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Too high a price? Re-examining the ethics of Phase I oncology trials

Give more credit to patients willing to participate despite risks

For cancer patients who have exhausted all available treatment options, Phase I research trials of new oncology drugs may be their only hope. But does that hope come at too high a price?

Not necessarily, say two researchers from the department of clinical bioethics at the National Cancer Institute's Warren G. Magnuson Clinical Center in Bethesda, MD.

Although the participation of cancer patients in Phase I trials is controversial for several reasons, the available evidence suggests that dying patients are able to understand the risks involved and often may be willing to undergo great hardship both for the potential to help others and for the chance, however remote, to fight their own disease, wrote researchers **Manish Agrawal**, MD, and **Ezekiel J. Emanuel**, MD, PhD, in the August issue of the *Journal of the American Medical Association (JAMA)*.[1]

"Part of the overall controversy centers on the fact that you have to test these very toxic drugs, or at least potentially toxic drugs, generally on patients who are terminally ill," Emanuel tells *Medical Ethics Advisor*. "They may not be dying in the sense that they are in the last

Audio conference clarifies final EMTALA regulations

The final version of the recently proposed changes to the Emergency Medical Treatment and Labor Act (EMTALA) takes effect Nov. 10.

To provide you with critical information on the updated regulations from the Centers for Medicare & Medicaid Services, Thomson American Health Consultants offers **New EMTALA Regulations: Are They Too Good to be True?** — an audio conference on Tuesday, Oct. 21, from 2:30-3:30 p.m., EST.

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stages of life, but they have exhausted all other treatments; and barring some other treatment, they will die of their cancer."

Phase I clinical trials are the initial stages of research that permit new therapies to move from the research lab into clinical use. Classic Phase I drug trials are cohort studies in which participants are treated at increasing doses so that researchers can learn about drug toxicities, the maximum tolerated dose and the pharmacokinetics of the drugs. Phase I trials are aimed more at determining the drug's safety than its effectiveness at treating the disease.

Some drugs demonstrate so much toxicity in Phase I studies that they never progress to Phase II and beyond. The potential for adverse events in Phase I studies is high, and the possibility that a patient will achieve a beneficial treatment result is very low.

Phase I oncology trials are particularly controversial because unlike other Phase I drug studies, they must be performed on the sick patients themselves rather than healthy volunteers, Emanuel adds.

"Cancer drugs are so toxic you can't try them out in the same way you would the latest drugs for hypertension medicine or migraine medicine on the average healthy person," he explains. "The only people you can possibly enroll in these trials are the actual patients."

Some ethicists have proposed that Phase I oncology trials are inherently unethical because there is no reasonable probability that the subjects will benefit. There is a small but definite risk of death from toxic side effects and a very high potential for physically debilitating side effects.

Surveys of patients participating in oncology trials have found that most list the possibility of personal benefit as a primary reason for participation — an indication, some argue, that these patients are not receiving appropriate informed consent.

Similar surveys of some oncologists also indicate they have unrealistic expectations about the potential for their patients to do well in Phase I trials, which is a disturbing finding given that treating physicians usually refer patients to clinical trials.

However, researchers examining these issues have not always had an adequate understanding of the unique situations that these cancer patients face, Emanuel says.

In addition, most of the existing research on these issues is old and doesn't take into account newer study designs that minimize risks or newer informed consent procedures and research surveys that attempt to more broadly assess cancer patients' understanding of the research objectives and their motives for participating, he adds.

"If you examine the literature on this topic, this has been an amazingly controversial topic in the literature, yet the available literature is really bad," Emanuel says. "There are very few articles

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analyzing, either conceptually or empirically, the issues involved. In some ways, the best of the conceptual articles is more than 30 years old."

Examining motivation

In reviewing the available articles for the *JAMA* piece, Emanuel and Agrawal found interpretations of the data that, they believe, may not accurately reflect the perspective of many terminal cancer patients.

"I am not convinced, for instance, that because a participant says that his or her primary motivation for participating is to receive personal benefit, that necessarily means that the person does not understand the purpose of the study or the risks involved," Emanuel explains. "I can hope something will be the case, even though I know the odds are against it. I think every person who buys a lottery ticket falls into that category. You know you're not likely to win. The odds are overwhelming, in fact, that you'll lose. But choosing to participate doesn't itself mean you lack understanding."

Some of the data obtained from studies of informed consent have not been properly understood, Emanuel notes.

"When you ask people what their primary motivation is, they almost universally say benefit for themselves, which is not surprising," he says. "On the other hand, when they are asked if they necessarily are going to benefit, the majority say they are aware they might not or probably will not. They recognize that and say that the advancement of knowledge for society is a primary benefit of the study. We think that these two beliefs can be held by people at the same time."

Clinical outcomes questioned

In addition, Emanuel says some of the empirical data about the outcomes experienced by participants in oncology trials has been misinterpreted.

Meta-analyses of Phase I studies show an overall response rate of just 5%, but that figure conceals other important information. More than 60% of the compounds evaluated had as least one objective response — tumor shrinkage of more than 50%. Additionally, more than 30% of the drugs also had a greater than 5% response rate.

There also have been individual cases in which the benefit of participation has been substantial.

"There is potential for people to experience improvements in their condition, and we know of at least one case where a patient was cured in a Phase I trial. We know of another case where there were substantial long-term benefits," Emanuel says.

SOURCES

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Paternalism vs. autonomy

When considering Phase I oncology trials, ethicists must remember that potential participants are patients without other treatment options — they either may decide to participate in a trial, resign themselves to only supportive care, or accept whatever fall-back remedies their doctor may decide to try, but which have even less potential for benefit, says oncologist **Mark J. Ratain**, MD, the Leon O. Jacobsen professor of medicine and chairman of the committee on pharmacology and pharmacogenomics at the University of Chicago Cancer Research Center.

"The bottom line is, when you have advanced cancer, your chance of responding to anything is low, whether you are getting a Phase I drug, a Phase II drug or a drug some oncologist has pulled off the shelf when he is trying to do the best for his patient," Ratain explains. "The chance of the patient responding is low."

Obviously, treating physicians have an obligation to their patients to make sure they understand the high risks and low potential for benefit of Phase I studies.

But, they shouldn't presume to determine what is in each individual's best interest. That decision is up to the patients themselves.

"Some patients may want to pursue treatment regardless of what the chances for success are," he says. "If I had a patient, I would say what you have to do is compare the experimental drug that we are talking about today with the standard available treatment — which is no treatment. If they have rejected the concept of no treatment, then that is not an option."

People who are healthy have much different perspectives than people who are sick, Emanuel agrees. "We make the case in the paper that evaluation of the risks and benefits depends on your perspective."

More research is needed into the true risk-benefit ratios of newer drugs, given that the existing data is more than a decade old, he adds.

"There have been a lot of changes in therapeutics in cancer — more immune modulators, more targeted therapies, more vaccines — and we need to know if these risks-benefit ratios are sustained, or are they better or worse," he explains. "We need to know whether improvements in supportive care have improved or decreased the risks of Phase I treatments."

More research also is needed into appropriate informed consent techniques, Emanuel believes.

"The studies that have been done have not been done carefully," he adds. "They don't differentiate between someone participating with a primary motive for benefit but who also recognizes that they may not benefit. These are very hard sets of questions to ask, and I don't think we've seen a lot of careful surveying in this area."

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Circumcision: Support or circumscription?

Middle ground is difficult to find

Would your ethics committee approve a request to perform nontherapeutic surgery that would permanently alter the body of a healthy patient without his or her consent? What if the patient was very young and the parents wanted the surgery for religious or cultural reasons? What if they argued the procedure was necessary to reduce a remote possibility of future illness?

You should weigh your answer carefully. Such surgeries are, in fact, very common.

Annually, more than 1 million infant males in the United States undergo circumcision surgery within a week of birth to remove the prepuce (or

foreskin) of the penis.[1] Approximately 60% of all American males are circumcised. Although the procedure is routine, it also is controversial.

"Perpetrating sexual surgery on healthy nonconsenting minors under the legal age of informed consent or refusal, to purportedly prevent an unlikely . . . future infection, is unacceptable," wrote **Eileen Marie Wayne**, MD, in a letter published in the journal *Infectious Diseases in Children*.[2] "Intentionally amputating healthy erogenous genital tissue from tethered, protesting infants is a surgical act of sexual sadism."

Proponents of the procedure are equally vehement.

"The lifetime health benefits of neonatal circumcision — including the long-known benefits of genital-hygiene improvement and prevention of local infection and penile cancer — far exceed the risks of the procedure," counters pediatrician **Edgar Schoen**, MD, in an issue of the American Council on Science and Health's *Health Priorities*.[3] "Circumcision prevents serious kidney infections, especially in infancy; and there is strong evidence that it has a protective effect against some serious STDs, including HIV infection, syphilis, and chancroid. A 1-week-old circumcised boy has a significant health advantage over his uncircumcised contemporary."

Although it would seem an issue ripe for debate in the bioethics community, the procedure has received little attention, notes **David Benatar**, PhD, associate professor of philosophy at the University of Cape Town in South Africa.

Benatar and his brother, fellow researcher and pediatric neurologist Michael Benatar, MD, recently published a paper examining the practice in the spring issue of the *American Journal of Bioethics (AJOB)*.[4]

"We are aware that people on both sides feel very strongly about the issue and that most people do not change their minds readily," David Benatar tells *Medical Ethics Advisor*. "We felt there was a need for a dispassionate analysis of both the evidence and of the arguments for and against."

Where are we now?

An ancient ritual practiced in numerous societies for thousands of years for both religious and cultural reasons, neonatal male circumcision became a commonly performed procedure in U.S. hospitals in the 1950s and 1960s because it was thought to prevent masturbation and make genital hygiene easier. By 1971, an estimated 90% of male infants in the United States were circumcised each year.[5]

In recent years, however, both parents and physicians have questioned the practice of removing part of a healthy person's anatomy without a compelling medical reason.

In 1977, the American Academy of Pediatrics (AAP) changed the designation of the procedure from "routine" to "elective" and currently does not recommend routine neonatal circumcision, though its policy statement indicates there are potential medical benefits to be derived and that parents can legitimately choose to have the procedure performed.[6]

Following the AAP's original decision not to recommend the practice, circumcision rates began declining. However, some researchers studying the incidence of sexually transmitted diseases, infections of the genitalia and urinary tracts in males, and penile cancer discovered a slightly higher incidence of such problems in uncircumcised men. Although the data are limited and only show a marginal possible benefit, some

Additional info on the ethics of circumcision

Other related articles about the ethics of male circumcision:

- Jones CM. Neonatal male circumcision: Ethical issues and physician responsibility. *Am J Bioethics* 2003; 3:59-60.
- Mullen MA. Who speaks for sons? *Am J Bioethics* 2003; 3:49-50.
- Benatar D, Benatar M. How not to argue about circumcision. *Am J Bioethics* 2003; 3(2). Correspondence. Accessible on-line at: www.bioethics.net/journal/correspondence.php?vol=3&issue=2&articleID=106.

Information on-line:

- **American Academy of Pediatrics** (www.aap.org): This web site contains a fact sheet on circumcision.
- **Circumcision Resource Center** (www.circumcision.org): This is an informational web site for health care professionals that contains information and advocacy against the practice of circumcision.
- **CircumcisionInfo.com**. The site contains information and articles from physicians and health care personnel in support of neonatal male circumcision. ■

clinicians feel they provide sufficient justification for performing the operation.

Not a crime, not a cure-all

In the *AJOB* article, the Benatars examine the evidence presented in the medical literature purporting to support circumcision, as well as the ethical and medical arguments against the practice.

The evidence, they conclude, does not strongly support either side but instead supports allowing parents' discretion in choosing what they believe is best for their child, David Benatar says.

Although there is some evidence of a small medical benefit, the data don't provide a strong medical justification for the procedure, he notes. Neither, however, is there evidence that the procedure is harmful, he says. And, for families where there is a strong cultural or religious impetus to circumcise, the procedure could be considered to be in that child's best interest.

"We went into this agnostic on the question of circumcision, and we didn't know whether we would be in favor of or against. We really went in wanting to assess the evidence to the best of our ability and see where it fell," Benatar says. "The conclusion that we came to was that there is not a compelling medical argument for it, but neither is there a compelling medical argument against it. There are, however, some very strong religious and cultural arguments for it. Given that it is not clearly damaging to the child, and given that it may be beneficial — although that evidence is not clear — we concluded that it was a matter suitable for parental discretion."

A nonmedical medical procedure?

But the absence of a clear medical reason for performing circumcision is precisely the reason that the medical community should not be involved in the practice, says **George C. Denniston**, MD, MPH, a physician and president of Doctors Opposing Circumcision, a Seattle-based nonprofit group opposed to routine neonatal circumcision.

"The AAP policy statement of 1999 stated the committee searched the literature published over the past 40 years and the data were not sufficient to justify recommending routine infant circumcision," he says. "If the data are not sufficient, they are not sufficient. No one should be doing them."

The practice is not widespread in other areas of the world, Denniston adds. Eighty-five percent of the world's men are intact and experience no detrimental effects.

Removing healthy genital tissue because of the remote chance it might one day become infected or contribute to an infection makes no more sense than removing a healthy earlobe or eyelid and can be much more damaging, he contends.

Only one in 100 uncircumcised infant males gets a urinary tract infection, and circumcised males get them too, albeit at a lower rate. Penile cancer occurs in one in 100,000 men and occurs mostly in men older than 50. Circumcising 100,000 infants to prevent one case of penile cancer is not justifiable from a risk-benefit perspective, especially considering that complications from circumcisions can also occur.

Infants who die of infection after being circumcised typically are not reported, and some estimates have estimated that as many as 200 deaths per year in the United States can be attributed to complications from circumcision, he argues.

"No one, especially not a doctor, has the right to remove normal body parts from another human being. In so doing, he or she is violating the fundamental human right of every individual to an intact body," Denniston says.

Weighing cultural needs, values

Given that the United States outlawed female genital mutilation (FGM) in 1997, it seems obvious that continuing to perform male neonatal circumcision is unethical and harmful, Denniston adds. "Congressmen and women want to protect little girls from having their genitals mutilated, while leaving the field open to continue the mutilation of little boys."

Benatar agrees that many people appalled by accounts of FGM consent to male circumcision without giving it a second thought. However, comparing the two situations is not necessarily appropriate.

SOURCES

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- **George Denniston**, MD, MPH, President, Doctors Opposing Circumcision, 2442 N.W. Market St., Suite 42, Seattle, WA 98107.

"People are much less critical of practices that are culturally familiar," he acknowledges. "They are much more critical of practices which are culturally strange. Of course, it doesn't follow that our more ready acceptance of our cultural practices is mistaken, just as it doesn't follow from our criticism of other cultures that they are mistaken. One of the things we are trying to do is alert our readers to these potential biases."

The procedure normally considered to be "female circumcision" is a much more radical procedure than removal of the male foreskin, and it is incorrect to directly compare the two, Benatar says.

It would be instructional to compare male circumcision with similar female procedures, he adds. Not all societies that perform alterations of female genitalia conduct procedures that remove all of the clitoris or outer labia. In some cultures, the prepuce of the clitoris is removed — a procedure similar to the practice of male circumcision.

However, when immigrants to the United States have attempted to bring these same practices to the United States or have requested modified versions of genital-modifying procedures on female babies, these attempts often have met with complete rejection.

In the journal article, Benatar relates the failure of what is known as the "Seattle Compromise." The Haborview Medical Center in Seattle was faced with repeated requests from immigrant Somali mothers to have their daughters circumcised, with the mothers indicating the babies would be circumcised with or without the doctors' involvement. Some hospital personnel suggested a compromise procedure whereby the clitoral prepuce would be nicked to draw blood. Though some of the mothers indicated agreement with the compromise, the plan was quashed by others opposed to any nontherapeutic alteration on a girl's genitalia.

Such a decision seems to reflect a cultural bias in favor of practices that are familiar to our society and a rejection of a similar procedure because it is strange, rather than due to its perceived harm.

"If the procedures you are comparing are analogous, then it is very likely that cultural bias is causing one to too quickly condemn another culture's practice or forcing one to too readily endorse one's own culture," Benatar explains.

Opponents of all FGM should give careful consideration to whether or not they should be comfortable supporting or ignoring similar practices on male children, he says.

However, given the available evidence, both pro and con, on neonatal male circumcision performed with analgesia, Benatar does feel that cultural considerations can support the practice.

"Not being circumcised can spell exclusion from some religious or cultural activities and this could be detrimental, given one's environment," he says. "We don't think cultural considerations should be overriding. If a culture required the amputation of both a child's ears or something, or its nose, we would not endorse that. Where the medical evidence is evenly balanced, then we think cultural considerations can tip the scales."

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Privacy regs complicate communication for care

Balancing confidentiality and safety is a challenge

The privacy regulations enacted as part of the federal Health Insurance Portability and Accountability Act (HIPAA) have caused some unforeseen complications for hospitals trying to ensure patient safety and improve communication between providers and patients, say health care professionals and legal experts.

And, as hospitals continue to develop new policies and procedures to comply, it's important that they carefully examine how their efforts will affect caregiver-patient relationships.

"Some of the good things about HIPAA, obviously, were the enacting of standards to ensure

continuity of care and maintenance of insurance coverage while switching jobs and health plans," notes **Arnold Rosenbaum**, MD, a practicing surgeon and president of Seacrest DocSecurity, a HIPAA consulting firm in Middletown, RI. "But some of the regulations are actually going to impede care in some ways by slowing things down. It is impairing simple communication where there really needs to be communication."

Because HIPAA allows patients to request total or limited anonymity while in the hospital and to have a significant amount of control of over the dissemination of information about their health conditions, most hospitals have done things such as removing the patient names from large boards behind the nurses' stations and replacing names and other information on wrist bands with bar codes to prevent unauthorized disclosures of information.

While these measures do improve the patient's confidentiality, they can complicate patient care, Rosenbaum says.

"Hospitals have, in good measure, replaced the patient boards with names in most nursing units with boards that have initials or some other identifier," he explains. "But it can become quite difficult to find your own patient. There are added difficulties to patients requesting anonymity because just finding the patient becomes a significant effort for anyone who has to do it, whether it is a physician, nurse, or technician needing to draw blood. You then have more potential for treating the wrong patient, operating on the wrong patient, etc. You have now this dual purpose in preventing errors and mistakes and in maintaining privacy and confidentiality."

Communications with family members

Provider communications with family members — already difficult waters to navigate — are even more complicated now because HIPAA requires that hospitals get written authorization before disclosing information to a third party.

If a patient has established ahead of time that his or her condition can be discussed with a spouse or a child, no problem. However, providers frequently find themselves in other situations, says **William J. Spratt Jr.**, JD, a former health care administrator now a health care attorney with the Miami law firm Kirkpatrick & Lockhart, and vice chair of the Florida Bar Association's Health Law Certification Committee.

"HIPAA has put some constraints and created some doubt as to what the health care provider can do when they are dealing with a patient who is either incapacitated or in an emergency medical condition," Spratt explains. "They are limited in their disclosure. Basically, they have to make a determination of what is in the best interests of the patient and disclose only the personal health information that is directly related to that person's involvement."

So if an 85-year-old woman in Miami suffers a heart attack and is taken to the hospital, and the woman's son in New York calls to speak to the doctor, barring any prior authorization from the woman, the doctor can only confirm to the family member that the patient is receiving care at the hospital and basic information about the patient's current condition.

"But they cannot talk about it," Spratt explains. "They can't say, 'Mom had a heart attack and we've taken a look at it, and it appears to have subsided; she has some weakness of the upper wall.' They cannot go into that level of detail."

Such efforts to protect the patient may do more harm than good, says Seacrest's Rosenbaum.

"Open communication — communication with both family and other individuals — frequently is very important in patient care," he notes.

Now, physicians and nurses may feel a dual responsibility — to provide information to worried family members about a patient who may need their support and at the same time to protect their hospital and comply with the privacy protections mandated by federal law.

With no clear guidance, hospital personnel can go overboard with compliance efforts and restrict the flow of information even further than necessary, he adds.

"This issue has not been adequately clarified in the hospitals where I have worked," Rosenbaum says. "There may be a specific form relating to who can be spoken with and who cannot be spoken with, but that is very difficult to work with in the heat of the moment."

The overcompliance problem

In their efforts to comply with the privacy regulations, some facilities have gone overboard and restrict information even when they don't have to and when the patient wants his or her health information transmitted elsewhere, Spratt notes.

HIPAA allows the free flow of information among covered entities for the purposes of treatment, payment, and health care operations, without prior patient authorization. But some facilities,

under the gun to develop compliance plans, have blanket policies that require patient authorization in all instances.

"My wife had a procedure done in the outpatient center of a hospital and requested that the results be forwarded to her physician once the radiologist interpreted the study," Spratt says. "She called and asked them to send it, and they said they needed either a written authorization or she needed to come down there and pick up the results herself. That is basically a covered entity to covered entity and a disclosure for treatment purposes between a hospital and treating physician, but they were being a little overly cautious, I guess. I had to speak with them to assure them that HIPAA certainly allows them to share the results of diagnostic tests with the patient's physician."

Spratt finds that he frequently has to correct misunderstandings among hospitals and physicians and other providers about the purpose and intent of HIPAA.

"The purpose of HIPAA is not to interfere with the regular ongoing exchange of health care information that is relevant to the common treatment of patients," he notes. "It is really intended more to protect that information from disclosure outside the scope of the treating people and put some limitations on exchange of information between health care providers and insurers so that insurers can't assemble huge databases on patients that may be used for improper purposes — denying coverage of determining pre-existing conditions, things like that."

HIPAA was enacted because the health care industry was so far behind most other industries in terms of automation and use of electronic data and electronic medical records because of myriad state regulations and an overdependence on paper systems.

"HIPAA was invented to set the stage for facilitating the electronic exchange of information in order to increase efficiency and reduce health care costs by eliminating duplicative testing and things of that sort and to make the information more available to treating physicians and providers so that there may be a reduction in errors because information was not available."

At the same time, Spratt notes, the federal government was concerned that facilitating the efficient exchange of information would enable the establishment of huge databases of medical information about individuals and that this had a huge potential for abuse.

"This is a recurrent theme in federal regulations," he says. "Any time there is an initiative to aggregate substantial amounts of personal data, this element of Congress raises up and says, 'No, that's not what this country is about.'"

So, though the intention of the privacy regulations was to prevent Big Brother from knowing everything about everyone's medical condition, the real-world impact is that a worried sister might not be able to obtain information about her sick sibling hospitalized across the country.

Further complicating matters, HIPAA allows health care providers to provide information to persons without prior authorization if they are allowed to do so under state laws, but only under the specific provisions under those laws.

The only recourse hospitals have is to ensure that they understand HIPAA and its interaction with the laws in their state and that they develop policies that accurately guide their staff interactions with patients, says **Linda Ross**, JD, a health law attorney with the law firm of Honigman Miller in Detroit.

"There are already differing laws in differing states that deal with things like confidentiality and patient records and disclosures and subpoenas, etc.," she explains. "Rather than have HIPAA just trump everything, the lawmakers created a system where if the state law is contrary to, but more stringent than, federal law, the state law remains in place."

In Michigan, the health law section of the state bar spent months in committee going over the different provisions in HIPAA and any related statutes in their state to determine which requirements held.

"We created this tool for the state that is available and a guideline that goes through our analysis and decides what requirements hospitals and other entities in the state must do to comply," Ross says.

As people become more educated about and comfortable with HIPAA, much of the confusion

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and conflicts will die down, she notes. But for now, hospitals must look at everything they do for how the privacy regulations may have an effect.

They must not only develop policies that require personnel to obey the law but also ensure that the policies don't encourage staff to become so rigid in protecting information that they harm patient relationships or impede patient care.

"Especially things like patient rights — patients have a right to access their records, request amendments, and say, 'Talk to my husband, but not to my son,' or 'Call me on my cell phone, but don't call me at home," Ross says. "The result is that hospitals need to implement behavioral changes, cultural changes, and administrative changes with how they deal with patient information." ■

Updated EMTALA rule eases hospitals' risk

A final rule regarding hospital obligations to patients under the Emergency Medical Treatment and Labor Act (EMTALA) clarifies that the law applies to sites that are emergency departments or are operated to treat emergency medical conditions without an appointment.

Other provisions of the rule state that in a national emergency, hospitals in the emergency area will not be penalized if they transfer patients elsewhere in a way that otherwise would technically violate EMTALA, and that EMTALA will not apply to inpatients, including those admitted through the ED. Violating the law can result in a fine of $50,000 for each violation, and hospitals and doctors can be prevented from participating in Medicare. Patients also are permitted to sue hospitals that violate the law.

The new rule, issued Aug. 29 by the Centers for Medicare & Medicaid Services (CMS), was published in the Sept. 9 edition of the *Federal Register* and will become effective Nov. 10.

The revisions to EMTALA are "designed to ensure that people will receive appropriate screening and emergency treatment, regardless of their ability to pay, while removing barriers to the efficient operation of hospital emergency departments," according to a statement by CMS.

The American Hospital Association said it "welcomes the helpful and practical guidance" provided by the rule. However, some patient advocates fear the changes could make obtaining emergency care even more difficult for very vulnerable patients who might need specialized services or seek care at off-site, hospital-affiliated clinics.

The rule expands the definition of emergency department to mean any department or facility of the hospital, whether situated on or off the main hospital campus, that: 1) is licensed by the state as an emergency room or emergency department; 2) is held out to the public as providing care for emergency medical conditions without requiring an appointment; or 3) during its previous calendar year, has provided at least one-third of all its outpatient visits for the treatment of emergency medical conditions on an urgent basis.

The final rule clarifies that EMTALA does not apply to individuals who come to off-campus outpatient clinics that do not routinely provide emergency services or to those who have begun to receive scheduled, nonemergency outpatient services at the main campus — for example, routine laboratory tests.

In addition, the rule clarifies that EMTALA does not apply after a patient has been seen, screened, and admitted for inpatient hospital services, unless the admission is made in bad faith to avoid the EMTALA requirements.

Other provisions of the final rule include:

- Clarification of the circumstances in which physicians, particularly specialty physicians, must serve on hospital medical staff on-call lists. Under the revised regulations, hospitals will have discretion in developing their on-call lists. In keeping with traditional practices of "community call," physicians will be permitted to be on call simultaneously at more than one hospital, and to schedule elective surgery or other medical procedures during on-call times.
- Clarification that hospital-owned ambulances may comply with citywide and local community protocols for responding to medical emergencies and thus be used more efficiently for the benefit of their communities.
- Permission for hospital departments that are off-campus to provide the most effective way of caring for emergency patients without requiring that the patient be moved to the main campus — when this would not be best for the patient.

For more information, visit www.cms.gov. ▼

Johns Hopkins program loses its accreditation

The Accreditation Council for Graduate Medical Education (ACGME), the organization that monitors medical residency programs at academic medical centers, has announced it is stripping the internal medicine residency program at Baltimore-based Johns Hopkins Hospital of its accreditation due to violations of rules on how long residents in the program can work, *The Wall Street Journal* reported on Aug. 28.

The program, with 110 current residents, will lose its accreditation on July 1, 2004.

David Nichols, vice dean for education at Johns Hopkins School of Medicine told the newspaper the ACGME review took issue with the program's practice of putting a resident on a night-call shift every other night for a short period of time, provided the resident is on call only one night out of three, averaged over a four-week period.

The council ruled that "no every-other-night call is ever allowed."

The ACGME has been under pressure in recent years to more stringently enforce resident work-hour guidelines and to reduce the number of hours residents work due to public concerns about the quality of care exhausted residents might provide. **(See "Reduced Resident Work Hours: Tough Enough?" *Medical Ethics Advisor*, August 2002, p. 88.)**

Last year, the ACGME limited resident work hours to no more than 80 hours per week, with no one shift longer than 30 hours, and a guaranteed one day off in every seven.

However, the rules could be averaged over a month's time. So theoretically, a resident could be required to work a 100-hour week and then get time off at the end of the month.

The Hopkins citation may indicate the council is taking a more strict interpretation of its regulations. The hospital now has the option of appealing the council's decision or submitting a new accreditation application. ▼

AMA to provide 'ethics alerts' to MDs

Got an ethics question? If you have a handheld personal digital assistant (PDA) and subscribe to content via the ePocrates Rx on-line service, you can receive free "ethics alerts" from the American Medical Association (AMA).

The AMA announced Sept. 8 that it would provide the alerts to physicians via the ePocrates' DocAlert messaging system for PDAs.

According to the AMA, the alerts are intended to increase understanding of the AMA's Code of Medical Ethics, and thus provide physicians with practical guidance on dealing with ethical challenges in medical practice.

The AMA's Ethics Standards Division will create the content for bimonthly ethics messages, which ePocrates Rx users will receive when they "hotsync" their handheld devices. The concise alerts, which can be stored for future reference, will provide links to in-depth coverage of current issues in ethics featured on the AMA web site.

The content of each alert will be written by medical and ethics professionals in the AMA's Professional Standards Group.

"Practicing physicians frequently face ethical challenges," said AMA President **Donald J. Palmisano**, MD, JD, in a statement announcing the program. "We believe that having information at hand from the Code of Medical Ethics will help inform physicians and support them in their decisions."

The alerts will cover clinical matters such as:

- What is the professional responsibility of physicians who are asked to render second opinions and disagree with the first physician's medical judgment?
- How should physicians respond to the increasing numbers of e-mails they are receiving from patients?
- Is informed consent necessary for routine lab tests and procedures?

More information about San Mateo, CA-based ePocrates, can be found at www.epocrates.com. ■

COMING IN FUTURE MONTHS

- Organ transplants for inmates
- The impact of new changes to EMTALA
- Involuntary sterilization laws
- Composition of ethics committees

CME instructions

Physicians participate in this continuing medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity, you must complete the evaluation form provided at the end of each semester and return it in the reply envelope provided to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CME Questions

For more information about the CME program, contact Customer Service at (800) 688-2421.

13. Which one of the following represents a reason some ethicists argue against Phase I trials of oncology drugs?
A. Low potential for participant benefit
B. A high likelihood of adverse events.
C. Documented problems with informed consent
D. All of the above

14. According to our article, the potential medical benefits of circumcision are:
A. Slightly lower risk of urinary tract infections
B. Demonstrated protection against cervical cancer in female sex partners of circumcised patients
C. Lowered incidence of sexual dysfunction later in life
D. None of the above

15 According to the article, HIPAA regulations can compromise patient care by:
A. Complicating communication between providers and family members of patients.
B. Slowing patient care by making it more difficult to for individual providers to quickly identify patients
C. Requiring written authorization from patients before releasing medical information to other healthcare providers
D. A and B

16. The internal medicine residence program at Johns Hopkins Hospital was cited for allegedly:
A. Not providing appropriate supervision of residents
B. Permitting residents to perform inappropriate procedures
C. Violating guidelines on resident work hours
D. None of the above

Answers: 13-D; 14-A; 15-D; 16-C.