Better Together: The Vital Role of Patients and End Users in Developing Safe and Effective Medical Devices

Chris Hayhurst
Medical device manufacturers and federal regulators have spoken of the need to incorporate patient feedback into the design, approval, and use of medical technologies. How is that idea playing out?

It’s common wisdom in the world of innovation and design that it’s better to “fail early,” when mistakes are more likely to be fixed, rather than at the eleventh hour. Still, according to Patricia Patterson, president of Agilis Consulting Group, it’s surprising how often this principle is ignored.

Agilis, Patterson explained, is a full-service “human factors” firm that deals exclusively with medical devices, providing, for example, device manufacturers with risk-based analyses of user interactions with product prototypes. The idea is to ensure that in addition to being well designed, the devices meet the expectations of the Food and Drug Administration (FDA). “If it’s a Class II or III device, more than likely it has to be cleared by the FDA,” Patterson said, and the only way to get that clearance is “by providing evidence that your product is safe and effective in the hands of users.”

Patterson said she has worked with manufacturers that neglected the “human factors element” early in the design process and wound up paying dearly for that omission down the road. She recalled that one company designed a hand-held device that was supposed to help people with diabetes calculate their insulin doses. For the product to work, the user had to input certain numbers based on a variety of factors, including the carbohydrate content of what they were eating. The designers, said Patterson, assumed that anyone with diabetes would know how to obtain those numbers and could easily plug them into the device. “But then, toward the end of their product development process, as they began thinking about the FDA and conducted formative evaluations to identify their product’s strengths and weaknesses, “they found most people were terrible with numbers and had no idea what they were supposed to do,” said Patterson.

Unfortunately, because her client “never really did early-stage human factors kinds of work,” said Patterson, and failed to get user feedback at the beginning, the component of their device they thought had made it valuable turned out to be its main limitation. The company was forced to remove its automated calculating features before they submitted the device to the FDA. “That was unfortunate, because it was a great idea that just needed a few changes. But it was too late to do anything about it; at that point, they couldn’t just go back and redesign it.”

A Push for Patient Input

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Still, before 2015, when the FDA took into account so-called “patient preferences” in its decision to approve a weight-loss treatment device, the agency didn’t have a reliable way to collect and incorporate patient input into the regulatory process. In this case, for the first time ever, the FDA used a survey that showed that patients would “accept risks associated with [the] device for the amounts of weight loss expected to be provided” by it. “Patients, physicians, and the FDA may have similar goals of maximizing treatment benefit while minimizing risk,” an FDA report on the survey explained. “However, they may have different perspectives on tradeoffs among benefits and risks of treatment,” and those perspectives were worth considering if they could be captured and measured scientifically.

The first major sign of a shift in the agency’s thinking appears to have come 2 years earlier, in the summer of 2013, when the FDA’s CDRH announced it was launching the Patient Preference Initiative.

After so many years, what drove the FDA to finally pull patient preferences into the regulatory landscape? The first major sign of a shift in the agency’s thinking appears to have come 2 years earlier, in the summer of 2013, when the FDA’s Center for Devices and Radiological Health (CDRH) announced it was launching the Patient Preference Initiative. As part of that initiative, the agency reported that it held a workshop with patients, physicians, device makers, and others titled Incorporating Patient Preference Information into the Medical Device Regulatory Process. The initiative would be “all about the patients who may need these products, the caregivers who would be helping patients use them, and the health care professionals who may prescribe them,” wrote Michelle McMurry-Heath, MD, PhD, who at that time was the associate director for science at CDRH. “What do they want? What do they need?”

Within a few months, the Patient Preference Initiative was gathering steam: First came the announcement about the obesity-fighting device; then, toward the end of 2015, the FDA created a Patient Engagement Advisory Committee (PEAC) within CDRH. The PEAC, explained another FDA blog post, “will bring patients, patient advocacy groups, and experts together for a broader discussion of important patient-related issues, to increase integration of patient perspectives into the regulatory process, and to help drive more patient-centric medical device innovation, development, evaluation, and access.”

As a founding member of the Medical Device Innovation Consortium, the agency noted, it stood behind the MDIC’s recently issued “framework report” for industry stakeholders that outlined ways information on patient preferences could be measured and incorporated “across the total life cycle of a device.”

Next up, the CDRH made good on its promise with the publication of three final patient-focused guidance documents for industry and FDA staff. The first, Applying Human Factors and Usability Engineering to Medical Devices, was intended, according to the FDA, to “maximize the likelihood that new medical devices will be safe and effective for the intended users, uses and environments.” The second report, Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications, included, among other nonbinding recommendations, questions device makers should ask of the patients their devices are intended to help: “What benefit(s) from this device is (are) of most importance to patients?” “What risk(s) from this device is (are) of most importance to patients?”

According to the CDRH’s third guidance document, Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling, the FDA “values the experience and perspectives of patients” and understands that these individuals “have developed their own insights” on the devices that it evaluates.

As noted in the document, device makers are not legally required to submit patient preference information (though Part 820 of the FDA’s Quality System Regulation does mandate that device designs “are appropriate and address ... the needs of the user and patient”) and such information may not be relevant for certain devices. However, in
relevant cases, the FDA has stated that submitting data on patient preferences would help the agency in its decision making around a device’s approval.

Meanwhile, with its initiative in place and guidance documents either in circulation or pending release, in January 2016, the CDRH reiterated its commitment to including patients in the discussion around medical devices with the release of its strategic priorities through 2017. “We believe that if CDRH is to successfully achieve a mission and vision in the service of patients, we must interact with patients as partners and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices,” stated the agency.

According to Kathryn O’Callaghan, the center’s assistant director for strategic programs, “From top to bottom, CDRH is now focused on how we can better partner with patients. And that’s not only so we can improve the effectiveness of our work at the FDA, but more importantly, it’s to improve patient health and quality of life.”

Toward that end, added O’Callaghan, the hope within the agency is that the patient preferences initiative will help the medical device industry make considerable progress when it comes to designing devices that “meet real patient needs and get the outcomes that matter to patients the most.” At the moment, CDRH does not have data indicating the percentage of device applications that incorporate patient preferences. “The guidance is still relatively new,” O’Callaghan said, “so it’s too early for us to have hard numbers on that yet.”

However, O’Callaghan did note that a “wide range of companies are coming in with preference studies,” and while they’re all interested in using that information to support their regulatory submissions, “many are also using it to make business decisions.” As device makers consider forthcoming features and enhancements, it appears that they increasingly want to “partner with patients” themselves. “And to us, that is really good news. It’s a sign that we’re moving in the right direction,” said O’Callaghan.

Where Patients Provide Value

One industry expert who agreed with that assessment is Patricia McGaffigan, RN, MS, CPPS. Formerly the chief operating officer and senior vice president of programs at the National Patient Safety Foundation (NPSF), McGaffigan is now vice president of safety programs for the newly merged NPSF and Institute for Healthcare Improvement. The FDA guidance and its related initiatives are an “important step forward,” said McGaffigan—a nurse by training who also has worked in marketing and product development in both start-up and established medical technology companies. If the agency’s push for more patient involvement in the ongoing evolution of medical devices is working, “we should see medical devices become safer and more effective.”

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Still, McGaffigan and others in the medical device arena wonder just how far patient preferences should go—and whether there’s a point where patient input might be counterproductive. “Where do we draw the line?” asked Jim Piepenbrink, deputy executive director of the AAMI Foundation, a charitable organization that focuses on the safe use and adoption of healthcare technology.

Piepenbrink calls increasing patient involvement “something that really does need to happen,” but he also predicted forthcoming challenges related to defining the degree of involvement. “At what layer in the design process does it make sense to bring in patients? What if we’re talking about a really complex device? Do we benefit the patient by having them in on that discussion?”

The way Piepenbrink sees it, the technologies that stand to be most improved through patient involvement are those that are common in the home care setting (e.g., continuous positive airway pressure machines, infusion pumps), thereby allowing patients to self-manage their conditions, but also tend to be difficult to use because “they have too many features or were originally designed for the hospital.” On the other hand, noted Piepenbrink, he doesn’t see “as much of an opportunity” when it comes to those devices where physicians are the sole users, “such as the technologies you find in critical care or the operating room.”

Melissa Kozak, a clinical engineer with Toronto-based Techna Institute, an organization focused on reducing the time it takes to bring new medical technologies to the point where they can benefit patients and health systems, also believes that patient input has its limits. “I think the value of feedback from patients regarding device design depends on what kind of device you’re talking about,” said Kozak. “If it’s intended to be used by patients, or patients have the potential to be using the device, then patient feedback is important, as patients are the end users.” But “if a device is intended to be used by clinicians, then patient feedback is probably less important.” At the end of the day, Kozak added, what’s critical is that “end users are able to safely interact with the device.”

While agreeing with Piepenbrink and Kozak, McGaffigan also cautioned “that who we know and understand to be the user needs to be very, very carefully” evaluated. “The user technically may be somebody that...
is not a patient or their family, but they are the ones who experience that technology, so it’s a patient experience and a family experience,” she said. When asked whether patients and their families should be involved no matter what, McGaffigan responded: “I tend to believe that all device developers should consider how their solution will affect or be perceived by the patient and family, so I do think their interactions with these technologies should play some type of role in the design process.”

In It ‘for the Humans’
What do medical device companies think about the prospect of involving patients in their design decision making? According to McGaffigan, at her first job with a manufacturer, the firm’s CEO required “anybody who was involved in the design and the development of technology,” as well as others in the company, from board members all the way down, “to get out there in the environment in which the product was intended to be used.”

A Role for HTM
Patricia McGaffigan, RN, MS, CPPS, vice president of safety programs for the newly merged National Patient Safety Foundation and Institute for Healthcare Improvement, noted that many medical devices wind up in settings and in the hands of users for which they were never intended—moving, for example, from the intensive care unit to general care, then eventually out to patients’ homes. “So I think one thing healthcare technology management (HTM) professionals can do,” she said, “is keep a very good inventory of the technologies in their facilities so we can track how they are actually being used and migrated, as well as understand whether they’re truly designed” for their various users. The safety implications here are substantial, McGaffigan added. “Just think about user guides. If a technology was originally developed for intensive care, it probably doesn’t include directions written with patients and family members in mind.”

Similarly, McGaffigan believes that HTM professionals can serve as critical conduits between device users and manufacturers, relaying observations from their day-to-day work to engineers and others in product development. “We had a great example of this years ago with all of the sensors we were putting on patients,” she said. Because those sensors were inevitably wired, “we were basically tethering patients to their bedsides.” What many patients need most, of course, is to get up out of bed and move around, rather than being stuck in one place. “So we had a technology that was meant to help patients in one way but was preventing them from making progress in other ways.” Manufacturers have since developed wireless sensors, said McGaffigan, in no small part because of feedback from HTM professionals. “I think the healthcare community overall has had a very strong voice on that front; it’s really led to some great improvements in design.”

Jim Piepenbrink, deputy executive director of the AAMI Foundation, also thinks there’s a “huge opportunity for HTM professionals to get involved” in the patient-feedback arena. According to Piepenbrink, who was the director of clinical engineering at a hospital in Boston before he took his position with the AAMI Foundation, “HTM is in the middle between the clinical side of the house and the vendors.” Because the patient-generated information obtained by HTM departments is related to device performance, it “could be used in some way to provide feedback to the manufacturers.” Manufacturers, Piepenbrink added, would likely see this information as valuable, “especially when you’re talking with design engineers who don’t necessarily speak nurse or doctor language.” Of course, to get to that place of “knowledge sharing,” as he called it, biomeds must first stand up and be heard. “You can only share knowledge if you’re at the table, and a lot of HTM departments just aren’t there yet. They’re still in the basement, thinking ‘break-fix’—they’re not speaking up and voicing their experiences because they don’t see that as part of their job or don’t appreciate the tremendous value they can bring.”

Melissa Lemke, a biomedical engineer who is director of human factors engineering at Agilis Consulting Group, believes that manufacturers would do well to encourage HTM professionals to get involved. “On the premarket side especially, HTM professionals are often left out of the analyses,” which leads to deficiencies in their areas of expertise. “Calibration, service, maintenance, cleaning, sterilization ... when companies don’t talk to biomeds about these things, they wind up making design mistakes that can affect actual use.” For example, Lemke said, consider the reprocessing issues associated with endoscopes: “People have died because of issues that might have been prevented had HTM been considered as a user group early on.”
The company also employed medical ethnographers who would observe how providers, patients, family members, and others were affected by and interacted with the device in the healthcare environment. “That added incredible insight into what it was we were doing,” McGaffigan recalled. “It was absolutely vital to designing devices that really met people’s needs.”

Later, McGaffigan said, she worked with another manufacturer where once they’d developed a prototype for a device, they’d take it out to patient and family focus groups to garner their feedback. “If we had a sensor that would sit on the patient’s forehead, how does everyone around that patient react? What do they think of the colors and the labeling? How do family members respond when it’s their child who’s wearing the device?”

Unfortunately, McGaffigan said, that kind of attention to the details of design is not as common as one might expect. “So often, device design has been conducted at the upper echelons of expertise and authority,” and by engineers who are technically brilliant but have limited or no experience in healthcare settings, she said, adding that the “patient and family perspective is basically overlooked.”

According to at least one professional who’s still in the thick of device design, “partnering with patients” is on the rise. “‘User-centered design’ and ‘user-experience design’—also known as “UX”—are big buzzwords right now,” said Robert Schwartz, general manager of Global Design and User Experience at GE Healthcare. His division within GE Healthcare is responsible for the “look, feel, usability, and end-to-end experience” of GE Healthcare’s products and services, from its magnetic resonance imaging and computed tomography scanners to its ultrasound, patient monitoring, and anesthesia machines.

If GE Healthcare makes it “and it’s a medical device, our team will touch it at some point—and when we do we always bring the patient’s perspective into play,” said Schwartz. The company’s philosophy, he noted, is that “we’re here for the humans,’ because even if it’s a device that doesn’t touch a patient directly, it does connect to patient care.”

GE’s process, explained Schwartz, involves bringing ideas to life as quickly as they can by creating very rough prototypes out of materials such as wood and paper. “And then as the design develops, we’ll bring in the users,” including patient groups, “to get their advice and feedback” around what to do next. For example, as the company developed its new Senographe Pristina mammography system, women who had undergone mammography procedures in the past were asked to describe their preferences for such a machine.

“What we learned from these patients—no surprise—is that mammography isn’t always the most friendly experience,” said Schwartz. Traditional mammography machines are large and foreboding, he noted, “and they don’t adjust to you; you have to adjust to them.” Typically, the woman (but men get mammograms, too) is dressed in a paper gown, her breast is compressed, and the technologist then must step out of the way because of the radiation involved. “It’s uncomfortable and awkward, and the woman is left there alone with her anxiety.”

Using input derived from patient groups, as well as feedback from other stakeholders in the process—including equipment technicians, marketing and sales professionals, and the engineers responsible for bringing the device to life—Schwartz and his team eventually settled on a design that “gives the patient more control.”
sharp edges. “There’s no need to grip anything, so patients’ muscles are relaxed. And then, just giving them that ability to do it themselves—that makes the procedure much less stressful, and it also leads to better images,” Schwartz said. “This definitely isn’t rocket science, what we’re doing. But it’s something we learned by actually listening to patients.”

Schwartz and his team take the same approach with any medical device they work on. Although part of it’s about collecting all of the data required to gain FDA approval, Schwartz also said there’s a constant drive to “make the user experience the best it can be—and we’re looking for opportunities to improve things where we can, even if it’s in the next release of the product.” How many patients and to what extent they take part in the process typically depends on the complexity of the device, Schwartz added. “But it also depends on how much our company wants to put out there.” Nondisclosure agreements are standard in this line of work: “If we’re developing something that might be a competitive secret, we obviously don’t want people talking about it.”

For Safety, Effectiveness ... and Better Products

Ruey Dempsey, vice president of technology and regulatory affairs at AdvaMed, the trade association for the medical device industry, also has seen an uptick in interest among manufacturers to integrate patient feedback into their products. “It just kind of makes sense, if you think about it,” she said. “There’s FDA’s guidance, which is definitely a factor, but there’s also the fact that patients have become a lot more knowledgeable.” Patients, she explained, are now “healthcare consumers”; therefore, companies have had to adjust to their sensibilities. “Because obviously a product that is going to do well on the market is one that meets user needs. So knowing what patients want is very important to manufacturers, and I’d say that’s the case across the board.”

Nonetheless, said Dempsey, when manufacturers do consider patient feedback, they must weigh what they learn against a variety of other factors, including design limitations and budgetary constraints. “When manufacturers do consider patient feedback, they must weigh what they learn against a variety of other factors, including design limitations and budgetary constraints. “If I’m collecting this information and documenting it as part of my design-input process,” in compliance with the FDA’s Quality System Regulation, “I might...
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look at what those users have said and decide there’s just no way to make it work.” For instance, she said, “technology today doesn’t allow us to design a pacemaker the size of a dime.” Or perhaps the recommendation is for an alteration that would be so expensive to make that it would doom the product’s viability. “There are things you just can’t do if you want to remain in business.” As a result, according to Dempsey, most companies will review the input that they’ve gathered and then “reconcile what they have with what is feasible: ‘Yes, this is a good idea and this can be incorporated,’ or ‘No, this can’t be incorporated and here’s why.’”

Patient input around issues that might affect safety or effectiveness also must be looked at closely and taken “very, very seriously,” Dempsey added. “So if you’re trying to decide how loud an alarm is going to be, you might do that by looking at the range of hearing acuity of your patient population,” then ensuring that the alarm on your device is loud enough to meet that group’s needs. “If you ignore that—if you identify what they can and cannot hear but then don’t make the changes that you need to make—that would be problematic,” not only from a marketing standpoint but from the point of view of federal regulators. “It’s very important to FDA that you gather the data and then incorporate it as appropriate,” she explained.

At the end of the regulatory process, Dempsey said, before a company can offer its product to consumers, FDA requires successful completion of a “verification and validation” process. “It’s going back and saying, ‘Yes, I’ve met the design requirements that I’ve identified as appropriate and viable,’ and that ‘my product output meets my product input.’” Because of this, she said, it would be very difficult for a company to overlook including features in their device that would be critical to safety and overall effectiveness. “Because they would have documented those things, they would have tested them out, and, quite honestly, every company wants to bring a good product to market.”

It’s no surprise, said Dempsey, that the engineers responsible for turning ideas into reality might benefit from insight provided by their company’s customers. “It’s good marketing and it’s good business to make sure that you’re developing a device that is as suitable as possible for your users, including your patients.” It doesn’t matter “how talented you are as a designer,” she added. “If your users don’t care about that attribute you added,” or if it doesn’t meet their needs in some measurable way, “you have to go back” to the drawing board. “You might think you have the perfect device, but it’s probably not perfect if no one else sees it that way.”

Patricia McGaffigan of NPSF agreed: “There is plenty of evidence that when products of any kind are designed to meet customers’ needs, that’s a primary driver of their success.” But it’s impossible to know the needs of customers if you don’t take the time to ask them, she pointed out. “Collaborating with consumers,” or in this case with patients, “is critical if you want your product to do well in the marketplace and, more importantly, play a meaningful role in their care.” Although some companies will continue to design devices without input from users, “the FDA has put a stake in the ground,” said McGaffigan. Her hope is that far more devices will be commercialized with the meaningful input of patients and families, as well as healthcare end users.

In fact, said Patterson of Agilis Consulting Group, that does appear to be the case among the companies with which she works. “I think manufacturers are becoming more astute to the importance of human factors,” in part because places like hospitals and pharmaceutical companies are asking them for that kind of information. “They want to see their usability test data,” she said. “They want to know about that user interaction. This wasn’t so common even 5 years ago. I think a lot of this is relatively new.”

References


