




# TECHNOLOGY TARGETS WOMEN'S HEALTH

SUMKINI/OANN DICKEY



Women engineers, researchers, and  
entrepreneurs are working to find  
solutions to what ails women's health  
using high technology in a growing  
field called "femtech."

By Seabright McCabe, SWE Contributor



Heather Ross, M.D. (holding a pulmonary artery pressure monitor) co-invented Medly, a smartphone-based heart failure monitoring system.

The number one killer of women, worldwide, is heart disease — a “silent epidemic” at a time when it is still often seen as primarily afflicting more men. Heart failure, in which the heart muscle loses its ability to pump blood efficiently, currently affects 2.6 million women in the United States alone and is the number one driver of hospitalizations for women aged 65 and over.

“Right now, treatment plans include guidelines on how to manage the average patient. The plans are infrequently stratified into groups, let alone tailored to individuals,” said world-renowned cardiologist Heather Ross, M.D., division head of cardiology for the University Health Network (UHN) Peter Munk Cardiac Centre in Toronto. “This can be problematic for heart disease patients, particularly women, since the guidelines are based on clinical trials where women are underrepresented.”

Emily Seto, Ph.D., P.E., associate professor at the Institute of Health Policy, Management and Evaluation at the University of Toronto, agreed. “It’s not just in heart failure; women are underpre-

sented in research, period,” said Dr. Seto, who co-leads the institute’s health systems AI and health informatics research programs. “When more men do studies, they pull from a population that’s already highly biased toward men. Women receive fewer health care resources, and when more men prescribe care, women’s symptoms tend not to be believed, and they’re more subject to referral bias. These issues are systemic.”

### A personalized approach

In the early 2000s, Dr. Seto began developing a Blackberry phone-based platform for remote monitoring and management of heart failure, conducting a controlled trial with a small group of patients. Winning the support of co-inventors Dr. Ross and Joseph Cafazzo, Ph.D., leader of UHN’s Centre for Global eHealth Innovation, the platform began to take shape, evolving as smartphone technology began to appear.

Flash through 15 years of iterative design, and it is now Medly, a comprehensive, smartphone-based, self-management app and platform that offers around-the-clock care to chronic heart failure patients anytime, anywhere. Patients upload daily stats such as weight, blood pressure, and heart rate, and answer questions about shortness of breath, edema, and more. Medly’s advanced algorithm analyzes the data instantly, providing immediate feedback to patients and alerts to clinicians. “We can see trends and changes in a patient’s status and intervene prior to them worsening and requiring hospitalization,” Dr.

Ross said. “If we see adverse trends, we can provide on-demand care through the Medly program.”

Medly’s smartphone interface is patient friendly: no more written logs, faxing, emailing, or calling in information. There’s a manual data entry option, and it can also link to Bluetooth-enabled weight scales and blood pressure cuffs with the readings going directly to the app. “We have been able to show that the way we prescribe Medly, which is not dependent on whether or not a patient has a smartphone, scale, or blood pressure cuff, allows us to help bridge the digital divide and make access to this technology equitable,” Dr. Ross said.

Medly is now in use at four hospitals in Ontario. “We’re studying it for other heart failure applications, such as medication titration,” Dr. Seto said. “Currently, it takes frequent doctor visits to keep medications at an optimal level. Many patients can’t come in every two weeks as they should, due to distance, expense, and schedule conflicts. Some never reach optimization, or it takes far too long.”

A randomized trial found that Medly shortened the timeline to optimized medication by months, resulting in fewer hospitalizations and improved life expectancy. Currently, Dr. Seto is studying ways to embed and scale Medly for use in primary care, home care, and nursing homes.

Expanding Medly’s functionality may also enable more holistic care. “Right now, I’m doing a multi-state trial with people who have been hospitalized with multiple chronic conditions,” Dr. Seto said. “Medly could potentially address people with COPD [chronic obstructive pulmonary disease], diabetes, hypertension, and mental health issues like depression, helping us intervene before those conditions escalate.”

Currently, Medly is only available in English, but Dr. Seto is reimagining ways to adapt the interface for more languages, as well as to address cultural differences and patients who do not

read. “Health care equity is the goal, and only since AI came into play have we gained this capability,” she said. “We want to add speech-to-text and text-to-speech, on-the-fly calculation, and more graphics, to reach people who don’t have adequate access to health care.”

Deeply interested in global women’s health issues, especially in lower- and middle-income countries, Dr. Seto works with graduate students on technology to address them. One is a platform similar to Medly that targets preeclampsia patients in Pakistan, which has one of the highest mortality rates for pregnant women in the world. Other projects are a videoconferencing group therapy program for women with perinatal depression, and a platform and website centered on occupational health and safety for sex workers. “I feel fortunate to have landed in a very unique job,” Dr. Seto said. “There’s so much to be done in health informatics for women.”

### A breakthrough for endometriosis

“My periods were nothing short of excruciating. I would have to go to the hospital due to the pain. And no matter how many times I complained to doctors, I was told it was just period pain and something I had to live with.”

The story told by this woman, whose name is being withheld at her request, is all too familiar. An estimated 176 million women suffer from endome-

triosis worldwide, according to the U.S. National Institutes of Health. This painful condition, in which tissue similar to the inner lining of the uterus grows outside of it, can affect the ovaries, the fallopian tubes, and the tissue lining the pelvis. Its constellation of symptoms includes racking cramps, heavy periods, low back pain, and gastrointestinal problems. Worse, the average time it takes to diagnose endometriosis is 7–10 years — leading to up to 120 debilitating periods and untreated disease progression. And the standard of care, laparoscopy under general anesthesia, is a procedure that has not fundamentally changed in 100 years.

When a disease affects 1 in 10 women worldwide, why does diagnosis take so long? “That’s the billion-dollar question,” said Heather Bowerman, CEO and founder of DotLab, a high-tech medical diagnostics company. “In the U.S., women see an average of five M.D.s before endometriosis is even brought up. This is a public health emergency, one that requires high-quality samples, as far as molecular and clinical data training



Medly provides 24/7, AI-enabled care for heart failure patients via a user-friendly, multifunctional app.

sets, to reduce the time to diagnosis. That was my basis for founding DotLab.”

Bowerman studied bioengineering at the University of California, Berkeley, where she was an active member of the Society of Women Engineers. She was a McKinsey health care consultant and served in the White House Office of Science and Technology Policy under President Obama before moving into the startup space. “I’ve been at the intersection of health care and machine learning for over 10 years now,” she said, “and what stood out to me was that endometriosis is incredibly prevalent. One in seven women globally have unspecified or unattributed pelvic pain, which is the primary symptom of endometriosis.

“Women’s health receives about 2% of the biomedical R&D budget, and if you take out oncology, we’re talking about a fraction of 1% for *all* women’s chronic diseases,” Bowerman continued. “The dollars don’t exist at the government level to help understand the biology of endometriosis. I saw a real opportunity to apply modern machine learning approaches to develop and validate a diagnostic test.”

Bowerman and her team at DotLab went from early-stage scientific discovery to single- and multisite validation to a pivotal trial at more than 25 top academic sites across the United

UHN



**“IT’S NOT JUST IN HEART FAILURE; WOMEN ARE UNDERREPRESENTED IN RESEARCH, PERIOD. WHEN MORE MEN DO STUDIES, THEY PULL FROM A POPULATION THAT’S ALREADY HIGHLY BIASED TOWARD MEN.”**

– Emily Seto, Ph.D., P.E.

UNIVERSITY HEALTH NETWORK

MORGAN STANLEY



"THE DOLLARS DON'T EXIST AT THE GOVERNMENT LEVEL TO HELP UNDERSTAND THE BIOLOGY OF ENDOMETRIOSIS. I SAW A REAL OPPORTUNITY TO APPLY MODERN MACHINE LEARNING APPROACHES TO DEVELOP AND VALIDATE A DIAGNOSTIC TEST."

— Heather Bowerman

States. They collected blood and saliva specimens at the time of laparoscopy, visual assessments from surgeons, and histopathology from one- and two-year follow-up visits, resulting in a dataset that would allow validation of their endometriosis test.

DotLab's product, DotEndo, is a blood test that is screened and analyzed in its certified lab for mRNA biomarkers indicating the presence of endometriosis. "We have a novel approach for analyzing mRNAs we've identified as sensitive and specific for endometriosis," Bowerman said. "We then apply our in-house machine learning algorithm to the results of the blood sample analysis and send a report back to the ordering medical provider."

How long does DotEndo take to process? "We like to say we're reducing the timeline to diagnosis from 10 years to 10 days," Bowerman said. "Really it's just a few business days for the blood sample to be accessioned once it arrives in the lab and for the algorithm to be applied."

Earlier diagnosis can impact treatment decisions in many ways. "Today, unspecified pelvic pain might be referred to a gastroenterologist or be mistaken for appendicitis or any number of things," Bowerman said. "But if a primary care provider can order our test, the results can lead to an earlier referral to the right physician type."

The initial therapy option for endometriosis is the birth control pill — or, outside the United States, the IUD. Other oral medications are gonadotropin-releasing hormone (GnRH) antagonists, such as elagolix (Orilissa), which lower estrogen levels that trigger pain. "It's about offering interventions to patients earlier, presumably when the disease is earlier staged," Bowerman said, "when treatment can be more effective at reducing pelvic pain and potentially even slowing progression, instead of treating the wrong thing or not pursuing treatment at all."

The final option is surgical removal of endometrial growths. Currently, diagnosis and excision typically occur in the same procedure, years after a woman presents with symptoms. "If surgery can be offered on a shorter diagnosis timeline, it's a total game-changer for patients and health systems," Bowerman said. "The cost to find the source of acute pelvic pain is enormous in the absence of a non-invasive diagnostic test."

DotEndo is currently being offered to top global pharmaceutical partners with an eye toward making the tests available to clinicians soon. "Getting the highest-quality, well-labeled molecular medical and clinical data has been our top priority," Bowerman said. "But it's exciting to think about research opportunities in the comorbidities of endometriosis, like ovarian cancer and various autoimmune conditions. Unlocking that means understanding the biology of endometriosis, being able to stage the disease and measure the disease burden. None of that is possible today, either in a laboratory outside the DotEndo platform or in a commercial capacity. So, there's a lot of work to do."

### What's "NXT"?

Amanda French is a mechanical engineer and serial entrepreneur in technology geared toward women's health, known collectively as femtech, a term coined in 2016 by entrepreneur Ida Tin, who helped launch a menstruation tracking app called Clue. French is the executive in residence at tech incubator NXT Biomedical and CEO of IFPx, one of its portfolio of companies. "For me, femtech is inclusive of technologies that can help improve the health and well-being of women and people with ovaries," she said. "Initially, it was



DotEndo is a highly accurate blood test for endometriosis that can lead to diagnosis in days instead of years.

DOTLAB



thought of only as digital products for women, but if you look at the unique ways women are impacted by the health care system, femtech becomes a broader landscape of technologies that address vast unmet needs.”

French pointed out that women often have their symptoms questioned when they go to the hospital — they’re often told their symptoms aren’t real and sent home. “We’re fighting back against the perception that women’s health isn’t important — when we’re half the world’s population,” she said. “Challenging symptoms when a woman presents them is not normal; it’s not ‘just part of being a woman.’”

French was drawn to the femtech category while studying mechanical engineering at Duke University, working on a project that sped antiretroviral medications to postpartum mothers with poor access to pharmacies. She’s

“AT IFPX, WE’RE DEVELOPING THE WORLD’S FIRST AND ONLY MONITOR THAT DIRECTLY TRACKS CONGESTION, THE FLUID OVERLOAD THAT HEART FAILURE PATIENTS EXPERIENCE AND THE NUMBER ONE DRIVER OF THEIR HOSPITALIZATIONS.”

— Amanda French



DREW ALTIZER PHOTOGRAPHY

had a passion for the space ever since. After developing cardiology devices as a research and development engineer at Edwards Lifesciences, French created her first femtech startup, Emme, in 2017. The company launched the first internet-connected medication adher-

ence system for birth control pills.

The Emme product consists of a “smart” case for pills and an app that reminds users to take them. It connects users to a wealth of information and services, including a mood tracker. It’s been shown to reduce anxiety over

## Know the Signs of Heart Failure in Women

CLEVELAND CLINIC



“In my experience, the patients who have the hardest time understanding why they have heart failure when they’ve ‘done everything right,’ are very intelligent, STEM-focused women — and they are among the hardest for me to give that diagnosis to.”

Maria Mountis, D.O., is a cardiologist at Cleveland Clinic specializing in heart failure. She explained some distinct differences between women and men in why they experience heart failure, and when they present with symptoms. “Estrogen is the biggest player. In youth it’s a woman’s friend, protecting us from heart disease,” she said. “Once we start perimenopause and menopause, we begin losing that estrogen benefit and become more vulnerable.”

Though most women develop heart failure later in life than men, they often report symptoms sooner. “Women are often more tuned in to their bodies,” Dr. Mountis said. “They tend to not wait until they’re overloaded with excess fluid; they notice palpitations, shortness of breath, and their fatigue and stress levels.”

She emphasized the importance of knowing family medical history. “We can’t get away from our genetics,” she said. “But it’s not guaranteed that you’ll get heart failure because your mother or aunt did. Epigenetics also play a role, where gene expression can change from one generation to the next based on stress and environmental factors and even the gut biome.”

Dr. Mountis urges women to focus on prevention. “Women need to ask, ‘What is in my power to change this?’” she said. “Know your blood pressure and heart rate and keep them low. Keep an eye on your weight. Use the smartwatch, the wearables, the apps. Have basic blood work done by a professional to know your cholesterol, thyroid, blood sugar levels. You can be your own best advocate.”

Offering hope that genetic testing and personalized medicine will become routine in the future, Dr. Mountis added, “CRISPR [gene editing] is already on the horizon for treating amyloid cardiomyopathy, a type of heart failure that predominantly affects Black people. Innovations like this will change and level the playing field, in both health equity and in what’s possible.”

EMME INC.



ABOVE: The Emmé smart case for birth control pills relieves anxiety over medication compliance. RIGHT: The IFPx fluid pressure monitor and delivery system directly track heart congestion.

birth control pills, and during beta testing, an 80% reduction in missed pills among its customers was reported.

"Emmé's device is still in the market today," French said. "I'm so proud of it — we've crossed a million pills tracked at this point."

French took what she learned from Emmé about connected hardware devices and an understanding of how data can improve

quality of life to IFPx, where she has come full circle back to cardiology. "At IFPx, we're developing the world's first and only monitor that directly tracks congestion, the fluid overload that heart failure patients experience and the number one driver of their hospitalizations," she said. "Until now, there's been no direct way to track congestion, and so many patients struggle in silence until it becomes an emergency."

Now in its preclinical stages, IFPx's device is a subcutaneous monitor. Placed under the skin in a simple procedure, it measures the congestion and fluid pressure that cause frequent hospitalizations. "It gives both doctors and patients a better understanding of how to tailor medications and lifestyle adjustments for better-quality, longer life," French said.

The device is Bluetooth-enabled and automatically uploads data to clinicians. "Where patients often go to great effort to upload their data, we do it through

## Femtech: Products and Pioneers

In "The Role of Engineers in Women's Health," published by the National Academy of Engineering, Nicole Danos, Ph.D., wrote that because women are often the primary caregivers of the young and the elderly, "improved health outcomes for women are associated with improved life outcomes for all."

Here's a sampling of femtech innovations and researchers working for those better outcomes:

**Ava (Switzerland):** The first FDA-approved wearable for tracking fertility, Ava is a bracelet that tracks physiological signals and fluctuating hormone levels, letting the user know the optimal time to conceive. Visit [www.avawomen.com](http://www.avawomen.com).

**Marianna Alperin, Ph.D.:** Dr. Alperin's laboratory is developing evidence-based bioengineering approaches for pelvic floor reconstruction. Her research collects data on the biology of pelvic floor muscles throughout a woman's life and designs bioengineered solutions based on these data.

**Women of Wearables (WoW):** WoW is a global organization based in the U.K. connecting women entrepreneurs with health technologies and investors. Its website bursts with inspiring news about women's health technologies and

products addressing a full range of health issues unique to women in every stage of life. Visit [www.womenofwearables.com/wow-women-1](http://www.womenofwearables.com/wow-women-1).

**Make the Breast Pump Not Suck:** Affiliated with the Massachusetts Institute of Technology Media Lab, this group is a catalyst for breastfeeding innovations. Watch its documentary and hackathon: <https://makethebreastpumpnotsuck.com/>.

**Bloomer Tech:** A new bra is embedded with washable, flexible circuits that send cardiovascular data through an app, helping women and their care providers manage heart disease and improve heart health. Visit [www.bloomertech.com/](http://www.bloomertech.com/).

**Menopod:** Offering handheld relief for hot flashes, Menopod's copper plate drops to 41 degrees F (5 degrees Celsius) at the touch of a button, with no condensation, no need for refrigeration, and fast recharging. Visit <https://menopod.com/>.

**Ananya Health:** This company's product, CRCL, is a portable, user-friendly cryoablation platform for clinics that's been shown to prevent cervical lesions from becoming cancerous. Visit [www.ananya.health/](http://www.ananya.health/).



automation, so clinicians can quickly see when patients need more attention at home, instead of having them show up in the emergency room,” she said. “Proactive outreach is a much better experience for everyone.”

IFPx has published promising clinical research in the last year and has been presented globally at conferences. “Reception has been positive,” she said. “We’re continuing to develop the technology with a focus on that first clinical experience.”

While immersed in IFPx, French is also thinking about future projects. “Right now, I have a growing interest in solving the challenges that come with pregnancy,” she said. “I recently had my first child, and even though I’m spending

my career in women’s health, I found so much misinformation, confusion, and anxiety around all the choices you make when you’re pregnant.

“How can we improve access to information and the overall experience of pregnancy, labor, delivery, and postpartum aftermath? Now that I’m in this next chapter of life, I see what’s needed. And when you see unmet needs, you want to do something about it.”

For women engineers who may wish to join French in the field of femtech, she offers a word of advice: “Creative skills are something that you bring to everything in life,” she said. “With each project, it becomes easier to prototype, to come up with new ideas without fear of rejection because you know

it’s an iterative process. Ask questions [and] make connections because those conversations are what ultimately lead to innovation.” ✨

#### Sources:

[www.ncbi.nlm.nih.gov/pmc/articles/PMC3181845/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3181845/)  
<https://crowelec.com/engineering-areas-for-femtech-experts/>  
<https://uhnfoundation.ca/stories/uhns-medly-is-revolutionizing-heart-failure-care/>  
[www.dotlab.com/press-releases/clinical-validation-for-dotlab](https://www.dotlab.com/press-releases/clinical-validation-for-dotlab)  
[www.nae.edu/271946/The-Role-of-Engineers-in-Womens-Health](https://www.nae.edu/271946/The-Role-of-Engineers-in-Womens-Health)