo**, BCC, CSSBB, director of health services research and quality at the HealthCare Chaplaincy Network in New York, NY, says it's still unclear whether there is an actual link between less hospice care and spiritual support, and that more research is needed to determine this.

"We shouldn't be rushing to judgment about what is good or bad for individuals, because people have a right to decide for themselves," he adds. A certain percentage of people will choose aggressive care, and should have the opportunity to do so, he says.

"We assume that hospice use is good and aggressive care is bad; and so, we get in an uproar because here are people who apparently are not choosing hospice and are choosing aggressive care," he says.

The goal of palliative care is for people to exercise their own treatment preferences, whatever these are, says Handzo.

J. Vincent Guss, Jr., director of medical bioethics at Kaiser Permanente West Los Angeles (CA) Medical Center, says that based on his own experience as a hospital chaplain and clinical ethicist, he has found that individuals who are more spiritual are more likely to use hospice care, rather than less likely.

"Those who receive spiritual support from their communities are more likely to engage in end-of-life discussions; avoid non-beneficial, aggressive interventions; and welcome hospice care," he says.

EXECUTIVE SUMMARY

Patients with high spiritual support were more likely to receive aggressive end-of-life medical treatment, according to a recent study. However, palliative care experts have found the opposite to be true.

- The goal of palliative care is for people to exercise their own treatment preferences, whatever these are.
- Discussions about how patients' religious and spiritual beliefs affect their treatment choices are needed.
- Bioethicists can encourage institutions to develop systems to ensure discussions occur before a crisis.

Discussions needed earlier

The study's findings underscore that a better job needs to be done in having discussions with people about their religious and spiritual beliefs and how these affect their treatment choices, according to Handzo.

"We don't do that often enough or in-depth enough," he says. "It may be that lack of those discussions leads to more use of aggressive care and less use of hospice care."

Some patients choose aggressive care because they believe their religion requires them to do everything possible to preserve life, and may need to arrive at a deeper understanding, adds Handzo. "Until you talk it out, people may take a very simplistic view of it. This is something that is not addressed in their churches, synagogues, or mosques," he says.

Handzo says that bioethicists should "redouble our efforts to find out what each patient and family wants, and help them to have a full look at their belief systems. Right now, we have holes in the process."

Better systems are needed to ensure that those discussions are held with patients and families before a crisis occurs, however.

"Bioethicists can play a key role in reminding the institution that it has a duty to build these systems upfront, and to deliver care that respects patients' choices," emphasizes Handzo. ■

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Patients apparently eager for pharmacogenics-based prescribing

Bioethicists can ensure benefits are understood

Tests are now available to determine whether individual patients will benefit from certain drugs, with the goals of physicians no longer needing to rely on "trial and error" prescribing.

"This seems to be something that patients understand and gravitate toward more than just about anything. They like the idea of having drugs that work that don't make them sick," says **Ellen Wright Clayton**, MD, JD, Craig-Weaver Professor of Pediatrics and professor of law at Vanderbilt University's Center for Biomedical Ethics and Society in Nashville, TN.

Vanderbilt's Pharmocogenic Resource for Enhanced Decisions in Care and Treatment (PREDICT) program, launched in 2010, has genotyped more than 14,000 Vanderbilt patients for 184 different genetic variations that affect the body's response to various drugs.

More than 12,000 of the patients (88%) have genetic variations that increase their risk of adverse effects from one or more of the five drugs currently included in the electronic health record. Here are some ethical considerations with pharmacogenomics:

• Whether there is an evidence base to show that the testing is really going to make a difference.

"This is an ongoing problem in medicine as we introduce new technologies, and is really no different here," says Clayton. "What is a little different is that many of the enzymes that are involved in drug metabolism have a variety of substrates, and may affect other biological pathways."

Some have effects that are not just limited to drug metabolism. "So one challenge is defining what are you going to tell patients about other implications of their variants," says Clayton.

This concern is not unique to pharmacogenomics, however. "We run into this all the time in medicine," says Clayton. "But it is certainly something that needs to be considered."

• Whether all patients will have the opportunity to benefit from the testing.

EXECUTIVE SUMMARY

Pharmacogenics-based prescribing can determine whether individual patients will benefit from certain drugs, and there is broad public support for this. Some ethical considerations:
• Whether there is an evidence base to show that the testing is really going to make a difference;
• Whether all patients will have the opportunity to benefit from the testing;
• How to respond to people wanting to be tested when a good evidence base is lacking.

"Justice is obviously a pervasive issue in our health care system even now," says Clayton. "I think that what we will see is that as the testing proves its worth, as it is likely to in many instances, it will become a routine part of medical practice."

Third party payers will recognize the benefits of avoiding adverse events and ensuring that people get effective drugs, she predicts, because "nobody benefits if people get drugs that don't work or make them sick."

Broad public support

During qualitative interviews conducted with Vanderbilt's patients over the past few years, the typical response has been, "What could be bad about this?"

"People feel differently about this than they do about predisposition testing," says Clayton. "What makes this more salient to patients is that the information is used to make a decision that is pertinent to that point in time."

Vanderbilt offers people at high risk for needing any of the drugs the opportunity to be tested in advance, so the results are available at the time they need it.

"Most people do not seem to worry if they have genetic information sitting in their medical record until such time as they need it," says Clayton. "They are not going to be fretting about it the same way they would a predisposition to cancer or a neurological disorder."

Technology is evolving

"As these tests prove their value — and some will and some won't — then they will become a part of what clinicians are prepared to offer patients," predicts Clayton. As the value of the testing becomes clear, with proof that outcomes are improved, she says, it is only a matter of time before it becomes incorporated into clinical care.

"The more difficult ethical issue is people wanting to be tested for things when we don't have a good evidence base to say that it's warranted," says Clayton.

Bioethicists can contribute to the process by asking these two questions, says Clayton:

- Do we have the evidence to ensure that doing these tests provides value to patients?
- If there are pleotropic effects, how can these be communicated to patients in a way that is going to be meaningful to them?

"People who work in ethics are certainly devoted to making sure patients make as informed decisions as they can," says Clayton. "By asking direct questions, they can ensure that the new tests are beneficial and that patients know what they are getting into." ■

SOURCE

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Steps needed before pediatric anthrax vaccine trials could be considered

The federal government would have to take multiple steps before anthrax vaccine trials with children could be ethically considered, according to a March 2013 report from the Presidential Commission for the Study of Bioethical Issues.

"Research with children is ethically distinct from other research, especially when the research in question promises no prospect of direct benefit for the participants," explains **Lisa M. Lee**, PhD, MS, the Commission's executive director.

While competent adults can consent to accept risks for the benefit of others during research, children are legally prohibited and ethically unable to consent to accept this burden.

"Pre-event pediatric research involving medical countermeasures, like Anthrax Vaccine Adsorbed, involves testing children for a hypothetical condition with an undefined — and perhaps unknowable — likelihood of occurring," says Lee. No child

EXECUTIVE SUMMARY

Absent extraordinary circumstances, pre-event medical countermeasures research with children is ethical only if it presents "no more than minimal risk" to study participants, according to the Presidential Commission for the Study of Bioethical Issues. The report recommends:

- Assessment of the level of risk likely posed by pre-event pediatric medical countermeasures research;
- Ensuring that data from an older age group inform the research design and risk level for the next younger age group;
- Continuing research to the next younger age group only if the risk is determined to be minimal;
- If minimal risk research is not possible, national level review is necessary.

today, for example, is suffering from an inhalational weaponized form of anthrax; therefore, there is no prospect of direct benefit. "While the knowledge gained could be profoundly useful in the event of an attack, we may never have — and hope never to have — occasion to use it," says Lee.

No more than minimal risk

Because individual children who would be enrolled in pre-event medical countermeasures research do not stand to directly benefit from the research, or have no condition about which generalizable knowledge is likely to be gained, the Bioethics Commission concludes that, absent extraordinary circumstances, pre-event medical countermeasures research with children is ethical only if it presents "no more than minimal risk" to study participants.

"Minimal" risk means no greater risk than that routinely faced by a healthy child in daily life or during a medical check-up, explains Lee. If minimal risk research is not possible, national level review is necessary.

In keeping with its recommendation of a strict risk limit in pre-event pediatric medical countermeasures research, the Bioethics Commission calls for completing all prior ethically sound testing — for example, modeling, testing in animals, and testing in the youngest adults — to assess the level of risk likely posed by pre-event pediatric medical countermeasures research.

If the risk level for the oldest group of children is determined to be minimal and it can be scientifically inferred that the risk would be similar in the next youngest group, the Bioethics Commission recommends that progressive testing with younger and younger children could be employed, beginning with the oldest children in order to provide additional protection to younger children.

"This approach — called age de-escalation — would help to ensure that data from an older age group inform the research design and risk level for the next younger age group," says Lee. "The research could only continue to the next level if the risk is determined to be minimal." ■

SOURCE

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Ethical "pushback" may be needed with cost-containment efforts

Narrow focus on profitability is concern

Some worry that economics rather than ethics is driving change in the health care system; and that profitability, rather than justice and patient benefit, is becoming the focus of cost-containment, says **Bruce Jennings**, MA, director of bioethics at the Center for Humans and Nature in Dobbs Ferry, NY.

The 2013 Hastings Center Guidelines for Decisions on Life-Sustaining Treatment and Care Near the End of Life (Oxford, 2013) acknowledge cost as an ethical concern in health care.

Discussing treatment costs and advocating for patients who lack the means to pay for potentially beneficial treatment supports informed decision-making because unforeseen out-of-pocket costs can create burdens for patients or families, says **Nancy Berlinger**, a research scholar at The Hastings Center and first author of the Guidelines.

Berlinger recommends supporting a constructive, ongoing process of internal discussion about how organizational resources are allocated, including charity-care funds, and about the pressures that cost considerations place on professionals and teams.

"This can lessen tensions, and support the development of institutional policy that is fair to different patient populations and that compensates for known problems," says Berlinger.

Controlling costs is essential

The Guidelines offer detailed discussion strategies for institutions on this challenging issue, in addition

EXECUTIVE SUMMARY

Cost as an ethical concern in health care was addressed in the 2013 Hastings Center Guidelines for Decisions on Life-Sustaining Treatment and Care Near the End of Life.

- Health care providers expressed concerns that financial goals are adversely affecting patient care.
- There is concern that there is too narrow a focus on cost-containment and profitability.
- Physicians need to be more aware of the costs of treatment options.

to recommendations for professionals on how to talk with patients and families about cost.

"Although we avoid the word, we do have implicit rationing in our health care system, and controlling rising health care costs is essential," says Jennings, one of the authors of the Guidelines and a senior advisor to The Hastings Center and a Hastings Center Fellow. The central ethical concern is that a narrow point of view about cost containment and profitability will drive both access to care and individual treatment decisions unfairly.

"The fact that health care systems are increasingly profit-oriented is a bigger social policy issue than the Guidelines could tackle; and frankly, bigger than the field of bioethics," he says.

Clinical ethicists and other ethics leaders in health care institutions can help institutions move toward the goal of cost-effective care that is also better care in these ways, says Berlinger:

- Becoming well-informed themselves;
- Including health care cost as a regular topic in ethics education for clinicians and administrators;
- Looking for opportunities to collaborate with colleagues in areas such as care utilization, which explicitly aim to control costs;
- Promoting institutional discussion of resource allocation and the cost of care. For instance, they can convene and facilitate discussions, using the strategies described in the Guidelines.

"Better care is not necessarily the least expensive care," notes Berlinger. "Providing patients with access to needed care may require upfront investments."

Patient care adversely affected

The authors of the Guidelines heard concerns from many health care professionals about their perception that financial goals are adversely affecting patient care, through management pressures being placed on health care facilities and physicians.

"It would have been silly to try to come up with guidelines to address this in a straightforward sense — to say, for instance, that 'It's ethical to spend an unlimited amount of money on this patient, but not for this patient,'" says Jennings.

Instead, the authors tried to imagine systemic ways in which a group medical practice, hospital, or health care system could address this concern. One important issue identified in the Guidelines is the need to educate physicians and other providers.

"First, they need a better understanding of what the cost factors are," says Jennings. Many physicians don't know the cost of the treatment options that they are discussing with their patients.

"Ethical, humane patient care can also be good business. There need be no real conflict between the two," underscores Jennings.

Many studies indicate that cost-effective systems can also have good outcomes. "It's really hard to make a case that we are being unethical to patients and families if we practice more comparative effectiveness and research-based care," says Jennings. "But the devil is in the details, and any system can be gamed by greed."

There is a need to guard against slipping into a narrowly cost-conscious mentality, he says, but there is also a need to embrace cost-containment as a good thing for society.

"The financial payers might say, 'Let's just pay less and let the chips fall where they may,'" says Jennings. "The ethics pushback has to be, 'Let's spend less to drive profits, worry less about shifting costs to patients, and concentrate more on spending effectively for better care.'" ■

SOURCES

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Smartphones posing new ethical challenges with clinical photography

Unscrupulous use is growing concern

The exponential increase in smartphones and social networking sites has led to concerns from some patients regarding the possible unlawful distribution of images outside the realms of their care.[1]

EXECUTIVE SUMMARY

Ethical concerns involving clinical photography using smartphones include patient privacy, unscrupulous use, informed consent, and security. To address these, hospitals are:

- Ensuring that clinicians balance the benefits of clinical photography against the patient's rights of autonomy and confidentiality;
- Providing clinicians with apps that upload pictures directly to the patient's medical record;
- Ensuring correct storage and disposal of photographs.

"This creates a unique ethical concern," says **Rhys Van der Rijt**, MBBS, of St. Vincent's Hospital in Sydney, Australia. "As technology and social media become an integral component of modern life, it inevitably creates a potential interface between the clinical environment and non-private domains such as social media sites."

The unscrupulous use of clinical photography can affect the doctor-patient relationship, breech ethical codes of conduct, and have legal ramifications for the clinician, warns Van der Rijt.

"As everyone now walks around with a fully functional recording device, it becomes harder to prevent unauthorized recordings," says **Jessica Wilen Berg**, JD, MPH, a professor of law and bioethics at Case Western Reserve University in Cleveland, OH.

Patient consent and confidentiality are two fundamental ethical codes that may be breeched if the right approach is not taken in regard to clinical photography.[1]

However, overenforcing rigid hospital policies and disallowing clinicians to take photographs disrupts an efficient tool for communication and compromises patient care, argues Van der Rijt.

"The clinician's obligations to respect the patient's rights of autonomy and confidentiality must be balanced against the benefits of clinical photography in each case," Van der Rijt says. Here are some of the primary ethical concerns involving Smartphone photography:

• Informed consent.

The expectation is that one will get the patient's informed consent before any kind of recording, says Berg. If recordings are designed to be used solely for internal educational purposes, an "opt-out" model of consent might be used. In this model, patients are informed about the photography in general institutional documents and allowed to opt-out if they choose, but specific informed consent isn't obtained for each use. Photographs used for non-clinical purposes, or for research, will need a specific, detailed informed consent, however, says Berg.

"The key, for either a specific consent or for an opt-out system, is a description of how the recording or picture will be used," she says.

• Security concerns.

Smartphones raise significant security concerns because the devices are rarely used for purely professional purposes. "It seems inappropriate to take photographs on a personal device unless the consent specifically allowed for this and, thus, allowed for the personal use by the photographer," says Berg.

Partners Health Care recently rolled out applications that allow clinicians to take pictures that are directly uploaded to the patient's medical record, and are not stored locally on the phone.

"This is obviously a big advantage with respect to security, when you want to take a picture that's going to be used for clinical care," says **Thomas Cochrane**, MD, MBA, senior ethics consultant at Brigham and Women's Center for Bioethics and assistant professor of neurology at Harvard Medical School, both in Boston. "We still need to use caution and get consent when we want to take those images and use them for teaching or publication purposes," adds Cochrane.

Photos from personal devices should have strict electronic security and should be deleted as soon as possible if they are not used for patient records, advises Van der Rijt.

"Some hospitals are providing specific clinicians with work mobile phones to aid in the security of photographs and to ensure correct storage and disposal," Van der Rijt reports.

• Privacy.

"Photography and videography in the clinic is becoming extremely common because we all have these great cameras in our pockets, built into our phones," says Cochrane. Photographs, especially when they're personally identifiable, are a particularly sensitive type of health information, however.

"Once they are beyond the control of the photographer, these can be distributed to a large number of people or posted publicly," says Berg. "Of course, this concern exists with all digital images." ■

REFERENCE

1. Van der Rijt R, Hoffman S. Ethical considerations of clinical photography in an area of emerging technology and smartphones. *J Med Ethics* doi:10.1136/medethics-2013-101479

SOURCES

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• **Thomas Cochrane**, MD, MBA, Senior Ethics Consultant, Brigham and Women's Center for Bioethics/Assistant Professor of Neurology, Harvard Medical School, Boston, MA. E-mail: tcochrane@partners.org.

COMING IN FUTURE MONTHS

- Becoming involved in organizational ethics
- Ethical concerns for patients with limited English
- Educate providers on end-of-life care
- Responses when patients can't access care

CME QUESTIONS

1. Which is true regarding demonstrating the effectiveness of clinical ethics consultations, according to **Ellen Fox**, MD?
   A. Showing that patients and staff are satisfied is sufficient.
   B. It is necessary to show that the outcome was better than it would have been without the ethics consultation.
   C. It is not advisable to compare groups that received an ethics consultation with similar groups that did not.
   D. It is much easier to demonstrate effectiveness of ethics consultations than to evaluate consultation quality.

2. Which is true regarding ethical concerns about microbiome research, according to **Jean E. McEwen**, JD, PhD?
   A. There is no way that information generated can be tied to a particular person because no human DNA is involved.
   B. People may misinterpret information due to the direct-to-consumer sale of human microbiome analyses.
   C. There is no possibility that particular patterns will be found more frequently in some racial or ethnic groups than others.
   D. Results carry no risk of stigmatization of groups or individuals.

3. Which is true regarding ethical considerations of pharmacogenics-based prescribing, according to Ellen **Wright Clayton**, MD, JD?
   A. There is much less public support for pharmacogenics testing than for predisposition testing.
   B. There is no evidence base to show that any of the tests affect outcomes.
   C. It is unethical to offer patients likely to need one of the drugs in the future the opportunity to be tested in advance.
   D. Testing is expected to be incorporated into clinical care, with evidence of improved outcomes.

4. Which is recommended to address ethical concerns involving clinical photography, according to **Thomas Cochrane**, MD, MBA?
   A. Hospitals should consider providing clinicians with a secure application to use on a phone to ensure correct storage and disposal.
   B. Hospitals should disallow applications that upload pictures directly to the patient's medical record.
   C. Hospitals should encourage clinicians to use their own personal devices instead of providing them with phones.
   D. Only an "opt-out" model of consent should be used, even if photographs are used for non-clinical purposes or for research.

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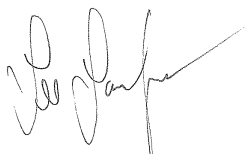

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