Biodesign at 15: New name and new focus

By Ruthann Richter

A specialist in heart rhythm problems, Uday Kumar, MD, always thought there had to be a better way to monitor the cardiac rhythm activity of his patients when they were outside the clinic, going about their usual activities. Traditionally, patients were prescribed a camera-sized device, hooked to their body via electrodes, to track their heart rate during the day and while sleeping.

These devices have been around for decades, “but they are cumbersome and difficult to use,” Kumar said. “I think this is a need that people had overlooked for a while: something you could use to monitor patients with a suspected arrhythmia that is more cost-effective and easier for the patient to use.”

As a fellow in the Stanford Biodesign Program in 2005-06, Kumar set his sights on finding a more cost-effective, user-friendly solution. His invention, the ZioPatch, which has been worn by more than 400,000 patients, is one of dozens of innovative devices to emerge from the program’s innovation process, which has become the international model for inventing new medical technologies.

Focus on affordability

This year, the program celebrates its 15th anniversary. It has been renamed the Stanford Byers Center for Biodesign and is moving forward with an emphasis on creating new health technologies that not only benefit patients, but also take into consideration the economic challenges of health care today, said Paul Yock, MD, founder and director of the program at Stanford.

“We have been very successful in training high-tech innovators in the last 15 years,” said Yock, a professor of bioengineering and of medicine, who is a successful inventor himself. “Going forward, with the monumental changes in health care and the many cost pressures on the system, we need to create technology that enhances care and does it in a way that’s not unduly expensive. That is a sea change.”

The center is being renamed in honor of longtime Silicon Valley venture capitalist Brook Byers, who has mentored, coached and supported fellows since the program’s inception.

“This program is uniquely positioned to improve human health around the world,” Byers said. “Their fellows and medical innovations change health care and have already directly benefitted hundreds of thousands of patients. And they’re inspiring and empowering others by sharing best practices globally.”

Legacy of inventions

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Promoting abstinence, fidelity for HIV prevention ineffective, study finds

By Ruthann Richter

The U.S. government has invested $1.4 billion in HIV prevention programs that promote sexual abstinence and marital fidelity, but there is no evidence that these programs have been effective at changing sexual behavior and reducing HIV risk, according to a new study.

Although PEPFAR has been gradually reducing its support for abstinence and fidelity programs, the researchers suggest that the remaining $50 million or so in annual funding for such programs could have greater health benefits if spent on effective HIV prevention initiatives that encourage men and women to limit their number of sexual partners and delay their first sexual experience and, in the process, help to reduce the number of teen pregnancies. However, in a study of nearly 500,000 individuals in 22 countries, the researchers could not find any evidence that these initiatives had an impact on changing individual behavior.

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Overall we were
Scientists identify age-dependent changes in pancreatic function

By Krista Conger

Age-related changes in the human pancreas govern how our bodies respond to rising and falling blood sugar levels throughout our lifetimes, and could affect whether we develop diabetes as adults. But it’s been nearly impossible to study this process in detail because human pancreatic tissue is not readily available.

Instead, most researchers have relied on animal models to learn more about the development and function of the pancreas.

Now researchers at the School of Medicine have for the first time compared the patterns of gene expression in the insulin-producing cells and other cells of the pancreas from dozens of deceased donors ranging in age from 6 months to 66 years. They found significant differences in gene expression patterns and DNA modifications between donors under the age of 9 and those older than 28.

The findings, published April 28 in Cell, help highlight the importance of two genes not previously implicated directly in pancreatic function, and show that the pancreas continues to develop and mature during the first decades of life. They may also have implications for current clinical trials testing stem-cell-based therapies for diabetes.

“Pancreatic islets, which are the sites of insulin production, mature and change in their function after a baby is born,” said Kim. “We think our findings suggest that this maturation process goes on for nearly a decade. There’s been growing realization among diabetes researchers that human islet development differs significantly from islet development in typical laboratory animals like mice.”

Cells in the pancreatic islets called beta cells are responsible for modulating fasting blood-glucose levels. When glucose levels rise, the beta cells release insulin to cue cells throughout the body to squirited away the sugar for later use. Type 1 diabetes is caused by a failure to produce insulin; Type 2 diabetes is caused by combined deficits in the body to respond to and make insulin. Both types have been linked to reductions in the number of insulin-producing beta cells.

Although beta cells proliferate robustly during the first decade or so of life, this proliferation slows dramatically with age understanding the age-related signals that cause this slowdown could one day lead to new diabetes treatments. But something more significant than the changes in cell number is also going on. Studies in rodents and in human fetal beta cells have shown that the responses of young beta cells to increases in blood glucose are blunted when compared to their more mature counterparts.

**Sorting the cells**

Kim and his colleagues worked for over six years to develop a multi-institutional collaboration that quickly cataloged pancreatic tissue and isolate and analyze islet cells from deceased donors. They also developed a unique cell-sorting technique to isolate islet cells from other cells in the pancreas. Once they had pure populations of cells, they compared their patterns of gene expression as changes from childhood to adulthood.

“Our study charts a unique and valuable resource for researchers wishing to begin to understand how pancreatic development and function change from childhood to adulthood,” said Kim. “It is very important to the field of diabetes research. The researchers also anticipate that their gene expression data and newly described islet-cell isolation technique, coupled with the ongoing tissue procurement effort, will be helpful to others studying pancreatic development and diabetes.

“This is a unique and valuable resource for researchers wishing to begin to understand how pancreatic development and function change from childhood to adulthood,” said Kim. “It is very important to the field of diabetes research. The researchers also anticipate that their gene expression data and newly described islet-cell isolation technique, coupled with the ongoing tissue procurement effort, will be helpful to others studying pancreatic development and diabetes.

“Studying human islet cells has been a major challenge in the field of diabetes research,” said Kim.

**Translational Research and Applied Medicine Program symposium set for May 20 in Berg Hall**

The Translational Research and Applied Medicine Program will hold its annual research symposium from 9 a.m. to 4 p.m. May 20 in Berg Hall, at Li Ka Shing Center for Learning and Knowledge.

Registration and breakfast begin at 8:30 a.m. The theme this year is precision medicine.

Two speakers from industry — Robert Chess, MBA, chairman of Nektar Therapeutics; and Frederic de Sauvage, MD, PhD, vice president of Genentech — will join several Stanford faculty members to discuss how precision medicine is applied in their areas of expertise.

Presentations will cover a diverse number of topics, including hyperinsulinemic hypoglycemia, dengue, pharmacogenomics and cancer therapies.

Six recipients of TRAM pilot grants will also speak about the research their grants supported.

The focus of this year’s program will be a performance by the acclaimed St. Lawrence String Quartet, which will present a special musical program called “Precision Listening,” with Strings Attached.

The event is free, but attendees are encouraged to consider making a donation to support music at Stanford.

1 How do you determine neighborhood quality from data?

HAMD: Sweden, like many European countries, collects centralized, real-time data on health-care access, medication prescriptions, income, housing, education and how many people live in each home. We don’t have that kind of data access in the United States.

For the Sweden study, we created a composite ranking that factorized in levels of poverty, unemployment, average schooling and how many people were enrolled in social welfare programs. Then we categorized neighborhoods as high-deprivation, moderate-deprivation and low-deprivation areas.

2 Why do poor neighborhoods increase diabetes risk?

HAMD: We’re still working on this analysis, but we hypothesize that deprived neighborhoods make it harder for people to access healthy food and food outlets. There may be fewer opportunities for education and employment, making it harder for them to purchase quality food and health care. And the chronic stress associated with living in a high-poverty or high-crime area might contribute to the onset of diabetes.

3 What was the most surprising finding?

HAMD: After analyzing 10 to 20 years of health data, we were surprised to find that living in a deprived neighborhood had a cumulative effect on diabetes risk, even when about half of the refugees later moved to a different neighborhood. Their diabetes risk increased by 9 percent on average for every five years after they were settled in high-deprivation areas.

4 Based on these findings, what will you research next?

HAMD: We want to do this analysis in other settings and countries. Denmark is next, and we will be traveling there in May with funding from Stanford’s Center for Population Health Sciences. It’s pretty amazing that we will be able to access several decades’ worth of health and socioeconomic data on almost all 5.6 million individuals living in Denmark.

Within Sweden we’re continuing to work with our collaborators at Lund University. They have a lot of great data on neighborhood characteristics such as walkability and food access. Next, we want to analyze the effect of neighborhood quality on other outcomes like mental health or child health.

5 How might your findings influence policy abroad?

HAMD: Our data suggest that decisions affecting the settlement and integration of immigrants can have long-term consequences for the health of the new arrivals, and that these societies may end up paying the price decades later if refugees don’t receive adequate support upfront.

Even though the U.S. doesn’t have a national health-care program like Sweden’s, the health care of vulnerable populations such as refugees eventually hits everyone’s bottom line. Providing poor housing and putting families up in emergency rooms and on Medicare and Medicaid, and these costs get passed on to taxpayers. Our study on the impact of refugees on social services and better neighborhoods for disadvantaged groups can prevent costly chronic diseases such as diabetes.

By Tracie White

Ulysses Rosas, a fourth-year medical student, was inspired to become a physician by the excellent care he received from his childhood doctors. So it’s not surprising that when he went searching for a topic to research during medical school, he chose one focused on bedside care.

“I had a lot of good doctors growing up who encouraged me to do well in school,” said Rosas, who saw a physician once per month for orthopedic problems until he was 10. An explanation of his recovery after surgery for a “dumb bone” injury inspired him to choose medicine. “I want to be a good doctor,” he said.

Rosas was one of about 45 medical students that participated in a hands-on care as they head off to residency programs this summer. Each Stanford medical student is required to conduct at least one quarter of research, but most do more than that.

Opportunity to focus on interests

“If this is an opportunity for students to take their interests and really focus on them,” said Laurence Baker, PhD, director of the Scholarly Concentration Program, a required program of study for medical students that promotes in-depth learning and scholarship. “This is the first time for many making the transition from student to the role of ‘thinker’ as a real investigator.”

Rosas, who has chosen a career in internal medicine, will be staying at Stanford Medicine after he graduates in June for his residency program. As a soon-to-be resident himself, he was particularly interested in the best way to gain the necessary new skills that may not have been taught in medical school — such as how to read an EKG, or respond to hospital emergency codes.

“How do you tell someone they have cancer? Or what do you do when a patient dies?” said Rosas. Pointing to his poster board, he explained that his research involved measuring the success of a voluntary four-day course to prepare students for their residencies. The results? “Students who did the course increased their level of confidence and reduced levels of anxiety,” he said.

Who’s healthier: Americans or Brits

The students’ research, which was being judged by faculty and staff, ranged across a variety of topics, including deep dives into primary care, basic science and public health issues.

One project by student Thanh Truong posed the question: Who is healthier, Americans or British people? The Brits won, at least when it comes to rates of diabetes and hypertension.

“It’s fun to see the final projects,” said Laith Caglar, MD, associate professor of medicine and one of the judges for the event who made the rounds interviewing students. “That the students manage to do all this on the side, while doing all their other work, it’s just amazing.”

The symposium drew a crowd of spectators, among them students and faculty members. At the end of the event, the judges picked 10 winners of the poster competition. They received a monetary award funded by the Stanford University Medical Center Alumni Association. Some of the projects are still in progress, and have a Stanford faculty advisor. Funding comes from a variety of outside fellowship awards and internal fellowships from the Medical Students Research Program.

TB in Brazil

Second-year student Tarub Mabud chose to explore his interest in global health by researching the problem of the high transmission rates of tuberculosis among prisoners in Brazil. Incarceration rates in Brazil are some of the highest in the world, the prison system overcrowded, due primarily to the drug trafficking in the region, Mabud said. The project involved a mathematical modeling of various strategies for controlling the spread of TB. Mabud also spent a summer in Brazil visiting prisons.

“There is a lot of TB in prisons around the world due primarily to overcrowding,” Mabud said. He conducted data analysis comparing the prison populations in Brazil to a national database and found the risk of TB increased dramatically the longer the time of incarceration. The risk of prisoners in Brazil contracting TB was 20 times that of Brazil’s general population.

“I’ve been working on this project for about a year,” Mabud said, “I have about two more months. There’s always the hope to publish, right?”

Across the room, Sara Aziz, another second-year student, was busy explaining her research project on deep brain stimulation to one of the judges. She described the process of how neuroscientists drill holes into the skull of a patient with Parkinson’s disease to implant electrodes on specific parts of the brain.

A medical device called a “brain pacemaker,” implanted beneath the clavicle, sends electrical impulses to the brain via these electrodes.

“It’s very cool how little we know about the brain,” Aziz said. “There is so much to learn, and I think that is very exciting.”
Researchers at the School of Medicine are releasing a new version of a web-based video game that will harness the creativity of thousands of nonscientist players.

The goal in coming months is for Eterna Medicine players to design a molecule that could help spur the development of a new tuberculosis test.

Tuberculosis infects a third of the world’s population and kills about 1.5 million each year. Yet health organizations lack a simple-to-use test that can be washed away in a few minutes by any patient, especially in remote villages.

Like a previous iteration of the Eterna game, the new version challenges players to build molecules of RNA with increasingly difficult-to-design shapes.

RNA is DNA’s inventive cousin. DNA molecules form the standard two-stranded double helix; their threadlike shape is stable and comparatively stiff. In contrast, RNA is single-stranded, floppy and can spontaneously fold into myriad shapes. Each shape has its own biological purpose, many of which can be useful to biomedical researchers.

Eterna’s co-creator Rhiju Das, PhD, said, “Eterna Medicine could someday allow citizen-scientists to invent their own pharmaceuticals. “It’s going to sound like science fiction,” he said. For now, Das hopes that associate professor of biochemistry at Stanford, is turning loose 100,000 registered Eterna players to pilot a new route to controlling the tuberculosis pandemic.

Games with real-life consequences

Eterna, the first version of the video game, was launched five years ago as a way to let nonscientists design potential pharmaceutical molecules that are stable enough to function inside a living cell. Over the years, the players have become more expert in designing complex RNA molecules. They are so good at it now that the players recently co-authored an article in the Journal of Molecular Biology describing a set of rules for predicting how difficult it will be to build a given RNA molecule.

Now Das has set a new challenge in front of them: design a molecule that could help save the lives of millions of people worldwide.

Recently, assistant professor of medicine Purvesh Khatri, PhD, and his team came up with a simple test to predict how well their new molecules would work in a living cell. They are now using this test to get tens of thousands of designs, of which perhaps a thousand may have potential. Das’ lab will then test all of these molecules to see how well they work in the lab. If successful, a subset of 10 to 20 molecules will be tested to see which work best in a real stick-test.

“Eterna Medicine is a little different from the original Eterna because we are trying to recruit people to make something with an eventual real-world impact.”

Molecular problem-solver

When a person is being tested for tuberculosis with the Khatri TB test, RNA molecules circulating in the blood reveal the levels of expression of three genes. If Eterna players succeed, they’ll come up with an Eterna-built RNA molecule, called “OpenTB,” that has three parts. RNA readily binds to other RNA molecules. So, if designed right, each part of OpenTB can bind to one of the TB-related RNA molecules. And when each TB-related RNA from patient blood binds to OpenTB, it will change its shape.

The OpenTB molecule will assume different shapes depending on the proportions of the three kinds of TB-related RNA present in the blood sample. “If I have a lot of RNA molecules A and B around,” said Das, “OpenTB will fold into shape 1. But if there’s a lot of C around, OpenTB will fold into shape 2.”

For Das’ plan to work, shape 1 also must be able to bind a fluorescent tag, while shape 2 must not bind the tag. So individuals who can accurately diagnose TB from a simple blood sample.

The test looks at the expression levels of three different genes. Cells “express” genes when the cell transcribes a gene into a length of RNA. In the Khatri TB test, when the three genes are expressed in certain proportions, doctors know the patient has TB. But how to calculate those proportions in a simple test on a stick — like a pregnancy test — is the challenge. To do so, Das said, they need a molecule that can calculate the proportions of three molecules. Right now, there’s no single molecule that can make that calculation.

But Das said the Eterna game, powered by the minds of thousands of players, can theoretically create a molecule of such a shape. His hope is to get tens of thousands of designs, of which perhaps a thousand may have potential. Das’ lab will then test all of these molecules to see how well they work in the lab. If successful, a subset of 10 to 20 molecules will be tested to see which work best in a real stick-test.

“Eterna Medicine is a little different from the original Eterna because we are trying to recruit people to make something with an eventual real-world impact.”

Perfect challenge for Eterna players

Khatri said the idea for using a TB test came about when he and Das were seated together at a conference having dinner. They got to talking, he said, and realized that the TB test might be a perfect challenge for Eterna players.

But Das told him that anything more complicated than three or four genes would involve so many possible configurations, it would be almost impossible to solve.

“I love this idea because it changes the biological research paradigm,” Khatri said. “If successful, it would allow us to say, ‘We can use publically available data — ultimately provided by patients themselves — to find a diagnostic signature of one of the biggest killers of mankind. And then we can engage the public to design molecules that can help deploy that test to help other patients using a video game platform.’”

Trauma team mobilizes to save 10-year-old’s hand — and life

By Erin Digitale

When the emergency call came on the evening of Oct. 19, 2015, doctors on Stanford’s pediatric trauma team realized the case heading their way could hardly be worse. Ten-year-old Elijah Olivas was being helicoptered to Packard Children’s Hospital in central California to Stanford Children’s Health emergency department after being ejected from a moving car during an accident. He had serious head injuries, and his right hand had been severed at the wrist. Das said he had no plan on how to save his hand — and his life.

“We knew that when Elijah arrived, we’d need to get him to the hospital as quickly as possible but also as safely as possible,” said orthopedic surgeon Garrett Comer, MD, one of several dozen experts from the Level-1-certified pediatric trauma service who cared for Elijah.

“Elijah had a potentially life-threatening cranial injury, and we had to stop the bleeding before there were any life-threatening bodily injuries before taking him to the operating room,” said pediatric neurosurgeon Samuel Cheshire, MD, PhD. “It was incredibly important because being thrown from a car could have caused a severe bowel or aortic injury, for instance.”

While Elijah was en route, the pediatric neurosurgery and trauma teams gathered in the emergency department to plan the day’s surgery. Down the hall, the staff of the Ford Family Medical Center at Lucile Packard Children’s Hospital Stanford reserved two operating rooms: one for Elijah’s upper arm above where his hand had come off; a few fractured vertebrae; two breaks in his collarbone; and a break in his pelvis. None were critical enough to take precedence over surgery to reattach his hand, which had the best chance of success if it began without delay.

Team effort

“As within a matter of minutes, he had clearance to proceed to the OR,” said Comer, a clinical instructor of orthopedic surgery. “It was very impressive how everybody came together.”

After Elijah arrived in his operating room, Cheshire placed a pressure monitor in the boy’s hand to warn the surgeons if the brain hemorrhage began to endanger his brain. If this happened, the neurosurgery team was prepared to perform a craniotomy, in which they would surgically open the skull to drain blood.
By Tracie White

Alfred Spivack, MD, a medical innovator who championed the deeper involvement of nurses in patient care, died April 23 at his home at Vi at Palo Alto, a retirement community. He was 87.

He died swimming in the pool at Vi, but the cause has not been determined, according to his son, Peter Spivack.

A cardiologist and clinical professor emeritus of medicine, Alfred Spivack founded and was the first director of Stanford Hospital’s coronary care unit, which opened in 1966. At the time, only a handful of hospitals had CCUs, and many physicians did not yet recognize their value.

He graduated from the University of Pennsylvania in 1947 and completed his residency in internal medicine at Temple University in 1950.

He was among the first to encourage nurses to take a more active role in the care of critically ill cardiac patients, training them in intravenous therapy, electrocardiogram monitoring and defibrillation among other procedures that were primarily restricted to physicians at the time.

“Tireless in making us experts”

“Spivack was tireless in making us experts,” said Joaquin Alloza, one of the unit’s original nurses who is now a cardiovascular researcher.

“He really believed we could do these things, and he just did it.”

Spivack also served on Stanford Hospital’s board of directors and the medical school’s admissions committee and mentored medical students.

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Alfred Spivack, a clinical professor emeritus of medicine who died April 23, also was a ceramicist. He invented a new method of fusing clay and glass.

Alfred Spivack, who suffered a severe head and other major injuries in a car accident, was treated at Lucile Packard Children's Hospital Stanford.

Spivack graduated from Temple University and Jefferson Medical College. (He received the Alumni Achievement Award from Jefferson University in 2014.) He completed his medical residency in internal medicine at Philadelphia General Hospital and then began a research fellowship in cardiology at Stanford. He remained connected to Stanford until his death, regularly attending the weekly medical grand rounds.

“Seeing AI sitting front and center every week at medical grand rounds was one of the highlights of my week,” said Robert Harrington, MD, the Arthur L. Bloomfield Professor of Medicine and chair of the Department of Medicine. “He always stopped to say hello and talk with me about the history of Stanford. We talked about art and literature, cardiology and diving medicine. Al had a grace and a humility about him that was wonderfully inspiring. “I’m deeply saddened by this profound loss,” said Lloyd Minor, MD, dean of the School of Medicine. “Al was one of the first people I met when I arrived at Stanford. He will be well remembered for his many contributions as an outstanding caregiver, health advocate, mentor to generations of students and trainers.”

Last year, Spivack, along with many of the nurses he helped train, were honored at a dinner celebration of the 50th anniversary of the coronary care unit. He talked about the difficulty of selling the idea of a coronary care unit back in 1966 at what was then the Palo Alto-Stanford Hospital. Some couldn’t see the teaching benefit, and others thought the emerging technology of electronic monitoring for heart rhythm, for example, was gimmicky, Spivack said. “They thought it had no viable future,” he said.

Today, the role of the adult hospital’s coronary care unit belongs to Randall Vagelos, MD, professor of medicine at Stanford.

Seeing a need

“Al saw that the future of cardiology was headed toward an environment where patients would be intensely monitored in a high-surveillance nursing unit, where the sickest of patients could still get the best care,” Vagelos said. “He understood that all of this was going to depend on nurses. There were clearly not enough doctors to create that kind of surveillance.”

“I have a role that he to some degree helped create,” he added. “He saw the need, and he just did it.”

Spivack had many interests, including scuba diving, underwater photography and collecting and creating art. He was a ceramicist and invented a new method of fusing clay and glass, resulting in works of art that were displayed both on the Stanford campus and abroad. Most recently, he worked as a consultant for Vivas Inc., a drug development company.

He swam regularly with his lifelong friend and colleague Saul Rosenberg, MD, Stanford professor emeritus of hematology. “He and I would swim in the mornings,” Rosenberg said. “I was in the pool with him the day before he died. He was an excellent swimmer.”

His wife, Anita Spivack, died in 2000. He is survived by his partner, Marjorie Crosby; his son, Peter Spivack; his daughter, Laura Garfinkel; and grandchildren Sarah and Amy Garfinkel and William, Madeleine, Grant and Taylor Spivack.

Early signs are promising

Early signs for Elijah’s hand-reattachment looked good. When Comer gently squeezed Elijah’s fingers, he could see the nailbeds blanch and refill, a clue that squeezed Elijah’s fingernails, he could see the nailbeds blanch and refill, a clue that the blood vessels, nerves and arteries worked. By the time the pressure monitor was read, the nails were white, a sign of a successful response to his life-threatening injury, as Comer reconnected the skin. They also set Elijah’s broken bones, then the tendons, then — with the help of a few blood vessel grafts — the delicate process of reconnecting it home-schooled, working to improve patient care.

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Spivack had many interests, including scuba diving, underwater photography and collecting and creating art. He was a ceramist and invented a new method of fusing clay and glass, resulting in works of art that were displayed both on the Stanford campus and abroad. Most recently, he worked as a consultant for Vivas Inc., a drug development company.

He swam regularly with his lifelong friend and colleague Saul Rosenberg, MD, Stanford professor emeritus of hematology. “He and I would swim in the mornings,” Rosenberg said. “I was in the pool with him the day before he died. He was an excellent swimmer.”

His wife, Anita Spivack, died in 2000. He is survived by his partner, Marjorie Crosby; his son, Peter Spivack; his daughter, Laura Garfinkel; and grandchildren Sarah and Amy Garfinkel and William, Madeleine, Grant and Taylor Spivack.
Biodesign continued from page 1

more than 1,000 graduate students and nearly 200 fellows. The trainees have founded more than 40 companies and created products used by well over a half-million patients, said Yock, who is also the Mar- tha Mayer Weiland Professor in the School of Medicine. These include devices to forestall night terrors in chil- dren, prevent infections after surgery, relieve symptoms from an enlarged prostate, provide respiratory support in low-resource settings, as well as to treat dry eyes and women’s incontinence.

“Biodesign is a program that exemplifies the con- cept of precision health. Working at the intersection of medicine, engineering and business, Biodesign fel- lows are delivering path-breaking solutions to the most pressing human health problems,” said Lloyd Minor, MD, dean of the School of Medicine. “Moreover, these innovative fellows go back out into the world, taking with them not just their first invention but their ca- pacity to keep inventing — and to teach others how to invent — whether in their own startups, in existing companies or as faculty members in top universities. This is the multiplier effect: We seed the world with people who approach innovation using this proven, needs-based process.”

“Over the last 15 years, Stanford Biodesign has had an extraordinary impact on the world,” said Persis Drell, PhD, dean of the Stanford School of Engineer- ing. “It has done so in large part because its leadership recognized early on that solving big, complex problems requires teams of scholars from multiple backgrounds and disciplines to work together. Stanford engineers are very proud to be a part of this highly successful collabo- ration and look forward to continuing to do so.”

The program had its genesis in the late 1990s when Bio-X, the university’s interdisciplinary biosciences insti- tute, was taking shape. Yock was among a dozen facul- ty in medicine and engineering with an interest in medical technology innovation who wanted to create a unit within Bio-X, he said. The group was committed to having a fellowship training component in the pro- gram and reached out to Josh Makower, MD, MBA, a successful medical technology entrepreneur who had developed an interdisciplinary training initiative while at Pfizer. With help from faculty and industry col- leagues, Makower developed the Stanford training ap- proach and became the program co-founder and its first fellowship director.

The new program moved from its temporary head- quarters in the Center for Clinical Sciences Research into the James H. Clark Center, the Bio-X hub. Ini- tial funding was provided by a combination of private donors and industry gifts, followed by foundation and grant support, and the program continues to rely on these funding sources today.

In 2003, Tom Krummel, MD, then chair of surgery and a consulting professor of medicine at Stanford. He be- lieves many companies fail at innovation because they start with a technology and then try to find a place where it might be put to clinical use. But technology will only make meaningful, lasting improvements in how health care is delivered if it addresses a clear need, he said.

To identify compelling needs, the fellows spend two months observing patient care at Stanford’s hospitals and clinics, soaking up the clinical experience. As the first fellowship director, Makower said he encouraged fellows to sleep in the residents’ on-call room so they could observe every step of the clinical interaction and even visit patients’ homes when possible and appropri- ate to see how they were adhering — or not adhering — to a particular therapy.

During this time, the fellows may identify as many as 200 needs. Then they have to select the two or three that seem most promising, and ultimately choose just one of them.

In the past, Yock said, cost wasn’t a primary consid- eration, but that has changed as a result of increasing pressure from government and payers. “We’ve moved from asking, ‘How can we make this affordable?’ to talking about eco- nomics into consideration before, during and after they invent. That’s true for the United States’ health-care sys- tem and around the globe, where affordability is an even more important factor.”

“Objective take a hard look”

At this stage, too, the fellows have to take into ac- count many other issues that could influence whether a device is successful.

“You have to ask if there’s a clear regulatory path,” said Kumar, now the program’s director of strategy and a consulting associate profes- sor of biomedical engineering. “What is your path- way to reimbursement and is it feasible? Can you protect the intellectual property? What business model will provide sustainability? Is there global play beyond the U.S.?”

“Most needs and solutions don’t hit all of these,” he added. “The challenge is not to fall in love with any one idea but objectively take a hard look and find the one that has the best chance of reaching patients once you take all of these factors into consideration.”

Once fellows have settled on an idea, they begin the process of implementing their solution, possibly devel- oping a prototype and building a plan to help bring it to the marketplace.

To help the fellows better understand the universe of medical technology, the program brings in experts from various fields, including regulatory and patent experts, venture capitalists and marketing specialists, who do- nate their teaching time, Makower said.

Advancing the whole community, Yock described, has really crystal- ized the whole community around the program,” he said.

Stanford faculty also teach in the program, which of- fers one- and two-semester classes for graduate students in medicine and engineering, as well as a courses for undergraduates.

Interest from abroad

Over the years, the program has attracted consid- erable interest from abroad, leading to collaborations in India, Ireland and Singapore. More recently, Stanford Biodesign helped initiate a program in Japan, which was announced last year by Prime Minister Abe on his visit to the Stanford campus. Innovators trained in these international programs are developing life-changing so- lutions tailored to the specific needs of patients in their communities.

Through these partnerships, particularly in India and Southeast Asia, “we are trying to absorb their cul- ture of cost-effective innovation and benefit from the experience of entrepreneurs who may live and work in a resource-limited environment. He and his colleagues maintain ongoing relationships with pro- gram alumni abroad as they invent and develop tech- nologies and build biodesign training programs in their home countries.

“We are moving the entire fellowship to a more global orientation and will be accepting fellows from any country on a ‘best athlete’ basis,” Yock described.

He said the program will expose future fellows to global markets during their training through lectures and visit- ing speakers, and help make connections for those who want to go to the developing world after their fellow- ship year.

Yock and his colleagues have also documented the discipline of the Biodesign innovation process in a text- book, a 2-inch thick resource that he edited with Ma- kower; Stefanos Zenios, PhD, a professor of business at Stanford; and a team of others. The book is being used as a teaching tool in scores of major universities around the world, helping cement the center’s role as a global leader. Yock also helped launch the Biomedical Innovation Engineering, Design and Entrepreneur- ship Alliance, a group of faculty at 100-plus universities who share experiences, challenges and opportunities to advance training in biomedical engineering and innovation.

Makower said the business of developing new medi- cal technologies is a tough one, as there may be many needs of failures for every success. And the profits are modest compared to an internet or social networking megalith, he said. But the potential human impact is enormous.

“When you invent a device that addresses a compel- ling medical need and someone is successfully treated,” he said, “there’s nothing better than that.”

(Counterclockwise from top left) The Stanford Biodesign textbook is used by health technology training programs around the world. Fellows Craig Stauffer and Richard Timm; James Wall, assistant director of the innovation fellowship program; and fellow Veronique Peiffer discuss a project.

May 9, 2016
INSIDE STANFORD MEDICINE

Paul Yock

MUKTAI SINGH/JON ROY BURKE
Abstinence
continued from page 1
not able to detect any population-level benefit from this program," said Nathan Lo, a Stanford MD/PhD student and lead author of the study. "We did not detect any effect of PEPFAR funding on the number of sexual partners or upon the age of sexual intercourse, and we did not detect any effect on the proportion of teen pregnancy.

"We believe funding should be considered for programs that have a stronger evidence basis," he added.

A human cost
Senior author Eran Bendavid, MD, noted the impact of abstinence on a personal level because of the high cost because it diverts money away from other valuable, risk-reduction efforts, such as male circumcision and methods to prevent transmission from mothers to their children.

"Spending money and having no effect is a pretty costly thing because the money could be used elsewhere to save lives," said Bendavid, an assistant professor of medicine at Stanford.

PEPFAR was launched in 2004 by President George W. Bush with a five-year, $15 billion investment in global AIDS treatments for more than 200 nations and territories. The program has had some demonstrated success: A 2012 study by Bendavid showed that the program had reduced mother-to-child transmission of HIV and saved 740,000 lives in nine of the targeted countries between 2004 and 2008. However, the program’s initial requirement that one-third of the prevention funds be dedicated to abstinence and be fairly monitored with no major hiccups, was largely unmet. Critics questioned whether this approach could work and argued that focusing on these methods would deprive people of information on other equally life-saving options, such as condom use, male circumcision and ways to prevent maternal transmission from mothers to their children.

Abstinence, faithfulness funding continues
In 2008, the one-third requirement was eliminated, but U.S. funds continued to flow to abstinence and “be faithful” programs, albeit at lower levels. In 2008, $260 million was committed to these programs, but by 2013 that figure had fallen to $45 million.

Although PEPFAR continues to fund abstinence and faithfulness programs as part of its broader behavior-based prevention efforts, there is no systematic evaluation of the success of these programs. “We hope our work will emphasize the difficulty in changing sexual behavior despite substantial investment of scarce public health dollars,” said Lo.

Many in the medical community were critical of the abstinence-fidelity component, no one had previously analyzed its real-world impact. “Critics questioned whether this approach could work and argued that focusing on these methods would deprive people of information on other equally life-saving options, such as condom use, male circumcision and ways to prevent maternal transmission from mothers to their children.

Eran Bendavid

While many in the medical community were critical of the abstinence-fidelity component, no one had ever analyzed its real-world impact, Lo said. When he presented the results of the study in February at the Conference on HIV流行病学 and Economics of Health and Aging, the researchers, computer scientists, statisticians, machine learning, digital health, and learning health systems. The annual conference debuted in 2013, thanks to a grant from the Lila K. Shing Foundation. Last year’s event brought nearly 500 attendees to the campus, while another 3,000 watched online via live-streamed video.

Among this year’s speakers will be Kathy Hudson, PhD, deputy director for science, outreach and policy at the National Institutes of Health; Robert Califf, commissioner of the U.S. Food and Drug Administration; Blake Byers, PhD, general partner at Google Ventures; Shubha Shipman, senior health policy advisor at Intel; Carlos Bustamante, PhD, professor and chair of biomedical data science and professor of genetics at Stanford; Jody Heymann, MD, PhD, dean of the Fielding School of Public Health at UCLA; and Steve Lohr, a New York Times reporter and author of Data-ism: The Revolution Transforming Decision Making, Consumer Behavior, and Almost Everything Else.

The 2016 conference is part of Stanford Medicine’s Biomedical Data Science Initiative, which seeks to make powerful transformations in human health and scientific discovery by fostering innovative partnerships among medical researchers, computer scientists, statisticians and physicians.

To learn more and to register for the conference, please visit http://bigdata.stanford.edu.

The 2016 Big Data in Biomedicine Conference, set for May 25-26 at the Stanford University School of Medicine, will focus on advancing precision health by harnessing data from electronic health records, biomedical databases and wearable sensors.

The two-day event is expected to draw hundreds of researchers and leaders from academia, health care, government and industry. More than 40 presenters will discuss ways to deploy data analysis and machine learning to improve health care; from U.S.-based abstinence programs.

"We believe funding should be considered for programs that have a stronger evidence basis," he added.

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"We believe funding should be considered for programs that have a stronger evidence basis," he added.
A taste of medical school

Med School 101, a Stanford Medicine event that offers local teens a glimpse into the world of medical school, was held April 29 at the Li Ka Shing Center for Learning and Knowledge. More than 125 students from six Bay Area schools attended a day of talks and demonstrations. In the “Paging Dr. Gadget” session (above), a student presents his team’s suggestion for an invention that would be more hygienic than tissues for dealing with a runny nose. The team came up with iSteam, a device that would first inject steam into the sinuses and then vacuum out the mucus and liquid. A student (top right) peers through a Fieldscope, an inexpensive microscope made of folded paper and a bead of glass, in the “Frigal science” session. Students (bottom right) in “The brain whisperer” session learn how electrodes can be used to find out what parts of a living human brain are doing.

Michael Angelo, MD, PhD, was appointed assistant professor of pathology, effective Nov. 1. His research applies multiplexed ion-beam imaging, which visualizes proteins, to a variety of fields including the evaluation of cancer lesions and the status of immune-cell populations in solid tissues.

Ben Barnes, MD, PhD, professor and chair of neurobiology and professor of developmental biology and of neurology and neurological sciences, will receive the $25,000 Gill Distinguished Scientist Award from the Linda and Jack Gill Center for Biomolecular Science at Indiana University. He will present a lecture on reactive astrocytes at a ceremony in September. His research focuses on glial cells.

Rebecca Bernert, PhD, was appointed assistant professor of psychiatry and behavioral sciences, effective Oct. 1. She specializes in suicidology and directs the Stanford Suicide Prevention Research Laboratory. Her work investigates therapeutic targets for suicide prevention at all ages and the relationship between sleep and mental health.

Brendan Carvalho, MD, was promoted to professor of anesthesiology, perioperative and pain medicine, effective Dec. 1. He is the chief of obstetric anesthesia.

Mark Davis, PhD, is an investigator and associate professor (research) of medicine, effective Nov. 1. His work focuses on improving the quality of treatment for children and to mentoring young female oncologists. Her research focuses on improving the quality of treatment for children with cancer.

Tina Hernandez-Boussard, PhD, was appointed associate professor (research) of surgery and of medicine, effective Nov. 1. She directs the Surgical Health Services Research Unit at Stanford. Her research uses clinical data sets to evaluate the quality of health-care delivery and for comparative effectiveness research.

Seung Kim, MD, PhD, professor of developmental biology, has been awarded a $500,000 grant through the Type 1 Diabetes Program of the Leona M. and Harry B. Helmsley Charitable Trust. Working with other investigators at Stanford and at Vanderbilt University, he will test a new method that aims to use immune cells to enhance the survival of beta cells, which produce insulin.

Jonathan Maltzman, MD, PhD, was appointed associate professor of medicine, effective Nov. 1. He was also appointed staff physician at the Veterans Affairs Palo Alto Health Care System. His research focuses on how immune cells recognize antigens.

Sarah Donaldson, MD, the Catharine and Howard Avery Professor and a professor of radiation oncology, in June. She is being honored for her commitment to mentoring young female oncologists. Her research focuses on improving the quality of treatment for children with cancer.

Robert Negrin, MD, professor of medicine, was named the editor-in-chief of a new online journal, Blood Advances. It will supplement Blood, the American Society of Hematology’s existing hematology journal. Negrin’s research focuses on immune cells that are involved in responses to cancer or transplant.

Kim Roberts, MHA, chief strategy officer and chief administrative officer of physician practices for Stanford Children’s Health and chief executive officer of the Packard Children’s Health Alliance, was named a Silicon Valley Business Journal Power Executive for 2016. The executives were selected by the paper’s editorial staff based on reader nominations.

Nigam Shah, MBBS, PhD, was promoted to associate professor of medicine, effective Nov. 1. His research uses longitudinal electronic health record data to answer clinical questions, generate insights and build predictive models.

Barbara Sourkes, PhD, professor of pediatrics and the John A. Knerrwell and Elizabeth A. Hachel Director of Pediatric Palliative Care at Lucile Packard Children’s Hospital Stanford, received the Compassion in Action 2016 Award from Hospice of the Valley, a San Jose-based organization, in March. She was honored for her service and pioneering leadership in the field of pediatric palliative care.

Joanna Wysocka, PhD, was promoted to professor of chemical and systems biology and of development of techniques and strategies to improve postoperative pain control and other surgical outcomes.

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