

PATIENT-FOCUSED CARE AND SATISFACTION™

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INSIDE

More on family-centered care

- **Are you ready to involve the family?** Ask these key questions 87
- **Survey says:** Knowledge breeds satisfaction . . . 88
- **Help with paperwork:** Sample advisory council application 89
- **Further reading:** More information on family-centered care 90
- **Getting started:** How to form a council 90

■ **Millennium checkout alert:** FDA issues Y2K critical devices warning 91

■ **Classified devices:** List of potential high-risk, may-fail devices 92

■ **Electrophysiology test may predict SCD risk:** Investigators induce VT in CAD patients 94

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Want to bring the family into patient care? Look to pediatrics for a model

Your results should be improved satisfaction, lower costs, better outcomes

Often what works for adult medicine is distilled into practice for pediatric patients. But one area, pediatrics, has something to teach other branches of medicine: how to provide family-centered care. "It has its roots in pediatrics, but its principles apply across the board," says **Beverly H. Johnson**, president and chief executive officer of the Bethesda, MD-based Institute for Family-Centered Care. The institute is a nonprofit organization that promotes family-centered care and assists organizations interested in implementing its principles of collaboration and partnership between the patient, family, and caregiver.

For organizations that embrace family-centered care, there are many potential rewards, including improved patient and family satisfaction scores (see related story on how collaboration between patients and practitioners promotes patient satisfaction, p. 88), decreased length of stay, and less use of emergency departments. There are even ongoing studies that seem to suggest improved outcomes, too. For example, says Johnson, one Vermont group is doing a comparison of its 11 sites to see if outcomes are better at locations that use the principles of family-centered care.

"We work to help bring together health care consumers and professionals across all disciplines," explains Johnson. "If they can talk together about what works and what doesn't, they can design a better health care system. Maybe we can work better, more cost-effectively, and we could have people leave the system — patients, families, and staff — feeling better about it if we did more of this."

The facilities that truly embrace family-centered care do more than simply ask patients and their families for input. They get the family and

"[People] sue because they have a bad relationship with their care provider — there was no respect, communication, or sharing of information. The flip side of that is what family-centered care is all about."

consumers of health care services involved in the planning of hospital programs and facilities, in the decision-making process, and in acting on the results of patient satisfaction surveys.

Among the organizations that have done so is the Dana Farber Cancer Institute in Boston. Through its Patient and Family Advisory Council, consumers have had a voice in issues as mundane as getting patient weights taken in private, and as complex as getting involved in the design of a new inpatient facility at Brigham and Women's Hospital. In the latter instance, says public information officer **Todd Ringler**, patients and family members participated in move-planning committees, joined patient relations staff on daily rounds for two weeks after the move, and even escorted patients to the new unit on move-in day.

The advisory council includes four staff members and 12 consumers (**for more on forming an advisory council, see article, p. 90**). They sit on quality improvement committees, make up part of facility design task forces, and have even helped drive the creation of a task force on alternative medicine.

Most people believe that the technical care they get at a hospital is sophisticated, explains **Pat Tommet**, RN, PhD, CPNP, director of family-centered care at Children's Hospitals and Clinics of Minneapolis/St. Paul. But what can make the difference to patients and their families are the kind of value-added touches that come with having truly patient and family-focused care.

Consumers are more knowledgeable

Family-centered care is something that Tommet thinks no organization will be able to do without in the future. "Right now, consumers are growing more knowledgeable about what they want from health care, and are less willing to tolerate the status quo" she says. "Most consumers of hospital services can't measure the technical expertise of health care providers. But they can evaluate the care they received from a personal perspective. If their opinion is sought and they are treated as a partner and team member, they will feel respected.

Most people respond favorably to good service and to family-centered care. That is a collaborative partnership."

In implementing the kinds of changes family-focused care demands, there are bound to be some obstacles, says Johnson. For instance, nurses were the ones who instituted visiting hours. But in family-centered care, the family is part of the team that makes a patient well. They are not visitors, but are welcomed at any time, day or night, whether there is a shift change under way or rounds going on.

Physicians, too, have to change the way they work. For instance, many prefer to do well-baby exams of new babies in the nursery, without parents present. It is faster for them due to fewer interruptions. But in family-centered care, Johnson says, they do those exams with the parents present. "It allows the doctor to model how to communicate with the baby and touch and hold the baby. But for some doctors, this is a huge change."

At many hospitals, staff members think they already operate a family-centered environment. But, says Johnson, "hospitals are often convinced by their own PR. They don't really have family-centered care." Just getting them to accept this fact is hard. "And if you do, then you have to convince them this won't take more of their time, but less. After all, people don't sue for bad outcomes. The risk management literature says they sue because they have a bad relationship with their care provider — there was no respect, communication, or sharing of information. The flip side of that is what family-centered care is all about."

Tommet agrees that family-centered care is a journey, not a place, and that few hospitals have actually arrived there. "Many organizations do parent or patient satisfaction surveys," Tommet says. "Some even do focus groups. They see that as family input. But then they take that information to departments, units, or committees and let staff make the change happen. The next level in family-centered care is to make sure that patients

(Continued on page 88)

COMING IN FUTURE MONTHS

■ Bringing PFC to your ED

■ Teaching physicians to provide patient-focused care

■ Starting from scratch: Planning for PFC during facility design

■ Cross-training your nurses for PFC

■ Reaching out to male patients

Think you're family-centered? Try this self-assessment

According to **Beverly H. Johnson**, president and chief executive officer of the Institute of Family-Centered Care in Bethesda, MD, a lot of hospitals believe they already offer family-centered care to their patients. But she says that before you make that claim, you should do a self-assessment. The institute offers a comprehensive assessment tool that addresses each of the following 10 areas:

1. Vision, mission, and philosophy of care.

Vision, mission, and philosophy of care statements are key documents that set the tone and direction for the institution and the services it offers. Does yours convey an explicit commitment to patient-and-family-centered care? Do they show that the beliefs, values, and priorities of patients and families are key considerations in hospital services? And do these statements convey respect for families and their pivotal role in promoting the health and well-being of patients and families?

2. Facility design and allocation of space to support family-centered care. The physical environment of your facility can either support or hinder the practice of patient-and-family-centered care. Do your facilities — including parking, the lobby, and entrances to departments and units — convey positive and welcoming first impressions? Do your facilities encourage family participation in care?

3. Patient and family participation in care. The wording of policies and dissemination of information about participation in care can impact the patient and family's participation in decision-making, and the attitudes of patients' families about health care. You should ask yourself if patients and their families are seen as important members of the health care team. Are they encouraged and supported in care planning and decision-making? Are family members considered visitors, and are they welcome at all times, regardless of rounds, changes of shift, or other unit events? Can patients have their families with them during procedures and treatments? Even the words you use in policies can have an effect. Do yours include flexible, positive words like *offer*, *choose*, and *support*, rather than *allow*, *permit*, and *require*?

4. Information to patients and families.

Providing information in ways that patients and families see as helpful empowers and supports them in nurturing. Offering them the kind of information they want, in the format they wish, is important, says Johnson. Do patients and families have opportunities to ask questions of physicians and nurses? Are patients and families involved in the ways that the hospital and its staff provide information? Do you have a patient and family resource library? Can patients and their families use the hospital medical library?

5. Facilitation of peer support and family-to-family support. For many families, meeting others

who have gone through what they are experiencing is as valuable as getting support from health care professionals. Do you give patients and their families information about peer support groups? Do you hire patients or family members to facilitate peer or family-to-family support groups? Do you have a patient or family liaison on staff?

6. Documentation and charting. The charting policies and forms you use in your facility can foster patient and family dependence, or they can help encourage patient and family participation. Do your forms promote the identification of patient and family strengths and goals? Are patients and families (with the patient's permission) allowed to read their charts and record comments and observations in it?

7. Links to home and community resources. The transition to and coordination of services are important. Is there a single person assigned to help patients and families with discharge or transition planning? Do you link patients and families with services such as respite care, hospice care, home health services, or transportation assistance?

8. Recruitment and selection of personnel, job descriptions, performance appraisals. The human resources department can ensure that your staff, across all disciplines and departments, have the knowledge and skills to deliver family-centered care. Are your job descriptions and performance appraisals written in ways that are consistent with patient and family-centered principles — especially regarding communication and patient/family/physician collaboration? Do your orientation and continuing education programs convey information about family-centered care and the skills needed to deliver it?

9. Approaches to assist students and professionals-in-training in acquiring patient and family-centered knowledge, skills, and attitudes. To acquire patient-centered and family-centered knowledge, students and professionals in training need the chance to learn directly from patients and their families, and work both in the hospital and in non-clinical settings. Do you facilitate this?

10. Quality improvement. How are patients who have been consumers of health care services and their families getting involved in planning, evaluation, and quality improvement initiatives for your facility? Do you have a patient and family advisory council included in your quality improvement program? Do you use patients and their families to find solutions to ideas, suggestions, and concerns raised in your patient satisfaction surveys?

The tool asks the above-listed questions, and asks for a ranking of your facility's performance in each area. After rating each item, the tool asks for specific examples that illustrate how family-centered care is or is not happening in relation to each item.

Once you have completed the assessment, the tool helps you plan how to implement — or better implement — the principles of family-centered care at your hospital. ■

Empowered patients are usually more satisfied

New Press, Ganey study supports theory

When Beverly H. Johnson, president and chief executive officer of the Institute for Family-Centered Care in Bethesda, MD, says that providing information to patients and their families is good for patients and hospitals (see **related story on family-centered care, cover**), she has some empirical data to back up her assertion.

A new study by Press, Ganey Associates Inc. in South Bend, IN, compiled data from more than 250,000 patients in 476 hospitals. In particular, the consultancy looked at whether the hospital took the initiative to inform and explain to patients their rights as patients. Hospitals that provided this information to patients had higher mean satisfaction scores than those that did not — 84.9 for the former, 81.2 for the latter.

According to Press, Ganey president **Irwin Press**, PhD, organizations that embrace the idea of a patient bill of rights — whether it is law or not — are enhancing the idea of collaboration between the patient and the health care professional.

This isn't the first Press, Ganey study that supports the idea that informed patients are happier with their health care. A study earlier this year showed that patients who had communication from their health care provider about life support options and organ donation were also more satisfied with the care they received than those who did not.

"Patients are naturally more satisfied when they are empowered through knowledge," says **Rodney Ganey**, the firm's CEO. "They want to be informed, they want to have choices, and they want to be protected. Successful health care organizations will be those that respect the role the patient plays in decision-making." ■

and their families are involved in the design of the delivery of care, that they help effect the changes that the surveys indicate are needed. While doing a survey is better than nothing, it is still paternalistic, not collaborative."

There is a financial impact to bringing a family focus to your hospital — at least in the short run. For instance, if one aspect of your family focus is to

build patient and family resource centers, there will be a cost to staffing them, to providing the kinds of information and modes of providing it — such as computer terminals with Internet hookups — that patients and families demand.

And there are staff costs to family-focused care. You have to find staff members who have experience in this kind of atmosphere, or you have to train them, says Johnson. And your continuing education has to focus on the principles of collaboration and teaming with the patient and family. But down the road, says Johnson, there will be savings — in time and money.

Find the right people

Should you decide to go forward, you should start by pulling together an informal work group of consumers to conduct a self-assessment (**for more on assessing how family-centered your facility is, see box, p. 87**). "Don't just get a focus group together. Get a group that will work through the entire process," Johnson says. You'll also want to have some staff members involved.

To find the people to be part of that initial group, Johnson suggests contacting departments that work with patients over and over again — such as oncology departments, for instance. They will likely have the names of patients or families who might be interested. To get its initial group together, Dana Farber sent a letter to every patient, asking if they might be interested in working with the hospital. More than 100 people showed up.

Once you know where you are, you simply have to integrate patients and their families into the committee structure at your hospital. And, says Johnson, if you are in the midst of planning a new unit or facility or renovating an existing one, "never ever, ever do it without getting input from patients and families. A lot of health care dollars are spent on facility design, and a lot of it is not a healing environment — it is intimidating."

The impacts that family-centered care can have may seem small to a large hospital, but they can be huge to patients and their families. For instance, at Children's in St. Paul, one site didn't carry extra-large-sized diapers. The family of one recurring patient, a 4-year-old with developmental problems, was always told the hospital did not have the diapers and the family would have to provide them. The mother went to the family advisory council who worked with the director of materials management to solve the problem. "It took some time,

(Continued on page 90)

Sample application

CHILDREN'S HOSPITALS AND CLINICS

Parent Advisory Council Member Application

Name: _____

Home Address: _____

Mailing Address: _____

City: _____ State: _____ Zip Code _____

Telephone (include area code): _____

Names and ages of Children: _____

Relationship to Child: _____

1. Have any of your children been hospitalized at Children's Hospitals and Clinics?

____ Yes ____ No _____ Which site? _____

If yes, date of first and last admission/visit: _____

Age of child seen: _____

2. What units and services were involved in your child's care? _____

3. Have you used Children's Hospitals and Clinics Outpatient Services? Yes ____ No ____

If yes, which services or clinics were used and when? _____

4. Why would you like to be on the Parent Advisory Council? _____

5. Areas of special interest/skills: _____

6. Areas of concern you would like to see the Parent Advisory Council become involved with: _____

7. We believe the Parent Advisory Council should reflect the cultural diversity of families who are consumers of hospital services. In light of this, please share anything about yourself that you feel would add to the diversity of our Council. Some examples of diversity include: ethnic, racial, spiritual, social, economic, educational, geographic, gender, sexual orientation, unique family structure, single parent, full-time parent.

Please return the completed application to:

**Parent Advisory Council
Department of Family-Centered Care
Children's Hospitals and Clinics
2525 Chicago Ave.
Minneapolis, Minnesota 55404**

Rev. 1/99

Source: Children's Hospitals and Clinics, Minneapolis.

Suggested Reading

Editor's Note: This is not a comprehensive list. Further suggested reading is available by contacting the organizations listed on p. 91.

Maternity Care:

- Beckett P, Wynne B, Redmond S. Mother-baby care: A roadmap for success. *J Fam Cent Nurs* 1996; 1:10-13.
- Midmer DK. Does family-centered maternity care empower women? The development of the woman-centered childbirth model. *Fam Med* 1992; 24:216-221.

Newborn Intensive Care:

- Als H, Lawhon G, Duffy FH, et al. Individualized developmental care for very low-weight preterm infant: Medical and neurofunctional effects. *JAMA* 1994; 272:853-858.
- DeGuehery KA, Noyes SL. Family-centered care: Application to practice. *Mother-Baby Journal* 1998; 3:26-32.
- Griffin T. Nurse barriers to parenting in the special care nursery. *J Neo Nurs* 1990; 4:56-57.
- National Association of Neonatal Nurses. *Infant and family-centered developmental care guidelines*. Des Plaines, IL; 1995. Available from the association. Telephone: (847) 299-6266.

Family-Centered Care in Pediatrics

- Dunst, CJ. "Conceptual and empirical foundations of the family-centered practice." In: Illback R, Cobb C, Joseph H, eds. *Integrated Services for Children and Families: Opportunities for Psychosocial Practice*. Washington, DC: American Psychological Association; 1997, pp. 75-91.

- Horsburgh CR. Healing by design. *N Engl J Med* 1995; 333:735-740.
- Leyden CG. Consumer Bill of Rights: Family-centered care. *Pediatr Nurs* 1998;24:72-73.

Adult Health Care

- Beckman HB, Markakis KM, Suchman AL, et al. The doctor-patient relationship and malpractice. *Arch Intern Med* 1994; 154:1,365-1,370.
- Blank AE, Horowitz S, Matza D. Patient's Perspective: Quality with a human face? The Samuels Planetree model hospital unit. *Jt Comm J Qual Improv* 1995; 21:289-299.
- Gerteis M, Edgman-Levitan S, Daley J, et al., eds. *Through the Patient's Eyes: Understanding and Promoting Patient-centered Care*. San Francisco: Jossey-Bass Publishers; 1993.
- Levinson W, Roter DL, Mullooly JP, et al. Physician-patient communication: The relationship with malpractice claims among primary care physicians and surgeons. *JAMA* 1997; 277:553-559.

Medical Education/Professional Education

- Darling RB, Peter MI, eds. *Families, Physicians, and Children with Special Needs: Collaborative Medical Education Models*. Westport, CT: Auburn House; 1994.
- Heymann J. *Equal Partners: A Physician's Call for a New Spirit of Medicine*. Boston: Little, Brown & Co; 1995.
- Levinson W, Roter D. The effects of two continuing medical education programs on communication skills of practicing primary care physicians. *J Gen Intern Med* 1993; 8:318-324. ■

but this was a child who was hospitalized with some regularity," says Tommet. "And we are a children's hospital, so you can assume that this was not the only family affected, but was the only family who came forward. Because the council is an organized group with an inside knowledge of our organization, they could make this happen. It seems simple, but for that family, and for other families, it was important."

"At the heart of family-focused care is respect for people and families," says Johnson. "It boils down to communication and relationships and involving families in decision making. It means that the family that wants a lot of information can get it, but one that doesn't want it won't be forced to take it. And if they change their minds later, they can."

"You can have all the medical information about Down syndrome," says Tommet, "but not every child with Down syndrome is the same. And you may know all about Down syndrome, but you don't know all about a particular child with Down syndrome. The family knows more about their child. You have to respect that." ■

Attention, patient families: Hospitals need your input

Here's a guide to forming a family advisory council

You might think that getting patients and their families to serve on a family advisory council would be easy: After all, the press is full of stories that spotlight health care consumers who seem to want more of a say. But both the Dana Farber Cancer Institute in Boston and the Children's Hospitals and Clinics of Minneapolis/St. Paul have had trouble filling their slots initially.

According to **Pat Tommet**, RN, PhD, CPNP, director of family-centered care at Children's, it took an entire winter to get the 18 members of the council on board. And to do that meant posting signs in elevators, patient rooms, reception areas, and waiting rooms.

It also meant having a good application form (see sample form, p. 89) that expressed the interest of the hospital in having a committee that was

SOURCES

- **Beverly H. Johnson**, president and chief executive officer, Institute for Family-Centered Care, 7900 Wisconsin Ave., Suite 405, Bethesda, MD 20814. Telephone: (301) 652-0281.
- **Pat Tommet**, RN, PhD, CPNP, director, Family-Centered Care, Children's Hospitals and Clinics of Minneapolis/St. Paul, 2525 Chicago Ave., S., Minneapolis, MN 55404. Telephone: (612) 813-6044.
- **Irwin Press**, PhD, president, and **Rodney Ganey**, CEO, Press, Ganey Associates Inc., 404 Columbia Place, South Bend, IN 46601. Telephone: (800) 232-8032.
- **Todd Ringle**, public information officer, Dana Farber Cancer Institute, 375 Longwood, Boston, MA 02215. Telephone: (617) 632-5520.

Organizations:

- **Planetree**, 130 Division St., Derby, CT 06418. Telephone: (203) 732-1365. Web site: <http://www.planetree.org>.
- **Institute for Family-Centered Care**, 7900 Wisconsin Ave., Suite 405, Bethesda, MD 20814. Telephone: (301) 652-0281. Web site: <http://www.familycenteredcare.org>.
- **Association for the Care of Children's Health**, 19 Mantua Road, Mt. Royal, NJ 08061. Telephone: (609) 224-1742. Web site: <http://look.net/acch/>.

representative of patients on a racial, geographical, and socioeconomic basis. The hospital also wanted representation of families of patients from premature babies through teenagers. "In the application, we wanted families to think beyond race when we asked them what kind of diversity they could bring to the table."

Although the hospital found its members, recruitment takes a continued effort. The terms last three years and are staggered so that a third of the members turn over annually. "We look for representatives of different styles of family, from teenage parents to single parents to two-parent families," explains Tommet, "as well as culturally diverse families."

There has been a continued effort to try to encourage ethnic diversity, but Tommet thinks the way they look for members — through an annual campaign and application process each year — is more likely to attract the white middle classes than others. There is a new push to partner with outside community groups, doing presentations at

their meetings to try to get a truly representative group on the council. Council members also work to find replacements, bringing information to their primary care physicians and sending applications to good candidates. "We look for a diversity representation that is similar to our patients and families served," Tommet says. "We want to be truly representative." ■

FDA: Check Y2K problem list of high-risk equipment

What about your critical medical devices?

Recent surveys of hospitals and medical groups indicate that most think they will be ready for any potential problems related to the year 2000 (Y2K) computer bug. One recent poll by the American Medical Group Association of Alexandria, VA, found that more than 95% of its respondents have discussed Y2K; more than 90% had a strategy for dealing with potential problems associated with Y2K; and 86% had a contingency plan in development.

But according to the Food and Drug Administration (FDA), some biomedical equipment you may have might not work — or work correctly — come Jan. 1.

To help the medical community deal with the problem, the FDA has developed a list of types of computer-controlled, potentially high-risk medical devices that have the potential for the most serious consequences for the patient should they fail because of date-related problems.

The list (see p. 92) is very comprehensive, and the FDA notes that inclusion on the list doesn't mean that the device has a problem, or are not Y2K-compliant, that they pose a risk to patients. The administration plans to use the list to audit manufacturer claims of compliance and later issue a list of non-compliant devices.

The equipment included in this list includes items that are:

- **used in the direct treatment of a patient where device failure could compromise the treatment or could injure the patient;**
- **used in the monitoring of vital patient parameters and whose data are immediately necessary for effective treatment;**
- **are necessary to support or sustain life during treatment or patient care.**

The list does not include diagnostic devices whose failure would not result in immediate harm to the patient, even though the diagnostic information they provide might be unavailable or incorrect. However, a few diagnostic devices have been included, if the results of calculations or other information processing by the device would not be readily apparent to the user, and if a Y2K failure of the device could reasonably lead to serious adverse health consequences before being detected by the user.

The list below contains the potentially high-risk device types. Where the generic device type has been classified by the FDA, the list includes the section number in Title 21 of the Code of Federal Regulations where the device type is described. That information can be found at the FDA Web site, www.fda.gov/cdrh/yr2000/classification.html. For those devices cleared for market through the pre-market approval application process or have not yet been classified, no classification regulation number is given.

The Web site also includes links to the Federal Y2K Biomedical Equipment Clearinghouse Search — www.fda.gov/scripts/cdrh/year2000/y2k_search.cfm — to determine the compliance status of medical devices, as reported by the manufacturers. An additional link is provided to the Manufacturer Registration Database — www.fda.gov/scripts/cdrh/cfdocs/cfrl/registra/search.cfm — which contains names and addresses of manufacturers who have registered with the FDA. ■

Classified Devices

(Classification regulation number followed by classification name)

- **862.1345** — Glucose test system
- **862.2140** — Centrifugal chemistry analyzer for clinical use
- **862.2150** — Continuous flow sequential multiple chemistry analyzer for clinical use
- **862.2160** — Discrete photometric chemistry analyzer for clinical use
- **862.2170** — Micro chemistry analyzer for clinical use
- **868.1150** — Indwelling blood carbon dioxide partial pressure (pCO₂) analyzer
- **868.1200** — Indwelling blood oxygen partial pressure (pO₂) analyzer
- **868.1730** — Oxygen-uptake computer
- **868.2375** — Breathing frequency monitor

- **868.2450** — Lung water monitor
- **868.5160** — Gas machine for anesthesia or analgesia
- **868.5330** — Breathing gas mixer
- **868.5400** — Electroanesthesia apparatus
- **868.5440** — Portable oxygen generator
- **868.5470** — Hyperbaric chamber
- **868.5610** — Membrane lung (for long-term pulmonary support)
- **868.5830** — Autotransfusion apparatus
- **868.5880** — Anesthetic vaporizer
- **868.5895** — Continuous ventilator
- **868.5925** — Powered emergency ventilator
- **868.5935** — External negative pressure ventilator
- **868.5955** — Intermittent mandatory ventilation
- attachment
- **870.1025** — Arrhythmia detector and alarm
- **870.1750** — External programmable pacemaker
- pulse generator
- **870.3535** — Intra-aortic balloon and control system
- **870.3545** — Ventricular bypass (assist) device
- **870.3600** — External pacemaker pulse generator
- **870.3610** — Implantable pacemaker pulse generator
- **870.3700** — Pacemaker programmers
- **870.4220** — Cardiopulmonary bypass heart-lung machine console
- **870.4320** — Cardiopulmonary bypass pulsatile flow generator
- **870.4330** — Cardiopulmonary bypass on-line blood gas monitor
- **870.4360** — Nonroller-type cardiopulmonary bypass blood pump
- **870.4370** — Roller type cardiopulmonary bypass blood pump
- **870.4380** — Cardiopulmonary bypass pump speed control
- **870.5225** — External counter-pulsating device
- **870.5300** — DC-Defibrillator low energy (including paddles)
- **876.5270** — Implanted electrical urinary continence device
- **876.5630** — Peritoneal dialysis system and accessories
- **876.5820** — Hemodialysis systems and accessories
- **876.5860** — High-permeability hemodialysis system
- **876.5870** — Sorbent hemoperfusion system
- **876.5880** — Isolated kidney perfusion and transport system and accessories
- **880.5130** — Infant radiant warmer
- **880.5400** — Neonatal incubator
- **880.5410** — Neonatal transport incubator
- **880.5725** — Infusion pump
- **882.5820** — Implanted cerebellar stimulator
- **882.5830** — Implanted diaphragmatic/phrenic nerve stimulator
- **882.5840** — Implanted intracerebral/subcortical stimulator for pain relief

- **882.5850** — Implanted spinal cord stimulator for bladder evacuation
- **882.5860** — Implanted neuromuscular stimulator
- **882.5870** — Implanted peripheral nerve stimulator for pain relief
- **882.5880** — Implanted spinal cord stimulator for pain relief
- **884.1700** — Hysteroscopic insufflator
- **884.1730** — Laparoscopic insufflator
- **884.2660** — Fetal ultrasonic monitor and accessories

The following device classifications include radiation treatment planning systems that are accessories to these device types.

- **892.5050*** — Medical charged-particle radiation therapy system
- **892.5300*** — Medical neutron radiation therapy system
- **892.5700*** — Remote controlled radionuclide-applicator system
- **892.5750*** — Radionuclide radiation therapy system
- **892.5900*** — X-ray radiation therapy system

**The above-specified device classifications include radiation treatment planning systems that are accessories to these device types.*

Post-medical device amendments Class III devices, and devices not yet classified

- Ventilator, high frequency
- Cardioconverter, implantable
- Defibrillator, automatic implantable cardioverter
- Defibrillator, implantable, dual-chamber
- Pulse-generator, dual chamber, implantable
- Pulse-generator, program module
- Pulse-generator, single chamber, sensor-driven, implantable
- Pulse-generator, single chamber
- System, pacing, temporary, acute, internal atrial defibrillation
- Automated blood cell and plasma separator for therapeutic purposes
- Lipoprotein, low density, removal
- Separator for therapeutic purposes, membrane automated blood cell/plasma
- Pump, drug administration, closed loop
- Pump, infusion, implanted, programmable
- Kit, test, alpha-fetoprotein for neural tube defects
- Stimulator, cortical, implanted (for pain)
- Stimulator, electrical, implanted, for Parkinsonian tremor
- Stimulator, sacral nerve, implanted
- Stimulator, spinal cord, totally implanted for pain relief
- Stimulator, subcortical, implanted for epilepsy
- Device, thermal ablation, endometrial ■

T-graft technique promises longer-lasting bypasses

New configuration may avoid or delay re-CABGs

A new surgical technique for coronary artery bypass grafts has been shown to be safe, effective, and an economic improvement on surgical methods currently used for such operations. A study describing T-graft configuration was presented at the annual meeting of the Chicago-based Southern Thoracic Surgical Association in St. Louis earlier this year and will be published in a few months in the *Annals of Thoracic Surgery*. Investigators found that their technique results in longer-lasting bypasses with reduced chances for postoperative infections.

Researchers examined 650 patients who had undergone bypasses using T-graft configuration. They tracked operative survival, wound infection, and incidences of such conditions as stroke and found the operation to be safe and “a better alternative to current techniques used for bypasses,” stated senior study author **Hendrick B. Barner**, MD, professor of cardiothoracic surgery at Washington University School of Medicine in St. Louis.

The mortality rate for patients in the study was 0.2% — one person out of 650 died within 30 days of the operation. “That’s an incredibly low rate,” said Barner. “For low-risk patients, the rate for the standard procedures ranges from about 1% to 3%.”

The T-graft configuration technique uses arteries from both the arm and chest to form a T-shaped conduit around the diseased portions of the heart. The study’s authors say the method, while complicated to master, offers surgeons a longer, wider conduit to work with as they revascularize the heart compared with using both internal thoracic arteries.

Traditional bypasses that use a leg vein as the conduit work well, but for a limited time, commented Barner, because the vein doesn’t “like” being part of the arterial system. What’s more, he said, veins used in bypass operations harden — about half close within 10 years, leaving patients back where they started.

Within 15 years of a bypass operation, some 75% of all veins develop atherosclerotic plaque, and patients “end up needing another bypass 10 years after the first one,” he said. Over the last 20 years, surgeons have been substituting internal thoracic

arteries for the leg veins because arteries outpace veins and remain disease-free at least twice as long.

The Washington University study examined the effectiveness of using one artery from the chest, the left internal thoracic artery, and one from the forearm, the radial artery. The primary benefit, stated Barner, is that the radial artery is longer than the right internal thoracic artery, offering surgeons more flexibility when fashioning the alternate conduit. Using the radial artery also lowers the risk of chest wound problems. When surgeons use both internal thoracic mammary arteries, they run the risk of sternal infections because that artery provides blood to the sternum. Breastbone infection was experienced by only four patients, or 0.6% of the study group.

What's unique about Barner's technique, though, is the configuration, which uses fewer arteries without reducing blood flow. The body

hosts seven potential arterial conduits, two in the chest, two in the arm, one in the abdomen, and two in the lower abdominal wall, though the latter may be quite short and are of limited usefulness. With the T-graft technique, only two conduits are utilized instead of three, four, or five.

"If you use four arterial conduits in one operation, there's only three left," said Barner, "and that could be a problem if you needed another operation at a future date."

Some surgeons were concerned that the T-graft may not provide enough blood flow to the heart muscle. Not so, said the investigator. Only 2%, or 14 patients, experienced temporary low-output syndrome, meaning that the heart still functioned below expected levels despite the surgery. Compared with 2% to 5% incidence of low cardiac output after coronary grafting, Barner said, "that number was gratifyingly low." ■

Electrophysiology test may predict SCD risk

Investigators induce VT in CAD patients

Electrophysiology studies can help predict who is at risk for sudden cardiac death (SCD) and guide treatment to prevent a significant number of those deaths, researchers report. Information on their study was presented in May at the 20th annual scientific session of the North American Society of Pacing and Electrophysiology (NASPE) in Toronto.

Investigators for the Multicenter Unsustained Tachycardia Trial (MUSTT) evaluated more than 2,200 patients believed to be at high risk for SCD. Electrophysiology studies were conducted to determine whether sustained ventricular tachycardia (VT) could be induced in certain patients with coronary artery disease (CAD). Key results:

- **Patients in whom VT could be induced were 1.4 times more likely to subsequently die than those in whom VT could not be induced.**
- **Among patients in whom VT could be induced, deaths were reduced by 27% in those who received therapy compared with those who received no therapy.**
- **Among patients who received therapy, deaths were reduced by 74% in patients treated with a defibrillator compared with patients treated with antiarrhythmic drugs.**

- **At five years, 32% of patients in whom sustained VT could be induced had died, compared with 24% of those who could not be induced.**

Patients evaluated in MUSTT had a history of CAD combined with depressed function of the left ventricle of the heart and a history of spontaneous nonsustained VT. In patients in whom sustained VT could be induced, half were initially treated with antiarrhythmic drugs and half received no therapy. If electrophysiology studies showed that the initial drug therapy was not effective in preventing VT, patients received other drug therapies or were given a defibrillator. Of 2,202 patients enrolled in the study, sustained VT was induced in 767. Of these, a total of 704 were randomized, with 353 receiving standard drug therapy and 351 receiving no therapy. A total of 161 patients went on to receive defibrillator therapy.

Azimilide shows promise for PSVT and SCD

At the same meeting, a study was presented that showed that azimilide, an investigational antiarrhythmic drug manufactured by Procter & Gamble Pharmaceuticals, significantly reduced the risk of recurrence in patients with symptomatic paroxysmal supraventricular tachycardia (PSVT).

"For years, radio frequency ablation has been the standard of care. However, noninvasive drug therapy is preferred by many physicians and patients," said **Richard Page**, MD, a lead study investigator from the University of

Texas Southwestern Medical Center in Dallas. "Azimilide showed potential as a valuable addition to the range of drug therapies currently available to treat PSVT."

The studies showed that patients on placebo had a 135% greater risk of a symptomatic arrhythmia recurrence vs. patients treated with azimilide. On average, patients on azimilide were 60% more likely to be free of a symptomatic occurrence on any given day as compared to patients on placebo.

More than 130 patients were treated with once-daily oral doses of 100 mg, 75 mg, or 35 mg of azimilide or placebo and tracked over six to nine months. The 100 mg dose was found to have statistically significant and clinically important antiarrhythmic effects.

Azimilide is generally well tolerated, the most commonly reported side effect being headache. It is the first antiarrhythmic agent found to effectively block both the slow and fast potassium channels in the heart, and it significantly prolongs the symptomatic recurrence of atrial fibrillation. The drug is also being studied to understand its potential role in the prevention of SCD in high-risk patients after a heart attack. ■

Aorta patch 'promising'

There may be new hope for patients with aortic dissection in the form of "patchwork therapy." Researchers from four medical centers recommended the innovative treatment in two articles in a recent issue of the *New England Journal of Medicine*. Each cardiologist used a catheter to thread a mesh tube-type stent to the torn wall of the aorta where it covers the damaged area and keeps the artery open, preventing rupture.

The four studies are "promising," according to **Valentin Fuster**, MD, president of the American Heart Association and director of the Cardiovascular Institute at Mount Sinai Medical Center in New York City, but "the technique must be tested in additional, carefully controlled studies of larger population groups before it can become a recommended treatment for some types of aortic dissection."

Investigators at Stanford (CA) University School of Medicine and Mie University School of Medicine in Japan treated patients with acute, rapidly worsening dissections in which the death rate is typically high despite immediate surgery.^{1,2}

Three of their 19 stent patients died, a much lower death rate than usual in such cases. Other researchers from hospitals in Germany and Italy treated 24 patients with slower moving aortic dissections that generally can be treated by surgery or drugs. Half had surgery and the other 12 were given the patchwork stents. Four of the patients who had surgery died, while there were no deaths in the stent group.

The major symptom of aortic dissection is abrupt, severe chest pain. Research into its causes has linked the condition to high blood pressure, but more than that has not been determined.

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Editorial Questions

For questions or comments, call **Paula Stephens** at (404) 262-5521.

Fluvastatin benefits high cholesterol, CHD patients

Early treatment with fluvastatin (Novartis' Lescol), currently the least expensive statin, significantly reduces the risk of cardiac events in patients with hypercholesterolemia and coronary heart disease, according to new findings from the Lescol in Severe Atherosclerosis (LISA) study (*Atherosclerosis* 1999; 144:263-270).

A multicenter European team examined the effects of fluvastatin, 40 mg once or twice daily, in a one-year, placebo-controlled randomized study of 365 subjects with stable, symptomatic coronary heart disease. Study subjects had LDL cholesterol levels above 160 mg/dL and triglyceride levels of 300 mg/dL or less after four weeks on a cholesterol-lowering diet. The researchers report that fluvastatin significantly reduced the rate of cardiac events, including death, nonfatal myocardial infarction, and unstable angina among patients in the treated group. Ten events occurred in the control group during the study, compared to only three events in patients who were given fluvastatin. The investigators wrote that fluvastatin was safe and well-tolerated by study patients. ■

'ABCDE' angina guideline published by 3 groups

The American College of Cardiology, the American Heart Association, and the American College of Physicians-American Society of Internal Medicine have jointly issued a guideline for the management of chronic stable angina.¹

The guideline's recommendations are divided arbitrarily into four sections: diagnosis, risk stratification, treatment, and follow-up. For patients presenting with chest pain, the guideline recommends a "detailed symptom history, focused physical examination, and directed risk factor assessment." Then, based on findings, the clinician needs to estimate the probability of significant coronary artery disease — low, intermediate, or high.

Patients with angina may also need hemoglobin, fasting glucose, and fasting lipid panel tests. Resting EKG is indicated in patients without an obvious noncardiac cause of chest pain. It would be particularly useful during an episode of chest pain.

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Chest X-ray is recommended for patients with signs or symptoms of congestive heart failure, valvular heart disease, pericardial disease, or aortic dissection/aneurysm. The guideline also outlines cases in which exercise EKG testing and invasive testing might be warranted.

Easy to remember

The authors offer the following mnemonic for the 10 most important treatment elements of stable angina management:

- A — Aspirin and anti-anginal therapy
- B — Beta-blocker and blood pressure
- C — Cigarettes and cholesterol
- D — Diet and diabetes
- E — Education and exercise.

The authors also call attention to lipid-lowering agents as a means of reducing risk of infarction or death in this patient population.

[Editor's note: This document is available on the Web sites of the American College of Cardiology (www.acc.org) and the American Heart Association (www.americanheart.org). A single reprint of the executive summary and recommendations is available by calling (800) 242-8721 or writing the American Heart Association, 7272 Greenville Ave., Dallas, TX 75231-4596. Ask for reprint No. 71-0167. To obtain a reprint of the full text published in the June 1999 issue of the Journal of the American College of Cardiology, ask for reprint No. 71-0166. To purchase up to 999 reprints, call (800) 611-6083 or fax (413) 665-2671; 1,000 or more copies, call (214) 706-1466, fax (214) 691-6342.]

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