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MedTech STRATEGIST

EXECUTIVE INTERVIEW

How Eli Lilly is Leveraging Digital Diabetes Device Technologies to Help Grow its Future

Mary Thompson

PERSPECTIVE

Was Theranos a Cautionary Tale for Medtech?

David Cassak

OUTSIDE OPINION

The Challenge of Pediatric Device Development

Bridget Shaia & Andrew Millar, Health Advances

ARTIFICIAL INTELLIGENCE

Mayo Clinic's Eko Partnership Typifies its Approach to AI Innovation

Mark Ratner

START-UPS TO WATCH

Colin Miller

Orthopedics/Spine

AMB Surgical II: Getting Smart About Pediatric Orthopedics

Medication Adherence

Ōmcare: Ensuring Drug Adherence, Assuring Caregivers

The Challenge of PEDIATRIC DEVICE DEVELOPMENT


BRIDGET SHAIA & ANDREW MILLAR
Health Advances

The Boston Pediatric Device Strategic Partner Challenge was created to help develop novel pediatric device ideas. Here one of the winning teams of innovators discusses its new heart valve mapping device and the difficulties of pediatric device design and development.

In fiscal year 2016, the US FDA approved a total of 71 premarket approval (PMA) applications and humanitarian device exemption (HDE) applications. Of these 71 approvals, 13 were indicated for use in a pediatric population or subpopulation, only two of which were intended solely for pediatric use. For 2015, the numbers were similar: a total of 61 approvals, 11 indicated for use in pediatrics, and only one intended solely for pediatric use.

Pediatric device development is limited because of a host of unique challenges associated with designing and commercializing products for the pediatric population:

- Children are not simply small adults, so device design must take into account pediatric anatomy and physiology that not only differs from adults, but can change over time.
- Pediatric patients can be life-long device users, creating additional challenges of designing for growth, ensuring device durability, and studying long-term effects.
- Most kids are healthy, so the market size is small: in 2012, CMS found that children accounted for ~25% of the population, but less than 12% of all personal healthcare spending.
- In addition to its small size, the market is also fragmented into subpopulations: neonates, toddlers, young children, pre-teens, and teenagers, all with distinctly different characteristics and needs that may require separate device features or sizes.

These challenges give rise to significant unmet needs that can be met by creative innovators seeking to serve the unique population. In 2012, a social venture named **PediaVascular** gained approval for its *Mongoose* catheter, an angiography catheter with a softer tip and smaller diameter to enable angiography in pediatric patients. To date, the company reports that over 15,000 babies have been treated with the catheter and it remains the only product in its class designed for pediatrics.

FDA has recognized the opportunity for more innovation and development in pediatric devices. In 2013, the FDA secured grant funding for Pediatric Device Consortia programs that stimulate device development in pediatrics. The consortia, affiliated with medical centers across the country, fund innovators in the early stages of device development. Actual funding varies year-to-year depending on annual Congressional appropriations, but in FY2017, a total of $6 million in funding was awarded by seven consortia, and over $20 million has been awarded in total since FY2013. Current legislation authorizes the program's continuation through 2022.

In addition to providing funding to their chosen ventures, the consortia facilitate collaboration with industry leaders, improving the likelihood that pediatric device development will ultimately translate to commercial products that can help pediatric patients. The consortia's assigned responsibilities include:

- "Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

- Mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;
- Connecting innovators and physicians to existing Federal and non-Federal resources;
- Assessing the scientific and medical merit of proposed pediatric device projects;
- Providing assistance and advice as needed on business development, personnel training, prototype development, and post-marketing needs; and
- Providing regulatory consultation to device sponsors in support of the submission of an application for pediatric devices"

In 2017, the Boston Pediatric Device Consortium (BPDC) co-hosted with the Boston Children's Hospital's (BCH) Innovation & Digital Health Accelerator (IDHA), along with numerous strategic and provider partners from the device industry, the Boston Pediatric Device Strategic Partner Challenge. The call for applications went out for any technologies that serve the pediatric population, with a specific interest in five focus areas identified by the partners: cardiovascular/endovascular, asthma, obesity, sepsis, and general pediatrics. Challenge winners received up to $50,000 in funding, mentorship, and strategic support from IDHA and industry partners. Together the expertise and resources of these partners aimed to "take the novel ideas that individuals have developed in the prototype or early phase and give them the support that they need to advance them to the clinical world," as described by Pedro del Nido, MD, Director of the BPDC and Chief of Cardiac Surgery at BCH.

As one of the provider partners for the BPDC, Health Advances drew upon its expertise as a healthcare strategy consulting firm to provide the business analytics used in evaluating the applicants. Innovative ideas from 59 applications were narrowed down to a pool of 12 applicants who were invited to pitch their ideas to representatives from each partner organization. After the pitches, the industry and Challenge partners selected the most promising devices.

Ultimately, more than $200,000 was awarded to five Challenge winners, who also received ongoing strategic support and mentorship provided by industry partners. Other services such as product design and prototyping were also awarded by the provider partners. In addition, Health Advances selected a winning applicant to receive in-kind consulting: David Hoganson, MD, of Boston Children's Hospital for a cardiac device that allows surgeons to quantify heart valve leaflet coaptation height. The measurement allows surgeons to predict the success of heart valve repairs and replacements, thereby improving intraoperative decision making.

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Intraoperative assessment of the success of heart valve repair is qualitative in nature today, making it difficult for surgeons to determine if further intervention is needed. While insufficient coaptation can require re-operation for a child or an adult, the unmet need is greater for children who already have to undergo multiple valve replacements as they grow. Dr. Hoganson's device would enable surgeons to quantifiably assess the coaptation during the original procedure and, if necessary, improve the initial valve placement so as to avoid re-operation. The device is being developed for both open surgical and transcatheter valve procedures.

We sat down with Dr. Hoganson and his design partner at BCH, Peter Hammer, PhD, to learn more about their experience translating a patient need—particularly one with a pediatric application—into a new surgical solution.

Dr. Hoganson is a cardiothoracic surgeon at Boston Children's Hospital and an Instructor of Surgery at Harvard Medical School. He began his career as an Engineer at Kensey Nash before pursuing his medical training. His current clinical focus is on neonates and children with congenital heart disease, and his lab focuses on the development of devices to improve the safety and effectiveness of cardiac surgery.

Dr. Hammer received his PhD in Biomedical Engineering from Tufts University and is currently a Research Scientist in the Department of Cardiac Surgery at Boston Children's Hospital and an Instructor in Surgery at Harvard Medical School. His primary research interests include mathematical modeling of cardiac biomechanics and electrophysiology as well as biomedical signal and imaging processing.

Andrew Millar (Health Advances): ***Dr. Hoganson, as a pediatric heart surgeon, how does the complexity of pediatric patients affect your work?***

David Hoganson, MD: In adults, everything falls within predictable ranges, but for children the complexities can be very high for the different parts of the heart, and they frequently have conditions that do not occur in adults. We are forced to find creative solutions for these challenges, and that frequently involves medical devices. We either have to force an adult device to fit a child, or we have to make do with a first generation pediatric device when the adult version is on its fourth or fifth generation.

Bridget Shaia (Health Advances): ***What do you think the medical device industry can do to ameliorate this issue? How can companies better serve the pediatric population?***

DH: There are some real business challenges because every pediatric device has a fraction of the market compared to an adult device. In some cases, companies can take technologies that work well in adults and make variations that also work for children, such as when St. Jude (Abbott) took one of their heart valves and spent the money to design and test a smaller one for children. It is the first mechanical valve available and it is a great example of a company recognizing a need they could address. The bigger challenge is to invest in devices that are used only in children, and that is a hurdle that can be really hard to get over, and that is why device challenges such as this one are so sorely needed.

AM: ***Turning to your device now, when did you first have the idea to develop the heart valve mapping device?***

DH: I recognized the need several years ago when I was treating adults and it was hard to know when you had repaired the valve well enough, but as I did more surgery in kids, I realized it was an even more magnified problem in the pediatric population. I knew I wanted to measure the height of coaptation, but was not sure how to go about it.

BS: ***Certainly designing a completely new medical device from scratch is no small task. How did you and Dr. Hammer get started?***

DH: At the start, we just had ideas on a whiteboard. With the help of Dr. Hammer we put together some crude early prototypes that we could use in *in vitro* models that we already had on the bench to test out different sensors.

AM: ***Congratulations on being selected as a winner of the BPDC that received funding. How have you used that funding so far?***

Peter Hammer, PhD: We were fortunate in that we had some really great data from our preliminary prototypes that allowed us to show that the problem is very real. With the funding from the Challenge, we were then able to make the leap into designing a custom-made prototype and evaluate it in *in vitro* models as well as *in vivo* animal studies to answer the big questions about how it will work in this application. So all in all, we were able to accomplish a full cycle of advanced prototyping and testing.

BS: ***We know that the mission of the Challenge is not just about funding, it is also a forum for connecting early-stage innovators to those who have experience commercializing products. Have you been able to collaborate with industry leaders and, if so, has it helped you to develop your novel product?***

DH: The technology was exposed to several industry leading companies and a few did reach out and have stayed engaged with us, thinking about early involvement and co-development efforts. Now that we are through the first real design cycle with very real data we are in the process of discussing potential development partnerships. Early access to companies who are potential partners in the long term is really terrific for a device at this stage.

We were also able to use the market evaluation support from Health Advances to further define the market for our device and put together a very real story for where

we fit in. Our ability to tell the story helped when we recently applied for and won a grant with a significant amount of money that we will use moving forward.

AM: ***That is great to hear. What is next in terms of developing this product?***

PH: Most of our work so far has been on developing the device for use in an open surgery. With the new funding we have secured, we want to focus on a catheter-based device. The underlying technology remains very similar, but we will be working with companies who have expertise in catheter-based devices to tailor the sensor so that we can get it inside, navigate to the vasculature, and get it working at a distance, all with the heart still beating which is unlike the open approach.

BS: ***As a final thought, do you have any advice for early-stage innovators who find themselves in a position—much like yours a few years ago—with an idea for a new device and an aspiration to get it into clinicians' hands?***

DH: The hardest period in device development is the one from an idea on a napkin through the first successful animal study, because it is hard to gain enough traction to get funds and get a team together. I think the team is one of the most important parts, because you need clinicians, engineers, and others that together have the right skillsets at both a hands-on and advice level. Once you get the right team assembled, it gets easier from there.

The authors are from Health Advances, and Susan Posner, Darcy Krzynowek, Jungduk Seo, and Andrew Briggs, all of Health Advances, contributed to this article. Founded in 1992, Health Advances is a leading healthcare strategy firm advising clients in the biopharma, device, diagnostic, and health IT sectors. The authors can be reached at MedTech@healthadvances.com.