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Disclosure of medical mistakes becoming the new cultural norm in health care: Ethics at forefront

Bioethicists can integrate ethics into clinicians' conversations

With more hospitals and health care facilities developing policies, procedures, resources, and training modules to address disclosure of mistakes, the primary role of ethics committees and clinical ethicists is to support, encourage, and even insist that their organizations have such policies, procedures, and resources in place, says **Martin L. Smith**, director of clinical ethics at The Cleveland (OH) Clinic.

"The 'winds of change' have definitely had an impact on how hospitals and their personnel approach and view medical mistakes," says Smith. A former medical culture characterized as "shame and blame" has shifted to prevention of mistakes, learning from mistakes, disclosure and apology to patients and families, and offers of fair compensation, he notes.

The percentage of hospitals and health care systems that are revising or developing new disclosure policies is on the rise, according to **David M. Browning**, MSW, LICSW, clinical social worker at Massachusetts General Hospital in Boston and senior scholar emeritus at Boston Children's Hospital's Institute for Professionalism and Ethical Practice.

"When clear mistakes occur — and especially if a mistake results in serious or significant harm to a patient — honesty is the best policy," says Smith. This means an honest, factual disclosure to the patient and

EXECUTIVE SUMMARY

More hospitals and health care facilities are developing policies, procedures, resources, and training modules to address disclosure of mistakes to patients and families. Ethics committees and clinical ethicists can support disclosure by:
- Encouraging greater transparency with patients and families;
- Working to establish a core group of individuals to provide real-time guidance to clinicians;
- Training clinicians in ethical issues involved in disclosure.

family, and informing them what will be done to correct the problem or systems that led to the mistake so that it is less likely to happen again.

"Although patients and families are likely to be shocked and angry that a mistake has occurred, many will find consolation in knowing that actions are being taken to prevent the same mistake from hurting someone else," says Smith.

There are many challenges to disclosing errors — a feeling of shame, fear of what colleagues will think, concern about damaging a professional reputation, being blamed for a bad outcome, and the possibility of legal action, acknowledges **Lisa Lehmann**, MD, PhD, director of the Center for Bioethics at Brigham and Women's Hospital and associate professor of medicine and medical ethics at Harvard Medical School, both in Boston, MA.

"Nevertheless, I think health care institutions are beginning to realize that disclosure is the right thing to do," she says. "Ultimately, I believe that we need moral courage to ensure that we can tackle the challenge of error disclosure. But we also need a health care system that values disclosure and is not punitive."

Near misses vs. harm

"What is the threshold for disclosure?" This question is often asked when institutions begin making efforts to improve disclosure practice.

"There is always debate in institutions about disclosing near misses," says Browning. "Of course, from the standpoint of patient safety, near misses should always be reported and studied within the institution, in order to reduce the potential for errors in the future."

Smith says one approach is to view medical mistakes on a continuum, with near misses on one end of the spectrum and mistakes causing serious harm on the other. "The more significant or serious the harm to a patient, the stronger the ethical obligation to disclose the error to the patient and family," he says. "From my perspective, there is a weak or non-existent ethical obligation to disclose a near miss to a patient."

However, an organization still needs to have processes and procedures in place for personnel to report near misses to quality-improvement and patient-safety officers, says Smith. In this way, process improvements can be put in place to prevent similar situations from harming patients.

As medical systems become increasingly transparent, there are fewer and fewer situations in which it is ethical not to disclose an error, argues Browning. "There are certainly circumstances where the clinical argument can be made that disclosure is not in the patient's interest," he acknowledges. "But these arguments can sometimes be self-serving on the part of clinicians and, ultimately, paternalistic toward the patient."

In some hospital systems that have embraced open disclosure, clinicians are required to initiate an ethics consultation to justify not disclosing, in order to be able to thoroughly explore the ethical integrity of that course of action. "Disclosure should always occur when there has been harm. But it should also occur under less dramatic circumstances, when the error may result in a change in medical treatment now or in the future," says Browning.

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EDITORIAL QUESTIONS

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Patients or family members may already have the feeling that something untoward has happened. "Failure to communicate at these times can erode the patient's trust," says Browning.

Patients want apology

Patients and families want more than disclosure of mistakes, especially if serious harm has occurred. "They also want — and hope for — an apology," says Smith. "This can get tricky."

Providers often struggle with whether to convey an "expression of sympathy," such as stating, "I'm sorry this happened to you," or an "expression of responsibility," which includes a statement taking responsibility for the mistake such as, "I'm sorry that I/we did this to you."[1]

"I think patients and families greatly prefer and need an 'expression of responsibility,' while, in our litigious society, there will be fear that an 'expression of responsibility' can be used in court against the hospital and health care professionals," says Smith.

Browning says that the ethics of transparency require clinicians to be unambiguous from the standpoint of honesty and accountability in these situations with their patients, with words such as, "I/we made a mistake. This is my/our responsibility. I am truly sorry."

Increasingly, risk-management representatives and hospital attorneys are encouraging this kind of transparency, along with policies and practices ensuring that clinicians will be fully supported if any legal action ensues," he adds. Browning says that a good and ethical disclosure requires clinicians to:

- Make it explicit to the patient and family that an error has occurred;
- Explain what is known so far about what happened and why;
- Take responsibility and apologize for the error;
- Explain what will be done to prevent the occurrence or likelihood of occurrence of similar events in the future;
- Stay attentive to the medical needs of the patient;
- Be aware that the responses of patients and families may range from silence and sadness to anger and distrust.

"Essentially, there has been a rupture in the clinician-patient bond," says Browning. "Clinicians should enter these conversations with this recognition, and with the hope that the bond can be slowly rebuilt."[2]

Role of bioethics

Browning says that in his experience, bioethicists aren't always involved in developing disclosure policies. "This is not to say that bioethicists are not interested, or that they should not be centrally involved; only that the push towards more transparency in health care has come from broader forces and specific sectors of health care systems connected to improving quality and safety," he says.

In some cases, however, bioethicists have been central to the development of better disclosure policies and greater transparency with patients and families. "One of the interesting challenges here is for bioethicists to recognize the very wide range of ethical issues that manifest themselves in the context of patient safety and quality improvement efforts," Browning says.

For bioethicists to be helpful, says Browning, they need integrate their ethical insights with a host of other significant factors affecting these conversations. These include the nature of the error, the institutional context of the error, and the need for follow-through with patients and families that extends well beyond the initial disclosure.

In order to be more effective in disclosing serious errors, some health care systems have implemented a coaching model, as recommended by the National Quality Forum, the Leapfrog Group, and other organizations. "This was the model we taught in our educational workshops," says Browning.

The goal is to establish a core group of clinical and patient safety leaders who provide "just-in-time" guidance to clinicians who are about to disclose an error.

"When coaches are trained in the ethical dimensions of these conversations, they can convey these dimensions to clinicians," says Browning. "They can invite them to think about how they would want this error disclosed to them if they were in a similar situation, and how they would want to be treated."

Ethicists can be very helpful in ensuring that a high quality disclosure occurs when there is an error, says Lehmann, as follows:

- coaching the team prior to meeting with a patient or family;
- helping clinicians to focus on initially sharing the facts versus interpreting the facts;
- ensuring that an apology is given and that health care providers explain what will be done to prevent future errors.

"There is clearly a need for more education surrounding error disclosure," says Lehmann. "We need

to cultivate strong role models who acknowledge responsibility and are transparent about errors." ■

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Controversy over incidental findings in genetic testing

Clinicians ordering whole genome sequencing for a patient with cancer or another indication for sequencing are likely to generate incidental findings that were not being looked for, such as a cancer geneticist finding a gene variant associated with heart disease.

"Targeted genetic testing that focuses on one or more specific genetic variants will probably not generate much in the way of incidental findings," says **Karen J. Maschke**, PhD, a research scholar at The Hastings Center in Garrison, NY. It is when many genetic variants are being interrogated, such as with whole genome sequencing and whole exome sequencing, that incidental findings are more likely, perhaps occurring in 1% to 3% of patients.[1]

In April 2013, the American College of Medical Genetics and Genomics (ACMG) recommended that clinical labs doing exomic or genomic analysis be required to analyze 56 genes that increase the likelihood of diseases for which there is an intervention, with the results reported back to the ordering clinician, regardless of the specific disease the clinician intended to investigate when he or she ordered the test, and regardless of patient preference or age.[2]

"This is a huge controversy, and it crosses several domains," says **Susan M. Wolf**, JD, McKnight Presidential Professor of Law, Medicine & Public Policy and faculty member at the Center for Bioethics at University of Minnesota in Minneapolis. There are some limited indications in which sequencing is already moving into clinical application, notes Wolf. At times, individual patients are sequenced for a primary indication, in order to help clinicians determine a treatment strategy for their cancer, for example.

In 2012, the ACMG recommended that individual patients must be allowed to opt out of additional analysis to preserve patient autonomy.[3] "We know that genetic information can pack a wallop psychologically, and also can have significant social consequences," Wolf says. "To the surprise of a great many, the 2013 statement urged that whenever an individual is sequenced for any primary indication, [that the additional analysis] be done without the patient's specific consent." If the individual doesn't want the extra analyses, she explains, then the person's only choice is to decline the sequencing altogether, even if they need it medically.

Consensus has stood since at least 1995 that children should not undergo genetic testing for adult-onset disorders, adds Wolf, but should decide for themselves when they reach adulthood. "The reaction to the [ACMG's] rejection of autonomy and the long history of choice in genetics was explosive, and even more so because they said it applied to kids," she says. "What they said was that even if we are talking about variants for adult-onset disorders in kids, the 56 extra genes should be analyzed whenever clinical sequencing is done in children."

While the ACMG recommendations do not extend to research participants, the current controversy over incidental findings in clinical sequencing grows out of a longstanding debate over how to handle incidental findings in research. "There has been great debate

EXECUTIVE SUMMARY

When performing whole genome sequencing, clinicians may encounter incidental findings unrelated to the condition for which the patient was tested. The American College of Medical Genetics and Genomics recently recommended that clinical labs should be required to analyze 56 genes that increase the likelihood of diseases for which there is an intervention.
• There is currently controversy over whether patients should be able to opt out of this extra analysis.
• There is also debate over how to manage incidental findings in research.
• Bioethicists can work with clinicians and patients, as well as researchers and participants, to ethically manage incidental findings.

over which research results are eligible for return, how to offer the results back to people, and how to address the possibility of incidental findings when informed consent is obtained at the beginning of the research process," says Wolf.

Wolf has served as principal investigator of projects funded by the National Institutes of Health (NIH) beginning in 2005, which has issued consensus recommendations about when researchers should offer genetic and genomic research results and incidental findings to research participants.[4,5]

"There is a tremendous amount of research going on now to answer all of these questions," says Wolf. "NIH has really stepped up to the plate, and has formed a consortium of investigators to speed progress."

Actionable or not?

The two primary ethical considerations are whether the incidental findings are "actionable" to allow a better preventative or treatment outcome, and whether the patient wants the information, according to **Gail Jarvik**, MD, PhD, professor of medicine and genome sciences at University of Washington in Seattle. "Maybe searching is reasonable if the patients want the information. If they do not, then it is not," she says.

Jarvik says that if the lab is aware of an actionable finding and the patient wants the information, it should be shared; but if it is not actionable, sharing the information may have more negatives than positives. Notably, the ACMG recommendations extend only to "actionable" genes.

"Labs searching for actionable incidental findings is different than what we do in other parts of medicine. This is presented by some as a simple thing that falls out of a genome, but it uses extra resources," says Jarvik. "It is more akin to adding a glucose test to every blood sample, than noticing an extra spot on an X-ray."

Of the highly contentious issue of whether adult-onset findings in children should be returned to parents, Jarvik says this is reasonable if the parents want the information. "It may appear to differ from our general policy of not testing children for adult-onset disease, but is very different, in that the genetic variant would not be known in the family," she explains. "Thus, its detection may benefit the transmitting parent."

Both in research and in clinical care, there is debate about how much information should be offered back to individuals. Some argue that only information with clinical significance should be given to research participants and patients who are not in research. "Others argue that patients and research participants have a right to get access to their full set of genomic information," says Maschke.

Maschke says these are the central ethical considerations:

- individuals' autonomy to decide for themselves what they want;
- researchers' obligations to inform research participants to satisfy the principle of individual autonomy/decision-making;
- the potential harm of returning information to research participants and patients that has unknown clinical significance. For instance, an individual might obtain risk information about genetic variants associated with heart disease and misinterpret the information in a way that leads her to engage in lifestyle behaviors that are harmful to her health.

"Yet, survey data from some research participants and patients suggest that many people want broad access to their genomic information when their biospecimens are examined in the research context, even if there is not evidence of its clinical significance," says Maschke.

Bioethics role

There are still many significant questions about how to integrate the sequencing of the entire genome into clinical care. "That's why this debate is relevant to ethicists who consult with clinicians," says Wolf. "Also, the whole domain of exome and genome sequencing, right now, straddles the clinical and research worlds."

Most major medical institutions that are conducting studies using whole genome sequencing have some type of bioethics program at their institution. "So there is ongoing education and discussion at these institutions about the ethical issues involved with incidental genomic information," says Maschke.

In addition, many medical institutions are developing programs to offer whole genome and whole exome sequencing to selected patients. "These institutions are working with genetic specialists, clinicians, and bioethics experts at their institutions to develop appropriate educational materials about the issues surrounding genomic incidental findings," says Maschke.

The debate over incidental findings is "enormously important" for ethicists to understand, says Wolf, adding that any protocol that is submitted involving human subjects research needs to consider incidental findings. "Learning how to work with

researchers and clinicians to ethically manage incidental findings is essential, and a big challenge," she says. "This has become a crucial part of the ethicist's knowledge base and tool kit." ■

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Clinician's impairment not related to addiction?

Process is possibly unethical

Most institutions have protocols in place to address clinicians' impairment related to addiction, and most states have programs for clinicians to receive addiction treatment and counseling. However, the situation is likely to be much different if a clinician is impaired for other reasons.

"I worry more about the non-addiction related impairment," says **M. Sara Rosenthal**, PhD, director of the program for bioethics and chair of the Hospital Ethics Committee at University of Kentucky in Lexington. "These situations are murkier, with due process that may be all over the map, depending on the problem and the consequences."

The most typical impairment scenario is due to illness and aging that may elude the clinician until an error is brought to his or her attention. "The oft-cited example of the shaking hands of a surgeon with an early stage neurological disease is not usually the example we see," adds Rosenthal.

Undiagnosed depression can cause clinicians to act in problematic ways with patients or colleagues, for instance. Undiagnosed conditions causing vision changes, such as age-related macular degeneration, cataract, diabetic retinopathy, or glaucoma, can be disastrous for clinicians who have to interpret visual images.

"The tragic scenario is when a serious medical error related to an undiagnosed physical ailment occurs," says Rosenthal. "The clinician is suddenly faced with medico-legal issues in a state of health that is compromising."

In this situation, the clinician is actually in need of medical care, but also becomes embroiled in professional allegations of medical error. "It is a 'doctor as patient' problem. But the 'doctor as patient' may also lose his or her professional life as a result of an unintentional error," says Rosenthal.

Clinicians in this situation typically experience tremendous moral distress when they realize that they may have harmed a patient, while at the same time learning of a serious illness or medical condition they have to treat. They may find themselves struggling with an often harsh institutional due process regarding the legal implications of their impairment or error, says Rosenthal.

"The loss of their clinical privileges and professional lives may be more devastating to them than the news of their illness or condition," says Rosenthal. "But since they are ill, they are also not in the best condition to handle the medico-legal issues."

EXECUTIVE SUMMARY

Patient safety is at risk if clinicians with undiagnosed conditions causing impairment continue to practice, but colleagues often fail to report the impairment. Bioethicists could play a role by:
• helping their institutions develop a culture of compassionate due process for the impaired clinician;
• encouraging clear standards for reporting;
• advocating the creation of a group to assess cognitive competency.

Address "whole" clinician

Rosenthal says the institutional due process for impaired physicians is possibly unethical, if there are not clear protocols in place. "When employment law, patient safety, and risk-management approaches prevail, a harsh process may be initiated for the clinician in crisis, who may not be guided towards appropriate resources," she says.

In these situations, a culture of silence is secured to protect the interests of the hospital, with liability and patient safety issues top of mind. "While it's understandable that the institution just wants the impaired clinician to disappear as quietly as possible, the clinician is still in crisis," says Rosenthal.

At times, clinicians intentionally conceal an illness or condition that they know could cause professional impairment. "Unfortunately, in a patient care setting, this is a frank violation of professional ethical obligations to patient care," says Rosenthal. "There are many clinicians who work while having treatment for serious illnesses without interruption of their professional lives."

Clinicians typically inform their supervisors of their conditions, and ask for necessary accommodations. These may include changing duties such as being on-call or clinical teaching.

Rosenthal says that institutions must deal with impairment in a compassionate manner that addresses the "whole" clinician, not just the consequences of the impairment, which may be serious or even involve litigation.

"The impairment may be easily correctable with treatment, which does not need to end a professional life," says Rosenthal. "On a policy level, clinical ethicists could play a role in helping their institutions develop a culture of compassionate due process for the impaired clinician, who is, after all, also a patient."

Failing to report

"The most common situation we see is failure of peers or trainees to report impairment because of affection, fear, or politics," says Rosenthal. "Failure to report the impairment is a violation of their professional ethical obligations to patient safety."

Eric G. Campbell, PhD, director of research at Mongan Institute for Health Policy and professor of medicine at Harvard Medical School, both in Boston, says that failing to report a cognitively impaired physician is a well-recognized problem. "[Reporting] is the only way that we can get help for the physician and also ensure the safety of their patients," he says. "If a physician is found to be cognitively impaired, I think it is completely unethical to allow them to practice," says Campbell.

Institutions have a further moral and ethical burden to look at the extent to which patients may have suffered negative effects as a result of the clinician's impairment, argues Campbell, adding that ageism is another ethical concern.

"It is unethical to assume that simply because a doctor is older or even very old, that he or she may be cognitively impaired," says Campbell. "I don't think this should be framed as an issue of aging, although cognitive impairment is associated with aging." He says that institutions should:

- have clear standards for reporting;
- allow individuals to do so anonymously;
- identify a group of individuals with the ability to assess cognitive competency and advise the institution on further steps.

Campbell says the bioethicist's primary role is to "continually be the voice to say that the welfare of the patient is paramount."

"At every institution, I would suspect that many people could conjure up a few colleagues who they remember practicing with impairments," says Campbell. "The question is, what does that institution do about it? Do they assign a resident to go after them and clean up after their mistakes, or do they appoint them to be educators and move them into some other function?"

A systematic assessment could help by re-certifying physicians at periodic intervals, suggests Campbell, adding that one of the core responsibilities of medical professionals is self-regulation. "Clearly, in the case of impaired clinicians, the system that exists is completely inadequate to ensure adequate self-regulation," he says. "Hence, with regard to that, the profession is not living up to the implicit contract we've created."

While pilots have a mandatory retirement age, notes Campbell, physicians are allowed to decide on their own when it's time to retire.

"Some physicians have that decision made for them by state licensing boards or hospitals," he says. "One thing we can say with 100% certainty is that the one group we don't want making that decision on their own are people who are cognitively impaired." ■

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Bioethicists, hospitals both benefit from QA committee participation

A bioethicist interested in hospital-acquired infection policies could develop a better understanding of bacterial surveillance and contact precaution implementation through involvement in a nosocomial infection quality-assurance (QA) committee. Similarly, a bioethicist who wants to learn more about how health care providers discuss medical errors could become involved in an intensive care unit QA committee.

However, while QA committees often involve senior clinicians, health care providers, and administrators with specific interests or expertise in the QA area being assessed, bioethicists often lack a clear presence.

"Insofar as bioethicists are represented on these committees, it is more common that a member has separate training or a secondary interest in bioethics, as opposed to having a specific clinical or research bioethicist serve on the committee. There are, however, a number of potential benefits to bioethicists in joining QA committees," says **Andrew Courtwright**, MD, PhD, a physician at Massachusetts General Hospital's Institute for Patient Care in Boston, MA.

Most hospitals have a center for quality and safety that serves as an umbrella organization for the QA committees of individual medical divisions, such as obstetrics and gynecology or pulmonary and critical care medicine, notes Courtwright.

"These committees, in turn, are often subdivided into specific clinic areas — perinatal care, disaster preparedness, or medical intensive care," he says. Ad hoc subcommittees may also meet to consider specific issues such as appropriate intubation thresholds or hospital bed allocation during pandemic flu.

"Relying on patient feedback, morbidity and mortality conferences, self-report from staff, and hospital data collection, subcommittees review patient outcomes and develop system-level policies to prevent or to address adverse events," says Courtwright.

Bioethicists can contribute to discussions about such topics as disclosure of medical error, policy responses to root cause analyses, and adverse event publicity and reporting. "The QA committee environment can introduce bioethicists to a number of clinical conversations that are often handled more abstractly in the medical ethics literature," adds Courtwright.

Collaboration with clinicians

Developing collaborative connections to senior clinicians can foster an environment in which these clinicians are more likely to request clinical ethics consultation from their bioethicist colleagues. "Insofar as QA committee policies may impact clinical ethics consultation — for example, terminal ventilator weaning protocols or palliative sedation protocols — having a member with specific experience in these areas may be useful in developing policy," adds Courtwright.

The integration of bioethicists into QA committees may meet with some resistance from health care providers more accustomed to working solely with clinical colleagues. However, the committees can benefit by actively seeking bioethicist members. "Many QA projects straddle the border between quality improvement and human subjects research," says Courtwright.

Having a member with training in the Office for Human Research Protections requirements would help QA committees decide in advance whether to apply for a waiver of informed consent before embarking on a hospital-wide policy intended to change patient care patterns.

"QA committees are intertwined with the needs and expectations of patients, family, and staff, and are thus interconnected with values," says Marleen Eijkholt, PhD, LLM, a clinical ethics fellow at Alden March Bioethics Institute at Albany (NY) Medical College.

She says that participation of bioethicists in QA committees entails these benefits for the hospital:

• Bioethicists help to translate concerns of different stakeholders.

"By participating in QA, they help to ensure representation of the different stakeholders' perspectives," she says.

EXECUTIVE SUMMARY

Bioethicists often lack a clear prescence in quality assurance committees, but their involvement has many potential benefits for clinical ethics services, clinicians, hospital administrators, and patients.

- Collaboration may increase the likelihood of clinicians requesting ethics consults.
- Bioethicists can offer input on development of protocols such as terminal ventilator weaning or palliative sedation.
- Participation can increase awareness about the function of the bioethicist in the hospital.

• Bioethicists can contribute to the understanding of "good" and "bad" care as components of quality assessment.

For example, while physicians may want to pursue every avenue and technology for a patient, bioethicists may offer reminders that considering quality of life may call for limiting the amount of interventions for patients in defining quality of care.

"Understanding of these different perceptions may be time-consuming. The bioethicist is in a unique position to invest this time," says Eijkholt. "Similarly, bioethicists can broaden and enrich the understanding of effectiveness and efficiency in the process."

• Bioethicists can "build bridges" between patients, professionals, clinical areas, and management.

"Patients could be assured that they are heard on management level, while administrators will understand that their perspectives could be conveyed in the clinic," says Eijkholt.

• Participation by bioethicists enhances visibility of the service, and increases awareness about the function of the bioethicist in the hospital.

"Bioethicists are often faced with the preconception that we are 'policing,'" says Eijkholt. "Participation in these committees can help to debunk this myth, making us more approachable and accessible."

• Participation could enhance trust and validation in QA systems, on both the provider's and the patient's side.

"In order to build trust and optimize communication, familiarity with QA strategies and development is essential," says Eijkholt. ■

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Consent processes for mandatory vaccines are possibly unethical

Health care providers' autonomy is concern

Informed consent is the "bedrock of patient care," even when the patient is a health care provider consenting to a mandatory vaccination, says Christine Nero Coughlin, JD, professor and director of legal analysis, writing, and research at Wake Forest University School of Law in Winston-Salem, NC.

"Informed consent has two prongs — that the patient is informed, and that consent is voluntarily given," she says. "Voluntariness, in this context, means that the decision maker should make his or her own autonomous choice."

Where vaccination is a condition of employment, that autonomous patient choice is taken away. Thus, when the vaccine is mandated as a condition of employment, the health care worker is being coerced into the choice — even if they agree in principle with the vaccine.

"Coercion, in and of itself, is not necessarily unethical," says Coughlin. "When we look at public health legislation and legislation that surrounds the police power of the state, much of it is coercive and it is still ethical and necessary for the common good."

However, when the employee is faced with choosing between vaccination and the loss of employment, says Coughlin, consent to vaccinate is coerced and cannot be considered voluntary.

"While it may be necessary for the common good, it rises to the level of unethical behavior when the hospital or health care institution requires the health care worker/patient to sign the same consent form as those voluntarily seeking the flu shot," she says.

While it is not necessarily unethical to mandate the vaccine, says Coughlin, if the employer chooses to do so, the employer needs to acknowledge that it is a mandate in order to be ethical. "This significant fact should not be disguised by means of a consent form," she says.

While the employee can sign a form that sets forth the risks of the procedure, it should not be labeled a consent form, says Coughlin. "Health care

EXECUTIVE SUMMARY

Informed consent is a key ethical concern when health care providers are consenting to a mandatory vaccination, since autonomous patient choice is not possible where vaccination is a condition of employment.
• Employers should not require the health care worker/patient to sign the same consent form as those voluntarily seeking the flu shot.
• The employer needs to acknowledge the fact that the vaccination policy is a mandate.
• The risk of harm to the health care worker needs to be weighed against the risk of harm to patients.

employers can easily fashion an alternative form to satisfy institutional and liability concerns about a health care worker/patient's adverse reaction," she adds.

Some employers allow for exceptions, but then require a change in the health care worker's employment status. For example, they might require unvaccinated workers to use masks, respirators, or different colored badges or name labels during flu season; to take a leave of absence during flu season; or to be reassigned to a non-patient care area.

"If the health care worker refuses this change in employment status, in some cases, the health care worker's employment may be terminated," says Coughlin. "The severity of the sanction will increase the level of concern."

The determination of whether this rises to the level of an ethical concern will require an examination of whether the sanction is really necessary to improve public health and decrease the risk of infection, or whether it is simply punitive in nature, stigmatizes the employee, or somehow violates the employee/patient's confidentiality rights, says Coughlin.

"In the end, this decision would likely require a balancing of the risk of harm to the health care worker versus the risk of harm to the patients," says Coughlin. ■

SOURCE

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Is specific recommendation rejected? Continue work

Be persistent in promoting discussion

In a recent case, a nephrologist declined to confront a family member demanding continued hemodialysis for a permanently non-responsive patient in multi-organ failure. "We attempted to educate the doctor on ethics practice guidelines from his sub-specialty, indicating that hemodialysis is not beneficial and may appropriately be discontinued in such situations," recalls **David M. Adams**, PhD, MLS, a clinical ethicist at Pomona (CA) Valley Hospital Medical Center.

This case illustrates both the limitations of the effectiveness of an ethicist's advice and the results when such advice is ignored, says Adams. "In this case, the patient lingered near death in the intensive care unit for many weeks, creating moral distress for the dialysis nurses and utilizing resources that might better have been devoted to hospice care," he adds.

Adams says that the best approach for an ethicist to take when his or her advice is rejected, is to "not lose heart, to maintain working relationships with providers, patients, and surrogates, and look for opportunities to promote moral reflection, dialogue, and further education."

Seek continued dialogue

- If a family requests that information about a grave diagnosis be withheld from a patient, the ethicist might recommend in favor of offering the patient the truth.
- When a physician refuses to remove a feeding tube, maintaining it is not "medical treatment," the ethicist might disagree, arguing that artificial nutrition and hydration may be, and should be, removed.
- An ethicist might recommend that the treatment team adhere to the instructions in an advance directive, even though one or more members of the team don't feel comfortable following the patient's wishes.

Any of these recommendations might be rejected, says Adams. "The ethicist's response will depend upon the situation," he adds. "Because an ethicist's recommendations are advisory, he or she cannot demand compliance, but must instead continue to work with the involved parties."

If a family refuses to consider no-code status, Adams says the ethicist should be persistent in seeking to understand the goals of the family and promote further discussion with the treatment team. "If a physician won't consider discontinuing tube feedings in a

EXECUTIVE SUMMARY

Occasionally, clinicians, patients, or surrogates reject an ethicist's advice or recommendations. In this scenario, bioethicists should seek to maintain working relationships and continue dialogue. Some approaches for bioethicists to consider:

- Remind individuals of their obligations under the law as surrogate decision makers.
- Promote further discussion if a family refuses to consider no-code status.
- Call for support from the hospital's legal or risk management department.

patient with end-stage dementia, the ethicist should be prepared to support his or her recommendation with evidence from the literature regarding the ill effects of continuing medically provided food in patients whose gut and other organs are shutting down," he says.

The patient and the family may disagree because they are requesting more aggressive therapy than is being offered or recommended by the medical team, and the ethics team deems the medical decision ethically permissible. At times, patients or families want therapies removed or stopped when hospitals do not.

"Ethics consultations might side with the medical team not to remove therapies," says **Tracy Koogler**, MD, assistant director of the University of Chicago's MacLean Center for Clinical Medical Ethics. Examples might be high quadriplegics on ventilators, or parents who do not want traditional medical therapies for children with cancer.

"As long as the ethicist believes the plan of action being planned is not against a state law and does not harm the patient, then I think they need to let the decision stand," says Koogler. The bioethicist might seek further discussion with the medical team or family, she adds, and perhaps call for other support such as the hospital's legal or risk management department.

"For staff, many of these situations cause moral distress. Through the early engagement of bioethics, some moral distress can be relieved if the bioethicist is able to assist with or facilitate decisions that avoid harm, and do that which is beneficial — such as addressing pain management," says **Bob Parke**, BA, BSW, MSW, MHSc Bioethics, a bioethicist at Humber River Hospital in Toronto, Ontario, Canada. He offers these situations in which others have disagreed with a bioethicist's recommendations:

• Surrogates or family members not agreeing to pain medication being administered at the end stages of a terminal disease.

In this case, Parke and a colleague spent time with the surrogate and family to review the need for pain medication and explore why they did not want appropriate levels of pain medication. "We reviewed that the patient was incapable to make his own decision about treatments including pain management," he says.

Since the patient had not expressed any previous wishes, the ethicists reminded the surrogates of the legal principles for making decisions, including the law's "best interest" standard. "With time, we were able to get agreement to provide appropriate level of pain management," says Parke. "If we were not successful in the short term, we could have challenged the surrogate decision making through a legal process."

Another option, says Parke, would have been to recommend the application of the emergency provision of the law in which consent is not required to save a life or relieve immediate suffering.

• Families wanting "everything" done when there is no benefit.

If the surrogate decision maker or family does not agree with the proposed treatment plan, the bioethicist — with the team's agreement — can propose that a third party legal tribunal be utilized. The bioethicist explains the legal process to the surrogate decision maker.

"The bioethicist, using a checklist, also helps ensure that all the necessary steps have been taken prior to the hearing," says Parke.

These include making an assessment of capacity, having meetings to review the treatment proposal, and reviewing the laws for decision making, including making sure that the correct surrogate decision maker(s) is (are) identified. "If it is clear that a case is heading to a hearing, hospital administration, including risk management, is actively involved," says Parke. "This requires meetings in which the bioethicist is present as one of the team members."

If the hearing is taking place, the bioethicist may be called as a witness to establish that the consent and substitute decision-making process had adequately taken place.

In a recent case, the bioethicist was present during meetings with the family to remind them of their obligations under the law as surrogate decision makers and to inform them of the legal process. "The outcome was that the board sided with the hospital's treatment plan of palliative care rather than doing 'everything,'" says Parke.

• Surrogates insisting on feeding tube placement at the end stages of dementia.

"This is fairly common," says Parke. "In my experience, a lot of families still don't know that feeding and swallowing problems are part of the dementia trajectory. My goal is to try and help

COMING IN FUTURE MONTHS

- Ethical concerns involve microbes
- Ethical approaches for "difficult" doctors
- Evaluate effectiveness of ethics consults
- Translating neurotechnology to clinical practice

families to be at peace with a decision they need to make."

Parke takes every opportunity to discuss with physicians the need to inform patients or their families about the problem of swallowing. "By doing so, informed decisions can be made. This includes giving time to families to speak with physicians, clergy, dietitians, and/or speech language pathologists," he says. "I also try to attend family meetings at long-term care homes to address these issues before a crisis."

• Attending physicians' moral discomfort with de-activating an implantable cardioverting defibrillator (ICD).

A patient at the end stages of his life wanted to make sure his ICD was de-activated prior to his death. "He had heard that he could have painful shocks even as he is dying. His wife was a strong advocate for him and seeing his wish achieved," says Parke. The attending physician was reluctant to de-activate the ICD, as he had a moral concern that he could be causing the person's death.

"This disagreement was resolved relatively easily. I advised the attending physician to transfer care to a palliative care physician who was willing to ensure the ICD was de-activated, and that the patient's comfort was maximized," says Parke. ■

SOURCES

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