Medical Devices Made Better

New technology’s potential is huge; first let’s make it safe and user-friendly

By Anthony J. Montagnolo

What’s your blood pressure? Do you check it yourself at home? Terrific, if you do! But how do you know if your device is reading your pressure accurately? And how do you know if you are actually using it correctly?

As we all see every day, medical technology is not only increasingly embedded in our bodies, but it is also operated directly by patients and consumers themselves. But is it safe? And does it really work?

In effect, while the providers of care strive to become ever more patient-centric, so, too, must our medical technology become more patient-centric. In fact, in September, the Federal Drug Administration announced its first-ever Patient Engagement Advisory Panel. According to the agency, “This body will provide advice to the FDA commissioner on a range of complex issues relating to medical devices, their regulation and their use by patients [emphasis added]. It will give FDA the opportunity to obtain expertise on various patient-related topics, with the goal of improving communication of benefits and risks, and increasing integration of patient perspectives into the regulatory process.”

As the FDA realizes that patients are increasingly using medical devices themselves — or have them embedded in their bodies — it should come as no surprise that providers will have to adapt to this increasing trend as well. But what does this mean for providers?

Keeping Patients Safe

In some ways, providers already deal with patients who use medical technology every day. However, medical technology for home and personal use likely will rise, which will lead to new challenges and new opportunities. And the complexity of home medical technology is increasing, which raises the odds of mistakes and accidents occurring more, not less. So, patient safety becomes the first challenge and the first priority.

In a white paper published in 2010, the FDA noted that it received 19,000 adverse event reports from 1997 to 2009 in which the reporter listed “home” as the place where the incident occurred. Some of these events are serious. In one case, “a seven-month-old patient was at home on a ventilator with a back-up. The patient’s parent found the patient attached to the ventilator, but the ventilator was no longer cycling, and no air was coming out of the circuit. The ventilator alarm did not sound. The patient died.”

In another case, “a patient doing home nocturnal dialysis was found by her husband, unresponsive. She was disconnected from the dialysis machine, and her tubing was in a closed circuit filled with saline. There was a syringe attached to one of her lines, but the other line was open, and the patient had lost a significant amount of blood. It appeared that she had been unable to clamp her catheter by herself. The patient died due to blood loss.”

Patient safety issues in the home have unique characteristics compared with safety issues in a provider setting; patients and family members are not trained professionals and the home environment itself is unpredictable. How much training should a patient and family member receive...
to ensure safe operation of a home infusion pump? Do we simply rely on the instruction manual and quick show-and-tell conversations? Do we need more mistake-proof medical devices if they are going to be used by patients and family members? Could we provide a 24/7 website or hotline for questions about devices?

Improving and ensuring patient safety related to home medical technology will require a collaborative approach from providers, device manufacturers and regulators, as well as patients and family members. The commitment to patient safety does not start and stop at the steps of the hospital. And if care really becomes patient-centered, then our medical technology should incorporate patient-centric design, and our health care providers must help to ensure that medical technology used at home gets used properly and safely.

**New Opportunities**

Though home and personal use of medical devices presents a safety challenge, it also presents a huge and exciting opportunity to improve health outcomes. Many of us already monitor the steps we take each day, our blood pressure and blood glucose levels. Imagine continuous monitoring of chronic conditions such as heart disease, kidney disease or asthma, to name just a few. Better monitoring will lead to faster interventions and improved outcomes.

Some of these technologies will be attached directly to or inside our bodies. The latest advances in implants include everything from eye telescopes to neurostimulators for remediation of Parkinson’s disease. One of the most fascinating and life-altering new technologies is the “exoskeleton” that helps paraplegics walk upright by themselves.

We all know that technology and humans sometimes mix in rather complicated and unpredictable ways. To realize their potential, these technologies must be designed to be operated properly by the patients at home or in other settings. Providers and medical device manufacturers must work together to truly understand how to design the technology, and patients must understand how their technology works safely and effectively.

**Health Care Made Easy?**

The growth in home or personal medical technology also presents another opportunity to boost patient satisfaction. Getting a medical appointment can be time-consuming and frustrating. What if your bed could check you for sleep apnea? What if your couch could check your blood pressure and heart rhythm?

If everyone had his or her blood pressure taken every morning at home, and those data were tracked, recorded and sent to your personal health record, imagine how much better it could be controlled. While the technology to do that kind of thing already exists, it must become easier to use, cheaper and better connected to a real-time monitoring system. Providers should take the lead in driving these changes by tackling big health problems in innovative ways right in our own homes.

If we can carry a street-by-street map of the world in our hands, and if our banks can tell us someone stole our credit card information to buy gas on the other side of the country, we can find a way to warn ourselves of an impending heart attack before we hit the floor.

A heart attack avoided right before it happens? That’s a satisfied customer.

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Anthony J. Montagnolo, M.S. (amontag@ecri.org) is executive vice president and chief operating officer of ECRI Institute, Plymouth Meeting, Pa.