Rapid advances in remote patient monitoring
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In medical parlance, “stat” means important and urgent, and that’s what we’re all about — quickly and smartly delivering good stories. We take you inside science labs and hospitals, biotech boardrooms, and political backrooms. We dissect crucial discoveries. We examine controversies and puncture hype. We hold individuals and institutions accountable. We introduce you to the power brokers and personalities who are driving a revolution in human health. These are the stories that matter to us all.

Our team includes talented writers, editors, and producers capable of the kind of explanatory journalism that complicated science issues sometimes demand. And even if you don’t work in science, have never stepped foot in a hospital, or hated high school biology, we’ve got something for you. The world of health, science, and medicine is booming and yielding fascinating stories. We explore how they affect us all. And, with our eBook series, we regularly do deep dives into timely topics to get you the inside scoop you need.
More medical care is being delivered virtually than ever before — and remote patient monitoring is making it possible.

Thanks to rapid advances in technology and significant investment, the field of remote patient monitoring, or RPM, has expanded dramatically in recent years. Medical device stalwarts, health care startups, and tech giants alike have moved into the space, armed with everything from smartwatches that can detect heart problems to connected inhalers that forecast the chance of an asthma flare-up.

The Covid-19 pandemic has accelerated the shift toward RPM and provided companies an unprecedented chance to prove their devices can make care more convenient, cheaper, or more effective. It has also opened the door for RPM to play a new and more pivotal role in clinical trials, as researchers look to keep virtual tabs on patients’ symptoms or progress.

As the sector continues to grow, companies working in remote patient monitoring will face several key tests. Can their technologies improve patient outcomes, or meet the same standards as traditional care at a lower cost? And how will they earn the trust — and backing — of payers, regulators, and patients?

Here, STAT has collected stories that examine the explosive growth in remote patient monitoring and the questions it raises about the future of health care.
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In early May, a wing of Ohio State University’s Wexner Medical Center was eerily empty. The space had been cleared of patients as the pandemic raged. But it wasn’t going to waste.

Inside, a group of nurse practitioners were playing a game of digital tag. Lauren Chrzanowski, who has type 1 diabetes, was wearing a continuous glucose monitor, an implant with a transmitter that sends real-time glucose measurements to a dedicated receiver — when they’re close enough, anyway. On that day, she was trying to figure out just how far away her CGM could be from its receiver and still work.

Hospitals around the country were racing to answer the same question. Normally, they monitor patients’ blood glucose with a blood test, taken several times a day. But as Covid-19 began to spread aggressively in the U.S., “we all started to look at each other and think, ‘How are we going to in good conscience put patients on IV insulin when the nurse will have to go in every hour?’” said Eileen Faulds, an endocrinology nurse practitioner who works with Chrzanowski at OSU.
The answer, in part, was remote monitoring. In April, the Food and Drug Administration made a call to temporarily allow hospitals to monitor blood sugar using CGMs — which are only approved for home use — until the public health emergency passed. By May, several hospitals around the U.S., including OSU, had received hundreds of free and low-cost CGM units from manufacturers including Abbott and Dexcom.

To use them with patients, they had to figure out how to adapt a device designed for at-home use — which is why the OSU team was playing tag.

While Chrzanowski stayed in a windowed patient’s room, Faulds zig-zagged around the floor, carrying the CGM’s receiver. From the nurse’s charting station outside the door, they learned, they could both check the receiver — about 10 feet away from the patient’s bed — and inject the needed insulin through 20 feet of tubing. Other hospitals simply taped the PalmPilot-like receivers up to the patients’ door frames.

Early data suggests those jury-rigged systems have improved care and outcomes for hospitalized patients. And some care providers think CGMs have the potential to improve inpatient outcomes if adopted more broadly.

While the FDA hasn’t approved CGMs for that purpose, data being collected on their use during the pandemic could help establish in-hospital remote glucose monitoring as the standard of care, ushering in a whole new market for manufacturers of those devices.

For individuals with type 1 diabetes (and some with type 2), the at-home advantages of CGMs are clear. An embedded sensor means no more constant finger pricks; instead, a small needle sits just under the skin, measuring a proxy for blood glucose in the interstitial fluid around the body’s cells.
Thanks to that stream of data, many people who use CGMs have displayed improved control over their blood sugar, which comes down to two numbers that appear on their receivers: average blood sugar, and how frequently that value falls within certain targets, called time in range. Both can be improved by changes in diet or insulin delivery.

And for individuals with diabetes, it seems, “the same things that allow you to improve time in range in the outpatient setting translates to the inpatient setting,” said Christina Astley, a pediatric endocrinologist at Boston Children’s Hospital.

Evidence of that was emerging before the pandemic. Standard practice is for patients to remove their CGMs when they enter the hospital, but some doctors such as Irl Hirsch had their patients keep them on.

“I have been known, for patients wearing Dexcom, to go ahead and share their data with me or the fellow on the service so we could make sure that they weren’t getting into any trouble,” said Hirsch, an endocrinologist at the University of Washington Diabetes Institute. “Though the fellows weren’t crazy about their phone beeping at three in the morning.”

Learning how to respond to those alarms, which go off when a patient’s glucose gets dangerously high or low, is one barrier to systematically implementing CGMs in hospitals. It takes time and money to get hospital staff trained and comfortable with using a new technology, though Faulds emphasized that providers have a vested interest in using technologies that reduce their workload and improve safety.

Then there are the technical issues — like those the OSU team encountered in May. Some CGMs have the ability to transmit results to a phone app, not just a receiver, and “the intention was that we would also use the phones,” said Faulds.
But they came loaded with SIM cards and data plans that could jeopardize the privacy of patient data. The team got stripped-down phones, but the majority of them still wouldn’t penetrate the hospital’s firewall. In the end, the only option was to use traditional receivers.

Despite these hurdles, many care providers and device manufacturers were advocating for inpatient CGM use long before the pandemic. What had kept them from moving forward is an even higher regulatory hurdle.

“There was a little of a chicken and egg problem,” said Matthew Taylor, a med-tech device analyst at UBS. “Dexcom’s talked about this in their past conference calls,” he said. In conversations with the company before the pandemic, “FDA basically said, ‘We think this is a good idea in terms of value for patients, but you need data looking at use of CGM versus not.’”

But because CGM has reliably improved outcomes for patients with diabetes, denying the tech to a subset of patients in a randomized trial could be unethical. Audra Harrison, an FDA spokesperson, said the agency couldn’t comment on ethical issues involving future data submissions, but said that sponsors “can choose the appropriate control group for their studies and endpoints.”

So far, though, few studies of CGM in hospitals have studied patient outcomes. “We’ve got 50-plus studies, even pre-Covid, for using CGM in the ICU, but they were really focused on accuracy,” said Faulds. CGM’s interstitial fluid measurements often require calibration against actual blood glucose, and patients encounter stressors and drugs in the hospital that could interfere with their accuracy. Still, said Faulds, “I don’t think accuracy is going to be the biggest issue; I think it’s just proving how that ties to patient outcomes. We need outcomes data.”

In a silver lining, the pandemic is providing some of it.
“The pandemic has given [manufacturers] kind of a backdoor to be able to generate data,” said Taylor. Along with partners at Mount Sinai, Emory, Stonybrook, and NewYork-Presbyterian hospitals, OSU is pooling data about inpatient outcomes during the crisis.

“It’s not a randomized controlled trial, you know, we don’t have controls here, which is going to be the issue,” said Faulds. “But if we can get all of these institutions to publish our data, I’m hoping that they continue to allow us to use the devices.”

While robust results will take more time, small studies based on in-hospital CGM use during the pandemic have already pointed to better outcomes. At Scripps Whittier Diabetes Institute in San Diego, 110 non-ICU patients with type 2 diabetes on average saw reduced blood glucose levels and improved time in range. In a similar patient group in Baltimore, a randomized controlled trial showed that CGM use reduced instances of hypoglycemia, or lower-than-normal blood sugar levels.

Meanwhile, Dexcom is running its own registry to track outcomes. “This is something that Dexcom is taking very seriously to develop pathways to improvement,” said Tomas Walker, the company’s U.S. medical director.

“We have a very close relationship with the FDA, and we’re always working with our regulatory bodies to maximize what we can do for patients,” he added.

“I think the most likely outcome is that [FDA] will ask for more data of some kind to make the approval permanent and official,” said Taylor. He added that it still isn’t clear what format that data might take, such as a registry or new studies. “We encourage the collection of data on the safety and effectiveness of these devices in the hospitalized population,” said Harrison. “Provided their use is safe, such data may be helpful in supporting clearances or approvals of these devices for this use in the future.”
To Faulds, a permanent FDA greenlight to use CGMs in the hospital would be a big step forward.

“I’ve done inpatient diabetes management for eight years,” said Faulds, “and I can’t even tell you how this would change nursing practice. It would change the way we manage patients in the hospital, it would be huge. I have no doubt that this is the future of glucose management.”
Apple Watch research plows ahead, revealing the device’s health potential

By Mario Aguilar  @MARIOJOZE  MARCH 3, 2021

Apple has marketed its Watch for years as a tool to monitor and improve your health — and is working on a growing number of research projects to prove the device’s medical applications can be useful in both people’s everyday lives and in clinical contexts.

Across the board, part of what makes Apple’s devices compelling for health is the company’s reach: millions of people are using its phones and watches every day. If Apple can figure out a way to nudge behavior in a positive direction or reliably monitor for disease symptoms, its potential impact at a population level is enormous.

Here’s a rundown of some of the most prominent Apple Watch research efforts.

HEARING HEALTH

On Tuesday, Apple released a smattering of new findings from its ongoing Hearing Study with researchers at the University of Michigan School of Public Health.
The study, first announced in September 2019 and conducted through the Apple Research App uses data about environmental noise collected from users with an Apple Watch as well as information about how loud people are using their headphones. Participants who choose to share the most detail with researchers also complete regular hearing tests and questionnaires.

The results show many people are exposed to sound at higher levels than recommended by the World Health Organization, which puts them at risk of hearing loss. About 25% of participants exceed daily environmental noise recommendations while about 10% exceed the weekly headphone exposure limit.

The new research follows an update released in the fall showing that stay-at-home orders cut environmental noise exposure nearly by half in the early months of the pandemic.

In a briefing on the new findings, University of Michigan’s Rick Neitzel was careful to note that notifications and other prompts could help steer people to listen at lower levels or take precautions in noisy workplaces. The study has an arm investigating whether people who receive more information about their sound exposure will turn down their tunes.

**HEART AND RESPIRATORY CONDITIONS**

Heart health has been a focus of Apple’s research since at least 2017 when the company embarked on its [Heart Study with Stanford](http://www.heartstudy.com), which ultimately confirmed that the Apple Watch could be used to identify irregular heart rhythms that are the hallmark of atrial fibrillation. More than 400,000 people enrolled in the study, making it the largest ever virtual study at the time the findings were published in 2019.
Building on this work, Johnson & Johnson in collaboration with Apple, launched the Heartline study in 2020. Focusing on adults 65 and older covered by Medicare, the study aims to see if the Apple Watch’s irregular heartbeat notifications and electrocardiogram feature can, for example, reduce the risk of stroke by detecting atrial fibrillation. The study is expected to take several more years.

And a newly launched study with Toronto’s University Health Network will look into whether the Apple Watch can be used to detect signs of worsening heart failure, harnessing the Apple Watch’s new ability to track blood oxygen levels. Also tapping into the Apple Watch’s new blood oxygen monitoring is a randomized control study with Anthem and the University of California, Irvine, which is designed to see how digital tools and Apple’s devices can help people manage their asthma.

PARKINSON’S AND ALZHEIMER’S

Apple’s work could also be a boon for its research on trickier disease areas, such as Parkinson’s and Alzheimer’s disease.

In February, Apple researchers, in conjunction with scientists at several universities and neurology clinics, published a study that showed the Apple Watch can remotely track the motor symptoms of the disease. By monitoring tremors and other movements, the researchers were able to identify the characteristic “on” and “off” periods of a medication’s effects.

That capability could one day help improve treatment for people suffering from the disease by giving doctors an objective, all-day view of someone’s condition, as opposed to the snapshots they see in occasional clinical visits.
A **new Biogen** virtual study in collaboration with Apple, meanwhile, aims to find ways to use the Apple Watch and iPhone to screen for signs of cognitive decline. This could be used to identify digital biomarkers that indicate mild cognitive impairment, the elusive early sign of disorders like Alzheimer’s disease.

In the case of both diseases, developing robust remote monitoring systems with the widely available Apple Watch could speed up the development of new treatments by making it easier for people to participate in virtual clinical trials.

**WOMEN’S HEALTH**

Launched **at the same time** as the Hearing Study, the Women’s Health Study has yet to release any findings but has wide-ranging objectives. Conducted in collaboration with the Harvard T.H. Chan School of Public Health and the National Institute of Environmental Health Sciences, the study **hopes to** “gain a deeper understanding of how certain demographic and lifestyle factors could have an impact on menstrual cycles and gynecologic conditions including infertility, menopause, and polycystic ovary syndrome (PCOS).”

The study will rely on cycle tracking and other health data from the iPhone and Apple Watch as well as survey responses.
Apple’s quest to put a smartwatch on every wrist continues with its latest health research: a new study showing the Apple Watch can be used to monitor symptoms of Parkinson’s disease.

Researchers at Apple, working with specialists who treat Parkinson’s, designed a system that uses the Apple Watch to detect the motor symptoms that are a hallmark of the neurological disease. By monitoring resting tremors and other involuntary movements, the researchers were able to identify the characteristic “on” and “off” patterns of medication’s effects. Their findings were published Wednesday in Science Translational Medicine.

The research could be a boon to both clinical trials and care for the millions living globally with Parkinson’s. If further developed, the researchers’ system could be used to capture round-the-clock objective measurements of symptoms with the Apple Watch. Specialists often rely on infrequent clinical visits and self-reporting to monitor the disease’s progression and the impacts of medicine. While there are specialized devices in the market that can do such monitoring, there are advantages to using a gadget people recognize and feel comfortable around.
“Having the ability to take a commonly available device that’s already out there like an Apple Watch … and be able to do this type of monitoring is really nice because you’ll be able to give the clinicians who are caring for these people in their home a much clearer idea of what’s going on throughout the cycle of the day,” said Michael Okun, executive director at the Fixel Institute for Neurological Diseases at the University of Florida and national medical advisor for the Parkinson’s Foundation. Okun was not involved in the new research.

The new system, called the Motor Fluctuations Monitor for Parkinson’s disease (MM4PD), uses the Apple Watch’s accelerometer and gyroscope data to detect the presence of resting tremor or dyskinesia. Resting tremors, which can affect the hands, legs, and other parts of the body, are a common symptom of Parkinson’s. Dyskinesia, another type of involuntary movement, is a frequent side effect of medication used to treat the disease.

The algorithms underlying the model were developed using data from a pilot study with 118 people in which researchers matched subject’s smartwatch data to a scoring system called MDS-UPDRS Part III, the gold standard by which motor symptoms of Parkinson’s are measured.

Three movement disorder specialists rated video recordings of subjects, which were time-aligned with the smartwatch data, against the standard scoring. The pilot study was extended for one week of regular use to assess how the algorithm worked in real-world scenarios.

Following the pilot study, the researchers tracked 225 people with Parkinson’s disease for up to six months. Then, they used that measurement data to create symptom profiles. Those were evaluated by clinicians to see if MM4PD could be used to identify symptom response to treatment changes and more broadly whether the system might be used as a decision support tool.
The authors say that the measurements helped spot symptoms missed in regular care and identified changes after subjects underwent surgery for deep brain stimulation. The paper also suggests the tool helped pinpoint people who slipped on medication adherence, as well as cases in which a person might benefit from a modified medication regimen.

The researchers also looked at data from a control group of 171 older subjects without Parkinson’s, who were monitored for up to 12 months. In the pilot study, 36 participants were women and 82 were men. In the longitudinal study, 69 participants were women and 156 were men. The researchers did not report on the race or ethnicity of the subjects.

Doctors tasked with treating people with Parkinson’s are confronted with both many variables and imperfect information. Symptoms of the disease vary from person to person and can change over time as the disease progresses. Treatment plans are complex and highly personalized, and medical appointments provide only narrow snapshots of symptoms.

The researchers say using a device like the Apple Watch could help fill in some of the gaps in observation so that specialists can better tailor treatments to symptoms and outside experts agree.

“The hope is that some of this technological innovation will help in the areas of better tracking medications, better tracking symptoms, and having more real-time control over this because it’s complicated,” said Okun. “And you’re hoping that these systems are going to make it easier both for persons with diseases like Parkinson’s, but also for practitioners managing them.”

Continuous monitoring of symptoms could be useful for clinical trials as well, with the added benefit that it could help enroll more subjects who may have trouble with frequent visits to clinics.
Claudia Revilla, who was diagnosed with Parkinson’s in 2010 and serves on the Michael J. Fox Foundation’s Patient Council, told STAT that based on her experience with doctors and clinical trials, having objective measurements from a smartwatch could be “a big advantage.” She lives in Peoria, Ill., and drives three hours a few times a year to Chicago see her movement disorders specialist.

“We as patients can forget or can avoid discussing certain things,” she said. When she gets to appointments, she sometimes initially responds to doctor’s questions by saying that everything’s fine. “I don’t have a smartwatch for that purpose, but I have my husband,” He’s quick to clarify the situation: “Oh, no, that’s not true. You should see her in the morning,” he’ll say.

“The smartwatch is going to be… an additional witness, more evidence of what’s really going on with you,” she said.

Apple, which declined to make its researchers available for an interview, hasn’t expressed plans to create any kind of Parkinson’s monitoring system within the Apple Watch as it has for certain heart conditions. The paper’s authors also noted that FDA clearance may be necessary before their system can be used for clinical trials.

If it is to be used more broadly, though, the Apple researchers caution that there are limitations to MM4PD, including that the system focuses on only two motor symptoms. The watch also focuses on the wrist as a single observation point, which means it may not capture symptoms elsewhere on the body.

K. Ray Chaudhuri, a professor of neurology who treats people with Parkinson’s at King’s College, said that while it’s notable that the study addresses the “on” and “off” fluctuations experienced by people with Parkinson’s, not everyone experiences such fluctuations, and among those that do, it doesn’t always impact movement.
“So you have motor fluctuations, you have non-motor fluctuations, and the two usually go together but the pattern is very different,” he told STAT. A small percentage of people experience only non-motor fluctuations, according to Chaudhuri. “So what this device or this technique is validating is really the amount of fluctuation when this is defined by tremor when off [and] dyskinesia when on,” he added.

The paper acknowledges that MM4PD cannot monitor non-motor symptoms that can impact quality of life.

Chaudhuri’s clinic uses the PKG watch from Global Kinetics to monitor a patient’s motor symptoms, which also allows them to track sleep trends. And he’s studied using digital sensors to monitor bowel sounds, gait, and eating behaviors in people with Parkinson’s.

While devices like the Apple Watch may be widely distributed in the United States, Chaudhuri noted that Parkinson’s is a global problem with rates expected to increase significantly in coming years. “The largest impact of this will be felt in many countries where the standard of living is not very high. So that applicability and availability of a smartwatch or smartphone is very restricted and limited,” he said.

It’s also important to design digital systems so that they can be used by people with tricky symptoms. “You have to be conscious about how much you’re asking them to do [in terms of] monitoring, and particularly when they’re on and off, you know, even [using] a smartphone may not be very easy.”
Teladoc is teeing itself up to remain a dominant digital health provider long after the worst of the pandemic subsides.

The telehealth giant, like many other virtual care companies, has seen its business boom with the flood of patients turning to virtual appointments as the crisis continues. In a post-pandemic world, though, Teladoc will face challenges as in-person clinics and hospitals reopen their doors and virtual care is no longer the only means of getting health care. To capitalize on its success and grow its member base ahead of time, the company is adding new high-profile clients, increasing its average deal size, and selling itself as a one-stop shop for multiple health needs.

“Post Covid, their potential advantage is that they can manage patients remotely through their whole lifecycle,” said Matthew Holt, a health technology consultant.

If 2020 provides any indication of where things are going for Teladoc in the years ahead, the future is rosy.
The company added several high-profile clients, steadily increased its revenue, and boosted bookings in 2020, especially for those that included multiple chronic and primary-care products, Teladoc chief executive officer Jason Gorevic said during a presentation at the 2021 JPMorgan Healthcare Conference.

“We are still just scratching the surface,” Gorevic said. “There is a tremendous opportunity to expand our membership.”

Having already seen steady gains in visits and paid memberships since 2014, Teladoc was in a good place to solidify its presence as a powerful virtual care player during the pandemic. The crisis quickly led the federal government and some states to loosen the stiff guidelines around telehealth provision and reimbursement. Suddenly, millions of people in the U.S. began turning to virtual care for everything from everyday problems to consistent issues.

For its part, Teladoc’s number of visits more than doubled, from 4.1 million in 2019 to an estimated 10.6 million in 2020, according to a slide shared during its JPM presentation, and its membership figures increased from 36.7 million to an estimated 50-51 million.

“People woke up in 2020 to the power of virtual care,” Gorevic said.

That could continue to boost the company in the long run, said Holt. “Teladoc has now had this big shot where everyone knows what telehealth is.”

Teladoc also added four new major clients to its customer portfolio in 2020, including Geisinger health system and Tyson Foods, according to its slides, and doubled its revenue from $553 million in 2019 to an estimated $1 billion in 2020. Last year, two-thirds of Teladoc’s deals included bookings for multiple products, which rose 35% year over year, according to the slides.
Despite the availability of telehealth services like Teladoc during the pandemic, however, care for chronic conditions including diabetes, cancer, and hypertension slumped, according to research published in October in the journal JAMA Network Open. One big potential reason: doctors couldn’t perform blood pressure and glucose tests remotely.

That’s an area where Teladoc has the potential to tower above its rivals, according to Arielle Trzinski, senior health care analyst at Forrester. When Teladoc acquired chronic virtual care company Livongo last year, it also inherited a suite of connected devices that includes connected blood pressure cuffs and glucose meters — all tools that could help customers avoid dangerous lapses in care and unnecessary doctor’s visits.

“It enables them to do more continuous monitoring and more virtual-first primary care,” Trzinski told STAT in August.

Teladoc’s current dominance doesn’t guarantee it an easy path ahead, however. The company will need to prove to payers and patients that it can significantly reduce health care spending by helping customers avoid expensive procedures such as surgeries, and that it can successfully treat a variety of conditions on a virtual-first basis.

There are also a series of nationwide regulatory questions that could tip the balance for or against virtual care, including whether the Biden administration will make permanent the regulatory changes that increased its availability and whether the government will move to make broadband more readily available in rural and low-income parts of the country.

Looking ahead, Gorevic emphasized in his JPM remarks that Teladoc has the ability to use digital tools as a means of centering people’s homes as a primary site of care.
And if past acquisitions are any indication, Teladoc is poised to bring in other companies with additive, cost-cutting strengths in the future.

“When you think about combining the capabilities of InTouch Health, the capabilities of Teladoc Health, the capabilities of Livongo,” said Gorevic, “that is really the promise of the hospital in the home that will transform how care is delivered.”
In the last decade, the accessibility and use of actigraphy and physical activity tracking devices has dramatically increased in clinical research. From 2009 to 2019, there was a nearly 130 percent increase in registered active or recruiting Phase I–IV clinical trials that included actigraphy endpoints. Actigraphy measures and devices now offer researchers and sponsors the opportunity to address the shift toward patient-centric drug development, digital technologies, and remote measurement.

**THE FIELD OF ACTIGRAPHY**

A non-invasive method of collecting accelerometer data, actigraphy is leveraged in clinical trials requiring sleep and activity measures. Depending on a study’s objectives, data is typically gathered over a period of one to two weeks through a three-axis accelerometer, which may come in the form of a device worn on the wrist, waist, or ankle. With validated algorithms, trial teams can utilize devices’ dense raw and epoch data to produce valuable derived measures, including step count, activity intensity, and nighttime awakenings. This is where the field of actigraphy has shown tremendous growth—endless algorithm options available for unique study designs and age groups, diseases, and other measures of interest.
SIGNIFICANT STUDY BENEFITS

The field of actigraphy is beginning to embrace wearable technology to not only produce sensitive measures but also work around obstacles such as subjective patient reported outcomes and remote data collection that plague drug development research in multiple therapeutic areas. Actigraphy measures can benefit studies as primary or secondary efficacy endpoints, direct measures, supporting corollary measures, screening measures, or extensions of clinic-based assessments like the UPDRS and six-minute walk test. The introduction of digital devices means actigraphy has the potential to accelerate drug development timelines, enhance treatment efficacy, and help teams better manage project budgets.

Actigraphy devices, often with water-resistance properties for use during all activities of daily life, help studies gather dense data from patients in natural settings both remotely and continuously. Sensors in non-invasive wearable devices offer an objective alternative to patient reported outcomes like pain that are traditionally subjective. This alone can simplify study designs, improve patient experiences, and allow researchers to obtain data they may not have collected otherwise. In terms of patient satisfaction, actigraphy devices are more likely to produce ideal experiences and outcomes when they come equipped with a longer battery life, remain easy for patients to use, and integrate into everyday routines with little effort. Consumer grade devices finding success in clinical trials also give patients more autonomy in their healthcare journey and some control over appearances that would indicate study participation to the outside world.

EXPANDING OPPORTUNITIES

Deploying actigraphy in clinical trials necessitates careful planning: considering study objectives and patient populations, configuring devices and algorithms, navigating required measures, educating and supporting patients, and effectively collecting data.
But the industry and the regulatory agencies that govern it are anticipating expansion in the variety of applications that actigraphy endpoints can serve, especially during a time when in-clinic observations are limited and healthcare consumers are expressing interest in receiving convenient in-home care. As sponsors and vendors look for opportunities to incorporate physical activity tracking and actigraphy wearables, available tools and strategies will continue to improve the accuracy and efficiency of the health data bringing new treatments to patients who need them most.

Learn more about Koneksa’s digital biomarker platform, including actigraphy tools for clinical trials, at koneksahealth.com.
Telemedicine has become a lifeline during the Covid-19 pandemic, but it is not enough help for many patients whose medical needs demand in-person care.

It is that yawning gap in service that ex-Uber Health leader Dan Trigub and partner Inna Plumb are targeting with a new company called MedArrive, which was launched out of stealth mode Thursday. The startup will use paramedics and EMTs to deliver home-based care — from vaccinations and diagnostic testing to fall prevention — under the remote supervision of physicians. It plans to begin providing services early next year.

“In the long term, we absolutely believe a person’s home will become the center of the health care system,” said Trigub, the company’s chief executive. “For us, it’s really being the bridge between on-site clinical care and traditional telemedicine as we know it today.”

Now seems an ideal time to launch such a company, as hospitals nationwide are scrambling to care for more patients remotely amid a shortage of beds for Covid-19 patients. The Centers for Medicare and Medicaid Services also just expanded regulatory leeway for providers to allow for more patients to be cared for in their homes.
But like any health care startup, MedArrive must carve out a specific niche within the existing delivery system and convince providers and insurers that its service can target, and effectively treat, the right population of patients. The new company also faces competition from existing home care agencies, providers who are delivering remote services on their own, and other upstarts, such as Medically Home, which provides virtual hospital care in patients’ homes.

“They are not the only ones doing something like this,” said Harold Miller, chief executive of the Center for Healthcare Quality and Payment Reform, a research organization based in Pittsburgh. “The question becomes, how do I know this service is better than the nurse we’re already employing?”

Plumb, who will serve as chief operating officer of the company, said MedArrive seeks to reduce the cost of in-home care by relying on a workforce of paramedics and EMTs who cost less than clinicians to pay. She said the company will combine those workers with telemedicine services and an interoperable record-keeping and routing system to deliver a service that can integrate with existing providers and insurers.

“It gets you to a high-quality clinical experience in the home, but at a really cost-effective price,” said Plumb, who was previously director of supply chain strategy for the meal delivery service Blue Apron.

Trigub left Uber Health in September, after leading it through a period of rapid growth by partnering with more than 1,000 health care organizations to expand its nonemergency medical transportation business.

MedArrive has not announced partnerships with private EMS companies, but says it has developed a network of more than 20,000 providers. It is backed by Redesign Health, an incubator that funds early-stage companies. The company has also raised seed funding from the venture capital firms Kleiner Perkins and Define Ventures.
Trigub said the company does not intend to sell its services directly to consumers, but to partner with insurers and providers who are seeking to deliver timelier and more effective care to patients remotely. He said MedArrive is fundamentally a software company that will focus on helping hospitals prevent readmissions and provide better transitional services for patients following surgeries or other episodes.

“Those are extremely important use cases for any kind of risk-bearing player,” Trigub said, adding that the company has drawn interest from a mix of providers and payers, including Medicare Advantage plans and managed Medicaid organizations. “Regardless of who we’re talking to,” he said, “everyone has identified that this push into the home is critical, especially with the tailwind of Covid.”

Trigub said the company’s service model aims to make care more widely accessible, especially to low-income patients and underserved rural communities that might lack community hospitals, but where EMTs and paramedics are still present.

MedArrive intends to roll out its services initially in Florida, where it sees opportunity to assist large populations of elderly people and managed Medicaid patients. “We’ve got to be laser-focused as a company getting off the ground,” he said. “Florida is a place we want to start, but eventually we do want to scale beyond that.”
The pandemic has driven unprecedented demand for remote patient monitoring tools. But for all their tech-savvy convenience, they have yet to overcome major barriers that prevent their adoption among larger swaths of the U.S. population.

Once dominated by bulky devices designed for patients with a narrow set of severe chronic disorders, the RPM space has boomed in recent years, with tech giants and medical startups racing to develop everything from virtual diagnostics to health trackers. But the field still faces several big hurdles to reach its true market potential, from limited internet and device access among rural and low-income populations to public wariness around new tools and looming concerns about privacy.

Those challenges have proven difficult to address — and raise significant concerns about whether digital health tools may be poised to narrow or widen existing health disparities, particularly along the lines of race, age, geography, and income.

Here’s a look at some of the most significant challenges to broader RPM adoption.
INTERNET ACCESS

Most remote patient monitoring tools rely on patients having consistent internet access to broadband, a fast and reliable internet connection that 25 million people, or 13% of the U.S. population, do not presently have. The problem is especially dire in rural parts of the U.S., where roughly 1 out of every 3 people doesn’t have broadband access, according to a 2019 Pew Research Center survey.

Even in households with internet access, many people still lack individual access to their own laptop or smartphone, making the idea of conducting a sensitive appointment like a virtual therapy session, for example, seem far-fetched without extensive steps to protect privacy and confidentiality.

TECHNOLOGY UNREADINESS

There are further hurdles among older adults, many of whom don’t feel comfortable using digital devices or lack the tools outright. An estimated 38% of older adults in the U.S. say they can’t currently conduct a video visit — either because they have no internet-enabled devices, are hesitant to use them, or have difficulties hearing, communicating, or seeing, according to an August 2020 study published in the Journal of the American Medical Association.

On the positive side, the study’s authors concluded that adding accessibility features, such as closed captioning, could help address some of those obstacles and enable more older adults to use remote tools. Among the Medicare population, even fewer older adults have access to the necessary devices: In 2018, roughly 25% of Medicare enrollees owned neither a computer with a high-speed internet connection nor a smartphone with a wireless plan, according to another JAMA study published in August. Many of those same individuals already face barriers to care having to do with being systematically denied care due to their race and socioeconomic status, the study authors found.
“Although many older adults are willing and able to learn to use telemedicine, an equitable health system should recognize that for some … telemedicine may be impossible,” the authors of the latter study wrote.

CONSUMER CONCERNS ABOUT PRIVACY

Privacy concerns, too, pose a potential hurdle to the broader uptake of remote monitoring tools. While patients have in recent years grown more accustomed to the notion of sharing sensitive information with clinicians and medical device manufacturers, most people have not had time to fully comprehend the significance of the rush of new entrants to the field, which include tech giants like Google and Facebook. There are still critical questions, for example, around who actually owns health data and what can happen if — or when — that information is shared with external parties.

Facebook, for example, can receive personal health data including heart rate and menstrual cycles from dozens of popular third-party apps, often without users’ awareness, a 2019 investigation in the Wall Street Journal found.

For the remote patient monitoring industry to reach its full potential and avoid exacerbating existing health disparities, the players in the space will need to start addressing each of these obstacles. And while it remains to be seen just how each startup or tech giant will tackle these issues, many companies are relatively early in their digital health journeys, suggesting that many changes lie ahead.
As part of its landmark $18.5 billion deal to buy Livongo, telehealth giant Teladoc Health is poised to inherit a set of devices that the chronic care company has used for years to turn mountains of patient data into easily digestible health advice.

The technology — which includes connected blood pressure cuffs, glucose monitors, and weight scales — will be a key asset for the newly combined company, which will be called Teladoc. Not only does the trove of devices better position Teladoc to deliver chronic care, it also tees up the company to fully enter the remote monitoring space.

Remote monitoring has become a hot spot for the booming virtual health business, driven simultaneously by a global pandemic that has impeded access to physical clinics and a growing class of patient-consumers that want more control over their care. Health tech companies focused on remote monitoring have raised millions in recent months, while large hospital systems are flocking to the devices as a means of protecting clinicians and patients from Covid-19.
The tools offer another boon to Teladoc: They don’t require clinicians. Instead, the devices rely on a network of health professionals — including registered dietitians and certified diabetes educators — who are charged with translating the data generated by the devices into insights patients can act on. Prior to its deal with Livongo, the bulk of professionals Teladoc contracted with were physicians. Now, industry experts say the company can expand more rapidly by opening up its ranks to a broader range of workers.

“It makes health care more scalable and brings down the cost of managing patients — we’re not looking at paying physician salaries, but coach salaries,” said Arielle Trzcinski, senior health care and technology analyst at Forrester.

The deal enables Teladoc to offer what Chief Operating Officer David Sides calls “a new stepped care model” that starts with digital coaching and escalates to connecting patients with clinicians “when necessary.”

Livongo is one of a handful of prominent players in the industry harnessing connected devices to deliver health insights. Other diabetes-focused virtual care companies including Omada Health and Onduo similarly collect reams of data on patient behavior. Both companies use artificial intelligence to ping patients with health reminders and flag those who need additional support. If a patient’s blood glucose readings are consistently high late at night, for example, a health coach might reach out to that patient to suggest making a smaller dinner or balancing a meal with fewer carbs and more lean proteins.

Both companies make money by contracting with employers and health plans, which see the disease management platforms as a potential way to lower health spending in the long run.

But Livongo is unique in that its gadgets are proprietary, an asset that may have made the company a more appealing purchase for Teladoc than other virtual care providers.
Livongo built much of its device arsenal by acquiring smaller companies, such as Retrofit, which includes a Bluetooth-enabled weight scale in its weight-management offering, and EosHealth, maker of a connected glucose meter. (Former Livongo chief executive officer Glen Tullman, who had previously invested in EosHealth, relaunched the company as Livongo when he joined as CEO.)

“Livongo figured out the value they can get out of devices,” said Bill Evans, chief executive officer and managing director of digital health focused venture capital firm Rock Health.

For the newly combined company, there’s still a question of how the devices will fit into the picture. Teladoc could sell the tools directly to patients — as Livongo did — or to clinicians with brick-and-mortar practices. Or, the combined entity could merely integrate the devices into their existing care platform without charging an additional fee.

“I see it plugging nicely into their existing care spectrum,” Trzcinski said. “It enables them to do more continuous monitoring and more virtual-first primary care.”

There are some signs that Teladoc had been working on shoring up the data from digital tools into its offerings before the deal with Livongo. The company has a partnership with TytoCare that enables clinicians to send patients home monitoring kits containing stethoscopes and cameras. Teladoc also teamed up with smart thermometer maker Kinsa to monitor patients’ temperatures remotely.

The new deal, however, is a more direct and assertive play — and one that better cements Teladoc in the remote monitoring and chronic virtual care landscape.

“It’s the beginning of a new era in digital health,” said Trzcinski.
Remote monitoring is rapidly growing — and a new class of patient-consumer is driving the shift

By Erin Brodwin  @ERBROD | SEPTEMBER 16, 2020

A cardiac patient in Carlsbad sends their doctor in San Francisco a readout of their heart rate, courtesy of an Apple Watch. A New Yorker with hypertension texts with an Alabama health coach about data from their smart blood pressure cuffs. A person with diabetes snaps a photo of their dinner and uses an app to predict how it will impact their blood sugar.

Health care is undergoing a monumental shift toward remote patient monitoring — and a new class of patient-consumer is leading the charge, according to a new STAT report. The transformation — which began years ago as healthy people moved to optimize wellness and people with chronic conditions pushed for more convenient care — has taken on a more permanent tone amid the Covid-19 pandemic.

“Millions of Americans suddenly asked themselves, ‘Can I solve this care need without showing up in person?’” said Sean Duffy, chief executive officer and co-founder of Omada Health, a virtual diabetes care provider. “That consumer expectation change is going to be the thing that writes history the quickest.”

Tech giants and virtual care companies alike are rushing to meet that demand.
For established companies like Apple, Amazon, and Alphabet, the exploding popularity of health tracking is a boon to their push to make sizable inroads in health. Those companies are courting the new patient-consumer with a device-first strategy, transforming their bestselling wearables into health tools with medical capabilities.

Meanwhile, health tech companies like diabetes care providers Omada Health and Livongo are taking a platform-driven approach, catering to patients with remote monitoring programs that connect them with health professionals and provide useful data.

**THE TACTIC AMONG TECH GIANTS**

Tech companies are starting to chart their path to remote monitoring by transforming consumer gadgets to medical devices, with an eye on clinical evidence.

Apple was the first to enter the space this way, publishing a large and entirely virtual clinical study of its Apple Watch and embedded electrocardiogram, or EKG, which records the heart’s electrical signal. The study, which Apple brought to the Food and Drug Administration as part of its work to get the watch cleared as a medical device, showed the device could spot the heart condition atrial fibrillation, or A-fib. Fitbit, which was acquired by Google last year, is following the same path. The company launched a similar virtual study of its wearable in A-fib in May and plans to present the data to the FDA.

Even Facebook, which has yet to make its own wellness wearable, appears to be edging toward the heart monitoring space. In May, the social media giant formed a new team dedicated to health technology under the leadership of Yale cardiologist Freddy Abnousi and posted job ads for positions that include an expert in photoplethysmography, the same type of technology that Apple and Fitbit use for heart monitoring, and an expert skilled at interfacing with regulators like the FDA.
The tech- and consumer-driven shake-ups are already creating ripple effects throughout the health care system. Clinicians, for example, are increasingly being asked to interpret the results of Apple Watch EKGs in patients who are hesitant to come in for a visit during the pandemic.

“You’re really seeing a shift where it’s consumers and consumer electronics deciding things more than a doctor deciding which device to use,” said Ritu Thamman, cardiologist and assistant professor of medicine at the University of Pittsburgh School of Medicine. “We’re being pushed by the consumers themselves, and that’s creating the competition and the drive to create the best user experience.”

Still, by focusing on building out device capabilities — instead of creating comprehensive virtual health platforms that pair with devices — tech giants have created a new set of challenges. Without being connected to any sort of system, it remains unclear how, exactly, the devices will ultimately fit into a user’s care continuum. If Apple, Fitbit, and other big tech companies intend for their tools to remain relevant to users’ health for the long term, they’ll need to start integrating them with platforms that can help guide their care.

“Just because you have a watch that tells you things doesn’t mean you have remote monitoring. The platforms and the integration need to start,” said Mintu Turakhia, a cardiologist and executive director of Stanford Medicine’s Center for Digital Health.

Amazon’s new wearable, called Halo, may be a first step in this direction. Although the device does not currently have any medical diagnostic capabilities, it lets users share their body fat percentages with clinicians through an integration partnership with electronic medical record vendor Cerner.
Virtual care businesses, in contrast to tech giants, are jumping into the health tracking space with a platform-centric strategy. Companies including Omada, as well as Alphabet subsidiaries Onduo and Verily, offer care delivery programs that harness remote monitoring hardware made by other companies and use fleets of faraway health coaches to help patients interpret and understand their data.

Those devices — which include Bluetooth-enabled weight scales, blood pressure cuffs, and glucose meters — are connected to the company’s platform, where clinicians and coaches take a patient’s data, contextualize it, and use it to offer advice or guide a person’s care. Unlike tech giants and medical device makers who acquire customers by selling devices, these companies acquire patients by way of partnerships with employers, insurers, and health plans.

But virtual care companies’ business models often rely on reimbursement or buy-in from health insurers or employers, meaning their success depends on being able to consistently demonstrate their effectiveness with research. And while many of these companies have published small and short term studies, academics and researchers say larger and more comprehensive research is needed.

“There’s very little clinical trial data” for remote devices, Turakhia said.

The rise of the patient-consumer is also placing new pressures on more traditional health care players, including established medical device makers. Industry stalwarts like Philips and General Electric, for example, are being forced to consider fundamental changes to their business structure aimed at better serving the patient-consumer instead of the hospital or clinic.

“We are definitely thinking about ways to reach outside hospital walls,” said Anders Wold, vice president and chief executive officer of clinical care solutions at GE Healthcare.
Regulators have begun to respond to these changes in recent months with a mix of temporary and permanent policies geared at making remote monitoring tools more widely accessible. For example, the FDA introduced a series of pandemic-era authorizations that increase patients’ ability to use remote health tracking tools at home, including the EKG-containing Apple Watch and Livongo’s glucose meters. And starting last year, the Centers for Medicare and Medicaid Services began reimbursing providers who use remote monitoring tools with new billing codes explicitly focused on remote health tracking, including codes that focus on weight and blood pressure.

If those changes are to have real sticking power, however, companies including tech giants and health tech providers will need to figure out how to make their devices an established, long-term component of the existing health care system, rather than simply a temporary or one-off solution.

“There are a lot of consumer devices out there with [FDA] clearance,” said Turakhia. “But when you’re talking about remote patient monitoring, you’re really talking about the whole system.”