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INSIDE

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Ebola spotlights growing tension between patient autonomy and public health

Bioethicists "can and should" be part of conversation

Should cardiopulmonary resuscitation (CPR) be given to end-stage Ebola patients, despite the risk to health care providers? What training is necessary at this point to ensure staff and patients are protected?

As hospitals grapple with these and other questions surrounding treatment of Ebola patients, bioethicists need to be involved, urges **Janet L. Dolgin**, PhD, JD, co-director of the Hofstra University Bioethics Center in Hempstead, NY. Dolgin is also director of the Hofstra University's Gitenstein Institute for Health Law and Policy.

"Without prescriptions and guidelines, we flail around and fail. But once they get cemented in stone, we're in trouble," she says.

One ethical concern with Ebola is to avoid treatment "that's a product of fear rather than well thought-out responses," Dolgin says. "We need policies. But at the same time we need to be ready to challenge them."

Bioethicists are well-suited to help

EXECUTIVE SUMMARY

Bioethicist involvement is necessary as hospitals develop policies involving treatment of Ebola patients.

- Patient autonomy may have to be limited to protect the public health.
- There is a duty to provide necessary care, and to ensure a patient is not abandoned.
- Hospitals have an obligation to provide proper care for Ebola patients within the limits of their resources.

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craft organizational policies, suggests Dolgin, in light of their dual focus on population health and on the health of individuals.

R. Alta Charo, JD, Warren P. Knowles professor of law and bioethics at University of Wisconsin Law School in Madison, WI, points to other situations that posed similar challenges for bioethicists, such as the early years of the AIDS epidemic when there were no therapies for the disease.

"HIV infection was viewed as a near-term death sentence," she says. Many hospitals and medical practices had to decide whether any or all staff might refuse to provide care, based on fear for their own safety.

Many institutions viewed the duty to care as an institutional duty, and allowed individual providers to recuse themselves, provided that someone was there to care for the patient. "In other facilities, this was viewed as an unfair burden on those who would be left to provide the care, and [those facilities] insisted that all providers participate," says Charo.

Limitation of patient autonomy

The history of the field of bioethics is very relevant to understanding the current ethical concerns involving treatment of Ebola patients in the United States, according to Dolgin.

"Bioethics was put together as a discipline in the 1970s, at a time when it looked like we could handle disease, particularly contagious diseases," says Dolgin. "We had all sorts of vaccines, and there really wasn't much threat to clinicians."

Bioethics' current "enormous stress" on patient autonomy is really a product of that era, says Dolgin. "That now comes up against public health issues, where today we are faced with a whole slew of serious illnesses that are contagious or highly infectious," she explains.

This spotlights the public's discomfort with the limitation of patient autonomy to protect the public health. "If Ebola is controlled fairly soon, then we won't face these issues in the context of Ebola," says Dolgin. "But we will face them with other conditions."

How to strike a balance between beneficience to an individual patient and respect for patient autonomy "is one of the most compelling questions in bioethics today," says Dolgin. "Similarly, bioethicists focus on balancing protection of the public and of clinicians with the preservation of liberty interests."

No duty to provide futile care

Some have suggested that CPR not be given to end-stage Ebola patients both to protect clinicians and because it's essentially futile care.[1]

When developing policies to address this, Dolgin cautions against absolutes. "To say you will think very carefully before you offer 'everything,' including CPR, to Ebola patients is very different from saying you will 'never' do so," she says.

For many hospitals, it is not possible to ensure proper isolation and infection-control measures. "They don't have the space or personnel to do this without endangering other patients," Charo explains. There is an obligation, however, to provide proper care for Ebola patients within the limits of the hospital's resources.

Some procedures pose

significantly higher risk to providers than others, says Charo, but "those same procedures are typical of last-chance measures that, if needed by an Ebola patient, would indicate the disease had progressed to the point that heroic measures would likely be futile."

There is no duty to provide futile care. "But there is a duty to provide necessary care, and to ensure a patient is not abandoned," says Charo. "If a facility is unable to provide necessary care, the patient should be treated somewhere that can."

Improving preparedness: "Ethical imperative"

Hospitals and the U.S. health care system are frequently criticized, "often justifiably so," says **Jason. L. Schwartz**, PhD, the Harold T. Shapiro Fellow in Bioethics at the Princeton (NJ) University Center for Human Values. "But overall, the response to Ebola has demonstrated the U.S. health care system at its finest."

However, he says, the experience with Ebola diagnosis and treatment in the United States, to date, has "shone a bright light" on the critical need to enhance training, education, and preparedness in hospitals nationwide.

"This is not simply an essential component of high-quality medical and public health practice," says Schwartz. "It is an ethical imperative as part of efforts to protect health care workers and to best serve patients."

Some uncertainty was inevitable in the response to such an unfamiliar disease threat. "But the experience in Texas underscored the importance of developing clear guidelines to protect health care personnel that are tailored specifically to the U.S. health care environment," Schwartz says.

This highlights the need to ensure that all health care personnel are adequately trained and prepared to translate those guidelines into practice as part of patient care activities. "The response to Ebola cases in the United States also exposed troubling gaps in coordination among federal health officials, state and local authorities, and hospitals," adds Schwartz.

A key task for the U.S. medical and public health community moving forward will be understanding and correcting the deficits revealed in the response to the tragic case in Texas and the subsequent infections among nurses caring for that patient. "Bioethicists can and should be part of such conversations," says Schwartz.

To achieve ethical care, he says, bioethicists "should aim to strike an appropriate balance among the needs, rights, and concerns of potential future Ebola patients, non-Ebola patients in those same facilities, health care personnel, and the community at large." ■

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ACA shifts liability to patients: Bioethicists must be "watchdogs" to ensure ethical care

Unethical practices are concern

The ethical justification for the Affordable Care Act (ACA) is distributive justice, with the goal of making health insurance available to more Americans, notes **Dennis M. Sullivan**, MD, director of the Center for Bioethics at Cedarville (OH) University.

"This has clearly succeeded, at least in part, but at the cost of a loss of autonomy. Is it worth it?" he asks. "Now, more than ever, there is a strong need for bioethicists."

Ethics professionals must be advocates, both for physicians who want to be compassionate clinicians, and "to defend the human dignity of the patients who get lost in the shuffle," says Sullivan.

Ensure hospitals "play by the rules"

As the implementation of the ACA continues, medical ethicists must serve as "watchdogs" at the organizational level, urges **Philip M. Rosoff**, MD, director of clinical ethics at Duke University Medical Center in Durham, NC.

Bioethicists can play a major role in ensuring that healthcare institutions "play by the rules," says Rosoff — staying fiscally solvent while not sacrificing patient care.

"They can also scrutinize activities that may serve to aggravate already existing inequities between patients," says Rosoff. These include patients' ability to pay for their care and the quality and amount of insurance they carry.

"One could imagine that the habit of many institutions to treat so-called VIPs differently — bigger and nicer rooms, better food, more customized care — could become more exaggerated," says Rosoff.

This could further marginalize many populations already at risk. "It would also serve as a very poor example of fairness and equity to trainees, young physicians and nurses, and, of course, the public," adds Rosoff.

For institutions in dire financial straits, this approach could be seen as an opportunity to improve the bottom line. "I would hope that bioethicists could monitor these activities, and perhaps serve as calm voices — a conscience, even — to minimize their appeal," says Rosoff.

Patients face higher costs

The cost of care remains an ethical concern, especially in light of higher out-of-pocket expenses for insured patients. "Presumably, high-deductible plans, coupled with an ever-expanding number and scope of co-payments, is to lessen the cost of the overall premium that is paid," says Rosoff.

However, this means some people will avoid or delay needed care. Thus, health care institutions could be faced with patients presenting with more advanced disease, which could have been treated simply and more cheaply if therapy had been initiated earlier.

"For some people, this could be both a life-endangering procrastination and a threat to their fiscal solvency," concludes Rosoff.

Shifting financial responsibility to patients is presumably aimed at keeping plans affordable, with some modicum of coverage for major medical problems. "I suppose that the only way to determine if the goals are being reached — meaning inducing more responsible use of health care by people with high-deductible plans — is to see if that actually happens," Rosoff says.

If a delay in seeking treatment necessitated much more high-priced diagnostic and therapeutic interventions, however, this could easily offset the amount saved by the insurer upfront.

"It is unclear to me that this strategy will spur more health-related responsibility by the newly insured," says Rosoff.

Outcomes remain to be seen

The fact that many preventive services are now completely covered balances, at least in part, the increased out-of-pocket expenses for patients. "Whether the ACA will actually result in better health outcomes and reduced health care costs remains to be seen," he says.

The World Health Organization statistics indicate, for example, that the United States is 43rd in the world in infant mortality. "It will take a long time to see if better access to insurance will help decrease the infant death toll, especially among minorities," says Sullivan. Here are some other ethical concerns involving the ACA:

• Many physicians report that electronic medical records (EMRs) interfere with patient interactions.

"Mandated EMRs have been met with widespread disapproval by patients and doctors alike," Sullivan notes.

• Increased emphasis on efficiency and numbers may be detrimental to patient care.

"Current trends favor volume over quality, decreasing the time that a doctor spends with each patient to hear the main complaint and to do a good review of systems," says Sullivan. This increases the reliance on blood tests and X-rays, driving up costs.

• The ACA does not address tort reform.

"Defensive medicine and its contribution to high costs will continue," predicts Sullivan. "With the doctor-patient relationship deteriorating, this exacerbates the problem of litigation-minded patients." ■

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Providers need reminder: End-of-life decisions aren't only up to patient and family

Concept of futility "necessary and reasonable"

At the University of Missouri School of Medicine in Columbia, MO, about 80% of ethics consults are called for patients who are either dying or near death in the critical care setting, estimates **David A. Fleming**, MD, MA, FACP, professor of medicine, chairman of the Department of Medicine and director of the Center for Health Ethics.

"Where patients are not doing well and we continue to add treatments and support, hoping for a turnaround that does not occur, we find ourselves in a situation where we are using an immense amount of technology with the prognosis very poor," says Fleming.

This can also occur in the outpatient setting if patients get to a point at which the ongoing burden of treatment, such as dialysis or chemotherapy, is greater than the benefit they're deriving.

"Patients sometimes appear to be doing quite well from the family's or even the provider's standpoint," says Fleming. "That's often very tricky, because the patient is up and about."

In one such case, a patient's need for ongoing blood transfusions became much more frequent. He told Fleming, "This is becoming too hard for me." The patient went home and committed suicide.

"That was a wakeup call for me," says Fleming. "If the patient says, 'This is really becoming too hard for me,' we need to listen to them. That is a good time to call an ethics consult."

Providers are trained to treat patients, not to withhold treatment, and don't want to believe that their efforts have failed. "It's hard to know where to draw that line," Fleming says. "But at some point, futility is a reasonable and a necessary concept to embrace."

Early involvement is key

There will always be cases with conflicts, but "it certainly helps when ethics is involved earlier rather than later," says **Christine Mitchell**, RN, MS, FAAN, executive director of the Center for Bioethics at Harvard Medical School in Boston, MA. Here are strategies to avoid conflict when the clinical team anticipates there might be disagreement on what's best for a particular patient, or when ethicists identify such cases on rounds:

• Have a smaller number of clinicians care for the patient.

"When you flag a patient like this, you want to narrow the numbers of staff so there is better continuity of care than is sometimes the case, especially with big ICUs [intensive care units] with hospitalist services," says Mitchell.

A small team of primary nurses and attending physicians can then enter into a verbal agreement with the patient or the surrogate decision maker. The group might agree to trial a treatment and reevaluate it after 48 hours.

"In some cases, the team doesn't think it's beneficial, but the patient's decision maker thinks it is, and there's enough doubt to make it worth trying," says Mitchell.

Ideally, the same caregiver is there 48 hours later to discuss the situation, and to remind the family member that they would not continue the treatment if it wasn't beneficial. "Then it's possible to hold people to the agreement that they entered into," says Mitchell.

• Assign more experienced providers to difficult cases.

"Where staff recognize that there is going to be a mismatch of values, you can then be alerted that this is a family that needs some of the most experienced staff working with them," says Mitchell.

• Consider leaving the

EXECUTIVE SUMMARY

Early involvement of bioethicists can help avoid conflicts when the clinical team anticipates there might be disagreement on what's best for a particular patient. Bioethicists can:

- Have a smaller number of clinicians care for the patient.
- Assign more experienced providers to difficult cases.
- Remind providers that healthcare decisions are not entirely up to the patient or the patient's surrogate.

cardiopulmonary resuscitation (CPR) decision to a later point in time.

"There's a lot of controversy about this," acknowledges Mitchell. "But I think fighting about the CPR decision in the beginning is a big mistake." This can lead to families becoming fiercely protective out of fear that their loved one won't be resuscitated.

"Sometimes it's worth letting the CPR/DNR [Do Not Resuscitate] decision go. Recognize that if the patient's heart or breathing stops, that you will intervene and call a code, and when the code isn't effective you will stop," says Mitchell.

If the code only results in restarting the heart but the patient doesn't get any better and will code again, the clinical team can raise the issue again. "At that point, the family understands, especially if they attended the code, that it is a pretty traumatic set of activities," says Mitchell.

• Reinforce with providers that health care decisions are not entirely up to the patient or the patient's surrogate.

"Some of us working in the field for decades are pretty familiar with families who just don't accept that their loved one is brain dead, or has a diagnosis from which they can't recover," says Mitchell.

Providers struggle with deciding whether their responsibility to protect a patient from non-therapeutic medical treatment overrides their responsibility to respect the surrogate's view that treatment should continue.

"We have a policy with a process for handling disagreements about potentially harmful medical treatments," says Mitchell. "For us, that process involves the chief medical officer and hospital administrator."

When necessary, these individuals are made aware of such disagreements. "This is so bedside staff are not out on a limb making decisions about whether to refuse to do something they think is wrong," says Mitchell. In such cases, which are very rare, providers sometimes negotiate to transfer the patient if they can't come to an agreement.

"Patient autonomy has become so deeply embedded that some health care providers don't feel like they retain any responsibility themselves," says Mitchell. "We talk about shared decisions because those responsibilities are shared." ■

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Undocumented patients face unique ethical concerns with end-of-life care

Ethicists must "use their moral suasion"

In one sense, undocumented patients are like any other patients — some have health insurance, but many will not. "What's particularly challenging is that undocumented patients who are uninsured will usually not qualify for the safety net programs that provide assistance for similar patients with citizenship," says **Mark Kuczewski**, PhD, chair of the Department of Medical Education and director of the Neiswanger Institute for Bioethics at Loyola University in Maywood, IL.

As a result, undocumented patients are particularly vulnerable to unjust treatment, he says — especially those with chronic or long-term conditions.

"It is imperative that ethicists use their moral suasion to advocate for quality care and options equivalent to those established as standard for similarly situated uninsured patients," urges Kuczewski.

Avoiding care due to fear of deportation

Many undocumented patients lack access to medical care or treatment, unless they visit the emergency department. "It is important for medical providers to understand that failure to follow up with return medical appointments or medications may be because of limited funds and no health care insurance, rather than

resistance to medical treatment," says **Elaine P. Congress**, DSW, LCSW, associate dean and professor at Fordham University in New York City.

Some undocumented individuals avoid medical treatment completely because they view medical providers as associated with Homeland Security, Congress adds.

"Certainly the most dramatic unethical practice is forced medical deportation," says Kuczewski. "This situation arises when a patient needs long-term medically complex care but is no longer suitable for the acute care environment."[1]

For instance, a hospital might try to discharge an injured patient who needs long-term ventilator support to their country of birth. "To do so without the informed consent of the patient is ethically inappropriate, as it violates a basic norm of clinical ethics," argues Kuczewski.

Furthermore, forced medical repatriation is likely to harm the relationship between the hospital and the local immigrant community. "If the community views the hospital as an arm of immigration enforcement, many patients will not present until much later in their course of illness, resulting in poorer outcomes and more costly care," says Kuczewski.

"Ethically indistinguishable" care

End-of-life decision making for undocumented patients should be "ethically indistinguishable" from the decision-making process utilized with any other patient or family, says Kuczewski.

"End-of-life care [for undocumented patients] poses challenges at both ends of the ethical spectrum," he notes. As with any uninsured patient, there may be implicit pressures to transition to comfort care in order to relieve the institution's financial burden.

"However, anecdotal evidence also suggests that sometimes well-intentioned care teams may be reluctant to transition the patient to comfort care, out of fear that they might be using death to relieve financial dilemmas," says Kuczewski.

As a result, some undocumented patients end up being overtreated, because health care teams are reluctant to recommend forgoing or delaying procedures.

"The goal for ethicists must be to assist undocumented patients and their families to make end-of-life decisions in a manner that is appropriate for the patient, based on his or her medical situation and values," underscores Kuczewski.

Few receive organ transplants

Some high-profile cases have spotlighted the difficulties of undocumented patients in need of organ transplants such as kidneys or livers, including finding funds for follow-up care such as anti-rejection medications.[2]

"Again, the challenge is to help facilitate treatment that is similar to the way other patients are treated. This is the bioethical principle of justice," says Kuczewski.

U.S. citizens and residents who are patients with renal failure are virtually all covered by Medicare to receive dialysis or a kidney transplant. "Justice requires that the hospital do all within its power to deliver similar treatment to their patients," underscores Kuczewski.

Administering dialysis on an ongoing charity care basis is more humane and, often, more cost effective than having the patient represent in extremis at the emergency department each time they are in crisis, he adds.

"It may fall to the ethicist to help his or her colleagues understand that when an undocumented patient is uninsured, that patient is treated like any other uninsured patient," says Kuczewski.

In some cases, that may mean that the patient does not receive needed treatments. "Few indigent and uninsured patients receive liver transplants in the United States," notes Kuczewski.

A patient's undocumented status does not impose some new obligation on a hospital to provide care it normally does not offer to other uninsured patients, Kuczewski explains. "While this is tragic, and we can argue about whether such care

EXECUTIVE SUMMARY

Undocumented patients are particularly vulnerable to unjust treatment, particularly those with chronic or long-term conditions. Bioethicists can advocate for ethical care by:

- Adhering to the same good practices for end-of-life decisions that are used for other patients.
- Ensuring that providers are not erroneously evaluating the relative benefits and burdens of medical treatment.
- Seeking discussions with administrators who oversee charity care and medically complex discharge policies and procedures.

should be provided to everyone, we must be careful not to give significance to a patient's immigration status where it is not relevant per se," he says.

Kuczewski recommends these practices to ensure ethical care of undocumented patients:

• Adhere to the same good practices that are used to facilitate quality end-of-life decisions for other patients.

"Ethicists can help the health care team to be sure they are not erroneously evaluating the relative benefits and burdens of medical treatment," he says.

For instance, clinicians might assume that they cannot discharge a patient who has homecare needs because of a lack of benefits for such care. In such cases, bioethicists can suggest partnering with families to find potential alternatives such as hiring informal caregivers who can be trained to address the patient's basic needs.

"Conversely, out of fear of too quickly giving up on the patient because of immigration status, teams may cling to very low probabilities of meaningful recovery," he adds.

• Seek discussions with high-level administrators who oversee charity care and medically complex discharge policies and procedures.

During these meetings, bioethicists can actively participate in finding creative solutions to ensure undocumented patients receive the same level of care and options as other patients. "These discussions should not be one-sided," says Kuczewski. ■

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Patients need guidance when sharing genetic screening results: Consider ethics

Information isn't always beneficial to family members

A patient came for a consult for a prophylactic bilateral salpingoopherectomy — the removal of fallopian tubes and ovaries — because of a strong maternal family history of breast cancer.

"The patient's mother had breast cancer, but did not want to get genetic testing for BRCA mutation, as recommended, because she 'did not want to know,'" says **Janet Osborne**, MD, associate professor at Virginia Tech Carilion School of Medicine and Research Institute in Roanoke. Osborne is also section chief in the Division of Gynecologic Oncology.

The patient had the testing done and was found to be BRCA1 mutation positive. "By default, that would mean her mother was as well," says Osborne. "Our patient chose to disclose this information to her mother anyhow, in hope that her mother would have appropriate prophylactic surgery."

The patient also disclosed the results to other family members, several of whom went on to have testing themselves and were also found to be mutation carriers. "In this case, lives have been saved by disclosing information that was not requested initially by the individuals themselves," says Osborne.

EXECUTIVE SUMMARY

Patients are often reluctant to disclose abnormal results of genetic testing to other family members who may be impacted by the information. Ethical considerations include patient privacy and acting in the "greater public interest." Providers should:

- Assist the patient with communication of results to family members.
- Avoid assuming that obtaining genetic information is beneficial to all family members.
- Provide materials to help patients explain genetic results.

Patients need guidance

Because genes are shared in families, a genetic test of one person can alert others in the family that they may also have inherited the same flawed gene. "For example, a test result that indicates the presence of a BRCA1 or BRCA2 susceptibility gene raises the chances of breast cancer during a woman's lifetime from about 10% to as much as 80%," says **Doris T. Zallen**, PhD, professor in the Department of Basic Sciences at Virginia Tech Carilion School of Medicine in Roanoke and the Department of Science and Technology in Society at Virginia Tech in Blacksburg. Zallen is author of *To Test or Not to Test: A Guide to Genetic Screening and Risk and Does it Run in the Family? A Consumer's Guide to DNA Testing* (both Rutgers University Press).

Patients often do not want to disclose abnormal results of their own genetic testing to other family members who may be impacted by the information, however. "Ethical considerations are patient privacy and acting in the 'greater public interest,' which in this case, consists of a small group of relatives," says Osborne.

The United Kingdom General Medical Council's guideline allows a physician to disclose a patient's genetic information to at-risk family members if the patient refuses to do so. "However, in the U.S., many states have laws specifically protecting the confidentiality of genetic testing without the patient's informed written consent," notes Osborne. She advises that physicians or genetic counselors take these steps:

- **Address the possibility of inviting family members to participate in the testing process during pre-test counseling.**
- **Be available to assist the patient with communication of results to family members.**

Having genetic information about one person can open the door for others in the family to undergo testing to determine their own genetic status.

"If the same susceptibility gene is found, family members can have more frequent medical monitoring to detect any disease state early when treatment is most successful," says Zallen. They may choose to go further and opt for risk-reduction strategies such as drug treatments and even surgical removal of organs at risk.

"This ability to help others in the family, allowing them to take action to reduce their risk, is often the reason given for having genetic testing," explains Zallen.

For some, a burden

While genetic information can benefit some families, for others it can be an unwelcome burden. "Not every person in the family may benefit from knowing his or her genetic status," says Zallen.

Such knowledge can create emotional difficulties as people cope with effects of living with what some call a "ticking time bomb." "Emotional difficulties can be intense if there is no way currently available to reduce the risk, as is the case with Alzheimer's disease," says Zallen.

There can be survivor guilt if some family members are found to have the flawed gene, while others are spared. Parents may suffer when they learn they have passed on a flawed gene to children.

"In some cases, family tensions arise as people with the flawed gene are marginalized, or find that fingers of blame are being pointed their way," says Zallen.

Problems obtaining insurance is another concern. "Given the past history of genetic discrimination in the U.S. and the breaches of medical and other records that have been reported recently in the media, people are concerned about maintaining the privacy of their genetic information," says Zallen.

The Genetic Information Non-Discrimination Act of 2008 provides protection against the use of genetic-test information in health care insurance and employment, but it does not cover long-term care insurance, life insurance, or disability insurance.

"Obtaining genetic information cannot be assumed to be beneficial to all family members," underscores Zallen.

Obligation is on the patient

Health care providers should convey the strengths and limitations associated with genetic testing with patients considering genetic testing for themselves, or who are facing the challenge of informing other family members, recommends Zallen.

"Genetic counselors are trained to do this, but there are too few of them to meet the need," she says. "Many people simply do not have access to genetic services."

Health care professionals have pledged to maintain patient privacy and they have neither time nor resources to identify and track down family members, adds Zallen. Therefore, it is up to each patient to make the results known within the family.

"However, health care professionals should certainly encourage patients to do so," says Zallen. "They should provide them with written or other materials to help in explaining genetic results to others." ■

SOURCES

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Research participants' social media use can compromise study's validity

Blogs, message boards, and patient communities are being used not only by patients, but also by research participants. In some cases, this reveals whether or not a participant is taking actual medication or placebos, compromising the study's validity.

"Some research participants are using social media to have public discussions on the enrollment process and side effects experienced," reports **Katrina A. Bramstedt**, PhD, a clinical ethicist and professor at Bond University School of Medicine in Australia, and former faculty in the Department of Bioethics at Cleveland (OH) Clinic Foundation.

"Some people even attempt to use clinical trials as a 'second opinion,'" says Bramstedt.[1] "All of this creates the potential to impact the integrity of a study, due to the risk of the injection of bias."

This can lead to breaking of study blinding, or inappropriate participants falsifying information in order to meet inclusion criteria.

"The most important thing is to never violate the integrity of a study," says **Jonathan L. Halperin**, MD, director of Clinical Cardiology Services in the Zena and Michael A. Wiener Cardiovascular Institute at The Mount Sinai Medical Center in New York City.

Participants' communication on social media could alter the behavior of study participants, compromising the study's findings. For instance, if researchers are evaluating a treatment for hypertension and know that people are often non-compliant with the recommendation for an exercise regimen, social media could potentially skew the results.

"If suddenly the behavior of a group of participants was changed as a result of communication, the study would no longer reflect the real world," says Halperin. "That would reduce the generalizablity of results."

The study's findings would no longer apply to the typical patient with hypertension. "We would then need to quantify the results, to reflect that 93% of participants were engaged in a social network that potentially influenced their concomitant management," says Halperin.

Researchers go to great pains to validate outcomes, he emphasizes, and if social media use undermines scientific integrity, "it can be harmful and wasteful."

Results are undermined

The goal of research is to create reliable new knowledge, free of researcher bias and based on accurate information obtained from willing participants, says **Edward Goldman**, JD, associate professor of the ObGyn Program in Sexual Rights and Reproductive Justice at the University of Michigan Health System in Ann Arbor.

"To the extent that participants do things to undermine the validity of the research, the results are not useful," says Goldman.

If participants try to find out which arm of a study they are in, or compare information with other participants, they can harm the study's validity.

"The ethical goal of research is therefore damaged," says Goldman. While a participant can always decide to discontinue being involved in research, this does not mean a participant can decide not to follow the rules while continuing in the study.

"Of course, participants have rights to autonomy," says Goldman. "But in deciding to participate,

EXECUTIVE SUMMARY

A study's validity can be compromised if research participants communicate inappropriately with one another via social media. Some solutions:

- Have participants agree prior to enrollment that they will not use social media to attempt to determine which study arm they're in.
- Make participants aware that social media can harm the study's integrity.
- Specify participant confidentiality requirements in the consent form.

they are agreeing to follow the rules of research — even if that means limiting autonomy."

Some participants use social media to discuss adverse events, instead of bringing these to the attention of researchers. "Truly important matters that should be discussed with the research team can, instead, be taken directly to the Internet for 'community consultation,'" says Bramstedt.

Education before enrollment

Researchers should be proactive to limit harmful effects of social media use, advises Goldman, by stating prior to enrollment, "If you decide to participate in this research, you agree that you will not share information or use social media to attempt to determine which arm of a study you are in. You understand that research is not treatment, but rather, is a scientific approach to see if a theory has practical application, and that research only produces reliable results if the scientists and participants rigorously follow the rules."

Most research participants are likely unaware of the potential of their social media use to impact study integrity. Bramstedt recommends including a section in the consent form titled "Participant Responsibilities," or using the confidentiality section to specify participant requirements.

"Research teams and sponsors may need to patrol the Internet while their study is in operation, to ensure adherence to confidentiality requirements," she adds. "This should be disclosed in the consent form."

During the enrollment process, the research team can carefully review these sections of the consent form with the participant. Researchers could make participants aware that sharing information on social media could potentially lead to participants' loss of insurance or employment.

"We cannot prevent a participant or a patient from sharing medical or research information through social media," says Goldman. "But we can and should make it clear what the dangers of such sharing could be." ■

REFERENCE

1. Glickman SW, Galhenage S, McNair L, et al. The potential influence of Internet-based social networking on the conduct of clinical research studies. *J Empir Res Hum Res Ethics* 2012; 7(1):71-80.

SOURCES

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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

- Update on debate over unilateral DNR orders
- Ethical controversy over Ebola vaccine trials
- Ethical responses to bullying behaviors by clinicians
- Improve palliative care in emergency department setting

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

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3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.

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CME QUESTIONS

1. **Which is recommended if bioethicists identify cases in which there might be disagreement, according to Christine Mitchell, RN, MS, FAAN?**

   A. Narrow the number of staff so there is better continuity of care.
   B. If a family member agrees to trial a treatment with a particular caregiver, always have a different caregiver remind the family member that they would not continue the treatment if it wasn't beneficial.
   C. Always make a definite decision about whether cardiopulmonary resuscitation will be given early in the process.
   D. Avoid informing the chief medical officer or hospital administrator of disagreements over potentially harmful medical treatments.

2. **Which is recommended for researchers regarding social media use by study participants, according to Edward Goldman, JD?**

   A. Researchers should remember that there is no way in which a study's validity can be compromised if participants communicate with one another via social media.
   B. Researches should never have participants agree prior to enrollment that they will not use social media to attempt to determine which study arm they're in.
   C. Researchers should make participants aware that social media can harm the study's integrity.
   D. Researchers should avoid specifying participant confidentiality requirements in the consent form.

3. **Which is true regarding disclosure of abnormal results of genetic testing to other family members, according to Doris T. Zallen, PhD?**

   A. Providers can safely assume that obtaining genetic information is beneficial to all family members.
   B. Providers should provide materials to assist the patient with communication of results to family members.
   C. Providers should never address inviting family members to participate in the testing process during pre-test counseling.
   D. Providers should actively discourage patients from making results known to anyone within the family who did not specifically request the information.

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