Homeward Bound

*Healthcare Technology Is on the Move*

Chris Hayhurst

Once confined to healthcare facilities, medical devices now are commonly being integrated into homes, schools, workplaces, and elsewhere. This article explores how stakeholders are adapting to this change—and what the shift means for healthcare technology management (HTM) professionals.
Before Patrick Lashway began his first official job in HTM, he attended the Oregon Biomedical Association 2015 Conference and Exposition, where Patrick Lynch—a longtime leader in the HTM field—delivered the keynote speech. Then a student in Portland Community College’s electronic engineering technology program in Portland, OR, Lashway was struck by Lynch’s comments.

“One of the things he talked about was the potential opportunities for biomeds as more medical devices are used in people’s homes,” recalled Lashway. “I liked the idea of maybe living near a retirement community and being available to service their equipment. It seemed like it could be a good way to make a living while also giving back to people who could use the help.”

Riding on the coattails of this inspiration, Lashway decided to submit an essay to the Association for the Advancement of Medical Instrumentation’s (AAMI’s) “My Dream for HTM” contest. The competition, which took place this past May as part of HTM Week, an annual celebration recognizing the work of HTM professionals, asked entrants to describe their vision for their field in 200 words or less.

“I dream,” Lashway wrote, “of waking up every morning and taking a ride around my part of town on an electric bicycle, towing test equipment behind me. I’ll be stopping in at the homes of the elderly, the infirm, and the working professionals at times convenient for them. I’ll build relationships with them as I run PMs [preventive maintenance inspections] on their home medical devices, maintain network connections for the medical apps on their smart phones and tablets, and ensure that security patches are up to speed to provide them the maximum balance between patient safety and data utility. If there is a problem I can’t fix, I will be their first and greatest advocate. I will get their hospital to fix connectivity issues on their end. I will get OEMs [original equipment manufacturers] to send parts, manuals, and personnel necessary to have the equipment up and providing the life-supporting service they were purchased to perform. I will get them the training necessary to use their new equipment and to care for it on a day-to-day basis. I will be available to my neighbors; I will be their life line—their first line of defense and first strike for resolution. I will be a Beat Biomed.”

At the time he wrote the piece, which won third place, Lashway was an intern in the Clinical Technology Services Department at Oregon Health and Science University in Portland, OR. And while he didn’t know it then, he was also about to get several job offers from hospitals that hoped to hire him when he cleared this last hurdle to an associate’s degree. In fact, he’d eventually take a position as a BMET I (biomedical equipment technician) at Adventist Medical Center—Portland, just a few miles away.

For now, Lashway’s “Beat Biomed” vision will have to remain a dream. “I think one day there might be jobs like that, but right now the home opportunities are for durable medical equipment technicians.” Such technicians, Lashway noted, make a fraction of the salary of the typical hospital biomed, in part because the position requires little education (for example, see www.stateserv.com/career-opportunities/durable-medical-equipment-technician-albuquerque).

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“But then also, their main job duties really just involve the delivery and recovery of the equipment itself.” They might offer minor training to patients in how to use the equipment, said Lashway, “but it’s not a skilled electronics or technician job—or at least not in the way the HTM community understands it.”

Home Care Evolution
A cursory survey of healthcare facilities reveals that more and more of the equipment seen by HTM professionals is slated for use in nonhospital environments. One of the reasons, as Lashway hinted at in his essay, is the rapid aging of the U.S. population—a
trend led by the nation’s millions of baby boomers, two of three of whom have multiple chronic conditions.\(^1\) Thanks to advancements in medical technologies, as well as a push to reduce healthcare costs, older adults living with diabetes, heart disease, cancer, and other health conditions now are spending much less time in formal healthcare facilities and, instead, returning to their homes.

“I think a lot of it is a result of the Affordable Care Act,” Lashway said, pointing out that the law has incentivized healthcare providers to “move people with non–life-threatening conditions out of hospitals” as quickly as possible. “That and the explosion of medical apps and mobile devices capable of telemedicine. For a lot of conditions, if they have the right equipment, these patients don’t need to be hospitalized anymore.”

In fact, most indications are that the home healthcare market has not only grown substantially in recent years but will continue to grow for the foreseeable future. According to one market report, durable medical equipment expenditures in the United States are expected to increase at a compound annual growth rate of more than 5% over the next 4 years, from around $46 billion in 2015 to more than $60 billion in 2020.\(^2\) The list of durable medical equipment covered by Medicare shows just how many devices are included in such calculations (air-fluidized beds, blood glucose monitors and test strips, canes, wheelchairs, oxygen equipment, suction pumps, traction equipment—just to name a few).\(^3\)

The implications of this trend for the biomedical community, as Lynch, Lashway, and others have recognized, is that someday HTM professionals may find themselves working as much with devices that were designed for people’s homes and other environments as they do with devices that never leave the hospital.

“Healthcare is evolving, and medical devices are evolving with it,” noted Susan Martin, senior director of contracting, business development, and marketing at the Johns Hopkins Home Care Group (JHHCG) in Baltimore, MD. JHHCG has seen remarkable growth since it first appeared in the 1980s as a small nursing agency department within Johns Hopkins Hospital, explained Martin. As the technology has improved over the years, and as healthcare itself has gained ground, “this side of our business has expanded tremendously, and we only see it getting even bigger in the future,” she said.

Today, approximately 1,000 JHHCG employees provide a vast array of home-based services, including home health, infusion medications, programmable pumps, and respiratory equipment. However, Martin noted that the only way an organization like Johns Hopkins can provide this kind of service—“where you’re often relying on these really complex technologies to work in people’s homes, is with the support of the biomed
community.” HTM professionals, she said, have a tremendous role to play in ensuring such technologies are “not only working the way they’re meant to work, but that they’re also available when and where our home care patients need them—and most important of all, that they’re safe to use.”

**Significant Benefits, Unique Risks**

Safety, in fact, is the primary focus of a guidance document for medical device manufacturers that was released by the Center for Devices and Radiological Health of the Food and Drug Administration (FDA) in late 2014. In it, the agency describes home use devices as “integral” to the home healthcare market. Defining such devices as medical equipment “labeled for use in any environment outside a professional healthcare facility,” including, among other places, offices, schools, and retirement homes, the document provides nonbinding recommendations to assist manufacturers in developing devices “that comply with applicable standards of safety and effectiveness and other regulatory requirements.” Such devices “provide significant benefits to patients and families, including quality of life improvements and cost savings,” but they also come with “unique risks” that should be addressed during device development.

“From what I’ve seen,” said John Adamovich, administrator of innovation and research at JHHCG, “a lot of the devices we’re now using in home care are a little bit more sleek and less conspicuous. They’re designed to let people go about their daily lives”—and not have to worry, for example, about the functionality and transportability of a device like an infusion pump. “People don’t want to think about what they’re carrying around, and they don’t want the potential stigma associated with it.” Many of JHHCG’s infusion patients, Adamovich said, now carry their pumps with them everywhere they go, keeping them in backpacks “that look just like a pack you’d take with you to school.” Similarly, the continuous positive airway pressure masks JHHCG offers to their home patients tend to fit better and cause less irritation than earlier models. “They’re designed in a way that they’ll actually want to use them, which wasn’t always the case in the past.”

Noting that most home users will not have ready access to cleaning, disinfecting, and sterilization supplies, the FDA has requested that manufacturers provide clear guidance on the maintenance, calibration, cleaning, and other procedures, as well as make it clear whether patients or trained professionals should perform the work.

The FDA document spends less time on these obvious benefits of modern devices and more on the potential hazards that they may pose. Manufacturers, the agency recommended, should consider such hazards as they strive to mitigate risk, taking into account everything from environmental factors (e.g., temperature, airflow) to user-related issues (e.g., physical and cognitive abilities of individual patients).

Further, the FDA guidance suggests that manufacturers should minimize the maintenance, cleaning, and calibration of these devices to the greatest extent possible. Most home users, said the agency, “do not have easy access to the cleaning, disinfecting, and sterilization supplies” commonly found in hospital environments. According to FDA, manufacturers should ensure that all labeling clearly explains how maintenance, calibration, hygienic cleaning, and other procedures should be approached, as well as make it clear whether patients themselves can handle the work or if a trained professional should do the job.
Transitions of care from hospital to home need to be straightforward, standardized, and safe. A group of experts and volunteers is working to make this happen.

Building off of a 2013 AAMI/FDA summit, the AAMI Foundation formed a workgroup in 2015 to look at the process flow of transitioning a patient with medical equipment from a clinical to a nonclinical environment. Home healthcare professionals, infusion therapy agencies, durable medical equipment suppliers, pharmacists, medical device industry representatives, reimbursement specialists, and lay caregivers chose to focus on infusion therapy, including the medications and equipment. The group sought to develop one map based on the current reality of the home infusion therapy process and another based on best practices.

For purposes of the project and in order to keep the process focused, the group used the following assumptions:

- The process begins in the hospital and moves to the home setting.
- It involves adult patients only.
- The therapy is of any duration.
- All infusion devices are included.
- Medication that would be administered in the home by the patient is included.
- Access to a home infusion provider is available.
- A prescription for home infusion therapy is present.
- The type of service varies by geographic region.
- Communication across the interprofessional healthcare team is integrated in the process.
- Reimbursement weaves throughout the entire process.

The participants divided up into teams, based on their experiences, and moved forward with a mapping methodology known as “jobs to be done.” This framework was chosen because the group believed that it dealt with the large array of processes across systems, organizations, and technologies discussed during team meetings, and it aligned with the summit recommendations.

In looking at the “jobs to be done,” the teams focused on the “what”—not the “how,” “who,” or “when.” Such a focus allowed for the mapping to be kept at a high level. This reduced redundancy and permitted subsequent users of the mapping to customize the specifics of each job based on how their agency operates, the type of infusion therapy being prescribed, who is performing each job, and the environment in which it will be provided. For the infusion therapy mapping process, we identified five high-level jobs:

1. Prepare to discharge the patient on infusion therapy from the hospital to home
2. Prepare the prescription (supplies, equipment, medications) and discharge the patient from the hospital
3. Admit the patient to home infusion services
4. Provide ongoing home infusion care and services
5. Discontinue home infusion care and services

Each of these high-level jobs includes five to six sublevel job steps that are more specific. For example, to fully perform the first job noted above, healthcare teams need to perform tasks that include identifying the clinical need for home infusion therapy, confirming insurance coverage, aligning the healthcare team to understand the patient’s needs, preparing the patient and caregiver to administer the infusion safely and effectively, and finalizing the discharge plan. These sublevel jobs are not considered to be a step-by-step process. At any time, the steps can be modified based on the patient’s status and needs.

Teams will incorporate objectives and measures of success that include what we want to achieve at each sublevel; gaps, identified throughout the process review, will provide the baseline for the best-practices process map for home infusion therapy.

Developing the two process maps is the first step in realizing the goals of the AAMI/FDA summit—synchronizing the disjointed elements in nonclinical settings into a model that can be used and adopted. The team will recommend research needs and policy that needs to be developed or changed. The entire project will be presented in a formal document in January 2017.

“The jobs and substeps that the teams are developing underscore just how complicated home infusion therapy can be,” said Marilyn Neder Flack, vice president of patient safety initiatives and executive director of the AAMI Foundation. “It is not simply a matter of discharging a patient from the hospital with a set of instructions. There are many pieces to the puzzle and if that fact is not recognized and addressed by all stakeholders, we are not providing optimum care and could be putting patients in danger.”

References

Behind the Curve

“Ultimately the goal is to make your device simple to use,” said Dave Bonnett, senior manager of quality systems risk management at Fresenius Medical Care North America, which designs and manufactures dialysis products for use in healthcare facilities and homes. According to Bonnett, the home and other nonclinical environments are different because “they’re far less controlled than you typically see in a hospital or a dialysis center, and the patient”—the user—“is on their own; they don’t have the skills of a medical professional.”

Fresenius strives to take these differences into account in all of its design and development work, said Bonnett. “The development process includes a significant human factors aspect that we take very seriously,” he explained. “You really have to think about every different angle: the user’s educational level; the idea that the patient might have difficulty understanding directions because of the medications they’re taking or the effects of their illness; the fact they may be using this device in a distracting environment with children around or the TV on.”

The expectation of FDA, as well as that of his company, “is that any device you put in a person’s home be very intuitive to use, and not the kind of thing where you’re always having to refer back to the user guide. It needs to be operated in a way that makes sense no matter who the user is. If you can do that, you really minimize the risk that something might go wrong.”

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As a human factors engineer, Lewis looks at how devices are designed to facilitate the work of the end user. “In a hospital setting, an infusion pump is going to be used by a physician, trained nurse, or somebody who has been designated by the hospital to use that piece of equipment,” she said. In other words, it will be designed in a way that considers the training of clinical end users. “But when you then put that same pump in somebody’s home, there are all kinds of potential issues that might come up.” Lewis has seen, for example, infusion pumps that are designed to allow certain features to be blocked, in order to prevent home care patients from accidently hurting themselves.

“The problem is that it’s up to the discretion of the person training the patient to know what to block out—what features to give them or not to give them,” said Lewis. “And they’re asked to make those decisions based on their personal comfort level. They’re looking at that patient and they’re basically making a judgment call: Are they going to be OK once they get home? What can they do on their own?”

Home care organizations are compensating for this gray area by setting up 24-hour help lines or similar dial-in services that patients can use when they run into trouble, Lewis said. “I think they’re doing the best that they can with the resources they have. But I also think it’s a very precarious situation that needs to be addressed.”

Lewis used an example of a male patient who is discharged to his home after being treated for cancer. “Maybe they’ll give him an infusion pump so he can continue his
treatment at home. Well, he might not have someone at home who can help him with this pump and getting it to work. Maybe he lives alone.” That patient is probably nervous, said Lewis, and as a result, he may not fully understand what he’s being told. Further, he may not ask the right questions to help clear things up. “Some people are intimidated,” she said. “They don’t want to look dumb.” The danger, said Lewis, is that when this patient goes home with his pump, “while the nurse may have done the best that she could, he’ll still have to figure things out on his own.”

Although lauding 24-hour help lines, Lewis added that “they can’t make up for poor device design” or, for that matter, poorly written directions. “I’ve looked at the written instructions patients sometimes get, and they can be so complicated that there’s no way they can understand them.” She also has seen cases where delivery people who were expected to provide patient training when they dropped off medical equipment failed to do so—or they did provide training but the patient wasn’t in the right frame of mind to listen to the directions.

“There are all kinds of ways for things to slip through the cracks,” said Lewis. “So I think the onus should be on medical device manufacturers. They need to design their equipment right from the start so that it’s appropriate for the population that is going to use it.”

**Need for Better Testing**

Allison Strochlic, research director of UL LLC’s human factors engineering team (formerly known as Wiklund Research and Design, Inc.) in Massachusetts, agreed. Her suggestion to medical device manufacturers: Whenever there’s a possibility that a new device will be used in the home (or in any other nonclinical setting), it’s all the more important to conduct user research to learn about the intended use environments, then apply key aspects of those use environments during usability testing.

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Conducting usability testing in a simulated setting (e.g., in a usability lab), rather than in patients’ homes or other, actual use environments, is routine and accepted by regulators. That said, Strochlic further explained that “it’s important to simulate particular environmental factors, such as lighting, sound level, and distractions, to assess whether these factors impact participants’ ability to use the product correctly in the intended use environment.” Beyond understanding how the environment affects users’ interactions with a device, conducting usability testing enables manufacturers to identify product shortcomings and learn how such shortcomings might hinder safe and effective use.

Unfortunately, Strochlic added, not all manufacturers have fully embraced such testing. “The FDA has definitively stated that device manufacturers should conduct usability tests, but some manufacturers have yet to come around to it, or they wait until the final validation (i.e., summative) stage, when it’s often too late to modify a device’s design in response to identified interaction problems.”

Denny Treu, vice president of research and development at NxStage Medical, Inc., and co-chair of the AAMI Home Care and EMS Environments Committee, agreed. Although NxStage, he said, has made usability testing part of the routine, he’s seen other manufacturers dragging their feet on this subject. “People are starting to come on board in terms of looking at their devices from an overall systems perspective, as products that need to be integrated into the home” and not just plucked out of the hospital environment. But as the home care movement has picked up, said Treu, the response has been, “‘Hey, let’s send this product that we have available right now into people’s homes right away,’ because it takes years sometimes to develop something new from the ground up.”

NxStage, which makes dialysis systems that are currently used by more than 8,000 patients at home, has decided that a systems approach is the best path forward, according to Treu. “The equipment we make for home care use is noticeably different than what we place in the critical care environment,” he said. “It’s smaller; it’s easier to use. And the labeling and the training materials reflect the fact that this device is meant to be used by lay users—not by professional caregivers.” In the design process, Treu explains, “it’s important that you start with a clean sheet of paper to make sure you hit everything.” That includes not just the design itself, but how the device will be used, the disposables that go with it, the drugs it provides, and the service and support it might need. “You really have to make sure you look at the whole picture.”

Of note, in 2013, the AAMI committee that Treu co-chairs published TIR49, which provides recommendations for the design of training and instructional materials for medical devices used in nonclinical environments.5

Strochlic said that when providing human factors engineering consulting support to device manufacturers, she often sees clients neglecting to seek input from end users. Rather, manufacturers might have designed their product “in their lab with their engineers and R&D folks, all of whom are likely to be very knowledgeable about device development, but may be lacking experience in and knowledge about the true intended use, users, and use environments. Unfortunately, there are still cases in which a product is considered ready for validation, but has not been seen or touched by a representative user,” she said.

Ideally, according to Strochlic, companies should get users involved at the earliest stages of development. “You need to learn about users’ expectations, as well as their limitations. If you’re designing an insulin pen injector or a glucose meter, for example, you need to understand the extent of visual impairment your users might have,” said Strochlic, noting that these patients may have diabetic retinopathy or glaucoma. “If a product’s design doesn’t take those deficits
into account—by presenting text and numerals in large, legible, high-contrast fonts, for instance—users are likely to commit ‘use errors’ during product use.” Strochlic recommended “bringing in people with diabetes, their caregivers, and the nurses who’ll be training laypeople on how to use the product and have them try it out during a usability test. That’s how you’ll know if the product can be used safely and effectively.”

**HTM’s Role**

According to NxStage’s Treu, most of his company’s home machines are maintained through what he calls a “depot service” model. If a problem with one of their devices emerges, “the patient calls us, we send out a new machine, and they put the old one in a box and send it back.” The repair work, Treu added, takes place in the company’s own service facility. Therefore, in NxStage’s case, biomeds don’t do on-site, in-home repair work. “In hospitals, sure, they can do basic maintenance. But for our home devices, it’s easier for us to just send a replacement.”

It works exactly the same way at Fresenius, said Bonnett. “If there’s ever an issue, they just send it back and we’ll overnight them new equipment. Repairs are handled by our depot service.”

One of the reasons this business model seems to work, Bonnett said, is that when it comes to general upkeep and regular maintenance, their equipment rarely requires the attention of trained biomeds. “It depends on the product of course, but we try to make everything as maintenance free as possible, and when there are certain routine things that need to be done, we spell everything out. We want to make it easy for patients to do most of the work themselves.” For example, Bonnett said, if a device requires periodic cleaning, “we’ll include detailed instructions on how to wipe the device down to disinfect it.” If the product has a fan, “we’ll outline the procedure for replacing the filter.”

According to Melissa Lantz-Garnish, Johns Hopkins Home Care Group’s head of remote patient monitoring, that kind of service—where directions are clear and well thought out, and the manufacturers take responsibility for any major repairs—is critical to the success of programs like hers.

Patients may be overwhelmed by their medical condition and need for care, so it’s critical that HTM professionals who work on or provide training for home medical devices present themselves in an empathic manner and explain procedures in a simplified way using plain and clear terms.

“We don’t maintain our remote patient monitoring equipment through our hospitals or their biomedical departments. My team does all of that management ourselves. We have certain protocols for cleaning and assessing, making sure that everything is in working order. Then, anything we find that is not working properly, or if we’re having an issue in any way, we contact the manufacturer and go from there.” Sometimes, Lantz-Garnish said, that involves returning the equipment briefly for calibration or repair, and sometimes it involves getting new equipment altogether. Her remote patient monitoring group does not use BMETs or other HTM professionals for this work, “because the people who do the cleaning and switching out with patients don’t do any actual adjusting of the equipment.”

According to Martin, it’s a slightly different story in JHHCG’s home infusion and respiratory divisions, where the equipment (such as home ventilators) tends to be more complex and require more training. For these programs, she said, they have a shared
biomedical shop with technicians “who are trained and certified by the various manufacturers to do the checks for the switch outs and the calibrations of our devices here on site.” When patients transition from the hospital to their homes, a respiratory therapist will typically bring their ventilator into the hospital biomedical shop, “where they’ll look at the device and make sure it’s ready while the patient or their caregiver is instructed on how to use it” and any other supportive equipment (e.g., oxygen tanks, pulse oximeters).

“During that process,” said Martin, “the respiratory therapist will always go to their home to do an environmental assessment and make sure everything’s safe.” After the patient leaves the hospital, that therapist will again “follow the patient to their home, where they’ll work with them, and their caregiver if they have one, to help them adjust and get them properly set up.” As part of that process, the requirements for the machines are clearly spelled out, and a schedule is established for returning the equipment to the shop for regularly scheduled maintenance according to manufacturer recommendations and guidelines.

JHHCG, Martin added, is Joint Commission accredited and monitored by both the FDA and the Maryland Department of Health and Mental Hygiene. “Unannounced surveys can happen at any time, where they’ll come in and check that our weights and measures are accurate, or they’ll look at our preventive maintenance logs.” Visits to patients’ homes are often part of those assessments, she said. With a patient’s permission, “they’ll go in and look at the equipment, ask them how they were instructed to use it, and then they’ll write down the inventory tracking number on that device and come back to our biomedical shop” to check the records and ensure all maintenance has been performed per manufacturer guidelines. “They keep a very close eye on everything we do.”

Looking Ahead
For biomeds who do find themselves working on home medical devices or providing training for such devices in people’s homes and other nonclinical environments, Strochlic stressed the importance of remembering that the people with whom you’re interacting might be unwell. “They might not feel well physically or emotionally, and they might be overwhelmed by one or more aspects of their medical condition and need for care.” The medical device you’ve been asked to look at is “just one piece of the overall puzzle,” she said, and likely not the only thing the patient has to think about.

“They have to use this device, they have to go to their doctor’s appointments, they have to remember to take their medications on time. So as a biomed in that environment, where this person may have a lot on their mind, you really have to consider how you present yourself—make an effort to really listen and think about how you service the device, and also support the person or people using the device.”

“Don’t go in thinking you’ll just fix this machine and get out, and not delve into more personal aspects of the device’s use,” said Strochlic. “There may be people connected to this device all the time, and it might be a critical part of their care.”

When answering questions, Strochlic recommends using plain terms and simplifying things as much as possible. “Most of all, be patient,” she said. “In addition to not having in-depth clinical knowledge, users might not have a high level of education, literacy, or comfort with technology. Keep in mind that everyone is different; everyone has a different personality and perspective on the device, their care, and their needs.”

— Allison Strochlic, research director of UL LLC’s human factors engineering team

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One BMET who seems ready to take Strochlic’s advice—if, that is, he ever gets the chance to do so—is Lashway. In the short time he’s worked at Adventist Medical Center, said Lashway, he has yet to work on home medical equipment, though the organization

Standards Related to Home Care and Device Design Considerations

• AAMI TIR49:2013, Design of training and instructional materials for medical devices used in non-clinical environments
• ANSI/AAMI HE75:2009/ (R)2013, Human factors engineering – Design of medical devices
• ANSI/AAMI HA60601-1-11:2015, Medical electrical equipment – Part 1-11: General requirements for basic safety & essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

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does have a highly respected home care division. Still, he said, such work should eventually become part of his job.

“We apparently do work on some items that get sent home with patients, though I haven't touched any of it yet. I've been told we work on some physical therapy devices, coagulation analyzers, defibrillators, and infusion pumps,” he said.

Meanwhile, Lashway said he’ll continue to dream about one day being that “Beat BioMed.” “Maybe in a decade or so, this aspect of the industry will finally get some footing. I would think it has to eventually.”

References


