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AHC Media

'Buy one get one free' healthcare Is it unethical or just undignified?

Consumer web sites such as LivingSocial, Groupon, Locly, and Ebates are popping up in millions of e-mail inboxes across the United States offering everything from sushi dinners and massages to car washes and now, healthcare.

It appears that these daily deal web sites are becoming more and more popular. In fact, according to reports, Groupon recently turned down a $6 billion buyout from Google in lieu of its own initial public offering (IPO). It also appears that some physicians are now getting in on the coupon frenzy. The popularity of these daily deal sites is no longer limited to free yoga classes and restaurant deals, as the medical community is jumping on board with deals ranging from cheap dental cleanings to laser eye surgery.

When it comes to offering healthcare at a discounted rate, ethical issues can come into play. "I find the concept of offering discounted healthcare troublesome because it reinforces the notion that healthcare is a commodity like TVs or X-Boxes and that healthcare should be distributed according to the ability to pay as opposed to a basic, personal, individual need or basic human right," says **Linda MacDonald Glenn**, JD, LLM, assistant professor in the Department of Medical Education, Alden March Bioethics Institute, Albany (NY) Medical Center.

Additionally, there are possible legal ramifications. **Matthew K. Wynia**, MD, MPH, FACP, director of The Institute for Ethics and Center for Patient Safety American Medical Association, Chicago, says, "Before

EXECUTIVE SUMMARY

Consumer web sites offer daily deals to consumers via e-mail. Such deals were once confined to dinners and gym memberships, but now the medical community is also participating in offering coupons for medical services. When it comes to offering healthcare at a discounted rate, ethical and legal issues come into play.

- The concept of offering discounted healthcare is troublesome to some because it reinforces that notion that healthcare is a commodity.
- There are also potential legal issues in offering some types of discounts for any service that is covered by insurance, including Medicare.
- Ethically, the primary obligation of clinicians is to ensure equal high quality care for every patient.

addressing ethics, there are potential legal issues in offering some types of discounts. In particular, I would talk to a good lawyer before offering a discount program or coupon for any service that is covered by insurance, including Medicare," says Wynia. Otherwise, providers might violate self-referral or kickback laws.

Glenn adds, "No other civilized nation looks at healthcare in this way; no other country allows medical centers to be for-profit institutions with shareholders, where the profits are the main consideration as opposed to patient care. The United States ranks number 38 in the world in healthcare, right before Slovenia and right after Costa Rica."*

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Offering discounted healthcare could provide more access to individuals who are uninsured or underinsured, but it is akin to giving fast food coupons to those on food stamps, says Glenn. In the short term, it solves an immediate problem, but in the long term it is neither healthy nor good policy.

Ethically, the primary obligation of clinicians is to ensure equal high quality care for every patient, regardless how or what they are using in paying for the care, Wynia says. "Physicians must strive to provide care equitably, period. So, for example, if a discount program or coupon were to drive excess volume over a short period of time, and thereby reduce the quality of care that can be delivered, it would be ethically problematic," he adds. Barring adverse effects on quality of care, some ethicists agree that coupons or limited time discount offers are more undignified than they are unethical.

Where does the ethics board come in?

Because of tremendous growth in group coupons all over the United States, in the for-profit sector, an ethics committee could see using daily deal coupons as a way of providing healthcare for those who might not otherwise be able to afford care, which is not a bad thing. Glenn says, "The ethical problems arise at a broader national level."

An ethics committee might have a say over the use of these coupons if there is an ethical issue or reason that arises within the organizational ethics, says **Lisa Anderson-Shaw**, DPH, MA, MSN, clinical director, Clinical Ethics Consult Service, assistant clinical professor, University of Illinois Medical Center, Chicago, says. "For example, if the organization offers discounts, but only for services or practitioners that are not meeting their professional expectations, this might be something that the ethics committee might be involved in, but not alone; the organization's administration would be important in such cases, as well."

An ethics committee could play a role in addressing these sorts of marketing strategies and keeping them inside ethical bounds, just as they might play a helpful role in many other marketing endeavors, Wynn says. *(For more information on marketing strategies including smartphones, see related story, p. 135.)*

In the first quarter of 2011, there were more than 2,500 medical, health and dental offers published on daily deal sites in the United States, which is an eight-fold jump over the 300 offered during the same period only one year ago. There are many theories of why there was such a tremendous surge

in this market. "I think this really has to do with the economy," Anderson-Shaw says. "Extreme couponing is very popular among consumers, and there really have been no problems that I am aware of by using coupons for groceries, etc. In fact, it has really helped many people who have limited income during this recession."

Because of this trend, it is possible that many people see healthcare-related services in the same way. "Many folks have to pay out of pocket for healthcare services, and a coupon/discount can be very helpful to them, but the issue at hand is if the discounted care or service is of a lesser quality than those who pay 'full price' or have insurance pick up the bill," says Anderson-Shaw.

While these deals are appealing to consumers, some medical organizations believe that the wrong message is being conveyed. Consumers taking advantage of offers might pay too much attention to the low prices and not enough to the quality of care or the provider's track record. "I believe this is a valid concern, especially if the patient — aka the 'consumer' in market terms — doesn't feel as if he or she has a choice, because of lack of health insurance," says Glenn. "It certainly can create a power imbalance between the patient and provider, where the patient feels they are helpless and totally at the mercy of the provider." *(For more information about discounted healthcare, see related story, right.)* Anderson-Shaw says that the healthcare industry almost always has been part of a fee-for-service/free-market industry; even prior to insurance, payment for a doctor's fee was in whatever monies or goods that could be shared, such as food and services. "So, I don't think offering coupons or discounted healthcare, in and of itself, is unethical. For example, many private offices and healthcare organizations offer 'back-to-school specials on school physicals or even free school physicals through the health departments," she says.

The threat might be more related to the quality of the services as opposed to the discount for the service, and quality is something that is better measured through consumer word of mouth, by looking up the practitioners information online to see if and what kind of feedback has been left for that person. "Consumers of healthcare are as consumers in other areas of life, however, healthcare practitioners must be licensed, and institutions that hire them must do background checks, and the like, to ensure a level of competency that is acceptable and legal for their profession, Glenn adds.

Don't expect this discounting trend to stop anytime soon, sources say. Glenn says, "It is because of free market/for-profit approach that healthcare costs have skyrocketed out of control. Because healthcare is currently being treated and viewed as a commodity, we will continue to see more of these offers." ■

BOGO: Healthcare by smartphone

The smartphone has helped drive the astronomical growth of the group coupon market, since notifications of daily coupons, also known as "daily deal alerts," are sent directly to the phone and the codes can be redeemed directly off of the device.

It is questionable as to whether these deals for healthcare are on par with healthcare services that are paid through insurance or full price out of pocket.

"I would have to say that it depends on what service is being offered," says **Linda MacDonald Glenn**, JD, LLM, assistant professor in the Department of Medical Education, Alden March Bioethics Institute, Albany (NY) Medical Center. "Discounted plastic surgery, for example, depends on the provider's track record and providing that there are no unethical incentives, such as 'buy one tummy tuck and get a second surgery free,' encouraging patients to undergo combinations of procedures that could greatly increase the risk of complications."

Coupons and group rates can also discourage an individual from checking the doctor. **Lisa Anderson-Shaw**, DPH, MA, MSN, clinical director, Clinical Ethics Consult Service, assistant clinical professor, University of Illinois Medical Center, Chicago, says, "The coupon is what gets them in the door, so to speak. It is often that consumers look up a provider they are not familiar with on the internet to check out individual feedback. Those that do not are no different than when insurance coverage changes and they now have to pick a provider from a list, never having seen this provider before. The consumer does have a right to trust that any licensed provider is competent to do what they are advertising that they can do."

If a track record of a provider is poor, and that provider offers discounts to reach more patients, people might not check out the provider. However, it really is no different than going to a licensed tradesman. "In many ways we all take a chance with a provider or a plumber, if we don't check out the person's credentials, their feedback on web sites, or talk to folks who may have used their services in the past," says Anderson-Shaw. "There is no guarantee that the

quality of any provider, with or without a coupon or discount, is less or greater than par."

The fear is that patients will seek out treatment from places that give them the best deal regardless of the actual quality of the service.

SOURCES/RESOURCE

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* Web: World Health Organization's health system rankings http://www.photius.com/rankings/healthranks.html ■

Palliative care : advancing or deficient?

In an updated report[1] that appears in a recent issue of *Journal of Palliative Medicine*, researchers examined the ability to accessibility of palliative care in U.S. hospitals.

Within the last decade, the number of palliative teams has doubled, and it continues to grow. Even with improvements and advancements in the field, millions of Americans facing serious illness still don't have access to palliative care from the point of diagnosis and throughout the course of illness, so more progress is still needed.

"It is crucial that we understand variation in access to palliative care at the state level in order to help both the public and policymakers increase the availability of these services for all Americans in need," says **Diane Meier**, MD, FACP, director of the Center to Advance Palliative Care at Mount Sinai School of Medicine, New York City, and one of the authors of the report.

The original report was published in 2008, and the updated report shows that progress might be slow, but it is steady. "The nation overall gets a 'B' grade, up from a 'C,' when the report was first released in 2008. Out of a total of 2,489 hospitals nationwide, about 1,500 provide palliative care services," says Meier.

EXECUTIVE SUMMARY

Newly updated research examines the ability to accessibility of palliative care in U.S. hospitals.
• The number of palliative teams has doubled over the last 10 years and continues to grow.
• Even with improvements and advancements in the field, millions of Americans facing serious illness still don't have access to palliative care.
• The nation overall receives a "B" grade, up from a "C" when the report was first released in 2008.

While findings from the 2011 demonstrate considerable improvement in palliative care from the 2008 report, there are significant variations from state-to-state. "The report gives seven states plus the District of Columbia an A: Maryland, Minnesota, Nebraska, Oregon, Rhode Island, Vermont, and Washington," she says. That list is up from only three states, Vermont, Montana and New Hampshire, that received an A in 2008. "More than half of the 50 states received a grade of B. Seven states improved from a D to a C," including Georgia, Kentucky, New Mexico, Texas, South Carolina, Louisiana, and Wyoming," she says.

According to the report, Nevada saw dramatic gains, rising from a D to a B grade. "Only two states — Delaware and Mississippi — got an F. Oklahoma, Alabama, and Arkansas improved from an F in the last report card to a D in 2011," Meier adds. The highs and lows of Nevada and Delaware came to great surprise for the authors. "On a regional level, the West and Northeast went from a C to a B. The Midwest and South remained the same," she says, receiving a B and C, respectively.

Hospitals were included in the study if they admitted adult patients and the majority of admissions were identified as general medical-surgical, obstetrics/gynecology, cancer, or cardiac. Hospitals were excluded from the study if they were considered rehabilitation, psychiatric, or eye, ear, nose and throat hospitals; subacute and chronic care facilities; pediatric hospitals; fell under federal control (e.g., Department of Veterans Affairs); were located outside of the 50 states and the District of Columbia; or did not respond to the American Hospital Association (AHA) survey, which was the basis for the results.

Studies continue to suggest that in states with more hospital palliative care teams, patients are less likely to die in the hospital, are likely to spend fewer days in intensive care, and have better pain management and higher satisfaction with their healthcare. "Some studies have reported that palliative care

may also prolong life. And beyond patient benefits, the overall cost savings to hospitals have been well documented," says Meier.

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SOURCE/RESOURCE

• **Diane Meier**, MD, FACP, Director of the Center to Advance Palliative Care, Mount Sinai School of Medicine, New York City. E-mail: Diane.Meier@mssm.edu.

• To download a free copy of the full report, "A State-by-State Report Card on Access to Palliative Care in Our Nation's Hospitals," visit www.capc.org/reportcard. ■

Data collection comes to palliative care

Late to the game, it figues out the rules

Palliative care was only recognized as a specialty five years ago by the American College of Graduate Medical Education. Because of its newness, those working in the specialty are still learning how to effectively collect data and make use of the information once they have collected it. Even once they have decided that data collection is a good idea — and not all of those who work in the specialty are there yet — they often rely on measurements and tools that seem sensible, but lack evidence that they are appropriate.[1]

Amy Abernethy, MD, associate professor of medicine and director of the Duke Cancer Care Research Program in Durham, NC, has worked on figuring out what data are of value in palliative care. In an article published in *Current Oncology Reports*,[2] she and her peers looked at what data are collected and how they can affect "quality, value, and research within a palliative care organization." Without data, she notes, the specialty can't demonstrate its value and won't survive.

Several problems have to be addressed, she says. First, most of what is commonly collected in palliative care is from medical documentation, which Abernethy notes "isn't discreet and can't help you do the kind of predictive modeling you need to affect care. Plus, this is a distressing time, and data collection can be repulsive to both patient and family. I think, too, that those who go into palliative care aren't into data collection as much as they are into caring for their patients. They are just not number wonks."

EXECUTIVE SUMMARY

Because of the newness of palliative care, those working in the specialty still are learning how to effectively collect data and make use of the information once it is collected.
- Several problems have to be addressed when deciphering data.
- Once it is established what to collect, it has to be determined the best way to collect it.
- Among the types of data to collect include patient demographics — where care is delivered, and referral sources — and outcomes data that quantify the impact of care delivered to patients and their families.

While palliative care and hospice are good at using patient and family satisfaction tools to see how they are doing, says Abernethy, the environment is what she calls "data naïve." There are attempts by many organizations to improve the situation. Specifically noted in Abernethy's paper is the Center to Advance Palliative Care *(see Resource, p. 138 for more information)*, which has a variety of tools and articles available. Among the types of data to collect, Abernethy and her coauthors name process data — such as patient demographics, where care is delivered, and referral sources — and outcomes data that quantify the impact of care delivered on patients and their families.

Once you figure out what to collect, you have to determine the best way to collect it. "This is a poorly reimbursed and time-intensive specialty," Abernethy says. "You have to make people more likely to participate." Putting more data collection at the point of care and making the collection systems more streamlined and easier to use could encourage more providers to engage in data collection. "We can use electronic pens, iPads, or other tablets, and find ways to run algorithms in the background so that if you put in some incorrect data, you can be prompted quickly to correct it so that you don't have to go back to the patient or family and repeat something."

Abernethy has one leg up on others: There is a consortium of palliative care organizations in North Carolina that have agreed upon what data to collect and how to expand on that if desired. "If someone wants to do a study on difficulty swallowing, they can add something to the electronic form we have

already created. They don't have to create a complete new form," she says. The state now has a single large data pool, too, that can help the individual organizations monitor their quality and outcomes compared to their peers.

There undoubtedly will be more pressure on palliative care to prove its worth using data as time goes on. Meanwhile, Abernethy says that the data they collect can be used to improve care for patients and also to market palliative care services. "They can say they think about evidence-based practice," she says.

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SOURCE/RESOURCE

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• Web: Center to Advance Palliative Care: http://www.capc.org. ■

Suggested Data Points for Palliative Care

- Patient demographics: age, gender, race/ethnicity
- Consultation diagnosis
- Referring service and/or referring MD
- Admission date
- Discharge date
- Consultation date
- Disposition: inpatient death vs. discharge
- Consultation volume
- Disease distribution: cancer vs. non-cancer
- Location of consult
- Age distribution
- Consults by referring service or physician
- Length of stay
- Length of stay outliers: admission-consultation > 30 days or consultation-death > 30 days
- Origin of admission: direct to palliative care (hospice or non-hospice), ED, ICU, ward
- Type of inpatient unit: fixed bed unit (average daily census, average % occupancy) or swing bed unit (average daily census).

Source: Center to Advance Palliative Care, New York, NY

Palliative care hardwired into hospital system

Care consultations part of all aspects of care

Palliative care isn't just for hospice patients; it also is used to manage the symptoms of those with chronic or advanced illnesses. One hospital system in Michigan has brought palliative care into all aspects of hospital care for all patients. The efforts of St. John Providence Health System in Warren, MI, to develop a screening tool for palliative care needs has earned it a spot as one of the recipients of the American Hospital Association's Circle of Life Award — Celebrating Innovation in Palliative and End-of-Life Care.

The health system has integrated palliative care into all aspects of care. "This was a leadership-driven initiative," says **Elizabeth DiStefano**, RN, BSN, coordinator of palliative care services for St. John Providence. "I didn't have to spend time trying to talk anyone into it. Anything they can do for us, executive leadership is really supportive of the program. That's really unique. Oftentimes people have problems with their leadership, but this was something we needed to provide to the patients," she says.

St. John first introduced palliative care consultations in its hospitals in 2005, but there was no standard in place to identify prospective patients. To solve this issue, St. John partnered with Duke University's Institute on Care at the End of Life to improve the screening process for palliative care needs and develop criteria that all physicians in the system could follow.

Palliative care triggers

"We partnered with Duke to increase access to quality palliative care with an increase in attention to spiritual needs," DiStefano says. "We had five objectives: to screen for palliative care needs, to fully integrate spiritual care with palliative care,

educate all associates on basic palliative care, engage the faith community, and institute a culture change for these efforts."

From the collaboration came a trigger tool that medical staff could use to screen patients for palliative care that was pilot-tested in the ICU of St. John Hospital and Medical Center in Detroit, the system's largest hospital. "It was a larger tool that we did. It became cumbersome and lengthy, so we use the top nine triggers from our tool," DiStefano says. "Now, all patients are screened for palliative care needs upon admission, and after five days if they are still in the hospital."

Palliative care triggers include:

- code status changed to DNR;
- conflict about stopping/starting life-prolonging treatment;
- goals of care or code status discussion needed and/or surrogate or proxy distressed about decision-making;
- uncontrolled symptoms that interfere with quality of life;
- marked decrease in functional status/activities of daily living (ADL) in last 60 days;
- considering PEG tube placement;
- admitted from extended care facility with ADL dependence or chronic care needs.

Process is a joint effort

The palliative care process involves more than just physicians. According to DiStefano, St. John's palliative teams include a nurse practitioner, social worker, and chaplain for a multidisciplinary approach for the patient and his or her family. "We don't just care for the patient; we care for the whole family," she says. "We look at the dynamics, and we look at their needs and if they need spiritual care. The multidisciplinary approach is helpful to the families as well. They have the time to spend with the team to work out the care and what kind of care they want to receive. The team can have those difficult discussions with the family. If they want to see a spiritual care provider daily, they can have daily rounds with chaplains and clinicians.

It can be an extra layer of support for the patients. "Doctors find it very helpful because it saves them time and they don't have to do difficult family meetings. They have found it to be very valuable," says DiStefano. It is called value-added care, which is an extra team member.

However, DiStefano says, attending physicians initially were reluctant to order palliative care consultations. "When we rolled it out, there were issues that were going on," DiStefano says. "Staff education has been very helpful, and the culture has changed over time. Speaking with doctors about it one on one has been helpful, and having the support of the medical executive team has been key."

The response has been 'overwhelming.' In fact, the system has had "mass education from housekeeping staff to the CEOs" on palliative care, according to DiStefano. "We have annual training days and ask staff members to become champions and train four or five other associates," she says.

Response from the community on the program has been overwhelming. "I wrote an article about the program for a newspaper for seniors. A little old lady [patient] brought the paper with her to the doctor and said she wanted that kind of care, DiStefano says. The program constantly gets support from the community in the form of phone calls. "When people make comments like 'Where have you been?' … it's good feedback from the community," DiStefano says.

They are always willing to share information with other health systems because they want to improve the field of palliative care. "We want others to learn from our lessons and what we've done. We want to help other programs improve," DiStefano explains.

SOURCE

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Patients with ICDs learn of EOL options

An implanted heart rhythm device may generate repeated painful shocks during a patient's final hours, at a time when the natural process of dying often affects the heart's rhythm. Yet, clinicians rarely discuss options for limiting these distressing events at the end of life (EOL), according to a new review of literature[1], appearing in *American Journal of Nursing*.

The devices, known as implantable cardioverter defibrillators (ICDs), can be reprogrammed or deactivated by trained providers to avoid the unnecessary shocks. However, most patients don't understand enough about the devices to consider stopping treatment as death nears.

Healthcare systems should "identify ways to pro-

mote timely deactivation discussions and thus foster better patient-centered, end-of-life care in people with ICDs," says author **Jim Russo**, a certified cardiac device specialist at the Department of Veterans Affairs Medical Center in New York City.

Surgically implanted ICDs have become standard treatment for people at risk for life-threatening heart rhythm problems, with more than 140,000 implanted in 2009 alone. The programmable electronic devices can detect an arrhythmia and deliver a painful "kick in the chest" to help the heart regain its normal beat.

The review included 14 studies on how providers and patients handle discussions about limiting the shock function when a patient is near death. Although the studies were small, the results were fairly consistent: Most healthcare providers avoid these discussions, due to discomfort or lack of information about deactivation or reprogramming options.

David L. Hayes, MD, an internationally recognized specialist in cardiovascular disease, says, "Cardiologists and electrophysiologists have been notoriously poor at talking about end-of-life care." Hayes is a co-author of the 2010 consensus statement on device withdrawal published by the Heart Rhythm Society. "The discussion about end of life needs to occur at multiple points along the continuum of care," he says.

Russo suggests, "Discussions should occur at implantation and again at periodic follow-up visits." Providers periodically review and discuss advance directives, and that would be a good time to discuss this issue also, says Russo.

The review calls for healthcare services to develop written policies on device deactivation and for stronger alliances among primary care providers, cardiologists, and palliative care experts. Nurses also might have an important role as they are often responsible for patient education and might be the first to recognize when a patient's condition begins to deteriorate.

Hayes points out that end-of-life issues related to implantable cardiac devices are not going away. "Providers need to get over their reluctance to discuss death and dying. These are issues in this technically advanced world of treating an aging population that we are all going to need to deal with."

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Ethical complexities of conjoined twins

Ethical principles apply for other procedures

The case of a pair of "craniopagus" twins (conjoined at the head) illustrates the complex bioethical issues involved in deciding whether to attempt separation surgery, according to an article[1] in a recent issue of *Plastic and Reconstructive Surgery*, the official medical journal of the American Society of Plastic Surgeons (ASPS).

"Although separation of craniopagus twins is exceedingly rare, the principles discussed apply to a variety of cases in craniofacial and pediatric plastic surgery in which life-threatening procedures are carried out for conditions that affect the quality of life but may not be life threatening," comments ASPS member surgeon **Devra Becker**, MD, and colleagues of the Rainbow Babies & Children's Hospital in Cleveland, OH.

They hope their experience will be of value to other surgical teams; the ethical principles involved apply not only to rare and complex separation procedures, but also to more common plastic and reconstructive procedures involving children.

Traditional principles inform decisions

The authors outline the bioethical issues faced by their multidisciplinary medical team as they assessed whether to attempt surgical separation in a pair of craniopagus twins from Italy. The operation posed daunting medical and surgical challenges. The smaller twin was conjoined to the back of the larger twin's head. The larger twin had most of the brain blood flow; the smaller twin had two kidneys, while the larger twin had none. After separation, the larger twin would require a kidney transplant or lifelong dialysis.

In deciding whether to attempt separation, the researchers performed an indepth evaluation of the traditional ethical principles that traditionally guide medical decision-making:

- **Autonomy and informed consent**

Since the children were less than 3 years old at the time, they were "neither capable or competent" of making an informed decision about the proposed surgery. Nevertheless, the medical team along with the parents tried to focus on the children's role in the informed consent process. The intense media coverage of the case posed special challenges, and the team took steps to keep the twins' best interests in focus.

• **Beneficence and non-maleficence**

Under these two intertwined ethical principles, any treatment should be beneficial and cause no harm to the patient. The issues were particularly complex, as the proposed separation had a "double effect." The operation could potentially cause irreversible harm to one twin while improving the quality of life for the other.

• **Justice**

The team considered the ethics of devoting such enormous medical resources to the children's treatment. Rainbow Babies & Children's Hospital made the decision to cover most of the costs of the rare procedure, in the hope that the procedure would advance scientific knowledge.

After careful consideration, the family and medical team elected to proceed with the attempted separation. However, the procedure was halted because of unanticipated surgical difficulties, which altered the balance between doing good and doing harm. "The risk of death outweighed the gain in quality of life," according to Becker and coauthors. The twins recovered with no complications from the attempted procedure.

Craniopagus twins are extremely rare: approximately 4-6 in 10 million births. Although several papers have reported on the medical aspects of separating conjoined twins, few have addressed the ethical dilemmas. This is particularly relevant to plastic surgeons, who are often the leaders in organizing complex multi-disciplinary teams evaluating conjoined twins for possible separation.

"Once organized, these teams find that the ethical issues involved may be more relevant than the medical issues, since separation cannot proceed without clear understanding and documentation of the former both by healthcare providers and the family," Becker and colleagues write.

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Undocumented patients get a safety net

The Hastings Center is exploring the ethical challenges that clinicians and organizations face when providing medical care to undocumented immigrants in the United States. The project is supported by a grant from the Overbrook Foundation Domestic Human Rights Program.

Most of the estimated 11 million undocumented residents of the United States have no health insurance and are ineligible for public insurance programs. They are prohibited from obtaining insurance under the 2010 Patient Protection and Affordable Care Act (ACA).

When they become sick or injured, these low-income patients have limited access to healthcare. Organizations that are federally mandated to provide some level of care on the basis of medical need, such as emergency departments, federally qualified health centers, and health programs for farm workers, face difficult resource allocation challenges when undocumented patients' medical needs exceed available resources.

"Healthcare professionals can be deeply troubled when they encounter situations that seem unfair," says **Nancy Berlinger**, PhD, a Hastings Center scholar who is co-director of the project. "How to provide good care to patients who cannot afford to pay for care is one of those situations. When a patient is also undocumented, the situation becomes even more complex. This project aims to help clinicians and organizations by exploring the difficult questions of how ethical obligations compete with economic constraints, conflicting mandates, and political considerations."

Michael Gusmano, PhD, the other co-director of the project, adds, "We will review existing policies and regulations and identify how they shape access to care for undocumented patients. We know that some laws and programs are designed to provide access to healthcare for this population, and others explicitly forbid the use of public funds to pay for care for this population." This creates a complex policy environment that causes difficulties for the patients, healthcare professionals, and healthcare organizations. The project seeks to clarify, as much as possible, these policy choices and identify their consequences.

At a recent meeting in New York, the project's advisory group discussed several questions: Is there a right to healthcare implicit in the United States? In a society with a large immigrant population such as the United States, how are our social values expressed in how we view undocumented patients? What ethical guidance may help healthcare organizations and state and federal policymakers in a challenging economic environment at a time when the regulations are changing under the ACA.

The project's advisory group includes clinicians and healthcare leaders from organizations that serve

communities that include undocumented patients. Project advisors also include experts in human rights law and theory, healthcare ethics, and safety net health policy. The project will produce a special report, a web site with resources for the public, and journal articles. ■

Emotional toll of DTC genetic testing

Among the latest healthcare trends seeking to advance "individualized medicine" are private companies marketing genetic testing directly to patients. The mail-in kits, with price tags as high as $2,500, use a saliva specimen to identify small variations in the human genome (called "single nucleotide polymorphisms" or "SNPs") associated with heightened risk for diseases such as diabetes and prostate cancer. *(For more information on direct-to-consumer [DTC] genetic testing, see the July 2011 issue of* Medical Ethics Advisor, *p. 76.)* The Food and Drug Administration (FDA) has raised concerns about whether the tests are clinically beneficial and has advocated they be conducted under medical supervision, but few studies to date have investigated the emotional effects that direct-to-consumer (DTC) genetic screens have on patients.

In a recent issue of *Mayo Clinic Proceedings*, a group of Mayo Clinic physicians and bioethicists analyzed whether these genetic tests cause patients to experience excessive worry about developing diseases. "We looked for evidence of increased concern about disease based solely on genetic risk and then whether the concern resulted in changes in health habits," says co-author **Clayton Cowl**, MD, a specialist in preventive, occupational, and aerospace medicine, and a physician in the Mayo Clinic Executive Health Program, Minneapolis.

The randomized study found patients' worry tended to be modestly elevated one week after the genetic testing, and that people worried more about unfamiliar diseases — for example the thyroid condition Graves' disease — than those commonly known, such as diabetes. One year later, however, patients who had undergone testing were no more stressed than those who hadn't. One surprising result was that men whose genetic risk for prostate cancer was found to be lower than that of the general population, and who also had normal laboratory and physical screening results for the disease, were significantly less stressed about the disease than the control group.

The tests might be useful if they prompt patients to make health-conscious changes, such as losing weight or being vigilant about cancer screening. Some doctors are concerned, however, that patients who learn they have less-than-average genetic risk for a disease might skip steps to promote good health, notes Cowl. The study assessed only the emotional effects of the tests. "The ability to determine the actual utility of these tests, that is, whether a calculation of genetic risk accurately predicts disease, is still several years away," he says.

RESOURCE

Web: Mayo Clinic http://www.mayoclinic.org/bio/10854533.html. ■

Improvement checklists help quality processes

Thorough, efficient human subjects research

When review boards and research organizations' quality improvement (QI) offices work together, the net effect is a more thorough and efficient human subjects research process, experts say.

The Emory Healthcare Office of Quality in Atlanta created a clinical trial readiness checklist that is completed by researchers at the beginning of a study, says **Sarah Putney**, JD, institutional review board (IRB) director at Emory University in Atlanta.

The project was created after various clinical research stakeholders met to analyze and discuss ways to improve efficiency and safety, Putney says. While the review board assesses the overall safety of a clinical trial, it's less attuned to the study preparation process, notes **William A. Bornstein**, MD, PhD, chief quality and medical officer at Emory Healthcare. "This checklist is an attempt to create a linkage between the planned efforts and the reality and to see if the staff really knows about this trial," Bornstein says. "Do they know what kind of impact it will have on the laboratory and radiology and investigational drug services?"

The checklist is a collaborative effort between the QI office, the review board, and the office of clinical research, Putney says. "As with any good QI program, it has to include hard stops," she says. "So the way it works is the IRB helps to educate study staff when they submit a new study for us to review." Review board staff directs them to the

Clinical Trial Readiness Checklist

The Emory Healthcare (EHC) Office of Quality in Atlanta created a clinical trial readiness checklist that is completed by researchers at the beginning of a study. The checklist is a simple, one-page form in table format. It lists these items:

- Study title
- IRB number
- Principal investigator (PI)
- Clinical research coordinator (CRC)
- Protocol orders:

— Clinical facility approval of study site feasibility; signatures by EHC executive

— Approved/PI signed protocol orders written and reconciled with study and care delivery team and delivered to applicable care areas; signatures by PI, pharmacist, clinical nurse manager, and CRC

— Clinical in-service to entire clinical unit for protocol; occurs after all orders are signed off on; clinical nurse specialist (CNS) educated if applicable; signatures by clinical nurse managers

— Stakeholder ancillary services in-service (depending on study requirements); occurs after all orders are signed off on; signatures by PI, lab, radiology

- Education

— Protocol education and training provided to research team, including MD investigators, nurses, and CRCs; signatures by PI and CRC

- Investigational Drug Service (IDS)

— The study has fulfilled IDS requirements? Signature by IDS pharmacist

- Billing/compliance

— The study has been received by the Office of Clinical Resesarch (OCR),

—Signature by OCR representative.

Each item on the checklist represents an accountability sign-off step in the process.

checklist, which is listed on the web site. *(For a sample checklist, see box, top of page.)*

"The IRB tells the study team they need to complete this, and then we continue on with our regular protocol review," Putney explains. "The IRB can go ahead and approve a clinical study, but we won't release the validated consent forms and HIPAA forms until the Office of Quality says the checklist is complete." If investigators have any questions about the checklist, they are sent to the office of quality.

Bornstein add, "There are two ways to think of the checklist. It's useful to make sure researchers have done what they need to do, and it's also useful as a way to provide organizational controls around the way they get things done." The checklist itself is a simple, one-page form in table format.

"The intent is to give investigators something they have to look at and say, 'I haven't done this yet,'" Bornstein says. "Behind each sign-off there's another checklist to make sure things get done." For example, before the investigational drug ser-

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%.
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5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

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

- Ethics of end-of-life care
- The ethics of billing and coding
- Ethical issues in health research
- Surrogates and reciprocal responsibilities

vice (IDS) sign-off can occur, the investigator will have to complete the IDS checklist of tasks to be performed. "The pharmacist's signature represents they've checked and made sure they're responsible for saying the study team is ready to go from their point of view," Putney explains.

The clinical trial readiness checklist and the hardstop involving the IRB releasing the informed consent document and HIPAA form are a way to enforce responsibility and accountability along each step leading up to the initiation of a clinical trial. The quality improvement office doesn't monitor all of the steps required before officials sign the checklist, but it is assumed that if someone signs the form then the investigator has meet all of their requirements, Bornstein says. ■

CME QUESTIONS

1. According to Matthew K. Wynia, MD, MPH, FACP, director of The Institute for Ethics and Center for Patient Safety American Medical Association, a possible legal ramification that can come from couponed healthcare include:
   A. Consequences of offering a discount program or coupon for any service that is covered by insurance, including Medicare.
   B. Gaining profits as the main consideration as opposed to patient care.
   C. Clinicians not ensuring equal high quality care for every patient, regardless how or what they are using in paying for the care.

2. According to a report that appears in the *Journal of Palliative Medicine*, researchers examined the accessibility of palliative care in U.S. hospitals and found that overall, accessibility has:
   A. Improved
   B. Declined
   C. Stayed the same

3. According to Amy Abernethy, why is it a problem that data collection for palliative care comes mostly from medical documentation?
   A. Those that go into palliative care aren't into data collection as much as they are into caring for their patients
   B. It isn't discreet and can't help you do the kind of predictive modeling you need to affect care.
   C. Both A & B

4. What are the benefits when review boards and research organizations' quality improvement offices work together?
   A. A more thorough and efficient human subjects research process.
   B. The review board staff directs them to the checklist.
   C. The quality improvement offices assess the overall safety of a clinical trial.

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