U.S. Food and Drug Administration
FDA Consumer magazine
May-June 2001
Table of Contents

Emerging Trends in Medical Device Technology:
Home Is Where the Heart Monitor Is

By Carol Lewis

Medical devices, products and technologies are converging to revolutionize home- and self-care health systems in the United States, making it possible for people to play a greater role in maintaining their own health.

These systems are geared toward a prevention-oriented, consumer-driven model for health care that includes innovations such as "smart devices" that can "think" for themselves, customized wearable devices, electronic patient records, and wireless Internet-linked systems--all expected to deliver convenient, user-friendly, intelligent health care in the home.

For consumers, this could mean convenience in time and travel and reduced health-care costs, and--it is hoped--result in home-care systems that teach people to monitor themselves with gizmos that give timely warnings of illness so that they can turn to their physicians early--when intervention will do the most good. For doctors, it could mean more efficient--and effective--health care driven by patients who take greater responsibility for their own health.

William Herman, director of the division of physical sciences in the Food and Drug Administration's Center for Devices and Radiological Health (CDRH), which regulates medical devices, calls home-care systems "the fastest growing segment of the medical device industry."

'If You Build It, They Will Come'

The list of planned and imagined medical devices reads like a work of science fiction. For

example, imagine a toothbrush with a biosensing chip that checks your blood sugar and bacteria levels while you're brushing your teeth. Optimally, the brush would come with a holder that would transmit information to a database containing the person's medical file. Other devices on the drawing board include computerized eyeglasses with a tiny embedded display that can help those who wear them to remember people and things, and skin surface mapping, a new imaging technology that can collect images of the skin surface over time and would enable people predisposed to melanoma to detect malignant moles as soon as they begin to develop.

Also in the future, hand-held biosensors resembling the technological gadgets wielded by "Bones" on the TV series *Star Trek* could eliminate the need for maintaining large laboratories. A "smart" bandage could be made of fiber that could detect bacteria or virus in a wound, and tell the wearer if treatment with antibiotics is warranted and which to use. Using a wide range of advanced technologies such as wireless electronics and digital processing, heart monitors that can be connected to personal computers could make it convenient for people to track their own heart rates and other vital information at home and then transmit it to their health-care providers.

The Defense Advanced Research Projects Agency, within the U.S. Department of Defense, has developed a wearable system called the "smart T-shirt," which successfully monitored the vital signs of climbers on a recent expedition to Mount Everest. Another type of device that allows people with disabilities to operate machines and perform routine tasks is a hands-free instrument that is controlled by small muscle movements, such as a blink of an eye (electromyography), and brain activity (electroencephalography). Other devices include those controlled by tracking eye movements or by speech recognition technology. Devices that offer this kind of assistance show promise for individuals with spinal cord injuries or other nervous system disorders resulting in paralysis.

Products well along in the development pipeline are about to make possible dramatically improved pacemakers, cochlear implants (for hearing), and medicine delivery systems. Some of these devices will incorporate the most advanced product design and manufacturing on a molecular scale (nanotechnology) and other state-of-the-art technologies, such as microprocessors and miniaturization. The ability to bring these kinds of tools into the home adds a dimension of health care that people never had access to in the past.

"Do we know what's going to work?" asks Gilbert Devey, program director for biomedical engineering at the National Science Foundation. "Not yet," he says, "but there are ample precedents for these types of technologies. The focus now is on increasing the level of technological literacy for consumers."

Shifting Responsibilities .
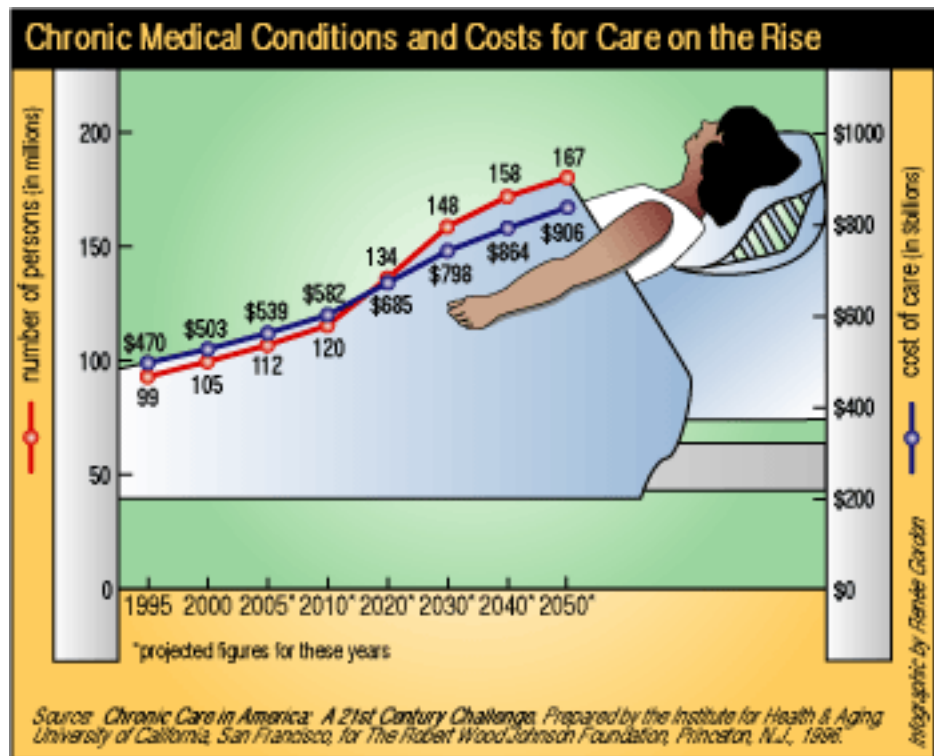
With some 76 million Americans born between 1946 and 1964 heading toward retirement, emerging technologies likely will help care for this aging baby-boomer generation. Technology is already being used to help keep tens of millions of older people in assisted living situations a lot safer.

At 9:30 a.m. on a recent Monday, nurse Linda McRae asks her patient: "How's your appetite? What about your bowels? Are you coughing up anything?" The questions sound routine; however, the physical exam is not. Elwin Geyer, a 69-year-old chronic lung disease patient, is at home--some 25 miles away from McRae. But from the video room in Kaiser Permanente's Sacramento, Calif., home health-care facility, the two are virtually connected by the flip of a switch, and McRae can examine Geyer long-distance, thanks to telemedicine.

Telemedicine connections like this one bring high-resolution images and audio through not much more than a telephone line and a computer monitor. A telemedicine device installed in the home allows a nurse to complete an exam without the person ever having to leave the house.

In February 2000, the FDA cleared for marketing one of the latest telemedicine devices that includes a blood pressure cuff, stethoscope, and thermometer, as well as a television monitor and camera. The medical information that Geyer's wife, Jean, helps obtain by maneuvering the stethoscope over her husband's chest and back is transmitted from the devices directly to McRae. New, cheaper devices connecting telephones and televisions to the Web have the potential to expand this technology even further.

"Telemedicine is simply a steppingstone to a more sophisticated home health-care future," says Steve Warren, Ph.D., assistant professor of electrical engineering at Kansas State University. It's a steppingstone that McRae says adds an element of reality to her job as a home-health nurse by allowing her to promptly see what's troubling her patient. She says that systems like the one used by Geyer "give patients confidence and reassurance that we can do more than just talk to them by phone."

But as information technology becomes a more robust resource for people and their health-care providers, the link to home- and self-care products will raise issues such as liability, privacy, financing, and most important, the safety and effectiveness of the products.

The National Association for Home Care in Washington, D.C., conducted several clinical trials of home-distance monitoring of blood glucose levels by computer and found improved outcomes in diabetes care. Similarly, trials of home-distance monitoring of blood pressures showed enhanced efficiency. But failure to improve outcomes of high-risk pregnancies through home-distance monitoring illustrates the difficulties in managing certain clinical applications in the home environment, and the need for further research and regulatory controls.

New FDA policies, guidelines, and regulations may be needed, says the FDA's Herman, especially once it's clear how the Internet will change device regulation. These guidance documents will require special consideration of the capabilities and limitations of people using the devices at home as well as in different types of environments.

User Issues--A Major Concern

Given the newness of various technologies and known problems with some home-use devices, CDRH is going to be skeptical of new medical technologies that are long on promise to consumers, Herman says. As technological developments become more complicated, so do the requirements for their design to ensure that they can be used safely and effectively in the home.

"Human factors" is the science of interactions between people and technology, and involves designing a device with the users' abilities, limitations, and operating environments in mind. Ron Kaye, a human factors specialist in CDRH, says that the possibility of user errors (unintentional mistakes) always is of particular concern.

Medical device design problems can lead to errors when they don't consider that consumers can become easily confused using devices in the home. Distractions, such as children or other family members, variations in lighting and noise levels, and the demands of using the device exceeding the user's capabilities, all can contribute. A patient receiving

oxygen, for example, died when a pressure hose loosened from the unit. The alarm was not loud enough to be heard over the drone of the device. Dropping a device or using it in changing temperatures or high humidity (such as a bathroom or shower) also may affect its performance. Kaye says other problems, such as not following procedures precisely or relying on the device too heavily, also are concerns.

"These risky behaviors can involve lifestyle changes, such as changes in diet or physical activity, or less attention to monitoring their health condition due to over-reliance on the device," says Kaye. And, usually once the user becomes accustomed to a device, failing to follow maintenance and calibration procedures, taking shortcuts when a specific technique is critical, or failing to communicate with health-care professionals as often as they should, also could lead to trouble.

The critical question, Kaye says, is whether consumers will be able to use new medical technology without unintentionally making errors that could compromise their health.

The ability of patients to operate a medical device, for example, can depend on medical training and experience, language barriers, literacy, memory, learning ability, dexterity, vision, and hearing. Difficulties using certain devices can be caused by advanced age, medications, or the actual medical condition that requires use of a product. The focus of most of CDRH's guidances will be on ensuring that users are able to safely operate and maintain the device--anything they would need to know about, such as controls, displays, software, labeling, and instructions.

Although new devices give people increasing control and a feeling of security when managing their health, users must remember to keep in regular contact with their health-care providers, Kaye says.

No Mistakes

Stephen B. Kaufman, a pioneer in home-care technology from Deerfield, Ill., supports device technology that has "simple prompts" and "no possibility of mistakes." He says, "There are just too many opportunities to make bad mistakes." For this reason, CDRH has provided human factors guidance to manufacturers on device design that will reduce the likelihood of user error. This guidance document, titled "Medical Device Use Safety: Incorporating Human Factors Engineering Into Risk Management," can be found on CDRH's Web site at www.fda.gov/cdrh/humfac/1497.html (the document is also available as a PDF).

"Design controls are another new regulatory tool for us that have a lot of potential to avoid use errors and other device quality problems," says Stewart Crumpler, a regulatory operations officer in CDRH. Design controls are a system of checks and balances that

increase the likelihood that a device is designed, manufactured, used, and maintained properly, and that the device is appropriate for its intended use. Design controls are the part of a quality system that requires manufacturers to consider both human factors and the intended use environment during device design. The controls, Crumpler says, are intended to "build quality into the device."

Another factor contributing to the increase in user errors is the difficulty that consumers have understanding instructions provided with devices. Most are written for health-care professionals. CDRH has prepared guidance for manufacturers of home-use devices to help them plan and write their manuals for consumer use.

"One of the biggest problems we're finding," adds Herman, "is the inability of systems to be used by people who have not been trained." Because of this, CDRH's guidances also will focus on patient education and training, proper technical standards for manufacturers, and safety issues that new technologies may generate.

A New Paradigm for Health Care

Today, what could be characterized as a return to home health care has much to do with the emergence of the Internet as a conduit of health information to patients. Those who remember huge mainframe computers can appreciate today's technology and the exponential advances in the compilation and distribution of information.

"For some time now, the technology forecasts of CDRH's office of science and technology have projected home- and self-care devices as a high probability area for dramatic growth," says Herman. Other forecasts, he says, are now mirroring those CDRH expectations. This unfolding wing of modern medicine means that 21st century home- and self-care devices could soon revolutionize health-care delivery systems in the United States. And when these potential technological marvels are ready for the market, some may lead to products that we may wonder how we lived without.

For more information on home health-care issues, contact:

American Association for Home Care
www.aahomecare.org
703-836-6263
Represents about 1,000 home-care providers, equipment suppliers and service providers.

American Nurses Association
www.ana.org
1-800-274-4ANA (1-800-274-4262)
Represents 2.6 million registered nurses. Has developed guidelines on use of telehealth.

American Telemedicine Association
www.atmeda.org
202-223-3333
About 1,300 members. Has a home-care policy committee.

National Association for Home Care
202-547-7424
Represents about 18,000 home-care agencies.

Driving Forces Behind the Home Health-Care Push

The primary need for today's home-care population is more frequent and convenient monitoring of chronic diseases and conditions, according to a 1998 workshop on future trends in medical device technologies sponsored by the National Science Foundation and the FDA. A wide range of health and social services gradually are being delivered at home to recovering, disabled, chronically ill, or terminally ill people.

Chronically ill infants and children are receiving sophisticated medical treatment in a familiar and secure home environment. Many younger adults who are disabled or recuperating from acute illnesses are choosing home care, whenever possible. Adults and children diagnosed with terminal illnesses also are being cared for at home.

Audrey Kinsella, a medical research librarian who specializes in home health-care product trends and applications, says that the trend toward earlier discharges from acute care settings to home while people still may need daily care also has been driving the home health-care market. "And some see it as a wonderful adjunct to the care they're already getting," she adds.

According to a study conducted by Kaiser Permanente's Medical Care Program, the greatest users of home-health services are older people--also the most rapidly growing segment of the population. Two-thirds of Americans over 62 have at least one chronic disease, and so may need to use home-monitoring devices daily, such as heart rate monitors. Heart disease, diabetes, and respiratory problems are the top chronic diseases of this age group. And more and more older people, electing to live independent, non-

institutionalized lives, also are receiving home-care services as their physical capabilities diminish.

- -C.L.

FDA/Office of Public Affairs
Web page created by tg 2001-APR-30.