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New disclosure requirements could have some unintended consequences

Misinterpreted data is ethical concern

If a patient finds out her doctor prescribed a medication manufactured by a drug company he happens to have a lucrative consulting contract with, will she view this as an indication that he's prominent in his field — or that he has "sold out" to the industry?

It likely depends on how the relationship is disclosed by the patient's physician, says **Eric G. Campbell**, PhD, professor of medicine at Harvard Medical School and director of research at Mongan Institute for Health Policy, both in Boston, MA.

Physicians will soon find themselves having many more discussions about financial relationships with patients, he predicts. "We are going to continue to see more and more disclosure of relationships between physicians and companies. The days of hiding these things are over," says Campbell. "What used to be a well-hidden secret in medicine will now be on the web for all the world to see."

The major effect of the Physician Payment Sunshine Act, part of the Patient Protection and Affordable Care Act, which requires manufacturers to submit a list of physicians and teaching hospitals who received any transfer of value of $10 or more, will be to "divert immense resources

EXECUTIVE SUMMARY

There is increasing focus on disclosure of financial relationships between physicians and companies, due to new requirements in the Physician Payment Sunshine Act. Bioethics can play a key role in debating these ethical concerns:
- Physicians might be deterred from participating in legitimate research and educational activities.
- Misinterpreted disclosures might result in physicians needlessly being disqualified.
- There is a need to educate patients and institutions that the relationships have both risks and benefits.

from research and development into regulatory compliance," predicts **Thomas P. Stossel**, MD, American Cancer Society Professor of Medicine at Harvard Medical School and director of the Translational Medicine Unit and Center for Medical Innovation at Brigham & Women's Hospital, both in Boston.

"This effect will be most harmful to smaller companies on the cutting edge of innovation," says Stossel. "The obsession with particular financial conflicts is an artifact of instigators who make a career out of 'corruption hunting.' They almost never find it, defined as physicians committing harmful acts."

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EDITORIAL QUESTIONS

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Here are some ethical concerns regarding public disclosures to be required by the Physician Payment Sunshine Law:

• Physicians might be unnecessarily disqualified from educational meetings and advisory committees because disclosures are misinterpreted.

"This concern has been raised as a reason why so many positions on FDA [Food & Drug Administration] advisory committees are unfilled, even though there are studies which suggest that voting is not necessarily biased by having general relationships with the pharmaceutical industry," says **Richard Payne**, MD, Esther Colliflower Professor of Medicine and Divinity at Duke University in Durham, NC.

A 2011 study looked at 463 retracted publications and found that commercial sponsorship was not linked to an increased risk for withdrawal of manuscripts due to fraud or plagiarism.[1] A 2006 study found that excluding FDA advisory committee members who had conflicts would not have altered the overall vote in any meeting that was studied.[2]

"If there is no evidence of corrupt behavior, then what are we really after here? It's the *appearance* of corruption," says **Lance K. Stell**, PhD, FACFE, Thatcher Professor of Philosophy and director of the Medical Humanities Program at Davidson (NC) College and clinical professor of medicine at Carolinas Medical Center in Charlotte, NC.

"We have 25 years of a rising chorus of claims that doctors dealing with industry are corrupt," says Stell. "A lot of it is based on survey research and people's perceptions. But when you look at the data, there is not much there."

Michael A. Weber, MD, professor of medicine at the State University of New York Downstate College of Medicine in Brooklyn, NY, argues that the term "conflict of interest" itself is misleading, since it implies the benefits of an activity must be offset by some sort of negative outcome.

"'Multiplicity' of interests or 'alignment' of interests seem more appropriate where the intention is that all those involved will benefit in some way," says Weber.

• Physicians might be deterred from participating in legitimate research and educational activities.

The implementation rules for the database called for under the Sunshine Act have been delayed several times due to concerns about the possible negative effects of the reporting requirements, notes Stell.

"There are serious concerns that research will be deterred, legitimate continuing medical education will be undermined, and that people will avoid activities that will put them on the Sunshine list," he

says. Campbell says physicians should avoid certain kinds of medical education events that are primarily focused on marketing of pharmaceuticals, and that this is particularly important for academic physicians.

"Doctors should not be part-time drug salesmen," he says. "The mission of academic health centers is to provide patient care and educate the next generation. I'm not aware of a single one that has selling drugs as part of their mission."

• The institution might benefit from the relationships as well by getting a share of the income generated by the activities and an increased flow of fee-paying patients.

Thus, the need for ethical conduct must be shared equally by the physician and the hospital, argues Campbell.

"In the end, the only protection for patients, either in the hospital or in an office setting, is the professional integrity of those providing the care," he says. "This should be covered by the well-established ethical precepts of medical practice that have been in place for many years."

• Disclosures might discourage innovative activities that could result in better, but potentially more expensive therapies.

"It's understandable that agencies wish to keep a lid on spending," says Campbell. "But the Sunshine Act is clearly intended to serve a financial agenda, rather than a clinical or humanitarian one."

The law will discourage many physicians from collaborating with industry, according to Stossel. "Little or no evidence supports that conflict-of-interest management has accomplished anything else except eating up time and financial resources," he says. "To the extent that institutions embrace it, it is for avoidance of any publicity."

Role of bioethics

Disclosure is only one small part of the management process of conflict of interest, argues Payne. "We need to better prepare and educate patients about what to do with the advice, and to not fall into the trap of necessarily being more trusting of the doctor simply because they have disclosed," he says.

It is the responsibility of institutions and organizations to build processes that can monitor and check these matters, says Payne.

There are no data on how well academic health centers actively enforce the rules they have regarding relationships with industry, says Campbell, and these might not be consistently enforced.

"The perception has always been that if you are a superstar in the field and found to have inappropriate or unreported relationships, that by and large, not much is going to happen to you," he says. "You might get a slap on the wrist, but that's not the case with junior faculty."

The public needs to be educated that some relationships exist essentially to market drugs, while others are necessary in terms of medical education, Campbell says. "Not all of them are good and should be allowed to continue, and not all are bad and ought to be stopped," he says.

Physicians practicing in rural areas might rely on drug representatives to keep their knowledge up to date, Campbell acknowledges, "but I would argue from an ethical perspective, that if teaching hospitals and medical schools are unable to appropriately educate their medical students, residents, and physicians without drug company help, they should get out of the business."

Bioethicists should be the group that leads the debate about what kinds of relationships are appropriate and which are not, suggests Campbell.

"Too often, debates about this are very polarized, with pro-industry and anti-industry people," he says. "The role of the ethics community could be to hammer home the idea that these relationships are not universally bad and they are not universally good. They have risks and benefits." ■

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ACA could facilitate shared decision-making

New ethical challenges with informed consent

There is still "a good deal of confusion" about what informed consent and shared decision-making really are, according to **Howard Brody**, MD, PhD, John P. McGovern Centennial Chair in Family Medicine and director of the Institute for the Medical Humanities at the University of Texas Medical Branch at Galveston.

"Sadly, some of the recent medical literature on shared decision-making has become confused, by resorting to a 'negotiation' model — as if physicians and patients are equally placed contractors trying to hammer out a deal," says Brody.[1] Other research has suggested that shared decision-making is appropriate for only some, and not all, medical encounters.[2]

Brody was co-author of a 1996 paper that addressed the concept of shared decision-making and patient autonomy.[3] "The message was that informed consent was *not* a formula for the physician to turn responsibility for decisions over to the patient and wash her hands of this responsibility," he says.

Shared decision-making means that the patient ultimately has the right to make his or her own decision, but that the average patient wants the physician's help in doing so, says Brody. The physician has an obligation to sensitively and compassionately provide as much of that help as possible without falling back into old-style paternalism of thinking he or she knows what's best for the patient, he adds.

"If you go back to the original statements of shared decision-making — notably, the President's Commission report of 1982, which is based on the writings of Jay Katz — I think you'll find a view that's ethically sound, and that somehow we've managed to obscure in some of our more recent writing," he says.[4]

Health reform adds both challenges and opportunities for the expansion of shared decision-making, Brody adds. For example, if reform is successful in expanding the model of the patient-centered primary care medical home, the structure and teamwork in such settings should enhance prospects for shared decision-making.

The most important ethical challenge at this time is to keep physicians actively engaged with patients when trying to help them identify what medical options make the most sense for them, "and then work through the patient's personal values to see which option is most suitable, avoiding the twin dangers of paternalism and abandonment," says Brody. "As physicians feel busier and more harassed by bureaucratic details, this type of relationship with patients is increasingly threatened."

Misinformation is concern

Another ethical concern is the vast amount of marketing to both the profession and the public of a variety of pharmaceutical and medical device products, says **Harold J. Bursztajn**, MD, associate clinical professor of psychiatry at Harvard Medical School and president of the American Unit of the United Nations Educational, Scientific and Cultural Organization Bioethics Chair.

"How can physicians share what uncertainty there is about a medication or medical device when that uncertainty is initially hidden from the physician by the manufacturer?" asks Bursztajn, adding that the Harvard Medical School Program in Psychiatry and the Law laid the groundwork for these questions more than 25 years ago.[5]

"Although patients want to be more informed, there is a vast amount of misinformation," says Bursztajn. "This is enabled by a range of practices, from industry-tied biased professional practice guidelines to direct-to-consumer advertising that may result in a premature cognitive commitment and uninformed consent." He says that informed consent must be practiced as a process rather than as a one-time event.

"Practice guidelines must be screened for undue industry influence and post-market monitoring of both pharmaceuticals and medical devices," says Bursztajn. ■

EXECUTIVE SUMMARY

Health care reform is expected to bring both challenges and opportunities to facilitate a shared decision-making approach to the informed consent process.

- Patient-centered primary care medical homes should enhance prospects for shared decision-making.
- Busier physicians may find it more difficult to actively engage with patients.
- Direct-to-consumer advertising can hinder the informed consent process.

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Ethics of new emphasis on comparative effectiveness

Cost-effectiveness is related issue

The Affordable Care Act (ACA) will put more emphasis on both comparative effectiveness and cost-effectiveness, and this raises important ethical considerations, according to **Gary E. Jones**, PhD, JD, professor in the Philosophy Department at University of San Diego (CA).

Jones notes that it is anticipated that under the ACA, a majority of the nearly 50 million Americans who presently lack insurance coverage will obtain at least a minimal level of health insurance.

"A nearly universal concern, however, is the overall cost associated with the ACA," he says. "The United States spends in excess of $2.65 trillion on health care. This amount is greater than that spent by any other country, both in terms of total amount as well as per capita."

Nonetheless, according to the Institute of Medicine, more than half of treatments rendered are not supported by evidence that they are effective.[1] "Consequently, in the last several years, there has been an interest in establishing the comparative effectiveness of treatments," says Jones.

EXECUTIVE SUMMARY

There will be continued focus on both comparative effectiveness and cost-effectiveness of treatments as a result of the Affordable Care Act, which has ethical implications for the informed consent process.
• More than half of treatments rendered are not supported by evidence that they are effective.
• Investigations of comparative effectiveness of treatments could ultimately result in calculations of the cost-effectiveness of treatments.
• Physicians might be influenced to recommend to their patients only those treatments for which there is reimbursement.

Research is ongoing

The Institute of Medicine defines comparative effectiveness research as "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or improve the delivery of care."[1]

Comparative effectiveness research has been performed in the United States for many years by the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), and the Department of Veterans Affairs, notes Jones, and was addressed in the American Recovery and Reinvestment Act (ARRA), adds Jones.

"ARRA earmarked $1.1 billion for research to be overseen by NIH, AHRQ, and the Office of the Secretary of Health and Human Services," he says. "To monitor the expenditure of funds, ARRA created a Federal Coordinating Council for Comparative Effectiveness Research."

The funds provided by ARRA constituted the initial stage of a more comprehensive comparative effectiveness research effort, says Jones. "The ACA established a new, nongovernmental entity, the Patient-Centered Outcomes Research Institute, to oversee the research," he says. "The ACA also established a source of funding for the research."

Beginning this year, Medicare and all private health insurance companies will pay a tax into a trust fund that will support the activities of the new Institute. "Thus, comparative effectiveness research will continue for the foreseeable future," says Jones.

Physician-patient relationship

The concepts of comparative effectiveness and cost-effectiveness "may be related, but are not identical," says Jones. The ACA defines cost-effectiveness as "an economic analysis that compares the relative costs and outcomes of two or more courses of action (or nonaction)," and defines comparative effectiveness research as "research evaluating and comparing health outcomes and the clinical effectiveness, risks, and

benefits of two or more medical treatments, services, and items."[2,3]

"Investigations of comparative effectiveness of treatments could — perhaps even should — ultimately result in calculations of the cost-effectiveness of treatments," says Jones. The results could ultimately be used to allocate government resources or mandate treatment decisions, he says, and as a result, the informed consent process might be affected.

"Physicians might be influenced to recommend to their patients only those treatments for which there is reimbursement," explains Jones. As a result, investigations into comparative effectiveness could influence the physician-patient relationship, he says.

"Will the United States adopt a system such as the metric called quality-adjusted life years, utilized in the United Kingdom to establish health outcomes as a basis for making cost-effectiveness determinations?" he asks. "Such concerns are unfounded — at this point."

Cost-containment is a concern

Issues of cost-effectiveness research are generally not addressed in the comparative effectiveness research programs established in the ACA, adds Jones. "Indeed, the federal government is prohibited from using algorithms based on measurements such as quality-adjusted life years to determine coverage, reimbursement, or incentive programs under Medicare," he says.

The ACA forbids the government from using cost-effectiveness estimates "as a threshold to determine coverage, reimbursement, or incentive programs" under Medicare. The government is also forbidden from making decisions relating to "coverage, reimbursement, or incentive programs" under Medicare "in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."[2,3]

Therefore, says Jones, "considerations of cost will likely not have any direct bearing on the physician-patient relationship or on the informed-consent process in the foreseeable future."

However, the emphasis on the effectiveness of treatments will remain a significant issue due to efforts to contain future medical costs, according to Jones. "Not only the comparative effectiveness of treatments, but their cost-effectiveness, are issues that deserve continued attention," he says. ■

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Change in DSM-5: "Step in right direction"

The use of bipolar disorder diagnoses for children whose primary symptoms were manifested by irritability, rather than the traditional cyclical mood symptoms of adult bipolar disorder, has been a major concern in child psychiatry in recent years, says **Paul S. Appelbaum**, MD, Dollard Professor of Psychiatry, Medicine, and Law and director of the Division of Law, Ethics, and Psychiatry at Columbia University College of Physicians & Surgeons in New York City.

"In the face of mounting evidence that many of these children did not share a common course, family history, and other characteristics with bipolar patients, it became clear that clinicians were really treating another kind of disorder," explains Appelbaum.

The disruptive mood dysregulation disorder (DMDD) category was created in the *Diagnostic and Statistical Manual of Mental Disorder*s (DSM-5), to be published in May 2013, to give clinicians an alternative option for the diagnosis of this group of irritable children who are subject to behavioral outbursts, he explains.

There are legitimate concerns about the reliability with which the DMDD diagnostic criteria can be

EXECUTIVE SUMMARY

The disruptive mood dysregulation disorder category was created in the *Diagnostic and Statistical Manual of Mental Disorder*s due to growing concerns over the use of bipolar disorder diagnoses for children whose primary symptoms were manifested by irritability.
- Clinicians have an alternative option for the diagnosis of children who are subject to behavioral outbursts.
- The diagnosis could potentially be applied inappropriately to children who are displaying normal behavioral variants.
- Most clinicians applying the criteria will be pediatricians and family practitioners, not child psychiatrists.

applied, given their poor performance in the DSM-5 field trials, says Appelbaum.

"However, it seems clear that the vast majority of children who would be eligible for the diagnosis of DMDD are distressed, dysfunctional, and in need of help — even if the precise label to be applied may not be clear," he says.

Whether the diagnosis will be applied inappropriately to children who are displaying normal behavioral variants will depend on the care with which clinicians — most of whom will be pediatricians and family practitioners, not child psychiatrists — apply the criteria, says Appelbaum.

"Although not a complete answer to the question of how we should understand the behavior of this group of children, DMDD seems to be a step in the right direction," he says.

Validity is concern

It is important to realize that about half of the DSM consists of "disorders" that may not be valid, cautions **Roger Peele**, MD, DLFAPA, chief psychiatrist at the Behavioral Health and Crisis Center of Montgomery County in Rockville, MD. "It is important to respect the DSMs, not worship them," he says.

The diagnostic entities in all of the DSMs are constructs that may not be the way nature has divided psychopathology, says Peele. "But we don't *know* how nature has divided psychopathology," he says. "So, we've divided up psychopathology into entities such as major depressive disorder, schizophrenia, and so forth that are educated guesses in about half of recent DSMs."

The other half are entities that are considered "valid," such as entities associated with the fact that if the etiological agent was not present, the disorder would not exist for the patient, says Peele.

The "not otherwise specified" (NOS) category in DSM-IV-TR and the "unclassified" category in DSM-5 — for patients whose presentation does not fit any of the established entities — might make it hard to say someone does not have a mental disorder if that individual is emotionally distressed or behaviorally disabled, adds Peele.

"Uses of recent DSMs have found that NOS is often the correct diagnosis. Yet, the less NOS, the better," says Peele. "So DSM-5 has added a few diagnoses, such as DMDD — an addition that we hope will decrease the use of NOS in children." ■

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Ethics of postmortem implant explantation are overlooked

Consent forms often omit it

Explantation of battery-operated implants such as pacemakers involves pressing ethical issues but receives little attention, according to **Katrina A. Bramstedt**, PhD, a clinical ethicist and associate professor at Bond University School of Medicine in Australia, and former faculty in the Department of Bioethics at Cleveland Clinic Foundation, Cleveland, OH.[1]

"The focus when bringing these products to market is their safety and effectiveness," says Bramstedt. "End-of-life issues have been an afterthought for many clinicians, regulators, and manufacturers."

Bramstedt says that the "big picture" thinking for these technologies needs to reflect the many clinical and ethical possibilities that can happen after implantation. One ethical consideration is whether informed consent of postmortem explantation of battery-operated implants should occur at the time of the implant, or at the time of the explant.

"Many consent forms don't mention the topic of explant, only implant," says Bramstedt. "The consent discussion can also fail to include this matter as well, unless the cardiologist has it on his radar." Often, the topic of explant does not come up until after death when surrogates are approached for a decision.

EXECUTIVE SUMMARY

Ethical issues involving explantation of battery-operated implants are often overlooked by clinicians, regulators, and manufacturers. Some considerations involving informed consent:
- Many consent forms don't mention the topic of explant, only implant.
- Often, the topic of explant does not come up until after death, when surrogates are approached for a decision.
- Patients or families might consent to implant, but refuse to consent to explant.

Patients or families might consent to implant but refuse to consent to explant. "Should we require implant and explant consent as a conjoined consent that does not allow refusal for explant?" asks Bramstedt.

Bramstedt identifies these ethical issues involving explantation:

- Failure to explant and analyze devices from the clinical setting allows product defects to be potentially hidden from patients, families, clinicians, manufacturers, and regulatory agencies.
- Bodies buried with battery-operated implants potentially harm the environment.
- Religious or philosophical objections to autopsy should not supersede the duty to explant and analyze battery-operated implants.

"In my view, the societal benefits of device analysis exceed any 'right' to refuse explant," says Bramstedt.

While it is very common for implanted pacemakers and defibrillators to be removed in the postmortem state if the patient is to be cremated, it is very uncommon for this to happen if the patient is to buried.[2]

If this were to become a common practice, then patients likely would be asked about this prospectively, as is the case with organ transplantation, says **George Crossley**, MD, FACC, a member of the American College of Cardiology Clinical Electrophysiology and Electrocardiography Committee and a cardiologist at Baptist Hospital in Nashville, TN.

"Even in organ transplantation, though, the formal informed consent comes from the patient's family members," he notes.

The process of evaluating devices in the postmortem state for quality improvement is certainly important, says Crossley, but most malfunctions of implanted pacemakers and defibrillators involve leads and not the pulse generators. "Catastrophic problems in the pulse generator can occur, and would certainly be picked up by the quality assessment done before using these devices," says Crossley. "If this practice becomes common, it will be very important for the reporting system to capture all devices that have electrical or mechanical problems."

Reuse of devices

Bramstedt says she *doesn't* think that the duty to explant also extends to a duty to donate to any specific philanthropic cause afterward. "I don't think they should be forced to consent to reuse in humans," she says. "They could consent to reuse in an animal if they wanted to, or they could simply consent to the explant and analysis of the device."

If reused devices are sold, they should be labeled as such and patients/surrogates informed of such, says Bramstedt. Studies should be conducted about patient safety, device efficacy, lifespan of devices, and limitations of devices when reused, she adds.

"Patients should be informed of any safety and performance differences between used and new devices, even if a country chooses to only offer reused devices to its residents," she says. "Patients should know what they are getting and not getting if they choose or are forced to accept a used device."

There is a great need for cardiac electrical implanted devices in the developing world, says Crossley, noting that he has obtained unused donated devices and shipped them to Romania and the former states of Yugoslavia.

Crossley says the most significant barrier to reusing devices is the concern over possible infection. "While a new device that does not have tissue or blood exposure is not difficult to sterilize, a 'dirty' device is fairly difficult to sterilize," he says. "The use of Q-tips or other devices up into the header to try to clean material away can be catastrophic for device function."

"Even if we manage to sterilize the device, DEA regulations really inhibit one's ability to ship them overseas," says Crossley. "There are reports in the 1990s of well-intentioned folks doing this for charity having serious legal consequences."

According to **Benedict S. Maniscalco**, MD, CEO and chairman of Heartbeat International Foundation, Inc., a Tampa, FL-based organization that provides cardiovascular implantable devices and treatment to the developing world, the biggest ethical issue involving reused devices in the developing world is whether restoring a patient to cardiovascular function is the priority. "Or do we make concerns about reuse and its potential complications override the concern for human life?" he asks. "In the developing world, ethical standards are quite different in many ways."

Physicians must ultimately make the decision regarding the reuse of a pacemaker if a new device is not available, in order to restore a patient to normal function or perhaps save a life, says Maniscalco.

"The problem is not one of the greatest good for the greatest number, but one made for an individual patient," he says. "There is no issue in my mind of fairness or equality. A patient is a patient." ■

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New requirements for organ donor screening

Providers in "difficult position" ethically

Some hospitals are now being required to inform living donors of the risks they face, fully evaluate their medical and psychological suitability, and track their health for years after donation.

The United Network for Organ Sharing, which manages the transplant system under a federal contract, voted to establish uniform minimum standards and will require hospitals to collect medical data, including laboratory test results, on most living donors to study lasting effects, with results reported at six months, one year, and two years.

The high demand for organs and relatively scarce supply put transplant hospitals and their personnel in "a particularly difficult position," says **Leslie M. Whetstine**, PhD, an assistant professor of philosophy at Walsh University in North Canton, OH.

EXECUTIVE SUMMARY

The high demand for organs and relatively scarce supply has ethical implications involving screening of living donors. Uniform minimum standards have been established requiring hospitals to collect medical data on living donors to study lasting effects.
• A small number of cases have involved harm to donors, and demonstrated poor practices in the transplant program.
• Most transplant programs and transplant physicians already adhere to high standards to ensure that donors are fully informed and free of coercion.
• Informed consent does not usually discourage donors.

"How aggressively must they vet a donor when there is a human life on the line and a person has come forward to save them?" she asks.

Whetstine says that in addition to psychological screenings, the use of donor advocates can be useful in safeguarding the donor's autonomy. "The presumption in this case is, of course, that a donor may feel pressured to sell his or her organs or may have second thoughts about going through with the procedure," she says.

In these scenarios, a donor advocate can simply tell the recipient that the donor isn't a match or was rejected on medical grounds, rather than disclose the donor's actual reasons, she explains. "While this is an important role, advocacy proves fruitless when a donor and recipient and/or a third party broker a deal to voluntarily engage in organ vending," says Whetstine.

Donors need to be comfortable with the realization that their act is permanent and might have future health consequences, says **Stuart M. Flechner**, MD, FACS, professor of surgery at Cleveland (OH) Clinic Lerner College of Medicine and director of the clinical research section of the Cleveland Clinic's Center for Renal Transplantation/Glickman Urological and Kidney Institute. Flechner is former chair of the Joint Societies Work Group charged with establishing standards for the informed consent, medical evaluation, and follow-up of living kidney donors.

"However, they should have easy access to outcome data that they can understand," Flechner says. "In the end, it should be the donor's decision about who they want to help and what degree of risk they want to take."

Cases are atypical

Unfortunately, there have been a few well-publicized cases involving harm to donors, which also showed poor practices in the transplant program regarding informed consent and other aspects of donor education and advocacy, notes **Mary Ellen Olbrisch**, PhD, designated living donor advocate for the liver transplant program at the Virginia Commonwealth University Medical Center, and professor of psychiatry and surgery/director of education and training in clinical health psychology at Virginia Commonwealth University in Richmond.

"Nevertheless, I do not believe that these cases are, in any sense, typical of donor care in the transplant community," she says. "If anything, I believe that transplant programs and transplant physicians, on the whole, are extremely conservative about allowing individuals to become donors."

Most transplant programs and transplant physicians already adhere to a very high standard, and are quite concerned that donors be fully informed and free of coercion, says Olbrisch.

"The existing interpretation and implementation of the [Centers for Medicare & Medicaid] rule pertaining to living donor advocates is based on the most extreme ideas about how an advocate might be tainted by a potential conflict of interest," says Olbrisch.

In reality, Olbrisch says it is "pretty much impossible" to have a truly independent living donor advocate, and it is essential that everyone connected with the transplant program be a person of integrity who respects the donor as an individual just as much as the recipient.

"Perhaps the trickiest issue would be how to protect living donors by taking away incentives for doing a larger number of transplants, or at least scrutinizing outlier programs that appear to have lower standards of donor acceptability and protection," she says.

Tightening up or standardizing what are already common practices with regard to donor screening and selection will not make much difference, according to Olbrisch.

"If there are a few programs that have not been doing as good a job as they should have been doing, perhaps they will improve and this will eliminate a few medically inappropriate, higher-risk donors," she says.

Informed consent does not usually discourage donors, says Olbrisch, adding that once a person requests to be evaluated as a donor, "little will discourage him except to be found medically unsuitable."

Encouraging transplants can be achieved by creating public awareness about people in need and about successful donor and recipient pairs, according to Olbrisch.

"It is not the job of transplant programs and transplant physicians involved in living donor programs to encourage transplants at the level of how donors are screened and cared for," she says.

The only legitimate goal is to assure the best interests of the prospective donor, adds Olbrisch. "Every time a donor is exploited or comes to harm because someone cut corners to help a recipient or to do more surgeries, it harms the entire field of organ transplantation," she says. ■

SOURCES

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Providers: Ethically obligated to give easier access to records?

Both autonomy and the law favor allowing patients access to their medical records, and there are clearly associated benefits, says **Gregory R. Moore**, MD, MPH, senior director at Stamps Health Services at Georgia Institute of Technology in Atlanta.

Recent health services research indicates a benefit to open records in which patients have access to their medical records via secure portals, says **Stephen T. Miller**, MD, MACP, Pearce Professor of Medicine at University of Tennessee and medical director of medical education and research at Methodist LeBonheur Healthcare, both in Memphis.

Of 5391 patients of 105 primary care providers at three sites who opened at least one note and completed a follow-up survey, 77%-87% reported that access to their visit records helped them feel more in control of their care. For example, 60%-78% of those taking medications reported increased medication adherence.[1]

"If open records are a benefit to patients, is the medical care facility obligated to provide that access as an acknowledgement of patient autonomy?" asks Miller. "My thought is that all facilities should proceed with the view of open records."

The Meaningful Use portion of the Centers for Medicare & Medicaid Services' Electronic Health Record (EHR) Incentive Program requires some patient portal functionality, notes **Peter Winkelstein**, MD, MBA, professor of clinical pediatrics and executive director of the Institute for Healthcare Informatics at the University of Buffalo (NY).

"Certainly, health care professionals have an

EXECUTIVE SUMMARY

There are benefits to open records in which patients have access to their medical records via secure portals, but also ethical concerns.
- Patients reported increased medication adherence.
- Patients might be harmed by finding unexpected information.
- Patients might misinterpret information.

obligation to provide the best care they can. Whether patient portals and open medical records become standard of care remains to be seen," he says.

Here are ethical concerns involving open medical records:

• Patients might be harmed by finding unexpected information.

For example, most physicians would want to tell a patient that he or she had a positive HIV test rather than having the patient find the result through a portal. "Patient portals typically allow for the physician to look at data before it is released for exactly this reason, which helps alleviate this concern," says Winkelstein.

A counter argument to having physicians always screen information before it reaches the patient is that it is really up to the patient to decide how he or she wants to receive information, adds Winkelstein.

• The patient and the physician have interests in the record that aren't always aligned.

A patient might not want an HIV test result to be in the record, whereas the physician wants a record that the test was performed and appropriate action taken, says Winkelstein.

• Systems might not be secure, and unauthorized stakeholders could gain access to the information.

The health information management professional is responsible for the protection of privacy and confidential information and has always had to respond to the ethical implications of technological applications — copying, faxing, EHRs, and now portals and health information exchanges, says **Laurinda B. Harman**, PhD, RHIA, FAHIMA, associate professor emeritus in the Department of Health Information Management at Temple University in Philadelphia.

EHRs have increased a patient's ability to gain access to their health information, and have also given access to family members, as authorized by the patient, notes Harman.

The facility is obligated to assure that the information will only be released if authorized by the patient or as required by law, accreditation bodies, or public health agencies, says Harman.

"Some facilities may give open access to the information with some caveats," she says. For example, someone, such as a patient advocate or health care professional, might need to assist the patient in the interpretation of the information.

• Patients might misinterpret information, causing worry or confusion.

"Medical records contain vast amounts of information, much of it insignificant or even meaningless," says Moore.

While the patient's physician may have correctly evaluated and dismissed a technically abnormal laboratory finding, the patient may demand further explanations and additional testing, thereby stressing the system and increasing costs, Moore says.

• Knowing that patients may be reading their medical records could result in physicians self-censoring records.

"This results in medical notes that are less useful and conceivably harmful to the patient," says Moore. ■

References

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CME OBJECTIVES

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

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

COMING IN FUTURE MONTHS

■ Unethical marketing practices by physicians

■ Ethics consults in the ER

■ Concerns with genetic testing in children

■ Patients secretly videotaping physicians

CME QUESTIONS

1. Which is true regarding ethical concerns involving new disclosure requirements, according to **Eric G. Campbell**, PhD?
   A. It is not advisable for physicians to openly discuss their financial relationships with patients.
   B. Studies have shown that voting on advisory committees is clearly biased by having relationships with the pharmaceutical industry.
   C. Research shows a clear link between commercial sponsorship and withdrawal of manuscripts due to fraud or plagiarism.
   D. There are no data on how well academic health centers actively enforce the rules they have regarding relationships with industry, and these might not be consistently enforced.

2. Which is true regarding shared decision-making, according to **Howard Brody**, MD, PhD?
   A. The vast majority of research indicates that shared decision-making is not appropriate for most medical encounters.
   B. Providers should view the shared decision-making process as turning responsibility for decisions over to the patient.
   C. Shared decision-making means that the patient ultimately has the right to make his or her own decision, but that the average patient wants the physician's help in doing so.
   D. If reform is successful in expanding the model of the patient-centered primary care medical home, the structure and teamwork in such settings will markedly decrease the opportunity for shared decision-making.

3. Which is true regarding the effect of the Affordable Care Act on comparative effectiveness research, according to **Gary E. Jones**, PhD, JD?
   A. There are far fewer incentives to establish the comparative effectiveness of treatments.
   B. There is significantly less interest in research on both cost-effectiveness and comparative effectiveness.
   C. The results of investigations of comparative effectiveness of treatments could ultimately be used to allocate government resources or mandate treatment decisions.
   D. Cost-effectiveness estimates will now routinely be used as a threshold to determine coverage, reimbursement, or incentive programs under Medicare.

CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.
1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice, or renewal notice.
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%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.