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An Arm and a Leg: Medtech Perspectives on Human-Centered Design

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An Arm and a Leg: Medtech Perspectives on Human-Centered Design

Cover Page Footnote
The author would like to thank Dr. Eric S. Richardson, Joshua S. Frei, and Koloa Wolfgramm for their generous contributions to this article.
IT’S A FRIGID DAY IN UKRAINE. Snowflakes flurry by, swirling around a man hobbling his way through the bleary scene. Not every day is so cold and bleak, but miserable weather or not, he must get to his job. All day, he is on his feet, climbing stairs and walking quite a distance to get to work. He winces, wobbling in place for a moment as his deteriorating prosthetic leg gives him a bit of a misstep. For this man, his subpar, breaking prosthetic is a critical part of his life. Notwithstanding his diligence, the daily rigors he faces are painful and exhausting.

That’s when 2ft Prosthetics was contacted.

In the field of medical technology, organizations like 2ft Prosthetics take the health and wellbeing of individuals into their collective hands. That responsibility comes with the ever-growing obligation to provide goods that suit the user’s specific needs. These medtech companies and outreach groups must gear up to address these needs, which can be some of the most personal and sensitive requirements a customer can have. As the technical capabilities of this and other industries grow, the potential to meet these needs increases, but even authorities in business and engineering alike must first learn the art that makes such success possible. This art of human-centered design accounts for both technological and emotional specifications in order to deliver meaningful products that meet the specific needs of the individual customer.

Every business professional can deepen his or her understanding of human-centered design—regardless of our industry of choice—by looking to perspectives that the business of medical technology offers. To that end, this article draws upon interviews with three figures in this remarkable field, distilling their insights on how to cultivate businesses that produce human-centered solutions.

DR. ERIC S. RICHARDSON

To investigate how companies and organizations can better tackle the challenges to human-centric design, I interviewed Dr. Eric S. Richardson, Associate Professor of the Practice in the Department of Biomedical Engineering at Duke University. Dr. Richardson teaches courses on medical device design and various advanced topics, guiding students not only in improving their technical aptitudes, but also in becoming adept at handling anthropological constraints on design.

FROM THE GROUND UP

When I asked Dr. Richardson about the origins of his human-centered medtech emphasis, he explained that even though he had always been interested in healthcare systems in emerging markets, it was in Guatemala that the vision came into focus. “I saw that there are trained and dedicated healthcare workers around the world,” he recounted. “These clinics were lacking not compassionate professionals but technology, so I thought, how can I help extend technology access throughout the world?” That lack of access extends far...
Beyond Guatemala alone. With 80% of medical devices serving only 10% of the world’s population, Richardson points out that 90% of people on the planet are left with access to a meager fifth of medical technologies.

Fiji 2017 2ft Trip
Source: 2ftprosthetics.org

With that epiphany, Richardson charted a new course in his career. Instead of helping these emerging healthcare systems by going to medical school, he turned to designing medical devices with the aim of making these technologies available to those competent yet underequipped workers.

After receiving a PhD from the University of Minnesota, Twin Cities in 2009, Dr. Richardson went to work for Medtronic, the world’s largest medical device company. There, he worked on high-end heart valves as well as other medical devices intended for emerging markets need to work hand-in-hand with local, sustainable business models. A device that succeeds with its roots in American healthcare may not find the support it needs in South American soil. Moreover, a device should be constituted of materials and manufacturing methods that can be sourced at a price point that is acceptable to local markets. This provides communities with not just an acute medical solution, but also with a maintainable manufacturing opportunity that strengthens economic potential.

Understanding

Such an approach necessitates awareness of more than just the singular need that the product hopes to meet. Speaking broadly, the human-centered design movement addresses the multitudinous facets of human life, considering how any and all of them can be impacted by the product’s features. “Design thinking” draws from ethnology and anthropology, in addition to relevant technical proficiency, in order to help designers better target their users’ needs. Understanding what the users’ needs are, Dr. Richardson explains, will mean that “those human constraints are ingrained in your heart as well as your mind.”

Competing against this paradigm of design thinking is a common, underlying pitfall for both engineers and businesspeople. As engineers, Dr. Richardson describes, we often look at the question, “How can companies build a reliable Toyota from the very start?”

Designing from the ground up means much more than starting from scratch. As Dr. Richardson explains, medical devices need to be flexible enough to meet the needs of local communities. A device that succeeds with its roots in American healthcare may not find the support it needs in South American soil. Moreover, a device should be constituted of materials and manufacturing methods that can be sourced at a price point that is acceptable to local markets. This provides communities with not just an acute medical solution, but also with a maintainable manufacturing opportunity that strengthens economic potential.

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SOCIETAL CONSTRAINTS

As I talked with Frei, one of the first points he made was how different the available support in any given country will be. Like Dr. Richardson noted, many medical devices are developed in the United States with the American healthcare system in mind, but what works easily in Arizona may completely fall apart in Africa. For prosthetics, Josh explained, the traditional process begins by making a plaster mold that will fit the person. That mold is then used to create the socket for the amputee, allowing them to slide their residual arm or leg into a custom-fitted, sleeve-like shell that connects their original limb with their prosthetic. Though this works temporarily, post-amputation limbs fluctuate greatly in their dimensions, expanding and contracting and stretching in unpredictable ways. In the U.S., these fluctuations are fine because trained prosthetists simply make a new mold and create an updated socket. However, the developing world at large does not have enough medical professionals to make this U.S.-oriented “custom fit” model plausible.

“Thats what’s hard about prosthetics,” Frei revealed. “A wheelchair only has to fit someone’s weight and size. But if there’s not a prosthetic professional who can fit a socket to the individual, [that kind of prosthetic is] not solving the problem.”

Given this societal difference, the root of the problem is not donating a nice leg; rather, it is training people. As part of their humanitarian trips, Joshua and the 2ft Prosthetics club help get prosthetic clinics off the ground, teaching community members how to fit, manufacture, and maintain their low-cost prosthetic devices. As Josh summarized, “You can’t just throw money at it and make it better. You need someone there.”

Societal factors also constrain the manufacturing process. Developing countries have comparatively few manufacturing facilities to begin with. They may also have limited ability to import other materials. Thus, making a device “easy to manufacture” requires sourcing locally available materials during the design stages of development, as well as ensuring that the equipment and skills required are inexpensive and easily taught to community members. From the 2ft Prosthetics engineers’ perspective, it is not enough for their own team to produce a durable, maintainable product. No matter how great their design is, it is not right if it is difficult for someone else to repair and make last for a decent amount of time. “If we leave and then no one has a functional prosthetic, then it’s back to the crutches, back to the wheelchair, back to the skateboard,” Frei reflected. The community must be able to keep the product going.

CULTURAL CONSTRAINTS

On the other hand, cultural constraints can prevent a product from ever getting off the ground. In addition to 2ft Prosthetics, Joshua Frei has also been involved with BYU’s Global Engineering Outreach program. Program participants work in interdisciplinary teams on sustainable projects that help villages and communities in Peru. GEO goes to great lengths during the two semesters of designing to understand the needs of the Peruvians they will help. Rather than merely designing and delivering something on their own, GEO students communicate regularly with natives to get a feel for what projects they want and how to go about building them. After those eight months of preparation, students go to Peru to implement their innovative technologies.

Of course, no matter how much research and coordination the students do in advance, unforeseen cultural constraints arise that require additional ingenuity. One such category of unexpected limitations is culturally held beliefs. Joshua recounted instances that the Global Engineering Outreach teams have encountered in the past. One such project was a shared water tower, intended to provide water to two adjacent villages. To the students’ surprise, one of the towns was devastated and insisted that a new tower be built. Why? The pipe that led to this town was situated lower than the pipe that led to the other. Surely, they complained, the water would always go through the other town’s higher pipe before it could even get to their lower one, so the other town would get far more of
the precious resource. The engineers tried to explain how hydrostatic pressure ensured equal distribution, but nothing would console them until the company’s engineering and business acumen completely undermined all the effort that had been put into an otherwise helpful product.

Cultural perceptions also impact product success. A simple example is the culture’s attitude toward broken things: Do these people tend to fix anything that becomes otherwise unusable, or do they think, “This thing just doesn’t work, forget it?” Similarly, some cultures may be more superficial, looking down at people who walk differently. Users may have apprehension or distaste when it comes to certain methods of putting a prosthetic on, or they may assume their walking gait will be precisely as it was before their amputation, rejecting any offering that fails to live up to their expectations. These culturally held views dictate their own set of design specifications. In Josh’s words, no matter how great a design is, “if it is culturally rejected, it is unacceptable, and it is no longer a viable option... It does not solve their problem.”

PERSONAL CONSTRAINTS

Even with similar circumstances, individuals lead dissimilar lives, and those lifestyles influence product development. Referring to the Tongan who commutes on foot, Joshua described conversations—much like those advocated by Dr. Richardson—discussing the maris typical day-to-day demands, the countless flights of stairs, his physical characteristics and measurements, expectations, needs, and everything they could learn. On a different occasion, the team worked on a prosthetic for a banana farmer in Panama. Again, the pattern began with talking with the patient, determining what specific limitations his profession and environment imposed. Details like these admittedly constrain the 2ft teams’ design approach substantially, and the group must occasionally put projects on hold, but this process of stepping into the user’s life makes the project easier to tackle. More importantly, whereas a more general, one-size-fits-all approach would have struggled to accommodate both these individuals, the 2ft Prosthetics teams were able to work on products that would serve their purpose: helping their users with their unique lives.

Emotions also permeate design considerations. We may readily recognize that a “normal” prosthetic would not be a great fit for an athlete seeking peak performance, recommending instead a model designed for sports and increased load capacity. However, we may not as readily recognize how that same “normal” device may not match a user’s emotional needs. Imagine a 13-year-old girl, excited for summer vacation and effervescently smiling as she always does at the thought of reuniting with her friends. Life is blue skies, a shining sun, and the lemonade her mom always makes. Summer abruptly closes with a car accident. She survives and for the most part is miraculously unscathed, barely touched at all except for her left leg, which disappears by amputation almost as suddenly and rudely as the incident that took it away. Handling everything with remarkable poise, she is determined to return to school in time for the new year at junior high, but she doesn’t want anyone to know that she has a prosthetic. The standard leg she was given works well, and pushing through all the physical training, she got the hang of walking with only a slight limp. Maybe no one would notice that, but with each step she takes, the knee makes an audible, unnatural click.

The sound feels deafening in her ears as she imagines everyone at school turning, revolving around to look at the source of the unfamiliar noise. The prosthetic that seemed quite suitable for her “typical,” non-demanding life ends up being wrong for her, in this fictional case because the thing that matters most to her is seeming normal. Just as was seen for various cultures, each of those constraints will differ for each individual person, not just in quantitative measure, but also qualitatively. As I quickly discovered by talking with Josh, in their world, there truly is no “typical” device.

TECHNICAL CONSTRAINTS

When a design meets societal and cultural limitations, there are still plenty of technical challenges to overcome. Perhaps the first constraint that members of 2ft Prosthetics consider is the kind of amputation. As Frei explained, different amputations require different approaches, and a given country will have a unique blend of amputation causes. For instance, many amputations in Mexico are the byproduct of diabetes, whereas American amputees are more likely to be veterans or car accident survivors. Tongans who need a prosthetic tend to require stronger support. Africans who escaped civil violence may have had their mangled leg hacked off with a machete, and unlike the American, they may not be as likely to have a car to help them get around, thus placing even more strain on their legs. These contrasting amputations alone create disparate technical needs, all on top of the engineering knowhow required for a standard device.

Getting started

With this realization, I wondered how organizations even approach human-centered design. Seeing all those variations, the concept of helping entire markets while meeting those individual needs seemed far more daunting than it initially appeared. Frei offered the following tips for tackling the beginning of such endeavors.

Specialize. First, pick your market. Once you have that decided, assemble a research team and learn everything you can. This is the population your product needs to entice, the lives your creation is intended to enrich, and the factors for which your solution must account, so get to know it and them deeply. Once you have progressed beyond the superficial, add that genuine understanding to what your organization can provide. This forms a guiding vision like “Best foot for Tonga” that your teams can pursue in all stages.

“Solving social problems is a question of both technical expertise and business acumen. A true social solution is going to add value in all aspects of the community.”
Subdivide. “It can kind of feel overwhelming at times,” Joshua admitted, “There are lots of needs out there, a lot of variables out there.” To overcome those potentially overwhelming feelings, break up your team’s specific, specialized vision into more manageable subparts. For instance, when 2ft Prosthetics identified a need for an adjustable socket in Ecuador, their strategy was to create subcomponent teams, smaller groups that were responsible for the research and development of individual parts like the socket’s base plate, strap network, and struts. Though these teams were interwoven and coordinated with one other, this tightened focus for each subgroup aided the entire team in producing a product that could account for the numerous constraints.

Serve. Though highly beneficial for any company, an attitude of putting users first is essential for anyone engaged in human-centered design. Embracing the perspective of serving the user breakthroughs the equivalent of writer’s block experienced by designers and directors alike. “I’d say communication is the key,” Joshua expounds, “You need to understand the constraints.” Figure out what the user needs, then go to work to meet them. Ultimately, by helping the individual in the company’s engineering and business plans, the company becomes enabled to help the masses.

With these foundational principles in place, any organization can follow the example of 2ft Prosthetics and proceed to help the individual in a human-centered process. With this mindset, any group can successfully design and distribute a product that offers well-rounded value to users in particular markets.

COLLABORATION

“Don’t get discouraged,” Josh begins. “Solving big problems takes a lot of brains, and not just brains from one person but multiple people.” To say that working as a team is important is no understatement. Team members see holes in designs that you then can fix, giving you the opportunity to provide an even greater product.

As Josh noted, they can also help compensate with their individual strengths. The engineers in his teams are great at solving problems, but they can for instance benefit from help with global supply chain. Teamwork is great for overcoming such issues.

By collaborating with each other and with the people you are designing for, you can embrace and employ inspiration wherever it comes from. Sometimes, that may not even be from your own team. “We want something to be fancy, innovative, fresh, and cool. But sometimes it’s just cheaper to use something that already exists than to make something on your own,” Frei pointed out. “We need to be careful to design things that are practical and not design superfluously.”

DISTRIBUTION

Even with a highly skilled technical team, Joshua notes that “solving social problems is a question of both technical expertise and business acumen. You could have a very good engineering design, but if you have a bad business model, it’s not going to work.” For models oriented toward an emerging market, one of the most critical components is the distribution strategy. As Joshua commented, if you can’t figure out a feasible way to get your “really sweet technology” out to people, we’re just leaving people in the dust. “It kind of marginalizes people if you have the perfect solution in a lab but someone in Ethiopia doesn’t have any access to it,” he asserts, “I don’t like how things have to trickle down.”

How are we supposed to take this technology to the world, to the people who are farther down the totem pole than are top laboratories and prosthetic practices? How can we stop leaving these “lower” levels in the dust? Instead of researching cutting-edge devices that push the envelope of possibility, firms can pursue distribution-oriented development. This is the sweet spot between technology and business, caring just as much about outreach and impact as findings and results.

As Joshua stated, the purpose of technology is to make peoples’ lives easier, better, and of higher quality. If we don’t get these technologies out to other people, we are failing in our calling as engineers, entrepreneurs, and executives.

WELL-ROUNDED VALUE

For Joshua, a successful business model goes beyond developing and distributing a product. The 2ft Prosthetics team aims not only to help individuals get a prosthetic, but also to promote the economy in the area, to train community members in prosthetic care, and to kickstart local manufacturing processes.

“A true social solution is going to add value in all aspects of the community,” he explained.

Designing toward human value is a group effort. During presentations, corporate leadership can steer conversations away from mere feasibility and profitability, instead redirecting discussion toward how the proposed program or technology will add value to customers’ lives on multiple levels. Lead engineers can

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KOLOA WOLFGRAMM

As difficult as balancing all these factors can be, the investment of a human-centered business model generates more than quality products: True solutions create extraordinary lives. Koloa Wolfgramm, an amputee due to childhood cancer, considers himself the beneficiary of such exceptional devices and opportunities. Never having been a shy person, Koloa gladly shares his experiences with others and has traveled the country as a motivational speaker in addition to his work with various organizations over the years.

HORIZONS

During much of Koloa’s time as an amputee, he has pushed the boundaries of what people think amputees can do. At the age of 16, Koloa joined the USA Para Bobsled team, the first national team for the sport. Competing as a pilot, he helped with developing bobsleds that their team could use, going on to assist in forming regulations for para bobsled at the international level. Thanks to the efforts of people like Koloa, the Paralympic Games debut of para bobsled is slated for 2022.

Around this same time, Wolfgramm also stepped onto the basketball court. Historically, amputees had been encouraged to play wheelchair basketball, but for Koloa, that suggestion felt like an invitation to limit the agility he had already trained and worked hard to achieve. Joining a group of fellow amputees, Koloa became part of Amp1 Basketball. “We eventually created a non-profit and travelled around the country playing basketball against able-bodied teams, doing NBA halftime shows, training amputees and prosthetists, and fulfilling speaking engagements,” Wolfgramm recounted.

In both cases, Koloa’s accomplishments were made possible by devices that had been made and improved to address the needs he had. By taking a human-centered approach to research and development, businesses will design products without artificial constraints of expectation. Companies can “get out of the way” and enable users to focus on their dreams without worrying about their needs. Businesses can consider a product successful when its users can concentrate on the horizon instead of the step right in front of them.

DIFFICULT DAYS

As it is, taking just one step forward can sometimes feel impossible. Koloa was diagnosed with bone cancer at the age of 5, yet it was not until he was 13 that his leg was finally amputated. Because of this, Koloa believes that he had an easier time adapting to his amputation than others; he points out that many who become amputees due to sickness or trauma later in life experience more difficulty because they were accustomed to an able-bodied life.

This transition is further compounded by the unexpected monetary burden prosthetics typically bring. “Prosthetic legs can be prohibitively expensive,” Koloa notes, grateful for the athletic sponsorships that paid for his feet. “Certain insurances will only cover walking-level feet and not ones that allow you to run, which can sometimes cost upwards of $30,000.” And for above-knee amputees, the more critical knee component can cost over twice the amount of the foot. These also come in athletic varieties.

Having separate devices for more rigorous activities holds more than merely financial implications: Users must change feet. Although there are benefits to being able to design an active and a less active device separately, the specialization comes at the price of inconvenience. Able-bodied individuals may switch footwear to fit an upcoming task better, but they do not have to even consider the logistics of bringing and switching between entire limbs, let alone deal with that everyday reality for amputees. These realities are considered in a human-centered design.

THE NEED FOR “NEW”

Reflecting on firsthand experiences as both a user and a businessman, Koloa offered several insights that any company or entrepreneur can benefit from. The first is simply to get past the planning stage. “I met a lot of smart and driven individuals who… had paralysis by planning,” Koloa shared. “A lot of good can be done even if all parts of the plan aren’t quite set in stone. Learning to react to a changing and evolving market was more valuable to us than the well-laid plans we started off with.” For that matter, Wolfgramm suggests that a perceived lack of information or experience is no longer a valid claim; 16-year-old Koloa knew barely a thing about non-profit management or negotiation, but access to a stack of library books and the internet gave him everything they needed. With such resources available, the primary obstacle is motivation.

As an amputee, Koloa added, a user does not always know his or her own needs. While asking questions and trying to understand the customer’s viewpoint is essential, it cannot be the sole source of design direction because the users are still trying to figure things out themselves. Thus, this process of understanding needs must be an ongoing process, one where both parties stay involved in the conversation. “The benefit of being involved in a human-centered industry is that both consumer and producer automatically come from a shared perspective.” Users can be proactive in offering continuing feedback, and companies can make the effort to lead engaging discussions with their customers.

Finally, sometimes businesses just need to get a product out there. Looking at the market for prosthetics, Koloa laments that there are only three “major titans in the… industry.” So while companies can and should implement the numerous principles of human-centered design, there are times where what the users really need is simply another option, another
choice that brings competition and motivation for innovation. Design quality products, yes, but be sure that they become a reality before the end of the day.

AN ARM AND A LEG

Every human has individual needs, unique desires, and specific expectations, yet adopting a human-centered business approach makes personally significant products a reality. From these interviews, we can condense the various insights into three key principles:

Cater. Human-centered goods and services are designed for their specific target audience. Just like many a fine meal, a catered product will often be made from scratch and not leftovers. The chefs will pay attention to detail, ensuring that everything from the flavors and appearance to the scent and aftertaste combine into a meal made to order. Such dishes dream beyond mere nutrition; they create an experience.

Empathize. When the managerial and technical teams both seek to understand the needs of their users, they ask themselves guiding questions throughout the entire development process: What would this user need? How would her life circumstances affect her experience? Might our product impact his typical day? Though the user is not the designer, the designer brings the user into his or her heart to complement the always critical expertise.

Converge. Successful solutions in these human-centered industries draw from an entire spectrum of people, from users to expert professionals. Such solutions go beyond addressing a single concern, striving instead to provide well-rounded value in all aspects of the user’s life and community. Even when the design teams and researchers struggle to identify a plan that they feel confident about, businesses with a human-centered mindset are willing to take a shot, knowing that whatever they make will help them come closer to the market’s bullseye.

As influential as theory itself can be, perhaps it is not surprising that human-centered design is best implemented by focusing on people. Behind these principles, we see the engineer and the business person, the user and the designer. We see their technical circumstances and emotional drives. We see the arm, motivating and directing this development, and we see the leg, distributing and actualizing the results. Ultimately, human-centered design is not a collection of precise concepts demanding exact execution: It is a standard and vision, a considerate paradigm of pursuing success by providing value to the one.

Notes:
Dr. Eric S. Richardson, telephone conversation with author, February 19, 2019.
Koala Wolfgramm, email message to author, March 21, 2019.