it to the country in which the device will be reused. Once there, the device is sterilized and tested at the hospital where the operation will take place. Patients receiving the device are also not charged for the surgery, hospital stay, or follow-up care. Heart Too Heart doesn't buy or sell the used devices. After a device is implanted, he writes to the donor's next of kin “thanking them for the pacemaker and letting them know it’s been put to the best possible medical use.”

Heart Too Heart’s efforts aside, the practice of making used cardiac devices available to individuals in developing countries is apparently not widespread, despite the preferences of surveyed morticians and patients for explanting such devices for reuse in other patients. Device manufacturer Medtronic Inc (Minneapolis), says the company does not support the reprocessing or reuse of its implantable cardiac devices, saying such practices have the potential to introduce unacceptable risks to patients safety and quality medical care. A spokeswoman for the US Food and Drug Administration (FDA) said the agency does not recommend the practice of exporting used cardiac devices. However, she added, the sending of such a device outside the country does not need FDA approval provided the importing country allows it and the device is not resold back to the United States.

**IMPROVING SAFETY**

While patients, morticians, and charitable groups favor altruistic uses for explanted cardiac devices, the Heart Rhythm Society, which represents cardiac arrhythmia professionals, focuses on improving the safety and performance of these devices. As a response to the recalls in 2005, as well as the FDA’s attempts to improve postmarketing safety monitoring announced earlier this year, the society put together a task force on device performance policies and guidelines (Carlson MD et al. Heart Rhythm. 2006;3:1250-1273).

In October, the task force issued recommendations calling for all devices to be returned to the manufacturers for analysis regardless of the cause for explantation: battery depletion, recall, device malfunction, or patient death. The task force called upon the Heart Rhythm Society to educate physicians, nurses, patients, families, pathologists, and morticians on the importance of notifying a deceased patient’s physician to expedite returning the device to the manufacturer. Other recommendations by the task force include getting legally binding patient consent for postmortem device evaluation and explantation and, in absence of such consent, seeking approval for explantation from family members.

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**Precautions, Skills Key for Child Sedation**

Bridget M. Kuehn

**NEW GUIDELINES FOR PEDIATRIC sedation are calling for practitioners to have greater levels of skill and to be prepared to provide emergency care if a child has an adverse reaction.**

The guidelines were issued jointly by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry in December after more than 3 years of development. They update and unify previous guidelines established by the 2 organizations independently and emphasize uniform standards for the growing number of practitioners who are sedating pediatric patients for procedures outside of the hospital. During the past decade it has become more common for pediatric sedation to be used in such varied settings as dental offices, physicians offices, imaging facilities, and ambulatory surgery centers, according to the guidelines.

As noted in the guidelines, children often require sedation to control their behavior and allow physicians or other health care practitioners to safely conduct a variety of procedures. But these younger patients are also more vulnerable to such negative effects of sedation as impaired breathing. Richard Gorman, MD, a member of the work group that produced the joint guidelines, explained that the same precautions are needed during sedation of both children and adults, but the much smaller margin of error for dosing in children mandates closer monitoring of sedated children. Children also are less able to alert observers if they become distressed than are adult patients.

To address these concerns, the guidelines call for appropriate physiologic monitoring of pediatric patients during and after the procedure. This includes having sufficient numbers of properly trained staff to monitor patients and having on-site monitoring devices available, such as electrocardiography machines, pulse oximeters, and end-tidal carbon dioxide monitors.

“Monitoring will give practitioners an early warning so they can intervene earlier and more effectively [if a child becomes distressed during] these procedures,” Gorman said.

Other recommendations include:

- Requiring medical supervision when sedating medications are administered to children
- Careful presedation evaluation for underlying medical or surgical conditions that could increase risks
- Proper training in airway management and venous access for clinicians
- Age- and size-appropriate equipment for airway management and venous access, as well as appropriate sedating medications and reversal agents
- Recovery to presedation level of consciousness before discharge and appropriate discharge instructions
- A clear understanding of the drugs being used, their effects, and potential drug interactions.