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Chaplains offer far more than just a prayer and a handshake

Hospital chaplains a critical part of health care team

The link between a person's religion or spirituality and physical condition is one that has gained increasing recognition and consideration in health care discussions, and hospital chaplains have been in the thick of the debate.

"Chaplains provide a spiritual dimension to health care," explains **J. Vincent Guss Jr.**, advocacy commissioner for the Association of Professional Chaplains and chaplain for the Alexandria, VA-based Inova Alexandria Hospital**.** "What we know is that what affects the body affects the mind and spirit. They're all interrelated, and to treat the whole patient, you have to address each of these [components]."

Hospital chaplains are ministers, priests, rabbis, and imams, but they have received additional training in ministering to patients in the medical arena, including counseling patients and their families in end-of-life settings, when confronted with medical decisions in conflict with their religious or cultural beliefs, or when facing an unexpected or serious health crisis.

"The importance of treating a patient's spirit is well recognized," says **Rabbi Stephen Roberts**, associate executive vice president of the New York Board of Rabbis and immediate past president of the National Association of Jewish Chaplains. "One of the things JCAHO [the Joint Commission on Accreditation of Healthcare Organizations] looks for is pastoral care [in accrediting hospitals]."

Roberts says the role of the chaplain is essential in modern medicine, because changes such as the increase in technology, insistence of managed care on limited lengths of stay, and cuts in hospital staff have robbed medicine of much of the human contact doctors and patients once had.

"It doesn't really do the work of letting the spirit help the body recover, and when the spirit becomes weak, the body doesn't have the same resources to heal," he says.

Chaplains encounter patients whose conditions are testing their beliefs, their faith in themselves, and sometimes, their trust in their

ability to deal with the health issues confronting them.

Serious illness or injury may cause patients to question the meaning or worth of their lives, or to wonder why they have to endure what lies before them. Even when the patient is not in crisis, practical questions can arise over the ethics of procedures such as *in vitro* fertilization, organ donation, blood transfusions, compliance with "do not resuscitate" orders, ending life support for a loved one, or the surrendering of a newborn for adoption. In many cases, a chaplain will know how various religious bodies view medical procedures, but in any case, a chaplain will first attempt to elicit the patient's own understanding or belief about the situation or procedure in question.

"A chaplain understands the medical arena, and also understands the patient's own clergy and community," says **Jeffrey Funk**, a hospital chaplain and executive director of the Placentia, CA-based Hospital Chaplains' Ministry of America. "In making health care decisions, moral issues arise, and most chaplains are trained in dealing with the moral dilemmas that are involved in those health care situations."

Guss says that in helping bridge the span between a patient's physical and spiritual well-being, "we are not talking about just religion, but about their spirituality. People can be spiritual without being religious, and we as chaplains help mobilize spiritual resources people didn't know they had."

Roberts says many of the patients he encounters aren't necessarily anxious for his services when they first meet.

"I am always surprised by how many people say, when I walk in, 'Rabbi, I'm not religious,' and then we end up spending an hour talking," he relates. "A good chaplain does not preach and teach; a good chaplain is trained to have someone look within and draw upon their own spiritual tools — and we all have them — to help them at that moment. There is almost no one who won't benefit from a visit from a chaplain."

Patients and families facing a crisis are often less concerned with a chaplain's own religious affiliation than they are about the spiritual guidance that the chaplain can offer when needed.

"I have been a chaplain for seven years, and in that time I have found that lots of patients don't care what my faith background is. They just want to know if I can help them through their crisis," says **Jabril Rashad**, an associate chaplain at Children's Hospital of the King's Daughters in Norfolk, VA. Rashad is one of only a handful of Muslim hospital chaplains in the United States.

Rashad says that while his fellow chaplains and many patients he encounters do not share the Islamic faith, the "universal" approach taken by many chaplains and patients has meant he has felt accepted by both groups.

"We share a lot and learn from each other," says Rashad. "When you see God in others, you

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Editorial Questions

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can see God in yourself."

Sometimes, the chaplain's role begins with being a communicator between the patient and physician. Funk says it's not uncommon for patients to initially question whether a physician — for example, a specialist whom a patient has just met — understands what is important to the patient. Likewise, a physician finding resistance on the part of a patient to a particular treatment course might not initially see a spiritual or moral dilemma that a patient is feeling.

Chaplains tell of patients resigning themselves to letting a treatable illness take its course rather than seek a cure because they feel the illness is some sort of punishment for previous wrongful acts in their lives. Or they might assume — sometimes incorrectly — that a controversial method of treatment might violate their religious beliefs. By understanding and communicating the feelings of the patient, both physician and patient can often reach a conclusion that is in the best interest of the patient.

This doesn't always mean that the patient is convinced to seek the medically recommended treatment, Funk says. Sometimes, religious or cultural beliefs require that a physician accept that a patient won't be following his or her recommendations for care.

"There is a code of ethics for chaplains that's a part of our training, and it emphasizes respecting people's cultures and beliefs, no matter what our own are," says Funk, whose chaplain's association is based in evangelical Christianity. "There are cultures that hold the belief that the soul is attached to or ingrained in certain parts of the body, so if amputation or removal of that body part or organ is the treatment indicated for their condition, then they are not going to want that surgery, so we have to help everyone involved deal with that. We have to respect the culture as well as the religious or spiritual beliefs."

Chaplains not only act as occasional intermediaries between caregivers and patients, but also between patients and their families, particularly when end-of-life decisions are being made. A patient refusing lifesaving treatment may need help in gaining the understanding, if not the agreement, of family members, and chaplains are sometimes called on to facilitate in these cases.

The medical field is increasingly relying on chaplains as integral components of the health care team.

"We are receiving more and more recognition from the medical community," Guss says. "Health care used to be based exclusively on the medical model, but spiritual, physical, and psychological [components] all are interrelated, and that is being recognized and incorporated into patient care."

Rashad points out, "In the hospital setting, I consider the mind, body, and soul, and take a holistic approach. The doctors take care of the body, and the chaplains take care of the mind and soul."

The comfort of having a chaplain present can be an important factor in a patient finding his or her emotional and spiritual bearings as he or she deals with a difficult health situation.

"I like to say we are the calm before, during, and after the storm," Rashad says. "Whether it's to pray with them or to just sit with them as they clench a fist in frustration, we're there through thick and thin."

Specialized training required

To become a chaplain in any clinical setting requires that the candidate earn a master's degree in religion or theology, and then to complete additional training in clinical pastoral education at an accredited hospital.

"Also, an open mind and heart are important, and the ability to adjust," says Rashad. "Life is a teacher. You have to experience things that can't be approached in academia, like dealing with families who have survived or barely survived a major crisis. Staff members commit suicide — nothing can prepare you for that.

"Then there are the miraculous things," Rashad continues. "Diseases, cancers that a person normally couldn't overcome, and the person has overcome it."

The minimum continuing education is rarely enough to keep abreast of the changes in medicine, Funk says.

"You have to keep up, with all the advances in medicine," he observes. "If you are at a facility that doesn't practice much in the areas of biotech and genetic manipulation, you might not read and study those areas, but then all of a sudden you realize that this is moving forward fast and you don't understand it."

A decade ago, says Funk, physician-assisted suicide and other end-of-life issues were the hot ethical topics chaplains were contending with. They have been replaced by new questions arising from scientific advances in cloning and genetic manipulation.

Guss says possibly the greatest challenge for not only chaplains, but also all caregivers, is the

mapping of the genome, which he says also is potentially the greatest breakthrough in medical science in this generation.

"The future is in genetic medicine, and our challenge is to learn about it and about the spiritual and emotional issues surrounding it," Guss predicts.

Caring for the caregivers

Chaplains are quick to point out that their role is not merely to serve the patients and their families. Hospital staff, including the clinical staff, frequently draw on the experience of chaplains to help them help their patients.

"Doctors approach a lot of ethical challenges, and they ask our opinion. We talk about that and discuss what will help them out," says Rashad.

Physicians, nurses, or hospital staff who are struggling with a bad patient outcome can come away with more peace of mind, he says, even if there are unanswered questions.

Roberts sees a chaplain as an "ambassador to the whole hospital," there to serve each person who is in the hospital, no matter if that person is a doctor, nurse, administrator, support staff, patient, or family member.

"I won't forget doctors who just agonize over patients' decisions," says Funk. "They're left with an unhappy outcome, so chaplains can provide appropriate support to those on the health care team, as well."

Guss says that chaplains are not the only members of the medical community who can act as spiritual support. Peer groups among nurses and physicians often work to counsel clinical staff through emotionally difficult situations, with chaplains involved to "motivate and educate," he says.

"Hospital staff, from the physicians to the housekeeping staff, have personal problems that we can help put in perspective so that while they're here [at the hospital], they can stay focused on the job," adds Rashad. "The reality is that not all surgeries go well, and they are left feeling, 'Well, where do we go from here?'"

Rewards for hospitals and chaplains

A consensus paper written by the five largest health care chaplaincy organizations in North America and published in 2001, *Professional Chaplaincy — Its Role and Importance in Health Care*,[1] reports that the benefits to the hospitals served by professional chaplains are not just intangible, feel-good qualities.

According to the authors of the consensus paper, chaplains assist their institutions in obtaining and maintaining accreditation standards associated with patients' rights to spiritual care and support. They can reduce a hospital's exposure to litigation by mitigating situations in which patients and families are dissatisfied, angry, or threatening, and thereby potentially minimize legal costs.

The only published chaplaincy cost study, reported in 1995,[2] reported that the services of professional chaplains range from $2.71 to $6.43 per patient visit — a cost that the consensus panel deemed cost-effective to the institutions.

But the true rewards, chaplains say, can't be measured on paper.

"Chaplains provide the institution's heart, and the rewards are what keep us doing the work we do," Roberts says. "It's when you see someone who says they have no ability to cope with what they're going through; and a week later, they're on their way out, having used skills they didn't even know they had."

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Simple steps, big payoff in patient safety

IHI aims to save 100,000 lives

You may think your hospital is doing a good job of preventing common errors that result in patient deaths, but the American Medical Association (AMA) and the Institute for Healthcare Improvement (IHI) think you can do better. In fact, they think hospitals in the United States can save 100,000 lives between now and June 2006.

The 100,000 Lives Campaign is designed to prevent common hospital system errors that can result in unintended patient deaths, and its goal is to involve 1,500 to 2,000 hospitals in an effort to do what the AMA and IHI say hospitals should be doing anyway — following established guidelines and practices so they can avoid mistakes that kill patients.

AMA to educate physicians

The AMA's contribution to the campaign, which was launched in December at the IHI's National Forum, will be to educate individual physicians — particularly those who work in hospitals — about the program's initiatives.

"The AMA plans to use its full range of resources to educate physicians about the campaign and secure their participation," AMA president **John C. Nelson**, MD, MPH, said at the time, "The AMA's position has always been (that) one preventable error is one too many. This campaign will allow the AMA to help physicians help their patients while improving health care safety."

Nelson pointed out that the campaign draws much needed attention to the patient safety movement and provides physicians and other health care professionals with specific strategies to meet an attainable goal.

"Saving lives and helping patients is why most physicians choose to enter medicine in the first place," he explained. "Physicians are on the front lines delivering care, and it's important that the AMA and its member physicians support this campaign."

The 100,000 Lives Campaign centers on six proven initiatives that studies have shown can save lives. The initiatives are:

- Using rapid response teams at the first sign of decline in patients who are progressively failing outside the intensive care setting.
- Ensuring the reliable delivery of evidence-based care for patients hospitalized for acute myocardial infarction.
- Preventing ventilator-associated pneumonia by reliably implementing a set of interventions known as the "ventilator bundle."
- Preventing surgical site infections (SSIs) by reliably implementing a set of interventions known as the "SSI bundle" in all surgical patients.
- Preventing adverse drug events by implementing medication reconciliation.
- Preventing central venous catheter-related bloodstream infection (CRBI) by implementing a set of interventions known as the "central line bundle" in all patients requiring a central line.

IHI president **Donald M. Berwick**, MD, MPP, says the initiatives are not new, but with strict adherence to what they already know is effective, the efforts of 1,500-2,000 hospitals can achieve the goal of 100,000 lives saved.

"The names of the patients whose lives we save can never be known," he comments. "Our contribution will be what did *not* happen to them."

In addition to the AMA, a host of other groups have enlisted in the campaign, including the American Nurses Association, the Centers for Medicare & Medicaid Services (CMS), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the Veterans Health Administration.

Hospitals committed to change

Hospitals enrolling in the campaign are committing to actively pursue one or more of the six key interventions. Other interventions devised by individual hospitals may be included, Berwick says.

Hospitals agree to report their mortality data, which will be used to gauge the success of the interventions and the campaign itself. Data will be made public in aggregate, not identified by institution.

IHI provides the information needed to participate in the campaign on its web site (www.IHI.org), and there is no cost to participate. However, participating organizations must be willing to implement changes and to participate in the reporting process.

The AMA will be making conference calls, state by state, to medical directors of all interested or participating hospitals, to assist in starting and implementing the campaign interventions.

Berwick says the campaign is not a retread of

SOURCE

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what hospitals are already doing — it's a new way of looking at what the medical community knows works.

"Hundreds of health care organizations have been making changes that improve care and reduce patient harm," he says. "Now is the time to harness those experiences and apply the best methods, reliably, 100% of the time."

He cites statistics that make the consistent use of these methods necessary:

• The Institute of Medicine estimates that as many as 98,000 people die each year in U.S. hospitals due to medical injuries.

• The Centers for Disease Control and Prevention in Atlanta estimates that 2 million patients suffer hospital-acquired infections each year.

• Studies show although the United States spends the most money on health care of all industrialized nations, it still performs poorly on many measures of health care quality.

Nelson pointed out that the results of simply doing what works, all the time, are impressive. A hospital in Heidelberg, Austria, achieved a 65% drop in cardiac arrests and a 37% drop in mortality after introducing rapid response teams, one of the 100,000 Lives Campaign initiatives.

Additionally, Berwick says, prompt administration of aspirin reduces the risk of death in vascular events by 15%, and using beta-blockers reduces death in the first week after acute myocardial infarction by 13% and long-term mortality by 23%. Despite this evidence, a recent RAND Corp. study found that only 61% of these patients received aspirin and only 45% received beta-blockers.

Other groups participating in the campaign include the American Nurses Association, CMS, JCAHO, and the Veterans Health Administration.

To prevent medication errors, a special focus will be on transition points where, according to the IHI, 46% of these problems occur.

Transition points include admission and discharge from the hospital and transfer from one hospital unit to another. Nelson said hospital-nursing home transfers would receive close examination.

To prevent central line-associated bloodstream infections, surgical site infections and ventilator-associated pneumonia, the campaign suggests that no one intervention will eliminate undesired outcomes single-handedly. Instead, a bundle of strategies are recommended, and it's suggested that the bundle be treated as a single performance measure instead of highlighting each of the individual interventions in the bundle. ■

Who decides when to turn off lifesaving devices?

MDs should discuss when to turn off ICDs

Implantable cardioverter defibrillators (ICDs) are lifesaving devices, as demonstrated by a 2004 study that showed ICDs reduced death by 23% in people with moderate heart failure and poor pumping function, compared to patients who did not receive ICDs.[1] But what if that lifesaving device outstays its welcome and prolongs death because its users haven't discussed when their ICDs should be deactivated?

Nathan Goldstein, MD, assistant professor in the Brookdale Department of Geriatrics and Adult Development, Mount Sinai Medical Center, NY, says a study he and several colleagues conducted on patient deaths and ICDs indicates that as many as one-quarter of patients whose families participated in the study had received shocks from the ICD in the last month of life, and some of those received shocks in their final moments of life, when defibrillation shocks cause discomfort, anxiety, and a prolonged death. Defibrillators are surgically placed inside a patient's chest to provide ongoing heart rhythm monitoring and standby intervention, and they automatically shock the heart during a cardiac arrest or irregular heartbeat.

"It was incredibly distressing to the families," says Goldstein, who helmed the study, "Management of Implantable Cardioverter Defibrillators in End-of-Life Care," published in the December 2004 *Annals of Internal Medicine*. "The patient may have been essentially unconscious; but when the shock is delivered, [had] grimaced, and this was very distressing to the patient's family."

Goldstein and his fellow researchers contacted the next of kin of people who had had ICDs implanted at Yale University but who are now deceased.

"We did a retrospective study, and what we

wanted to find out were details about the patient's death; particularly about ICD," says Goldstein. "We called the next of kin, and asked them details about the patient's death."

The questions included "Did the patient get the shock at the end of life?" and "Was there ever a discussion of turning off the lifesaving equipment?"

Goldstein says his team's first realization was that patients with implantable defibrillators were not having discussions with their physicians about turning off the defibrillator, and when.

Goldstein says the study found that discussions between physicians and patients about deactivating defibrillators took place in only 27 of 100 cases of terminally ill patients at Yale-New Haven (CT) Hospital. Even among patients with do-not-resuscitate orders, discussions about continued use of the device occurred in fewer than 45% of the cases.

Doctor-patient discussion needs work

What surprised Goldstein, he says, was the number of people he and his colleagues found who were not aware it is possible to deactivate ICDs. Those who did know still were not likely to have talked about it with the family member who had the ICD.

Of the 27 (out of 100) patients who did have discussions about deactivating their ICDs, 21 elected to turn off the devices. But Goldstein and his team found the discussions about deactivating the defibrillators were not conducted well in advance of death, but in the last few days or hours — even minutes — of the patients' lives, after some had received shocks that family members described as "distressing."

The authors also report that 27 people they talked with stated that their next of kin received a shock within the last month of their lives. Only nine of these patients had subsequent discussions with their clinician about deactivating their ICDs, and six of them elected to turn off their devices.

"I think if you glance at the study, the main takeaway point is that people should know they can turn off their ICDs, but some people never knew it was even an option," Goldstein says.

"Why don't we talk about them?" Goldstein asks. "One reason is that physicians in general don't have lot of experience in talking about this."

One resource physicians can call on is a palliative care team, with members who have the expertise to help patients and families weigh the question of quality of life vs. quantity.

Goldstein said the issue is a difficult one, because it involves deactivating a device the patients and physicians may have been relying upon heavily to keep the patient alive for the previous months or years since it was implanted.

"The device is not bad," Goldstein points out. "It is doing what it is supposed to be doing [in delivering shocks to restart or regulate heartbeats]."

What's the optimal death?

Talking with a family member or other loved one about deactivating an ICD when his or her health has reached a point at which "restarting" the heart may not be in the patient's best interest is not an isolated discussion, but one that should be part of a larger discussion of quality of life vs. prolonging life, Goldstein says.

When a patient has an ICD implanted, it typically is with the anticipation that he or she has years to live with a good quality of life. But what if, after a while, the patient is diagnosed with a disease that will result in death, with a significantly diminished (by the patient's standards) quality of life. Is there a point at which arrhythmia may be a better mode of dying than death from other causes?

"What is the optimal death? That can only be answered on an individual basis," Goldstein says. "This is an option — the patient can continue to live out his or her life as long as possible. But another option is maybe that dying suddenly might be a better outcome for some people.

"Would they rather die sooner, or live longer with more suffering or symptoms? That is a question that only each individual can answer."

But to answer it, people with ICDs need to know their options, he points out.

Finding the correct time for a physician to discuss the options of deactivating the device can be difficult. Some experts advocate making it part of patient education at the time the defibrillator is implanted. But others say the devices are so

SOURCE

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complicated, and the patient has to learn so much about how it works; implantation is not a good time to bring up deactivation.

Some institutions have included ICD deactivation as one of the subjects in its formal consent for care agreement; other patients learn of the options during discussions of do-not-resuscitate orders. However, Goldstein found that fewer than 50% of patients who had do-not-resuscitate orders had talked about deactivating their ICDs.

He says he plans a future study to determine some optimal times for bringing up the issue of turning off ICDs.

Goldstein says his study is not meant to indicate patients should be counseled to deactivate their ICDs should it become clear that death is imminent.

"There were families who said they did have discussions about deactivating the devices, but the patients decided to leave them on, and that was a good outcome because there was discussion and the patients' wishes were followed," he says.

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Elective C-sections continue to rise

Safety vs. vaginal delivery still debated

Women increasingly are electing to give birth by cesarean when there is no medical necessity to do so; meanwhile, the debate about the safety to the mother continues.

While there are some who insist the safety of elective cesareans in healthy mothers is comparable to birth via vaginal delivery, others say the risks of surgery should cause cesareans to be reserved for medical necessity. The American College of Obstetricians and Gynecologists (ACOG), is somewhere in between, advising member physicians that they are ethically obliged to "counsel" patients who ask about elective cesareans in otherwise healthy pregnancies, but has not come out with a guideline about when physicians should say "yes" or "no" (when the safest choice for the patient is not clearly indicated).

HealthGrades, a Lakewood, CO-based health care quality company (www.healthgrades.com) issued a report in 2004 analyzing 1,684 hospitals in 16 states, representing approximately 50% of all deliveries in the United States. The findings are that "patient choice" cesarean deliveries rose 25% in the United States from 2000 through 2002, representing 2.21% of all deliveries in the United States in 2002. HealthGrades released a similar study in 2003, examining data from 1999 through 2001, and found that the percent of elective cesareans grew from 1.56% to 1.88% — a 20% rise for those three years.

Questions about safety still debated

"When we conducted this study last year, we were able to show a clear trend toward an increasing number of women choosing cesareans over vaginal births," says **Samantha Collier**, MD, HealthGrades' vice president of medical affairs. "Now we see that this increase is continuing, and that the overall in-hospital complication rates for 'patient choice' cesareans may be lower than that of vaginal deliveries."

HealthGrades' report states that women who choose a cesarean over vaginal delivery have reduced overall in-hospital complications. But the authors of a statistical review that appeared in the on-line version of the *British Journal of Medicine (BMJ)* in 2004 is not so confident.

"Although some recent editorials have suggested that vaginal births carry risks comparable to caesarean births, health problems associated with caesareans have been amply documented," wrote **Eugene Declercq**, MD, the author of the *BMJ* article and a professor of maternal and child health at Boston University School of Public Health.

The article, "Rise in 'no indicated risk' primary caesareans in the United States, 1991-2001: Cross-sectional analysis," appears on-line at www.BMJ.com.

Declercq concludes that more research is necessary to determine whether the risks of elective surgical are outweighed by potential benefits.

Jeffrey Ecker, MD, a high-risk obstetrician at Massachusetts General Hospital in Boston and vice chairman of ACOG's Committee on Ethics, says that even though patients will ask for elective cesareans, and ACOG has not issued an opinion, "absent compelling data and appropriately

designed studies, I and many in ACOG believe that most pregnant women are best served by a trial of labor and vaginal delivery."

The authors of the HealthGrades report conclude that elective cesareans, as compared to traditional vaginal delivery, are not without real immediate-term risk, but describe those risks as "feasibly comparable." On average, HealthGrades states, about eight out of every 100 mothers who choose to have cesareans develop at least one major complication, likely related to bleeding, infection, or the surgical wound, while traditional vaginal delivery is associated with 12 out of every 100 mothers developing significant vaginal tears or lacerations, pelvic floor or organ injuries, or bleeding complications.

What to say to patients who ask

Whether because it is more convenient to schedule a cesarean delivery than to wait for the surprise of the onset of natural labor, or because mothers believe the long-term physical effects of giving birth will be lessened by surgical delivery, most researchers agree that the number of elective cesareans will continue to rise.

What, then, does an obstetrician say to his healthy patient, in whom neither surgery nor vaginal delivery is prescribed or contraindicated, who wants to schedule an elective cesareans?

In 2003, ACOG published *Surgery and Patient Choice: The Ethics of Decision Making*, a report on how physicians can help their patients make decisions on any surgeries when there is a lack of clear evidence for or against the surgery. In that report, the ACOG ethics committee used elective cesareans as an example of an elective surgery decision that doctors may be presented with. Ecker says this use of cesareans as an example has let some to erroneously conclude that ACOG supports elective surgical delivery.

"I, and many who practice, recognize that some patients will request elective cesarean delivery. The Ethics Committee statement offers guidance on how to appropriately approach such requests," he says. In the 2003 report, he continues, the Ethics Committee writers argue that in situations in which evidence is inconclusive or unavailable — as many would argue is the case with the issue of elective cesarean delivery — after informed discussion and careful consideration of alternatives, a patient may choose, and a practitioner appropriately offer, such elective surgical intervention.

"The obstetric community is split by this issue, with some believing that women who understand the risks should be able to choose," says Collier. "Others believe that it is malpractice to allow someone to choose major surgery when it is not necessary."

She points out that thus far, insurers and providers have largely stayed out of the debate; however, with some research indicating that cost might be a factor, Collier sees the debate widening.

"With C-sections costing more than vaginal deliveries, we can expect them to weigh in on this growing trend," she says.

Possibly adding to the debate are data from a study University of Texas researchers who concluded that elective cesareans may be the most cost-effective in terms of postpartum costs, when considering the expense of pelvic floor complications (urinary and fecal incontinence) that can result from vaginal delivery. In presenting a poster on the study, "Patient selection of mode of delivery: A cost-benefit analysis," (available at the University of Texas-Houston web site, www.research.uth.tmc.edu/researchforum/abstracts.pdf) author **Nora M. Doyle**, MD, told the Society for Maternal-Fetal Medicine in 2004 that while there might be long-term savings with elective cesarean in healthy women, "women need to be told this is surgery, and that any surgery is serious. It takes longer to recover from a cesarean than a vaginal birth, and there can be complications."

The University of Texas researchers recommend additional research into the long-term complications before adopting elective cesareans as a delivery strategy. ■

Drug re-importation: Risks worth the rewards?

Congress not taking a firm stand — yet

It's illegal, it may undermine international treaties, and there are warnings that patient safety is at risk — but for many, the cost savings of buying re-imported drugs outweighs all the arguments against it.

Pressure is on Congress to enact legislation that would make it easier for consumers to purchase prescription drugs from Canadian pharmacies. Many of the pharmacies are selling the drugs that were imported from the United States — thereby,

"re-importing" U.S.-made drugs.

Pharmaceutical manufacturers, who have federal law on their side at the moment, are reacting by refusing to sell their products to Canadian pharmacies that sell to American consumers.

The U.S. Food and Drug Administration (FDA) is watching closely, not yet ready to prosecute individual consumers buying prescription pharmaceuticals for personal use, but not saying it won't.

Just recently, American Medical Association (AMA) delegates attending the AMA's Interim Meeting offered conditional support to measures that would permit U.S. consumers to buy re-imported drugs, provided it was through a "closed system" that would ensure FDA oversight.

The ability of pharmacies and wholesalers to buy U.S.-made drugs back from other nations is a promising way to lower prescription prices, provided the system meets rigorous safety requirements, the AMA delegates said.

"This clearly is an advocacy position for our patients," according to AMA trustee **Edward L. Langston**, MD. "We're trying above all to advocate patient safety and appropriate medications for them when prescribed."

Laws not stopping some

"It is legal for pharmaceutical manufacturers to re-import their own drugs, but the importation of drugs by others, technically, is illegal," says **Crystal Rice**, public affairs specialist for the FDA's Center for Drug Evaluation and Research in Rockville, MD. "That said, FDA is not going to go after individuals who are buying drugs from other countries, but has and will continue to take action against commercial entities that are importing unapproved drugs into the U.S."

Chief among these are companies that are importing unapproved or potentially unsafe drugs and selling them to patients as brand name, approved, prescription drugs.

But individuals are not the only ones skirting the FDA. Governors in several states and mayors of some large cities in the United States have overseen the creation of programs that allow their citizens and public employees to purchase drugs from Canada, in hopes of containing the rising cost of prescription drugs.

The U.S. Department of Health and Human Services (HHS), in a report issued by a task force in December 2004, revealed that roughly $700 million in drugs came into the country from Canada alone in 2003. An equivalent number of drug products flowed from other nations during that year. While many of the purchases were by individuals who visited foreign pharmacies or imported drugs via overseas vendors, state governments aiming to look past borders to find lower costs facilitated some.

The FDA has issued a number of sternly worded letters of warning to mayors and governors, signed by FDA associate policy and planning commissioner William K. Hubbard, asking that they reconsider their administrations' ties to prescription drug sources that might not adhere to FDA safety criteria.

Wisconsin Gov. Jim Doyle, whose administration was one of the earliest to create a web site providing Wisconsin residents with links to Canadian pharmacies, was warned of the following safety concerns by the FDA (letters available at www.fda.gov/importeddrugs):

- The number of Canadian pharmacies that have been found lacking in safe pharmacy practices even in pre-announced initial inspections by state inspectors from Minnesota and have not been inspected by appropriate U.S. regulatory authorities.
- The Canadian pharmacies listed on [the Wisconsin] web site that sell drugs that have not been manufactured, shipped or held within FDA oversight, and to our knowledge the State of Wisconsin has not even attempted to inspect these pharmacies to assess their safety practices.
- The drugs listed on [the Wisconsin] web site have less expensive FDA approved, generic versions available in the United States. Consequently, Wisconsin citizens, on [the web site's] recommendation, may pay more for foreign drugs than they could pay in the United States for a FDA-approved generic version.

SOURCES/RESOURCES

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- **Crystal Rice**, Public Affairs Specialist, Center for Drug Evaluation and Research, U.S. Food and Drug Administration. Phone: (301) 827-1673. E-mail: ricec@cder.fda.gov.

- **Center for Drug Evaluation and Research**, web site: www.fda.gov/cder.
- **U.S. Food and Drug Administration**, "Buying Prescription Medicines Online: A Consumer Safety Guide." Available on-line at www.fda.gov/cder/drug/consumer/buyonline/guide.htm.

• The fact that [the Wisconsin] web site continues to include disclaimers that place the "sole responsibility for any purchase from the Canadian pharmacies listed" on Wisconsin citizens using the web site, while the state "expressly disclaims any and all liability from such importation." [The] disclaimer stands in stark contrast to our current U.S. prescription drug regulatory system that assures the safety and efficacy of all FDA-approved drugs.

Rice says the FDA has not yet taken any action against a state or municipality over facilitating U.S. residents in purchasing re-imported drugs, "but we have not said that we would *not* take action against a city or state. We have not sued one up to this point, although it is an option."

Patient safety issues dominated debate on the AMA Board of Trustees report that contained the AMA delegates' recommendations, and concerns that an AMA endorsement would encourage doctors to back risky practices prompted delegates to add language stating that the AMA would work to educate members about re-importation's risks, as well as possible benefits.

The AMA report cited recent FDA seizures of imported drug shipments containing drugs that are illegal here or were manufactured improperly, and questioned the ability of the FDA to oversee increased numbers of shipments of imported drugs.

Boom may be its own undoing

But the re-importation boom may be its own undoing. U.S. pharmaceutical companies have responded to the violations of the law on re-importation by refusing to supply foreign pharmacies that sell drugs back to U.S. consumers. This has led to a shortage of some drugs in other countries, driving those prices higher than prices for the same drugs sold in the United States.

Until re-importation to consumers becomes clearly legal, some patients may have trouble finding physicians who will knowingly assist them in obtaining prescription medications from overseas or, if the medicines require injection or intravenous use, to help them take the medications.

Physicians in Wisconsin are notifying their patients of the safety concerns and avoiding involvement in directing their patients to pharmacies.

The HHS report warns that lawsuits could become a problem even if Congress legalizes re-importation nationally.

"Allowing prescription drug importation would have uncertain effects on the litigation exposure of manufacturers, distributors, doctors, and pharmacists," the document states. "The primary factor in determining litigation risk — the number and severity of injuries — is not amenable to analysis at this time."

No federal action against individuals

The HHS report specifies numerous safety and cost concerns associated with re-importing drugs, but does not urge federal action against individuals who are purchasing their drugs from outside the country.

The AMA's support for a national policy on re-importation would come with hefty safety restriction. To get the AMA's backing, delegates said, a proposed system would need to approve only FDA-approved and regulated drug products, with all products distributed through a closed chain subject to reliable electronic tracking, and with necessary resources and authority from Congress to allow the FDA to ensure the safety of the products.

The HHS warns of another potential effect of legalized re-importation — the HHS re-importation task force estimates that research and development incentives will be lowered by legalized re-importation, resulting in between four and 18 fewer new drugs introduced each decade. This is based on the theory that if revenues fall for pharmaceutical companies, their research and development spending also would fall.

While the FDA is not currently prosecuting individuals who purchase re-imported drugs, it is offering tips to help consumers make safe choices. Chief among those warnings is that individuals check with the National Association of Boards of Pharmacy [www.nabp.net, (847) 698-6227] before ordering from a pharmacy on-line, to make sure the pharmacy is in good standing. ■

COMING IN FUTURE MONTHS

- Pediatric bioethics center
- How much is too much cosmetic surgery?
- Consent in mentally impaired patients
- Privacy in teaching hospitals

CAM, conventional therapies held to same research standard

In a new report, the Institute of Medicine calls for conventional medical treatments and complementary and alternative medical (CAM) treatments to be held to the same standards for demonstrating clinical effectiveness to make it easier for health care providers and the public to make evidence-based decisions about CAM use.

The report says the same general research principles should be followed in evaluating both types of treatments, although innovative methods to test some therapies may have to be devised. It says randomized controlled trials are the "gold standard" for providing evidence of efficacy, but that other study designs can generate useful information on treatments that do not lend themselves to such trials.

The National Institutes of Health (NIH) and Agency for Health Care Research and Quality sponsored the study to help NIH develop research methods and set priorities for evaluating CAM products and approaches. More than a third of U.S. adults report using some form of CAM, which includes chiropractic and acupuncture to herbal remedies. ■

CME Instructions/Questions

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.

5. Which of the following criteria must chaplains in clinical settings meet?
   A. Earn a master's degree in religion or theology
   B. Complete additional training in clinical pastoral education at an accredited hospital
   C. A and B
   D. None of the above
6. A recent study indicated that physicians should do a better job of letting patients know that implantable cardiac defibrillators can be deactivated. When, according to the study, should this information be conveyed?
   A. Near the time of death
   B. Immediately after implantation
   C. During discussion of do-not-resuscitate orders
   D. An optimal time for discussing deactivation has not yet been determined.
7. The American College of Obstetricians and Gynecologists recommends that, when faced with a healthy pregnant patient who requests an elective cesarean and who has no medical reasons not to undergo surgery, a physician is ethically bound to comply.
   A. True
   B. False
8. Which of the following could be subject to legal action by the FDA regarding purchasing re-imported drugs?
   A. Individual U.S. citizens
   B. City or state municipalities
   C. Canadian companies
   D. A and B

Answers: 5-C; 6-D; 7-B; 8-D.