Do you know someone who had to care for an ailing loved one at home, confronted with the task of learning how to use a home healthcare medical device? Experts say that’s not an unusual scenario these days and that such caregivers need to have a greater say in how such medical devices are designed.

At a recent workshop held by the U.S. Food and Drug Administration (FDA), several speakers called for simpler home healthcare devices and said that users—not just patients—should have a seat at the device design table.

Manufacturers, they said, need to take into account the needs and mental state of family caregivers who will be using the medical equipment. A majority of the family caregivers work full time and some suffer from depression, said Suzanne Mintz, president and chief executive officer of the National Family Caregiver Association (NFCA).

“The vast majority of people using home medical devices don’t have any training. You need to take that into account when creating equipment,” Mintz said. “We didn’t go to medical or nursing school. Even those people who are in the medical profession, when dealing with (their) own family member, everything they know goes out the window. There are reasons surgeons don’t operate on their own family members.”

Speakers said that caregivers, technicians, engineers, and clinicians should be consulted at the beginning of the design phase, possibly having them interact with device prototypes. “You are setting a real world condition and giving the user what is expected in the real world,” said Pat Patterson, president of Agilis Consulting.

Manufacturers also need to take into account a different environment for home devices, several speakers said. Beyond factoring in obstacles such as children or pets, manufacturers need to consider a home’s electrical services. “The electrical supply is different,” said Dave Osborn, director of international standards for Philips Healthcare and a member of the AAMI Board of Directors. “You don’t have a hospital biomed, and you don’t have back-up generators. What does that mean? Older homes also don’t have three-wire sockets and third-pin plugs can’t be connected to anything.”

Osborn stressed that manufacturers look to international standards to help in design, especially IEC 60601-1-11, which focuses on requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

The standard includes tests for devices to make sure they can withstand certain temperatures and durability. “Other than the electrical parts, the standard is a whole risk management standard that applies to all medical devices on issues such as cleaning and disinfection, temperature, pressure, and humidity,” Osborn said.

Labeling Dilemma

Speakers generally agreed that instructions for devices need to be simple and accessible for caregivers and users. But creating simple instructions can be challenging.

“Manufacturers perhaps feel the need to include a lot more information and warnings because of liability,” Patterson said.

Sometimes the clinician can cause complications. “The manufacturers will do the best they can, including validating testing their labeling, and then the labeling is handed off to a clinician,” Patterson said. What causes complica-