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## IN THIS ISSUE

- Parents whose children died in PICU share end-of-life advice . . . . . cover
- For parents, children's end of life is a spiritual journey . . . 15
- Lessons learned from parents of dying children . . . . . 16
- CMS now requires more training in using restraint . . . 17
- Newborn screening: False positives stress parents . . . 18
- Nurse charged with felony in fatal medical error . . . . . 20
- Should patients decide if their call is an emergency? . . . . . 21
- UC-David banning free pharma samples . . . . . 21
- Hastings Center examines QI, research . . . . . 23

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## Parents whose children died in PICU share end-of-life advice

*Honest, emotional care by staff helps bolster parents*

Parents of children who died in pediatric intensive care units want doctors and nurses to know that they respect and appreciate care providers' technical skills, but what they need more of is a personal, emotional connection with their children's medical providers.

"It's surprising, the depth of the relationship that can grow between caregivers and family," says **Elaine Meyer**, PhD, RN, an associate professor of psychology at Harvard Medical School and director of the Program to Enhance Relational and Communication Skills (PERCS) at Children's Hospital of Boston. "Families said emotional expressions from the staff were important to them."

Meyer and her colleagues asked 56 families of children who had died in pediatric intensive care units (PICU) in the 12 to 45 months prior to tell them about what was important to them as they were making end-of-life decisions for their children. The families, providing information via a questionnaire, identified six priorities for end-of-life care in children:

- honest and complete information;
- ready access to staff;
- coordination of communication and care;
- emotional expression and support by staff;
- preservation of the parent-child relationship; and
- spiritual or religious support. (See related story, p. 15.)

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*(Continued on p. 22)*

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"The death of a child is an unexpected and unimagined event for most families. Even families of children who are born with life-shortening conditions cannot truly be prepared, because the death of a child inherently violates the natural order and is always out of season," wrote Meyer in her report on the study, which appeared in 2006 in *Pediatrics*. Still, she added, "questions about what constitutes and how best to provide end-of-life care for children remain inadequately answered."

Physicians and nurses mostly agree — having conversations about end of life with the parents of a child is hard. One thing that might make it easier is that parents want the truth — honest and complete information.

"Some parents advocated that the 'big picture' be presented, to the extent possible, noting that

the broader clinical perspective aids with end-of-life decision making and psychological adjustment after the child's death," Meyer wrote.<sup>1</sup> "Listen. Answer all questions. Give all information — parents can handle it. What we cannot handle is not knowing what is going on."

Meyer says parents sometimes feel that technology and science sweep aside the personal and emotional segments of their child's care.

"I think that really, so much of our education resources and emphasis reflects our technical expertise, and it needs to, but I think what this [study] does is it reminds us of the importance to the families of our interpersonal skills and relational skills, and our ability to establish relationships and communicate well," she says.

In other words, parents want health care providers to keep in mind their "pure vocation" — the reasons that most of them entered health care — to help others and bring comfort to those in need.

Parents said that rather than shielding them from painful truths, medical staff should put all the information in context and be as open and honest as possible. Meyer writes in the journal article that knowing the truth is key to relieving some of the parents' guilt that can come if difficult end-of-life decisions, such as termination of care, need to be made.

"These parents had experienced end of life in a pediatric ICU, so we asked them to reflect back so that we could understand from their perspective what made for meaningful care," Meyer says. "They were quite poignant in their responses. The one thing they really felt was that staff had the capacity to really enhance those final days or hours, especially if we could be mindful of their parenthood even at the end of life and, to the extent we could, help them be the best parents they could be, even at the end of life."

### ***Emotional expression, support wanted***

Meyer says while parents want the best medical and technical care for their child, they want it to come from people with whom they can establish personal connections. Parents often had the feeling that staff — especially the primary care physician — were hurried and had little time to spend talking at the child's bedside.

"This takes us back to the purity of the original vocation — the reason you wanted to be a doctor, nurse, psychologist, chaplain," she explains. "The vast majority is because they

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1. Meyer EC, Ritholz MD, Burns JP, et al. Improving the quality of end-of-life care in the pediatric intensive care unit: Parents' priorities and recommendations *Pediatrics* 2006; 117:649-657.

wanted to help people. But sometimes the way we're socialized in medicine takes us away from that, with the demands and the paperwork.

"This is a call to come back to that. The things we associate with good bedside manner — our therapeutic use of self; here, we consider that an asset rather than a liability."

Developing — or rediscovering — those interpersonal skills is the goal behind PERCS, an educational initiative that trains staff on how to have difficult conversations with families dealing with end-of-life issues. (See "Lessons learned from parents of dying children," p. 16.)

"I think [the survey] was important, because it put [parents] in the position of expertise," Meyer explains. "Rather than us telling them what was important, we wanted them to tell us what was important." ■

## Children's end of life is a spiritual journey

*Parents draw on faith, religion to sustain them*

Despite the dominance of technology and medical discourse in the pediatric intensive care unit (PICU), many parents facing the end of their child's life view the experience as a spiritual journey as well as a medical one. Those families rely on religious faith or spiritual support as they struggle to find meaning in their children's situation and make end-of-life decisions for them.

These were two of the findings that came from

the study conducted by **Elaine Meyer**, PhD, RN, director of the Program to Enhance Relational and Communication Skills (PERCS) at Children's Hospital Boston, and **Mary Robinson**, MA, MDiv, director of Children's Hospital Boston chaplaincy. The study was an outgrowth of a survey Meyer conducted on the same group — parents whose children had died in PICU — in which she asked families what was important to them during their children's hospitalization and death. Many replied that their faith was an important resource, so Meyer and Robinson dug deeper.

"For many of us who work in the ICU, we view death as a medical event or course; but for many parents, they view it not only that way, but also as a spiritual journey, and they draw on their faith, their faith community, and religion as a source to draw on and to help guide their decisions," says Meyer.

The Parental Perspectives Questionnaire was designed to elicit parental ratings about the end-of-life care and experience, adequacy of pain management, decision making, and social support. The survey included five open-ended questions that were the focus of the analysis:

- What was most helpful to you in getting through the time at the end of your child's life?
- What was least helpful to you in getting through the time at the end of your child's life?
- How can the hospital staff improve their communication with parents at this difficult time?
- What advice do you have for hospital staff members in helping parents during this difficult time?
- What advice do you have for other parents who are facing a similar situation?

While the questions did not ask specifically about spirituality or religion, parents spontaneously offered spiritual/religious responses, Meyer says.

### **Parent-child bond transcends death**

Spiritual and religious themes were included in the response of nearly three-fourths (73%) of the parents who were queried. When asked what had been most helpful to them and what advice they would offer other parents in the same situation, four explicitly religious themes emerged:

*Prayer* — When asked what was most helpful in coping with their child's final days, and what advice they might offer to other parents, several

# Lessons learned from parents of dying children

*Hospital staff glean communication skills*

Communication between health care providers and the families of critically ill and dying children is simultaneously the most important and most difficult task in some cases. To make the best use of what staff at Children's Hospital Boston have learned about talking with families and very sick young patients, the hospital established PERCS — the Program to Enhance Relational and Communication Skills.

Through realistic enactments — doctors and nurses practicing communicating difficult information to actors posing as pediatric patients and their families — PERCS trains staff from throughout the hospital. The instructors might be staff, but it is parents and patients who teach the teachers, according to PERCS director **Elaine Meyer**, PhD, RN.

"What we teach staff is based on our findings [from interviews and questionnaires completed by families], and it is very powerful," Meyer explains. "Because it comes from the parents, usually, and it's their priority

and their recommendations, we felt like we needed to use that information to better train our staff."

Meyer says PERCS training brings many clinicians back to the "purity of their original vocation" — the human-to-human interaction and relation that drew them to health care in the first place.

"People want to do a good job with these conversations, but they're anxious and they are not feeling very well prepared," she says. "Through the realistic enactments, we have our staff learn how to have these difficult conversations, and they spend time as a team learning more about it."

The PERCS program is a day-long workshop, and is multidisciplinary in focus. Its core mission is to provide training to senior pediatric residents, fellows in critical care and emergency medicine, and nurses and other clinicians based in the Children's Hospital Boston intensive care units, though outside participants are welcome on a space-available basis.

*For more information about PERCS, go to [www.childrenshospital.org/clinicalservices.cfm](http://www.childrenshospital.org/clinicalservices.cfm), select "Critical Care Medicine" from the scroll-down menu, and scroll down the page to click on the link to PERCS. Or, e-mail Elaine Meyer, PhD, RN, director of PERCS, at [elaine.meyer@childrens.harvard.edu](mailto:elaine.meyer@childrens.harvard.edu). ■*

parents indicated prayer and urged other parents to pray often;

*Faith* — Many parents identified their faith in God when asked what was most helpful to them at the end of their child's life. Some specifically said they took comfort in their faith that their child would be cared for by God after his or her death, while others said their faith was central to their efforts to derive meaning from the event happening in their lives.

One parent, however, said faith was not the comfort she had hoped for, saying, "Just when I needed my faith, I hated it, for deceiving both my child and myself!"<sup>1</sup>

*Access to and care from clergy* — Several parents responded that ready access to their own community clergy, as well as the hospital chaplain, was important to them. One noted that a nurse had been instrumental in pointing out to the parents that bringing in a clergy member might be helpful;

*Belief that the parent-child bond extends beyond death* — Some parents offered heartfelt, emotionally charged advice to other parents, Meyer and Robinson say, and emphasized the transcendent nature of the parent-child relationship.

More than half of parents who shared their

experiences with Meyer and Robinson identified other themes that Meyer describes as "implicitly spiritual" — wisdom borne of experience; guidance according to one's own values; and virtues such as trust, hope, and love.

"These implicitly spiritual themes most often emerged in the context of advice to other bereaved parents," Robinson stated. That advice included suggestions that parents make preparations for their child's death ahead of time; not second-guess decisions after they're made; to let time and acceptance help heal; and to believe in their abilities as "terrific parents."

The parents also urged their peers to trust that the medical staff are doing the best they possibly can for the child.

Many parents emphasized the need for privacy at end of life, asking for "quiet time" and private, intimate communication with their children.

"This study gave us a deeper look into the qualitative questions [raised in the initial survey]," Meyer says. "Now that we know what matters, we can better equip our staff."

Robinson and Meyer point out that one of the more striking points made was that parents were more open about spiritual and religious themes when addressing advice to other parents than

they were when addressing advice to medical staff.

"This suggested that parents may be reluctant to share this perspective with health care providers for any number of reasons, including the fear that their spirituality may be misunderstood or judged," says Meyer. "Perhaps parents fear that their spiritual perspective might detract from the medical care of the child."

But to the contrary, Meyer says, "it's not so much what we [medical staff] think is important. If it matters to the parents, it should matter to us."

The findings, Meyer says, tell her that medical staff, hospital chaplains, and community clergy should make all efforts to be hospitable to parents' spirituality and religious beliefs and to integrate the spiritual perspective into the care of their child.

"It has taught us a lot about some of the social support aspects that are important in that intense setting," she adds.

Meyer and Robinson say hospitals can be sensitive to parents' spiritual and religious needs at their children's end of life by taking the following steps:

- Creating an environment that is hospitable to spirituality and prayer;
- Providing clinically trained, hospital-based chaplains as an integral part of the PICU care team;
- Offering a multi-faith chapel that has a flexible space, a variety of devotional materials, is convenient to the intensive care units, and is open at all times;
- Inquiring if parents are part of a faith community, and whether they wish to invite their clergy person to the hospital;
- Encouraging clinicians, hospital-based chaplains, and community clergy to partner in caring for families in crisis; and
- Being open to diversity of spiritual beliefs, avoiding imposing their own meaning to explain a child's death, and refraining from proselytizing. ■

## SOURCES/RESOURCE

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1. Robinson MR, Thiel MM, Backus MM, Meyer E. Matters of spirituality at the end of life in the pediatric intensive care unit. *Pediatrics* 2006 ;118:719-729.

# Restraining patients? CMS now requires more training

*Rule tightens use of restraint and isolation*

Nurses or physicians who place patients in restraints or in isolation now must meet stricter training and documentation requirements thanks to a strengthened federal patient's rights rule effective as of Feb. 6.

Chiefly, the new patient's rights rule issued by the Centers for Medicare & Medicaid Services (CMS), as it applies to physical restraints and seclusion, requires that health care workers who employ these measures undergo new, more rigorous training aimed at ensuring that the treatment is appropriate and that patients' rights are protected.

The new rule is a requirement, or condition of participation, that all participating Medicare and Medicaid hospitals must meet. The rule applies to short-term, psychiatric, rehabilitation, long-term care, pediatric, and substance abuse hospitals.

The new patient's rights regulation address a patient's right to notification of his or her rights in regard to care; privacy and safety; confidentiality of their records; and freedom from the inappropriate use of all restraints and seclusion in all hospital settings.

## **Increased emphasis on evaluation**

Prior to the new rule, CMS required that a patient have an in-person, face-to-face evaluation by a physician or other licensed independent practitioner (LIP) within an hour of being restrained or secluded.

Under the new rule, the list of LIPs extends to registered nurses (RNs) and physician assistants (PAs); however, when an RN or PA performs the one-hour evaluation, a physician or other LIP treating the patient must be consulted as soon as possible.

In developing the final rule, CMS took into account feedback from providers, patient advocates, and others in the health care and civic communities, dovetailing those concerns with the primary focus of patients' physical and emotional health and safety.

Under the new regulations, hospitals must provide patients or their family members with a

formal notice of their rights at the time of admission. These rights include freedom from restraints and seclusion in any form when used as a means of coercion, discipline, convenience for the staff, or retaliation. Restraint is intended to protect the patient from harm to himself or others.

CMS' final rule on patient rights adds training requirements for nurses, physician assistants, and other staff members that exceed the previous CMS rule or standards set out by the Joint Commission on Accreditation of Healthcare Organizations. The new regulation requires staff be able to show they are competent in restraining, monitoring, evaluating, and caring for patients in restraints before they are permitted to play any role in the restraint of patients.

Hospitals are mandated to ensure their staff receive training and demonstrate knowledge in:

- techniques to identify staff and patient behaviors, events, and environmental factors that could trigger the need for restraint;
- nonphysical intervention skills;
- determining the form of restraint or isolation that is the most effective and least restrictive;
- the safe application and use of all types of restraints their hospitals use;
- determining when restraints are no longer necessary in a patient;
- monitoring the well-being of the patient, including vital signs, injury, respiration, circulation, and any other requirements identified in hospital policy;
- first aid and CPR, including periodic recertification.

The CMS rule won't change much for many hospitals, which have taken patient restraint seriously as a patient safety issue, as well as a medical-legal issue, for some time. **Mike Cruz**, MD, FACEP, director of quality assurance for the emergency department at OSF Saint Francis Medical Center in Peoria, IL, says the one-hour evaluation window doesn't pose a problem in most emergency rooms, because the physicians are right there.

"In our department, by the time we decide to restrain a patient, it's an issue of the patient's safety and the staff's safety," he says; at that point a physician, as well as a nurse and physician assistant, probably has already been involved.

Saint Francis, like many hospitals, will not be impacted much by the new CMS rule, Cruz says, because it is already meeting or exceeding the requirements.

"I don't know that [CMS] is asking us to do anything more than what we already are," he says. "All nursing staff have to have that training, and that gets updated and audited two or three times a year. I specifically audit it because of the high-risk nature [of restraining patients]."

### ***Tighter reporting standards for patient deaths***

The new CMS final rule on patient restraints imposes stricter standards for reporting the death of a patient when the death is associated with use of restraint or seclusion.

Previously, CMS required hospitals to report all deaths that occurred during restraint or if restraint might reasonably be assumed to have played a role in the death.

Under the new rule, however, CMS must be informed about every death that occurs while a patient is restrained, every death that occurs in patients within 24 hours of being removed from restraints, and every death that occurs in patients within one week after they were restrained if it can be reasonably assumed that the restraints played a direct or indirect role in the death.

Deaths in any of these three categories must be reported no later than the next business day after hospital staff learn of the death, and the report to CMS must be documented.

"Through this regulation, CMS will hold all hospitals accountable for the appropriate use of restraint and seclusion," according to **Leslie V. Norwalk**, acting administrator of CMS.

The new CMS final rule on patients' rights can be found in its entirety at [www.cms.hhs.gov](http://www.cms.hhs.gov). ■

## **Newborn screening: False positives concern parents**

*Families urge better communication*

**F**or some parents who find out that genetic or metabolic tests on their newborns indicate a potential problem, finding out the results were false positive doesn't always mean the stress goes away. In some cases, the lingering stress from the false-positive scare influences how the parents perceive the health of their children for years afterward.

The solution, according to psychologist **Susan Waisbren**, PhD, is better communication — com-

munication about the meaning of newborn screens, the likelihood of false positives (and what “false positive” means), and the necessity of re-tests.

“The most surprising thing for us was that only 31% of fathers and 35% of mothers even knew the reasons for the repeat screenings” in their newborns, says Waisbren, of Children’s Hospital Boston, and director of the New England Consortium of Metabolic Programs.

“Another thing we found is that many of the physicians, according to the parents, told them ‘no news is good news’ [regarding test results], and kind of left them hanging,” she continues. “And the third thing we found was that many pediatricians feel uncomfortable talking about expanded newborn screenings, because they are so new and so many physicians don’t have experience with them. So poor physician information leads to poor family information leads to increased stress.”

Waisbren drew her findings from interviews she and colleagues conducted with 173 families who had received false-positive screening results and 67 families who had received normal newborn screening results.

What they found was that even when families who learned, after repeat tests, that their children were healthy and had no metabolic or genetic disorders, the stress of the experience colored how they viewed their children’s health status.

### **What does ‘false positive’ mean?**

Waisbren says with the expansion nationwide in newborn screens — many babies are screened for more than 30 metabolic and genetic conditions at birth — have come increased rates in false positive results. The results can come back as false positive for many reasons, and the first step when a positive result is received is to re-test the baby.

It is estimated that for every true positive result from a newborn screening, there are 12 false positives.

“That doesn’t mean you throw the baby out with the bathwater, so to speak; because the problem — the lingering stress — is not hard to fix,” says Waisbren. What is unethical, she says, is to expand newborn screening without sufficient education and follow up that includes both information and supportive counseling.

Waisbren says most families interviewed said they didn’t receive information booklets about

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Hewlett J, Waisbren SE. A review of the psychosocial effects of false-positive results on parents and current communication practices in newborn screening. *J Inherit Metab Dis* 2006; 29:677-682.

Gurian EA, Kinnamon DD, Henry JJ, Waisbren SE. Expanded newborn screening for biochemical disorders: The effect of a false-positive result. *Pediatrics* 2006; 117:1,915-1,921.

the screening, or didn’t remember if they got them. She points out that while the New England Consortium offers lots of brochures and on-line information on testing, there is a lack of information available on the tests and results. (**See box above for web address.**)

“A review of the information booklets that are available show that more are at a reading level beyond the comprehension of most families,” she adds. “And if they don’t get them or don’t remember getting them, that’s not helpful.”

A result of not knowing enough about what is happening when a newborn screen comes back positive and turns out to be false positive is that the parent doesn’t fully regain confidence in his or her child’s health.

When interviewed six months or more after their infants’ false-positive result had been ruled out, mothers in that group told the Children’s Hospital researchers that they continued to worry about their children’s health and future, said they perceived their children as requiring more care, and that both they and their children were less healthy, compared to responses from parents in the control group of families whose children did not receive false-positive test results.

Parents’ lack of comprehension about the screening process extended to understanding what was happening and when; for example, some thought the screening was actually the blood draw, or “heel prick” itself. Waisbren said her interviews revealed that two-thirds of parents with false-positive results didn’t understand why a repeat test was necessary.

“The message that families should hear is that

it's unlikely that they will get a true positive result, that here is what a false positive result is, and what markers [that can cause positive results] are," Waisbren explains. "Do markers go away forever? Does it mean the mom is a carrier, or the baby is a carrier? Being a carrier is not significant, and if parents hear that, then the worry goes away."

### **Parents need answers quickly**

Compounding incomplete information, parents said, was having to wait for results longer than they felt they should.

Some said they waited a month to get results from their child's re-test, and some said they were told "no news is good news," or worse, did not recall being told anything at all.

"Some said they were never called by the doctor's office, that they had to call themselves to get the results," Waisbren recounts. Others said they were told they would get no call unless the repeat test results were positive, so felt they were left hanging. A few parents weren't aware that their children had been re-tested.

"Families do better if they receive information sooner," Waisbren says. "They also understood more when they were able to meet personally with the physician, or got a call from the physician or nurse and could talk about the results and what they mean."

Waisbren says the take-home lessons for physicians are to ensure that: families get information about newborn screening early (rather than when they're at the hospital having the baby); the conditions that are being checked for are explained clearly; families are told what false-positive results are and why re-tests are needed; and follow-up includes making sure all questions are answered and unnecessary fears are allayed.

"I have a concern with many of the advisory boards who say the number of false positives is a reason not to expand newborn screenings," she adds. "You can do something about the false positives, but you can't do anything about the diseases if you don't screen for them."

Even parents who underwent stress as a result of the screening process told Waisbren they'd do it again.

"Looking at what parents can tolerate, they said it was a bad stress but that they would do it again" because of the importance of the diagnosis, she says. ■

## **Nurse charged with felony in fatal medical error**

*Nursing, medical societies warn of 'chilling effect'*

A Wisconsin nurse who was arrested on a felony charge stemming from an unintentional medical error that led to the death of a patient last summer will serve three years of probation after pleading no contest to reduced charges, but medical and nursing societies are concerned about the effect the case might have in future medical error situations.

**Julie Thao** was a nurse at St. Mary's Hospital in Madison, WI, in the summer of 2006 when 16-year-old Jasmine Gant was admitted to give birth. Through a series of actions, shortcuts, and omissions, all of which Thao accepted responsibility for at her sentencing in December, she mistakenly gave Gant an epidural anesthetic (Bupivacaine) intravenously. Gant was supposed to receive an IV antibiotic for a strep infection. Within minutes of receiving the epidural IV, Gant suffered seizures and died. Her child, a boy, was delivered by emergency Caesarean section and survived.

According to the investigator's report, Thao:

- improperly removed the epidural bag from a locked storage system without authorization or permission;
- did not scan the bar code on the epidural bag, which would have told her it was the wrong drug;
- ignored a bright pink warning label on the bag that stated the drug was for epidural administration only; and
- disregarded St. Mary's "5 rights" rule for drug administration — right patient, right route, right medication, right dose, and right time.

News reports quoted Thao saying, "This was my mistake, everything was my fault" at the time of her plea. She will serve three years on probation, her license has been suspended for nine months, and should she return to nursing (she was fired from St. Mary's), she will face close scrutiny of her hours and work performance.

Despite the action by the state nursing board in chastising Thao and suspending her license, medical and nursing associations have been almost unanimous in protesting the felony criminal charges in a case of a mistake.

"It is imperative that all health care professionals do everything possible to ensure that medical

errors do not happen. Patient safety is critical," according to **Ruth Heitz**, JD, general counsel to the Wisconsin Medical Society. "But to use the criminal justice system in this unprecedented manner to prosecute acts of unintentional medical errors is likely to have a chilling effect on the practice of medicine.

"Humans make mistakes. That is an unfortunate reality."

St. Mary's Hospital faced regulatory action and possible loss of its Medicare contract in the wake of Gant's death, but the violations were retracted when St. Mary's initiated staff re-education programs to address the issues that led to the error.

State and federal regulatory and licensing agencies' investigations "will improve the safety and quality of care" at Wisconsin hospitals and "will have a profound impact on the hospital, hospital staff" and Thao, according to **Dana Richardson**, RN, a spokeswoman for the Wisconsin Hospital Association.

"We are concerned, however, that unlike the other agencies involved in this case, actions by the [Department of Justice charging Thao] will actually have a negative impact statewide on the accessibility to and quality of care provided in Wisconsin," says Richardson. "Health professionals enter health care knowing that a mistake could cost them their license, livelihood, and financial stability. What is incomprehensible is entering a career where a single error could lead to imprisonment."

The state nursing board has suggested that Thao was overworked on the day of the error. She had worked a 16-hour shift that ended at midnight the previous day, and slept at the hospital so she could be back on duty at 7 a.m. Gant's death occurred shortly after noon.

As part of the sanction by the state board, if Thao returns to work as a nurse, she cannot work more than 12 hours a day, and she is limited in the areas of hospital nursing she can practice. ■

## Should patients decide if their call is an emergency?

*Answering services courting disaster*

If your after-hours answering service is asking patients calling in to decide whether their complaint is an emergency, are you asking for trou-

ble? Possibly, says a Minnesota researcher who evaluated 2,835 after-hours calls to a family medicine residency office in Denver.

Of the total calls (over a year), 288 were not forwarded to the physician on call because the caller, in response to the operator's inquiry, said their complaint was not an emergency.

Included in those calls were people who had suffered fractures, kidney stones, and at least one caller who complained of chest and radiating arm pain (who was later admitted with a gastrointestinal diagnosis).

Of calls that were not forwarded, says **David Hildebrandt**, PhD, of the department of family medicine at the University of Minnesota:

- 51% came into the office for an appointment;
- 4% went to the emergency room; and
- 2% were hospitalized within two weeks of the call.

Hildebrandt reports that 3% of the callers suffered harm due to their calls not being put through to the on-call physician; 26% experienced discomfort due to the delay.

"Although the level of harm is generally temporary and minimal, the potential exists for serious harm to occur," Hildebrandt wrote in the *Journal of the American Board of Family Medicine*.<sup>1</sup>

As in most metropolitan areas, most of Denver's primary care offices use an answering service, and 93% of those services required the patients calling in to "self-diagnose" whether their complaint amounted to an emergency.

"Although this study did not find any case of severe harm, the potential exists for serious harm and death, as in the case of the patient who called with chest pain," Hildebrandt concludes.

### Reference

1. Hildebrandt D. Physicians need to re-evaluate the way they handle after-hours calls. *J Am Board Fam Med* 2006; 19:437-442. ■

## UC-Davis banning free samples from pharma

*Move seen as way of reducing conflict of interest*

The number of academic medical centers that are banning free drug samples, free lunches, and other gifts from pharmaceutical company representatives remains small, but continues to

(Continued from cover)

new data management tool designed to help hospitals identify areas for improvement, 2007 is shaping up as a year of innovation and change for the Joint Commission on Accreditation of Healthcare Organizations and the facilities it accredits. This special paper is written specifically to explain the new standards so that you can plan appropriately.

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grow. Sacramento, CA-based University of California–Davis (UC Davis) Health System is the latest to approve policies aimed at reducing pharma’s influence on physicians and other health care staff.

Starting in July 2007, UC Davis will ban health system employees from accepting free drug samples, food, beverages, pens, notepads, and any other marketing items. Further, pharma sales reps will no longer be permitted “preceptorships” that allow them to accompany physicians during patient encounters.

“These measures are a reflection of our desire to reduce any real or perceived conflict of interest involving our relationships with the pharmaceutical industry,” UC Davis clinical care medical director **Timothy Albertson, MD**, said in announcing the new guidelines.

UC Davis joins Stanford University, Yale, and the University of Pennsylvania, all of which have adopted similar policies guarding against pharma influence.

### **Pharma gifts bring benefits, conflicts**

UC Davis’ prohibition on samples and gifts from drug companies mirrors a policy proposal issued a year ago in the *Journal of the American Medical Association*, which states that while pharmaceutical companies have provided benefits to patients through research into and development of new drugs, their fiduciary responsibility to stockholders frequently blurs the line between patient welfare and profit-

seeking.<sup>1</sup>

The *JAMA* proposal identified physicians’ behavior as part of the conflict-of-interest problem, and urged academic medical centers to prevent further compromises to professional integrity by prohibiting practices that could create conflicts of interest with drug and medical device companies.

The ban on preceptorships at UC Davis goes beyond what the *JAMA* proposal called for, however. The preceptorship program allows pharma sales representatives, in exchange for a fee, to accompany physicians during patient visits, giving the drug representatives the opportunity to cement their relationships with the doctors.

### **New committee oversight created**

UC Davis’ new system will include the Vendor Relationships Subcommittee, which will review and recommend policy changes for all potential conflicts of interest in relationships between health system staff and vendors, including equipment manufacturers, implant and device suppliers, medical supply providers, and pharmaceutical suppliers.

Acknowledging that some patients could suffer when free samples are eliminated, a new program will permit patients who meet specific income criteria to receive free or discounted drugs.

The *JAMA* proposal addresses academic medical centers specifically because of the ripple effect of their policy making and because of their role in training new physicians, but points out that physicians in any setting can be subject to an unconscious urge to reciprocate when gifts accompany drug samples.

Such proposals are opposed by the Pharmaceutical Research and Manufacturers of America (PhRMA), the largest pharmaceutical industry association in the country. PhRMA insists, in a policy statement issued in 2006, that restricting sales representatives’ access to physicians effectively cuts off doctors from prime sources of information on new medications and devices.

### **CE/CME answers**

**5. A; 6. B; 7. B; 8. D.**

## Reference

1. Brennan TA, Rothman DJ, Blank L, et al. Health industry practices that create conflicts of interest. A policy proposal for academic medical centers. *JAMA* 2006; 295:429-433. ■

# Hastings examines QI, research, ethics crossover

*Writings analyze similarities and differences*

Are research and quality improvement (QI) mutually exclusive, or natural partners? When QI crosses over into research, what ethical issues can arise?

The Hastings Center bioethics research center has assembled a collection of original papers that delve into the ethical and regulatory aspects of QI. *Health Care Quality Improvement: Ethical and Regulatory Issues*, edited by Bruce Jennings, Mary Ann Baily, Melissa Bottrell, and Joanne Lynn, is available as a free download from The Hastings Center web site (see editor's note).

Among the topics are discussions of how QI differs from research; the duty of physicians, nurses, and administrators in initiating and participating in QI activities; how to manage troublesome research ethics questions; and what oversight will ensure that QI does not harm patients.

The editors point out that ethical issues arise in QI because attempts to improve the quality of care for some patients may sometimes inadvertently cause harm, may benefit some patients at the expense of others, or may waste scarce health-care resources. Ethical issues also arise because some activities aimed at improvement have been interpreted as a form of medical research in which patients are used as subjects. If this interpretation is correct, QI would be subject to the same complex review and regulatory

requirements that have been set up to govern biomedical and other types of human-subjects research.

(For more information and to download *Health Care Quality Improvement: Ethical and Regulatory Issues*, go to [www.thehastingscenter.org](http://www.thehastingscenter.org).) ■

## 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 credit letter. When your evaluation is received, a credit letter will be mailed to you. ■

## CME objectives

After reading each issue of *Medical Ethics Advisor*, you will be able to do the following:

- discuss new information about hospital-based approaches to bioethical issues and developments in the regulatory arena that apply to the hospital ethics committee;
- stay abreast of developments in bioethics and their implications on patient care, risk management, and liability;
- learn how bioethical issues specifically affect physicians, patients, and patients' families. ■

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## CME Questions

5. Families interviewed about their children's end-of-life experiences in hospital ICUs identified six priorities for end-of-life care in children. Which of the following is NOT one of the priorities mentioned?
  - A. information screened to protect family from distress
  - B. ready access to staff
  - C. emotional expression and support by staff
  - D. preservation of the parent-child relationship(answer: a)
  
6. The Centers for Medicare & Medicaid Services' new rule on patient rights includes new requirements for the use of restraints and isolation; however, those rules apply only to patients and staff at psychiatric hospitals.
  - A. True
  - B. False(answer: b)
  
7. Some studies estimate that there are \_\_\_\_\_ false-positive results from newborn genetic and metabolic screenings for every one true positive.
  - A. 5
  - B. 12
  - C. 20
  - D. 1(answer: b)
  
8. The University of California–Davis Health System, in announcing its efforts to curtail pharma influence on physicians, has banned which of the following pharmaceutical sales perks for physicians?
  - A. free lunches
  - B. free drug samples and medical devices
  - C. marketing items
  - D. all of the above(answer: d)

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