A series of ebooks
featuring practical advice from
healthcare entrepreneurs
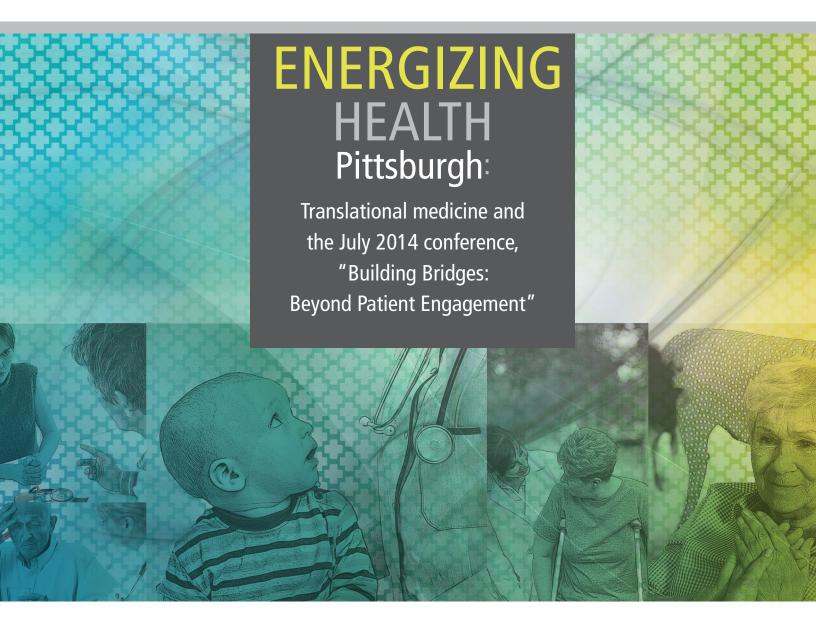
ENERGIZING
HEALTH
Pittsburgh:

Translational medicine and
the July 2014 conference,
"Building Bridges:
Beyond Patient Engagement"

TABLE OF
CONTENTS

Readers on digital devices can click on the headings to get directly to the page.

A letter from the Guest Editor

Matt Keener
Event Architect

The past 30 years have seen the advancement of select regional ecosystems which have thrived during an era of unprecedented biomedical innovation. Cities like San Francisco, Boston and Pittsburgh have thrived.

Over this time, there was a massive growth in federal funding for academic research, as well as escalating costs of medical goods and services. Health systems previously driven by simpler clinical revenue began to grow and thrive on a one-two punch of obtaining federal grants and moving "upstream" in this fee-for-service environment, leveraging their ability to care for the sickest of patients in expensive intensive care units.

For instance, 50 years ago Dr. Tom Starzl invented the process to undertake the world's first liver transplant, which now saves about 6,000 lives every year. He was recruited to Pittsburgh where, in addition to saving lives, he brought in revenue through these highly complex operations treating the sickest of the sick. To better understand and help these patients, he brought in millions of dollars in grant funds from basic research, then "translated" this knowledge into the creation of new therapies like the immunosuppressive drug tacrolimus, the revenue for which continues to support a thriving health system.

The future isn't what it used to be

This century has already seen massive changes in how health innovation will occur. Federal biomedical research funding has flattened, and the ACA has changed the "gravity" of health economics toward providing value-based care and keeping people healthy.

At the same time, our understanding of disease complexity is improving. That patient who required a liver transplant perhaps had known genetic risk factors for processing alcohol and behavior impulsivity which, combined with poor access to mental healthcare and cerebrovascular disease, resulted in a worsening of the alcohol addiction, cirrhosis and liver failure.

With this in mind, we see how a new era of medical innovation might seek to prevent the cirrhosis in the first place through interventions like leveraging inherent social supports to improve the patient's addiction recovery during key risk periods for relapse. This might require simple solutions but involves complex thinking.

Bridging the old and the new

As mentioned in this piece, this complex thinking may require new training models.

During this early phase of health technology innovation, it will suffice for more simple solutions to be implemented for quality improvement and care delivery.

The creation of value at this stage does not necessarily require the deep biomedical knowledge of a translational medical researcher, but does require the ability to rapidly execute the piecing together of disparate knowledge and strategies in a systematic fashion that matters to patients, providers and payers alike.

However, to move into the next phase that will see the integration of bleeding-edge systems science and information technology that provides evidence-based, value-driven, preventive healthcare delivered through novel global business models, it will be key to have the personnel in place who can do this work. To develop this type of scalable medicine, it will be necessary to educate, train and support health entrepreneurs who are able to bridge these worlds. The current training models that are geared toward creating either bench researchers or clinician-educators are inadequate.

The next generation of therapies may require a new breed of translational innovators capable of bridging the old and the new: those like Armen Arevian, Dan Bishop and Mike Mamoun, each of whom has been interviewed and whose insights are featured within. They are unique in that they are doctors at different stages of training in translational medicine but are also leading efforts to bridge bringing new solutions to patients in this new model.

The Pittsburgh Energizing Health Symposium

Pittsburgh is the city that has built the most bridges in the entire world (446 in the city alone). Our goal for the Pittsburgh Energizing Health series was to see how we build bridges between the relevant stakeholders in this emerging space, focusing upon the inherent engineering, design and business modeling challenges. To do so, we created a venue that brought entrepreneurs and enterprise to the table, and had focal discussions exploring best practices and collaborative innovation models.

The event was in July and already the results are impressive. Executives from warring hospital systems are engaging one another in thinking through human-centered design challenges, a "bootstrapped" startup is now partnering with a global pharmaceutical company and several pilot projects are underway.

(Stay tuned for more focal updates!)

Matt Keener

Why we need entrepreneurship + translational medicine

In the translational medicine space – where medical research is "translated" into health tools and solutions for patients – most engaged physicians are either biomedical researchers interested in advancing our understanding of the basic science or practicing doctors who want to improve clinical practice while focusing on patient care.

Few physicians receive training in understanding this translational research space, and even fewer are able to take this skill set into the market to develop new technologies based on this understanding.

Despite the fact that successful companies like Medtronic have a significant portion of physician-driven innovations, there is not currently a robust movement to teach, train or recruit translational researchers in the process of developing new solutions.

There are several factors leading to this which include the lack of training mechanisms to support those interested in innovation, a loss of those innovators from the academic training environment, as well as the very real need to minimize and manage conflicts of interest.

Unfortunately this can then result in a divide between those scientists who are looking to translate science findings to patient care, and those who have "nothing to disclose," (i.e., those with no financial ties to therapies or conflicts of interest). In fact, when you come from an academic background like me, you're often viewed as "going to the dark side" if you collaborate with industry or set off to develop solutions for your patients. The safe bet for our best and brightest, saddled by medical school debt, is to avoid all ties with commercial entities.

For the most part, this is fine. For the most part, we need doctors overseeing patient care and not building businesses. The incentive of academic researchers should be aligned toward finding the underlying biological truth and not finding a pathway to market.

That said, as the delivery of high-quality, low-cost healthcare becomes ever more critical to our national health and national economy, and the science of health becomes more complex, we need innovators with a real grasp of the evolving state of the science in facilitating the movement of treatments "from bench top to bedside."

This translation of medical science to clinical care, translational medicine, is a movement I've always aspired to make matter to patients today – and that's why I've chosen to become an entrepreneur during this critical time period.

I stepped out of full-time academia to create my company, emodt, in order to bring the science of emotional health to individuals today, not in decades. In the emotional health space, we're still hung up on an outdated framework: The patient describes her symptoms and she receives a diagnosis only when they match a given set of criteria. She then receives a treatment that has been shown to work against only this particular cluster of symptoms, regardless of the underlying biology and the variety of symptoms it may generate.

But through a deeper understanding of the underlying neuroscience, we're not only helping people manage these defined, diagnosable symptom clusters, such as Generalized Anxiety Disorder. Rather we're addressing each person's challenges in a personalized, biologically relevant manner that aligns with what is being discovered every day in the lab. Notably, we're not waiting for the science to be perfected, as we know this is decades off. So we begin with an evidence-based model, but gather ongoing evidence as we go, to re-inform the product and our understanding of emotional health. We hope to craft the next generation of science research while at the same time creating new solutions.

Does B2B come after ACA?

Here's a portion of an amazing article from Josh Rosenthal, an adviser for our Energizing Health: Pittsburgh event. (See here for the full monty.) However, I wanted to offer you a glimpse while calling attention to this specific portion. Here Josh does a great job of summarizing some of the ways the Affordable Care Act (ACA) will be the gravity around which orbits are forming, and around which any innovative solution will need to be engineered.

Specifically, the changes will require a better understanding of designing business-to-business (B2B) economic models that ultimately result in a tighter connection between patients and providers to deliver value. Because it's novel territory and healthcare B2B isn't exactly sexy, even savvy VCs have limited clarity on these emerging models and limited precedents to follow.

In our Energizing Health series, we'll examine these models as we bring together selected entrepreneurs and key stakeholders within healthcare, discussing collaboration and facilitating focal development opportunities across a network of key cities. Our next city is Pittsburgh, where we'll examine what comes beyond patient engagement and examine these business models and how we design and engineer systems that deliver health in this new space.

The Business Life Cycle of a Movement

Youth is an apt metaphor for open health data, but not the best one. Consider open health data as a startup. It's relatively easy to sketch out an idea on a napkin. A little harder to build a prototype or even throw together some seed funding and do a beta.

This year's Health Datapalooza saw open health data as an emerging midsize company, working on V2 of its production platform with clients and employees, filing taxes, doing HR, and taking out business insurance.

In other words, we're making the transition from founder to operator, from creation to scale.

And that's the toughest turn in some ways.

It's a little tricky, but worth parsing. You've been seeing two markets develop side by side and now grow apart, and often media can't tell the difference between them, or even recognize a distinction.

Direct-to-Consumer is easy to wrap your head around. It's about consumers, patients, even doctors and hospitals and things like apps, brands and devices. These folks were at Health Datapalooza in force. But this hasn't been healthcare as much as 'wellness,' and that's a different market with a different story to date. When the Silicon Valley folks have made bets in healthcare, the results have not been stellar.

Releasing weather and geo-location created not just cool apps but real value, because those are classic markets, whereas healthcare has, up until now, functioned differently.

In healthcare supply drives demand, a fact that the Dartmouth Atlas shows quite clearly (full disclosure: we're big fans of these folks).

More importantly, before the Affordable Care Act, and in the parts of the healthcare landscape that are not yet bearing ACA banners, quantity drove payment rather than quality creating value – which means bad things happened and good things died on the vine.

Open health data is really cool, but it would have died young, like so many other good ideas in healthcare, without the ACA creating the market context where it can be made valuable.

The reason open health data has made it so far is because the same folks releasing the data have also created incentives to develop a real market around using it to improve patient experience and clinical outcomes... but this means Business-to-Business economic models and those are harder to understand, much less to explain in sound bites.

The B2B startups aren't as sexy, but they're in vogue for a reason, and with healthcare – and particularly open health data – they're more important... at least for the near future.

Getting Down to Business...

Essentially we're using market forces, incentivizing private enterprise to create public and social good.

While public/private cooperation sounds great, in healthcare it has, up until now, been an awkward dance.

Part of that is because of an educational failure, with MPH-ers and MBA-ers rarely dating.

Part of it is because healthcare has lagged a bit developmentally behind other verticals or, more actively worded, healthcare has often successfully fought off the disintermediation found in other domains.

Last year, Kickstarter gave away more money to the arts than the National Endowment for the Arts, with the youthful efficiency of the consumer market. Healthcare is always concerned that something like that will happen with a DTC play getting through the gates of the quantified self movement and planting a flag on the real delivery system. (Other verticals such as media stay up late at night in a cold sweat worried about how to recapture the cash cow, now that it's bolted from the revenue barn.)

There is some legitimate tension, as you'd expect to find in any emerging market.

Like any evolving market, the bar to play is getting higher and startups wanting to innovate around products, services and even companies need an expertise beyond pirate metrics – specifically a wide-ranging expertise across a number of fields. The ACA essentially transformed the business from underwriting large-group commercial risk to government-sponsored, direct-to-consumer lifetime value funnels.

If you're a startup looking to crack it, you'll need something beyond a cool viz with a nifty API – you'll need to know product, pricing, delivery, actuary and finance, and sales and marketing and how they interrelate across payers, providers and long-term care, not to mention consumer and government. That's a high bar for a pure play tech or data startup.

Factoring emotional distress in a tech culture

Whether one is a Millennial or Gen-Xer, a Boomer or a hipster ('fess up man...), we all have something in common: emotional distress. Looking back at the 1950s, it all seemed so easy. If you were "tense and irritable," all you needed was an Anacin and your troubles vanished. But as we've learned in the past six decades, the real battleground for modulating mood wasn't just "in our heads" it was, more specifically, in our brains.

Modern life is a whole new kind of headache (rather brainache)

Although a migraine headache can be triggered by loud sounds, light or emotional distress, the end result is a change in brain patterns (1) triggering adaptive behavior (withdraw from the loud sound, avoid light). Similarly, in this fast-paced modern world there are numerous social interactions, biological triggers and well-trained psychological thought patterns that interact in our brains to create neural patterns we call emotions. When everything is working well, they help us adapt to our ever-changing environment.

Much of our ability to adapt is formed when our brains are developing – principally in adolescence, the transition between childhood and adulthood. Both tribal and modern cultures have realized that the process of development into adulthood typically takes place through acculturation in strange and sometimes harsh environments, experiences that provoke and harness these emotional waves. Activities like military service, cultural initiations, college and moving away for that first startup experience are all cultural immersions that have the opportunity to trigger and harness brain development. In fact, it is experience itself that helps mold the structure and wiring of a brain (2).

It is during this time that our inquisitive and growing brains break loose from their family of origin, seek wisdom from others in a larger tribe and receive hard-won lessons as they tackle new challenges. During this period, emotional distress is a given. Period. If provided the right guidance and tools during this time, most adolescents will adapt. They will weather the storm as they suffer defeats and heartbreak, but eventually bring new ideas and innovations back to their own tribe. Where mentorship and tools are lacking, where the emotional stressors accumulate, we see the emergence of role confusion, violence and increased risk for lifelong emotional disorders. It is not surprising, then, that the peak onset of mental disorders is during adolescence (3).

Proper care and maintenance of a modern adolescent mind

Parents worry about their children spending an increasing amount of time with digital technology for fear of what it will do to the developing mind. And they are right to be concerned. Early studies had suggested that increasing digital technology could be driving

increased emotional distress (4) and, as spelled out by the Surgeon General, there is a critical shortage in systems, caretakers and institutions serving the emotional needs of children and adolescents (5).

However, looking at the sociological, psychological and neurobiological data from another viewpoint, "technology" is not the problem. It is the limitations in our adaptation to technology that is the problem. Technology is simply the application of tools and knowledge toward practical applications like achieving goals and solving problems. Technology is used by humans and other animals alike to adapt. Technology is a stick used for digging, it is controlling fire – writing, agriculture and the Internet are all technology. Applying tools and knowledge toward solving problems in the form of technology is actually how we grow our brains. It is how we train and adapt – as we've always done.

And here's the really interesting part. As human culture becomes more complex as a result of technological advancement, technology itself becomes a major component of acculturation. It is becoming both the soil and the trellis upon which we are trying to grow healthy, constructive and culturally adapted brains. And more recent findings that take into account this normalization of technology in adolescent culture demonstrate enhanced well-being in those who use social media (6).

And if all this weren't tricky enough, adolescence is becoming longer. Much longer. Defined as the space between puberty and "the taking on of adult roles and responsibilities" (7), adolescence used to occur from about years 13 to 15, and is now starting from roughly 11 years old and stretching to the 20s or 30s. That's right – 30s – a 10-fold increase from our generally accepted understanding. Although scientists are not sure, it's likely due to caloric abundance pushing the overall age of puberty younger while changes in cultural mores are pushing adulthood back. Also, as the life span of the population grows, the phases of human development may spread out somewhat within that elongated timeline. This increased development time frame allows for ever more complex roles and goal formulation. It allows one's mind to naturally and organically assimilate to a technologically informed culture but it also creates an increased window for real emotional distress.

#techculture becomes #culture

The farther in time we go, the more technology embeds in our lives, the more the distinction of technology disappears into the concept of culture itself. For better or worse, once integrated, it is difficult to localize any particular advancement as a source or dissociation or pain. The technology that scares us now, in time (like fire or the bicycle) will be the next accepted thread in the fabric of human existence. It's starting to happen now with digital technology. As it does we can begin to look at adolescence holistically, considering technology as a force to shape the culture in which future generations will live and thrive.

So how are emotional health and prolonged adolescence connected? Given that they will both forever be impacted by the inclusion of technology over an increasingly long developmental period, it is essential for us to develop technologies that support healthy neurodevelopment in this new normal so that we might build the next generation of emotionally healthy individuals and tribes.

In Pittsburgh, I and others believe that technology based on current scientific understandings of brain development and positive culture can be directed for good, to help individuals manage emotional distress during the cultural gauntlet of adolescence. We are creating tools born from the very technology that has become the fabric of our lives to further our emotional intelligence in this modern world. It is our belief that this and other tools will help individuals and their trusted advisors build emotionally healthier brains for themselves across this extended adolescence.

--

References

1. Pietrobon and Bogsby, Nature Reviews Neuroscience 2002

2. Kleinschmidt et al., Science 1987

3. Kessler et al., Arch General Psychiatry 2005

4. Kraut et al. American Psychologist 1998.

5. http://www.surgeongeneral.gov/news/2001/01/children.html

6. Valkenburg and Peter, Current Directions in Psychology. 2009.

7. Dahl and Gunnar, SCAN 2009

This article was originally published by inquiri.

Creating new pathways in translational innovation

In my first eMed column, I explained the world of translational medicine – and the opportunities it presents for entrepreneurs in a "translational innovation" space. Many people might not realize that some of this work merging translational research and innovation is already taking place in academic departments.

To start from the beginning: Translational medicine is a focus in which medical research is "translated" into health tools and solutions for patients. To take these findings from bench top to bedside requires teams of individuals, each with their own area of focus. We'll be covering some of this at Energizing Health, where researchers, academicians, clinicians and innovators will convene in Pittsburgh for a symposium examining collaboration models addressing the next generation of patient engagement solutions.

Although there has been some hesitation from the academic community to embrace a merger of scientific discovery and enterprise, Dr. Amanda Christini at the University of Pennsylvania reports we are seeing the emergence of a new paradigm, "one in which revenue-driven commercialization is replaced by the realization that health systems have an opportunity and responsibility for mission-driven commercialization." With this shift, and a prioritization of those solutions delivering value to patients and stakeholders, departments are increasingly utilizing novel methods to mobilize, reward and train those cutting new paths through the wilds of healthcare innovation.

Dr. Christini, an internist working with Dr. David Asch at the Penn Medicine Center for Health Care Innovation, highlights approaches that they and other top-tier institutions are taking to mobilize how innovative thinking can be cultivated within academic health systems. "In the past, these departments had typically worked in a serial approach. They would take a known asset of [intellectual property], and then pass it on to the tech transfer offices, who would then find a business team to take the product to market."

By leveraging her background in biotech business development, Dr. Christini informed an organizational approach that better mimicked an iterative startup workflow. Using this more dynamic approach, they were able to get more accomplished quicker, getting an antimicrobial susceptibility program from concept to patient pilot in six months.

Another approach taken by both Penn and other departments is the growing use of competitions similar to those in startup culture. As one example, the Clinical and Translational Science Institute at the University of Pittsburgh ran a $300,000 Pitt Innovation Challenge competition, looking for novel solutions. Leading QuitNinja, one of the winning teams, was Dr. Ellen Beckjord. Dr. Beckjord is a translational researcher using behavioral

research to better inform behavioral change. She has noted the growing attention paid to those junior faculty members who are able to bridge translational research with the development of novel programs or innovations that can advance the mission of the university. She cautions, however, that for the purposes of advancing the careers of junior faculty members "right now commercialization per se is not incentivized; however, doing research that has the potential for commercialization definitely is."

Therefore, one of the more exciting developments in this space is that there are junior faculty members whose advances in moving the needle in translational innovation are being recognized and are driving new models. One example is Dr. Armen Arevian, who was just hired as a junior faculty member in the UCLA Health System and the Semel Institute. He will be starting an Innovation Lab in the Center for Health Services and Society.

"The idea really is to form a translational lab where we can take the advances from our research and combine them with directly observed challenges in the health system for immediate translation/pilots to improve care, quality, efficiency," he said.

Dr. Arevian reports finding a nice balance between academic research and technology innovation within a major health system. "On the one hand, you have the capacity on the academic/research side for the ability to generate intellectual capital and obtain grant funding. This is synergistic with the opportunities provided by the health system that has its own complementary capacity, including access to patients, and refining business models that attempt to deliver value to our patients."

All those interviewed noted that, although there were some changes afoot in how innovation was valued in their department, there was no one clear path emerging toward success in this space. And that's why they call it trailblazing.

Entrepreneur Interviews

Why healthcare entrepreneurs should embrace the iterative

Dan Bishop

In the early days of the patient safety and healthcare improvement company Qualaris, the startup's team installed wireless tracking sensors in hospitals to help healthcare providers improve compliance with best practices. But Qualaris wasn't a hardware company for long, said co-founder and CIO Dan Bishop. "We realized that we weren't solving enough problems, and we weren't doing it efficiently enough," he said.

The shift from hardware to software data analytics allowed Qualaris to offer more value to customers, Bishop said. Embracing the iterative nature of early-stage entrepreneurship and following through with the pivot, Bishop said, "was one thing that has been an interesting journey for us."

Here are other entrepreneurial insights from Bishop:

Let customers design solutions – Qualaris lets customers design their own solutions on the company's platform. "We don't have the bandwidth to be the expert on everything," Bishop said. For instance, most hospitals already have best practices for tasks like getting a bed from point A to point B. Instead of Qualaris reinventing the wheel, customers take those best practices and apply them to the platform. "By empowering end users to design their own solutions, we let our users be the experts," he said.

Identify a challenge – The Qualaris team started the company by identifying a large, unaddressed market challenge in healthcare, Bishop said. "We know patient safety is an issue. We know healthcare improvement is a challenge," Bishop said. Once a worthy challenge was identified, the team built ideas around solving it, he said.

Find the right early customers – When you're trying to do healthcare innovation on the enterprise side, access is everything, Bishop said. Early-stage companies need to find customers who will let startups understand their processes, and are willing to be iterative. "That's really transformative for an enterprise company," Bishop said. The key to finding the right early customers, is to understand what's important to the customer's stakeholders and develop trust. "You just have to hustle really hard," he said.

If entrepreneurship is a lock and key, start with the lock

James Lomuscio

There are two ways to start a company, said James Lomuscio, co-founder and CEO of the physical therapy patient management software company Hability. Entrepreneurs must begin with either the lock or the key.

The key in this metaphor is a new piece of technology that could provide value in certain business environments, Lomuscio said. An entrepreneur could take his key from one industry to the next to see if it will unlock a problem there. An alternative is to start with the lock, learning where the pins are to create a key that fits.

Hability initially developed technology meant to improve patient compliance in physical therapy. "For a long time, we were attached to this piece of technology," Lomuscio said. But as the team learned more about the specific problems facing physical therapists, it realized its technology wouldn't solve them. "Do we take the key out of this lock and try another lock?" Lomuscio said.

Instead, team members decided to pick the lock they'd learned so much about. In the future, Lomuscio said, they would start with the lock, rather than the key. "Entrepreneurs would do well to spend more time carefully considering the problem from beginning to end," he said. "It should begin with learning."

Here are other entrepreneurial insights from Lomuscio:

Keep your pitch brief – If your pitch is more than two steps, it's probably wrong, Lomuscio said. The team initially had a three-step pitch to explain to physical therapists how the Hability system would save them money. "It was a really long path," he said.

Find a team that fits – Hability has no physical therapists on its team, nor anyone with a medical background, Lomuscio said. He and his co-founder are award-winning game designers interested in tackling the medical compliance space. Most important, is working with people you can trust, who are comfortable doing many jobs within the company, he said. "Forming the team is tough. You have to make sure that people are the right fit for the company culture," Lomuscio said.

Why client needs should dictate your business plan

Armen Arevian

Many entrepreneurs develop their business plan before landing clients. Yet that wasn't the case for Insight Health Systems, which sells the web application Chorus, said co-founder Armen Arevian. Instead, he said, the process of creating and selling Chorus, which lets users create mobile web applications visually with point-and-click, has been dictated by client needs.

For instance, Arevian said, Chorus was originally a self-service product. But it quickly became clear that clients wanted support. With that realization, the business model shifted. "We learned that by working with customers to see what their needs were," Arevian said.

Here are other entrepreneurial insights from Arevian:

Stay close to the problem – An aspiring entrepreneur should embed himself in a space where he can observe problems and work to solve them, Arevian said. "That's helped me develop something that has quickly solved the need for a large group of people," he said. This approach has also attracted customers to Arevian – without him having to seek them out.

Seek complementary skills in partners – Though Arevian and his two business partners are all clinicians, the others are at a more senior level. Their additional clinical and business experience has been helpful for the company, Arevian said.

Keep it lean – "I'm a big fan of keeping it lean and doing it really simply first," Arevian said. He bootstrapped to develop a basic prototype, and then approached a UCLA professor who became his first funder. "Other researchers said, 'We need this. We'll give you some more money if you can add these things to it.' It grew organically like that," Arevian said. "That helped us only add features that were really important."

How an entrepreneur validated his business model in a crowded market

Michael Mamoun

With so many products marketed to people who want to quit smoking, the market might not seem ripe for another smoking cessation service. But NicoDart founder Michael Mamoun, who performs neuroimaging research on how smoking cessation products work in the brain, believed he saw an unmet need. Mamoun set out to validate his business model: to develop smoking cessation technology loosely based on electronic cigarettes.

"The first question is just how much of an impact on society smoking has," Mamoun said, adding that smoking is the world's leading cause of preventable death. "It's a tremendous impact." With that in mind, Mamoun worked to validate his mission beginning at the middle of the problem. He told his study subjects about his idea, garnering helpful feedback. "Smokers thought it was a great idea," he said. Mamoun next spoke with addiction and smoking cessation specialists, who expressed interest in the technology. Finally, he got a product assessment from the Wisconsin Innovation Service Center. "That's how we started validating the idea," Mamoun said.

Here are other entrepreneurial insights from Mamoun:

Cut through the noise – In the medical world, patients have many choices, which are then narrowed down by a provider, Mamoun said. "In the world of business, there are so many perspectives and no clear answers," he said. One of the most important skills for Mamoun to learn was to cut through the noise. "It's very helpful to hear and appreciate a lot of people's opinions on different matters," he said. But Mamoun quickly learned to focus most intently on the advice of a few experts. "If not it becomes way too messy," he said.

Make quick decisions – NicoDart is beginning to fundraise, and bumping up against a key problem, Mamoun said. The company's product is part device and part system, and funders tend to specialize in one or the other. It's tough to approach potential investors without knowing whether the product will be an FDA-approved medical device or a consumer service, Mamoun said. If he could start over, Mamoun said he would have tried to make that decision more quickly, after collecting a reasonable amount of information. "In business, there are things you aren't going to know before trying," he said. "You can always change directions."

Health and Human Services makes push for patient engagement

Finding ways to involve patients in taking more responsibility for their own health has been a perennial topic in healthcare, and the discussion has taken on new urgency with the growing need to control costs while improving quality of care.

What is the current state of efforts to engage patients?

"We've been treating disease with standard responses, with the status quo," said Bryan Sivak, chief technology officer at the U.S. Department of Health and Human Services. However, the department is trying to change that, he said.

Sivak spoke in Pittsburgh as part of the Kauffman Foundation's Energizing Health Collaboration Series, a six-part series of events to empower entrepreneurs to better succeed in healthcare.

He described recent efforts by the department to "encourage new ideas to move forward and experiment with new concepts.

"We define innovation as the direct result of freedom to experiment. If we can give people the freedom to experiment, that can result in new ideas, improved processes and better ways of doing things," he said.

The process of innovation requires not only successful experiments, but ones that fail, also. "In government, we are bad at failing," Sivak said. "But, nothing new is going to happen unless we try some things that don't work and then recognize why they aren't working."

Entrepreneurs must play a key role in making the healthcare system function more effectively on every level, and HHS is committed to helping them do that, Sivak said. "We want to encourage the spirit of experimentation, both inside and outside of the enterprise. And we always 'default' toward action; if somebody has an idea, we can encourage low-cost experiments" to test it, he said.

Sivak pointed to the department's new Idea Lab as one major effort along that line. It consists of six "pathways to move people from the old, command-and-control, risk-averse, bureaucratic style of government agencies to a new world where we recognize and leverage the skills, interests and abilities of people," particularly entrepreneurs, he said.

One of those pathways is the HHS entrepreneurs' program. In one example, an IT entrepreneur developed a mobile app to reduce errors in shipping and tracking organs slated for use in transplants. The app enables doctors and nurses to replace the error-prone

process of hand-writing package labels, with the ability to easily create and print labels with scannable bar codes for tracking.

"It made their processes much better and safer," Sivak said. "The projects have been growing in importance and complexity."

Another pathway is a partnership among HHS, West Health Care and the Institute for Innovation, called Project Sandbox. "We're just getting started with that one. We need to figure out ways to get people involved with early-stage products or prototypes involved and figure out ways to test them in a clinical setting."

Panel weighs challenges of getting patients to use digital devices for health

The new digital devices designed to gather and transmit real-time patient data have great potential to transform healthcare. But, to realize that potential, those who engineer and design the devices need to figure out ways to fully engage patients in using them.

That was the consensus of a panel discussion on "Engineering a Partnered Patient" during the Pittsburgh leg of the Kauffman Foundation's Energizing Health Collaboration Series, a six-part series of events to empower entrepreneurs to better succeed in healthcare.

Panelists included Stacey Chang, managing director for healthcare at IDEO, a Palo Alto product-design firm; Keith LeJeune, VP of innovation at Indiana-based American Health Network; Casey Helfrich, chief architect at University of Pittsburgh Medical Center; Jim Osborn, M.D., executive director of Carnegie Mellon University's Quality of Life Technology Center; and Drew Schiller, chief technology officer at Validic, a digital health data technology firm in Durham, N.C.

Panel moderator Osborn said that, when it comes to handheld and wearable devices, healthcare consumers are often ahead of care providers in adopting new technology. Healthcare providers and payers need to take notice that "consumers are pulling technology into the healthcare mainstream; whether or not providers and payers want it, it's going to happen," he said.

It isn't just tech-savvy Millennials who are eager to adopt new healthcare devices, Chang said. As Baby Boomers age and want to continue to live independently, "they are more than willing to subject themselves to technology if it enables them to do that."

Osborn raised the question of how much control patients should have over the flow of data coming from their bodies. "Who can turn it on and off?"

"The question is how you can motivate that person to keep the device 'on;' to do that, you have to give them ultimate control," Helfrich said. "We need to decide how we are going to treat issues like that."

For a variety of reasons, physicians are sometimes slow to embrace new data technology, but that is starting to change, Schiller noted. "It's not widespread, yet, (among providers) but there is a lot of thought about how we can take data from wearables and make use of it," said Schiller, whose firm's API (application programming interface) connects healthcare organizations with individual health data recorded by mobile apps and devices. Schiller said he's also seeing much more interest among providers in harvesting and aggregating data

from traditional clinical devices such as monitors and blood glucose meters, "in the same way consumer wearable companies have been able to engage patients."

One challenge in convincing physicians to make full use of the data streams from wearable and implantable devices is that most physicians would rather spend time seeing patients than sitting in front of a computer, LeJeune said. "Raw sensor data is useless because there are so many layers of abstraction before any human looks at it. To let the work flow be efficient and get the tools out of the way, we need ways to reduce large amounts of data to valuable, actionable information," he said.

The panelists were asked what may be on the technology horizon as a major game-changer for the healthcare system.

Schiller: "One of the most unique things I've seen is the idea of an intelligent pill – like Proteus has developed – that can take real-time readings and communicate with (patients') phones. By using actual biometrics from that (specific) point in time you can get an amazing amount of information … (enabling) that kind of intervention would be really fantastic."

LeJeune cited CardioMEMS, which recently received FDA approval for its miniature wireless sensors which can be implanted to transmit critical data on patients' cardiac output, blood pressure and heart rate. "They can give you almost cardiac MRI-quality data, so they have a lot of potential."

Osborn noted that one of the other crucial objectives for device makers is figuring out how technology can be used to motivate behavior change. "So much technology is forced on people who don't want to use it, or embraced by (young) healthy people who don't need it," he said.

The Affordable Care Act and other efforts to make people more responsible for their own healthcare costs will help accelerate the acceptance of new data technology, LeJeune said. "As people have more visibility as to what things cost, they start to do value calculations for their own healthcare. I think that's when things will change," he said.

Human-centered input helps steer design of 'smart' healthcare devices

Even if the designers of 'smart' healthcare devices have the technology figured out, they need help in figuring out what matters to the people they hope will use the devices. That means obtaining timely, meaningful input from patients, physicians and other end-users.

A panel on "Designing Shared Engagement" explored that topic in Pittsburgh at the Kauffman Foundation's Energizing Health Collaboration Series, a six-part series of events to empower entrepreneurs to better succeed in healthcare.

Panelists included Kristin Hughes, founder of Fitwits, developer of a suite of educational games to help fight childhood obesity; Amy Cueva, founder and chief experience officer of Mad*Pow, a New Hampshire-based "experience design" firm; John Stivoric, VP of R&D at San Francisco-based Jawbone, which develops health and fitness tracking devices; and Julia Bernstein, head of business development and strategy at Ginger.io, whose smartphone app enables patients to identify changes in behavior that could be early warning signs of severe mental illness.

Hughes, a Carnegie Mellon University professor of information design, described how "doctors and kids" helped design Fitwits' educational games for children and tools for parents, educators and physicians.

"It's critical that all stakeholders be involved in designing (health) solutions," Hughes said. The testing was conducted in Allegheny County public schools and clinical waiting rooms, she said.

Stivoric said tech device creators and their ideas are sometimes ahead of the public. "There are plenty of things sitting on the shelf waiting for people to figure out they are needed. There are a lot of 'crazy,' wearable ideas nobody would wear today – but five years from now, I guarantee you they will. They're waiting for the market to catch up," he said.

Often, the marketplace helps a developing company clarify what it should be. Bernstein said Ginger.io began as a software-focused company incubated at MIT. Since entering the marketplace, "we've learned that we are a platform company that focuses on designing operational models, work flows and implementation tools that patients use and physicians use to interact with patients on a daily basis," she said.

Even though the Ginger.io app has proven its value to patients, convincing physicians to implement the device is still a challenge, according to Bernstein. "To get clinicians excited, we have to demonstrate why it's valuable not only to them but also to the patient; create a sense of connection and partnership to get them excited."

The ability to quickly collect patient data with mobile devices has given birth to a new form of "human-centered" research, something different from the traditional randomized, controlled trials.

Health care institutions and traditional researchers need to understand the validity of the new, human-centered method, Stivoric said.

"I don't understand why a non-controlled trial of millions (of device users) doesn't have more benefit than a controlled trial of hundreds of people," he said. "A lot of time could be accelerated and money saved if people would pay attention to those opportunities."

Bernstein sees a positive trend in an increase of "people participating in trials, experiments and registries because they want to contribute to the progression of technology and science. We've taken part in this," she said.

Stivoric also voiced optimism. "The companies doing it are influencing each other in how to go deeper and faster, and bringing healthcare systems along with them; everyone is pushing each other, which is really cool," he said. "Consumers are teaching us where their motivations are, to tap into; it's interesting how that is starting to come together."

For more ebooks and
other content featuring
**practical advice from
healthcare entrepreneurs,**
go to

www.entrepreneurship.org/emed

eMed

***A Kauffman Foundation online ecosystem for the
Life Science and Digital Health Entrepreneur***

SUBJECTS INCLUDE

Insights from Physician Entrepreneurs

Insight on Early-Stage Fund-Raising

Insights from Medical Device Entrepreneurs

Lessons for Fundraising in Digital Health