

# The Journal of mHealth

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## DIGITAL FIRST

The New Normal for Healthcare

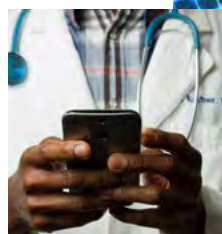
### RESEARCH

A Growing Demand for On-Demand Care



### TELEHEALTH

Does this mean the end of the Doctors' Waiting Room?

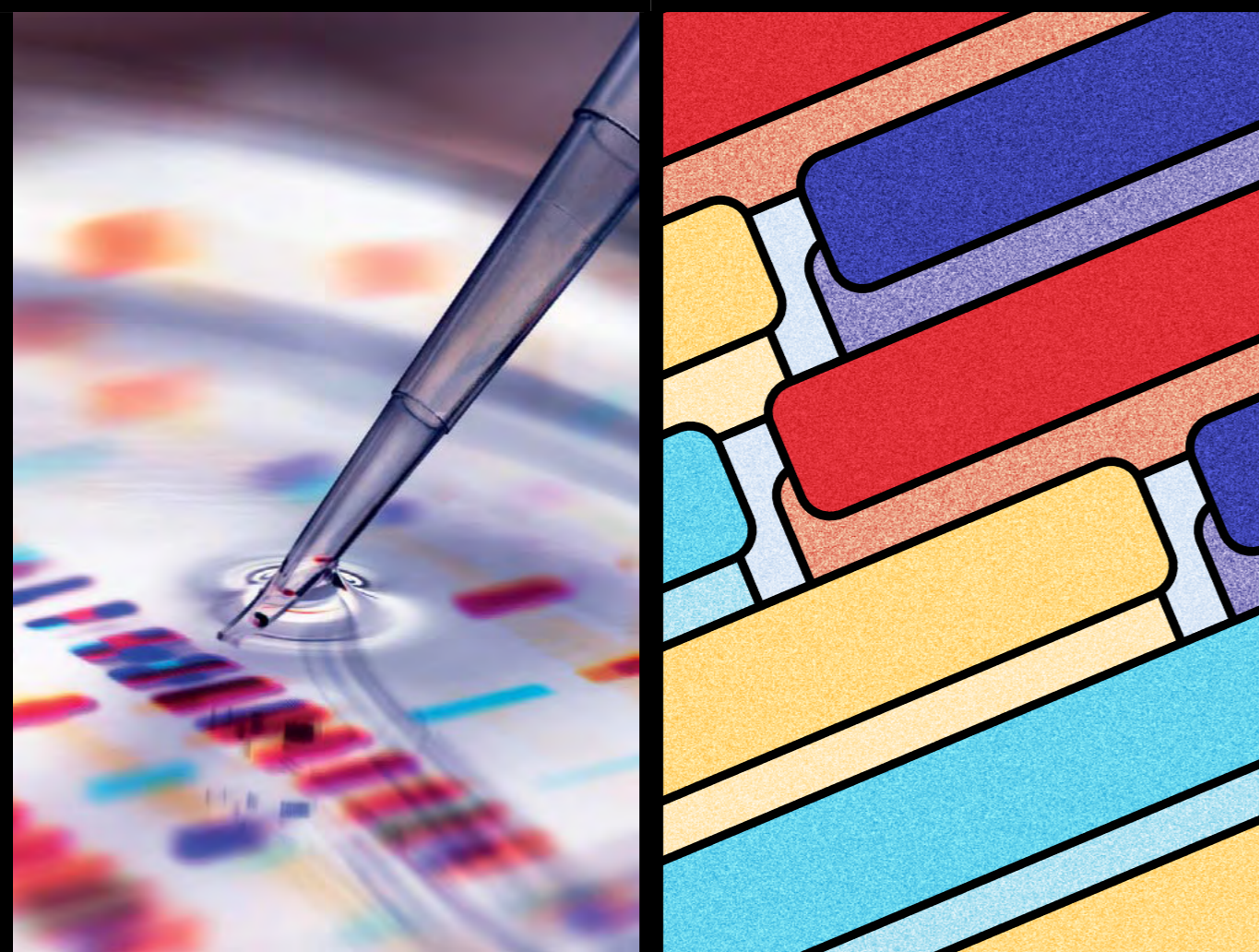


### COVID-19

Providing Patient Power Post-COVID



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## In This Issue

2 Editor's Comment

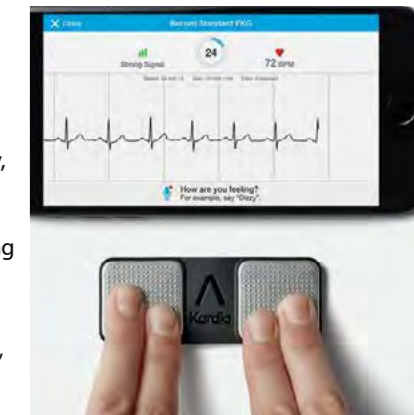
4 Does the Rise of Telehealth Mean the End of Doctors' Office Waiting Rooms?

With the COVID-19 pandemic necessitating the need for healthcare providers to adopt a digital first approach when it comes to the provision of care, we spoke to Matt Fairhurst, Co-founder and CEO of Skedulo the platform for intelligent mobile workforce management, about this transition, and what it means for care provision in the future.



5 A Growing Demand for On-Demand Care: Perspectives from the AliveCor ECG Usability Study and the Implications on Future Cardiovascular Care Models

This original research article seeks to understand the demographics, behaviours, levels of comfort with technology, and other characteristics of people who use cardiovascular monitoring devices, in a bid to better understand the implications that these devices have on patients' ability to self-learn about their diseases and leverage those findings to design future cardiovascular care models and devices.



8 Providing Patient Power Post-COVID

20 What can the Pharmaceutical Industry do to Ensure it is Ready for a Future Pandemic?

21 How AI is Helping Predict and Prevent Senior Falls

23 A Roadmap for Medical Affairs Transformation

25 Why the Time to Go Digital in Care Environments is Now

27 The Bittersweet Reality of Digital Transformation



Healthcare's digital transformation journey has been paved by advances in technology, policy initiatives and incentives. Yet the road to transformation has also been littered with potholes, which slows and prevents adoption.

The zeitgeist of the health IT industry is that the next solution will be revolutionary. Yet, to date, it has been less of the start of a "revolution" and more like Waiting for Godot. Unfortunately, when our proverbial Godot came, it was in the form of Covid-19...

28 Technology is Key to Relieving Poor Mental Health among Healthcare Workforce

30 Private Mobile Networks in Healthcare: Increasing the Dose of Predictability for Wireless Connectivity

31 Driving Results with Data: Using Real-world Healthcare Data to Reduce Health Inequalities

### Industry News

10 Ocutrx Vision Technologies Receives Patents for AR Technology

11 NIH Commissions PhysIQ to Develop COVID-19 Digital Biomarker

12 GE Healthcare Unveils AI-Enhanced Women's Health Ultrasound

13 B-LiFE Deploys Mobile Laboratory to Carry out COVID-19 Tests in Italy

14 Hospital Becomes One of the World's First to Create Fully Digital Microbiology Lab

15 Joint UK-US Research Team Use AI to Improve Diagnosis of Heart Failure

16 Oxford University Hospitals Achieves 100% Digitisation of Surgical Histology Slides

17 Caltech Sensor Rapidly Detects COVID-19 Infection Status, Severity & Immunity

17 94% of Care Environments Benefit from Going Digital amid COVID-19

19 Moletest Aims to Revolutionise Melanoma Skin Cancer Screening with New Test





## Does the Rise of Telehealth Mean the End of Doctors' Office Waiting Rooms?

With the COVID-19 pandemic necessitating the need for healthcare providers to adopt a digital first approach when it comes to the provision of care, we spoke to Matt Fairhurst, Co-founder and CEO of Skedulo the platform for intelligent mobile workforce management, about this transition, and what it means for care provision in the future:

### How has technology enabled the healthcare industry to adapt during the pandemic in order to effectively treat patients?

The silver-lining of the pandemic is that it has propelled the healthcare industry forward decades in terms of digital transformation. When the pandemic hit and it was necessary to quarantine and stay-at-home, telehealth had to be widely adopted in order to limit potential contamination.

New technology innovations, from biometric devices to IOT sensors, are enabling healthcare workers to effectively treat

patients even from a distance. For example, Apple recently expanded its Apple Watch electrocardiogram capabilities with guidance from the FDA, to now enable EKG tests. These types of insights are key to understanding the patient's health and their environment, making virtual visits comparable to in-person services.

### How has the technology of telehealth services evolved, and what are some other areas that the technology can be improved to enable better services?

Telehealth has had to evolve rapidly in order to meet the needs of healthcare providers utilizing this technology at-scale. From virtual waiting rooms, to integrations with healthcare software, to mass communication abilities, these are all functions that are continuously being improved upon.

Technology to help with data security and management is more important than ever and a particular challenge. To

manage, healthcare companies are prioritizing investments in two critical areas. The first is network security and access technologies to ensure that any system can be accessed remotely and securely. Companies like Okta are winning big in this area. The second area of investment is interoperability, technology that connects disparate systems reliably and securely. Skedulo has partnered with a leader in this space, Bridge Connector, which enables mobile healthcare workers to consistently and reliably access patient EHRs and hundreds of other systems from anywhere while maintaining HIPAA compliance.

### How has the rise of telehealth services enabled care providers to "see" increased volumes of patients during a time when in-person visits have been limited?

Telehealth is making the scheduling of health appointments more convenient than ever before, expanding access to enable more frequent care. For mental

health services, such as therapy or medication management, this is making a huge difference in terms of access. Virtual care also opens the door for underserved groups to receive more regular check-ins and preventative services. Think of rural parts of the United States, where it may be a several-hour drive to access a specialist, or low-income communities where blue-collar workers can't afford to take the day off to go physically see a doctor. These types of individuals are able to receive preventative care more easily, helping improve their long term health and preventing more costly issues down the line.

### Have health providers fully embraced telehealth? What will telehealth be used for once in-person appointments are deemed safe?

Telehealth has its pros and cons, but the

majority providers have embraced practicing telehealth in some capacity. For example, some providers are still offering predominantly virtual services or will leave it up to the discretion of the patient. Both physicians and patients are seeing the value of permanent telehealth practices. A recent study showed that 72% of individuals had their first virtual care visit ever during the pandemic, with over 75% saying they were very satisfied with their experience.

Skedulo customers', Catalight and Solace Pediatrics Home Healthcare, both switched from 100% in-person services to 100% virtual services at the beginning of the COVID-19 outbreak in the United States. They are both home healthcare agencies that deliver autism therapy services. Solace Pediatric Home Healthcare were able to complete 85%

of the "normal" level of appointments in their first week of operations. By week two, they completed all of their typical appointments, and in week three, they set a new record, exceeding their pre-pandemic level of operations.

It's clear that there's a demand for telehealth services and that we'll continue to see demand once the pandemic passes. Providers are now beginning to think about how they want to incorporate telehealth into their regular model of care. While it won't replace in-person care, it certainly will stick around once the pandemic passes and be incorporated into how healthcare systems practice their business of care. Moving forward, healthcare providers will need to embrace telehealth and the necessary digital transformation that comes with it to meet patient's needs and remain competitive. ■

## A Growing Demand for On-Demand Care Perspectives from the AliveCor ECG Usability Study and the Implications on Future Cardiovascular Care Models

Rupan Bose, MD, MB, Rebecca M. Ebert, BS, Leslie A. Saxon, MD

### INTRODUCTION

We now live in an on-demand era. The majority of Americans have access to almost any type of information right in their palms. It is estimated that not only do 96% of Americans own a cell phone, but approximately 81% own a smartphone (Pew Research Center, 2019). Additionally, these statistics are relatively consistent across demographics. The ubiquity of these devices, paired with an ever-growing app ecosystem, allow for on-demand access to almost any kind of personal information, including access to entertainment, finance, retail, and work data (Saxon, 2016).

This unprecedented access will change how we interact with services and workflows and recalibrate our expectations regarding data ownership. Previously, product and service offerings were at the mercy of predetermined schedules for end-consumers. Before Netflix, consumers resorted to television guides to determine when to watch a certain movie – now consumers stream at their convenience. Before Uber, consumers looked up public transportation schedules to design their trip – now consumers order rider on-demand. With this digital revolution, consumers are dictating when and how they access data instead of relying on traditional providers. However, one area that is missing from this on-demand transformation is access to personal health data and care.

However, over the last decade, the trend towards personal cardiac monitoring has changed this dynamic broadly and swiftly. Smart-

phone enabled Electrocardiogram (ECG) recorders have flipped the workflow of how patients self-monitor and identify concerning findings and then seek care (Bose & Saxon, 2019). These devices offer a novel way to capture cardiac metrics such as heart rate, heart rhythm, and intervals in a form factor that is seamless. Devices like the AliveCor Kardia mobile ECG device and the Apple Watch have emerged as prototypical examples of these convenient, medical-grade diagnostics that integrate with smartphones and provide long term monitoring outside the confines of brick-and-mortar clinics. Apple reportedly shipped over 30 million Apple Watches in 2019, meaning that on-demand ECG monitoring has now reached the literal hands of tens of millions of people globally (Naas, 2020).

We have seen numerous stories of patients identifying arrhythmias using these devices and then taking their recorded ECGs to a cardiologist, thus further reinforcing the value of such devices (Saxon, 2013). This contrasts previous care models where patients presented to clinic visits endorsing past symptoms that need to be investigated retroactively. As cardiovascular disease continues to be the leading cause of mortality globally, novel innovations in the diagnosis and management of such diseases using ubiquitous technologies are bound to permeate to the care models of other diseases (Mensah et al., 2019). However, in order to continue this evolution, we must continue learning what motivates patients and consumers to use these devices and incorporate these findings into future designs.

We looked back at the AliveCor Mobile Device ECG Usability Study (2013 – 2015) to better understand how people interacted with these types of devices. We wanted to understand the →

demographics, behaviors, levels of comfort with technology, and other characteristics of people who use such devices. We sought to better understand the implications that these devices have on patients' ability to self-learn about their diseases and leverage those findings to design future cardiovascular care models and devices.

### EARLY EXPERIENCES – THE ALIVECOR MOBILE DEVICE ECG USABILITY STUDY (2013 - 2015)

The AliveCor Mobile Device ECG Usability Study enrolled subjects into a six-month longitudinal study to understand the characteristics and behaviors of those using the commercially available smartphone enabled AliveCor Kardia ECG monitor.

Recruited subjects were consented virtually using the DocuSign platform (DocuSign, San Francisco, CA). At the time, each step was done individually. However, today, Apple's ResearchKit platform has since emerged as a seamless way to obtain informed consent, deploy surveys, and monitor active tasks (Jardine et al., 2015).

AliveCor Kardia ECG devices were distributed to participants. Participants were taught how to capture 30-second single lead ECG rhythm strips using the device. The rhythm strips were automatically analyzed for normal sinus rhythm or an arrhythmia such as Atrial Fibrillation (AF) using AliveCor's FDA-cleared AF algorithm (AliveCor Inc., 2014). The rhythm strips could then be uploaded to a cloud-based secure database, where they could be accessed by authorized physicians via a secure portal.

All users were sent periodic surveys throughout the six-month period. Users received a survey prior to receiving the device with questions pertaining to their background, occupation, and general behaviors around technology and medical devices. Users then received subsequent surveys at one month, three months, and six months. Survey questions pertained to device-use and behaviors. Surveys were completed virtually, and results were statistically analyzed.

#### Study Population

From October 2013 through December 2015, a total of 1,345 participants were enrolled into the study. Recruitment was aimed at both members of the medical community and from the general population. Of this initial group, a total of 1,166 completed the entry survey and submitted an ECG transmission. In this group, 58.1% were male, mean age was  $38.2 \pm 13.6$  years, and 44.1% were medical professionals. The majority of participants had previously used a digital device for health monitoring (75.7%), believed it is "very important" to use digital devices to monitor health (88.2%), and stated that the use of a mobile ECG recorder would make them more conscious about their health (77.6%). Also, 71.6% reported having experienced palpitations before, and 74.3% reported never having heard of AliveCor prior to the study. Additionally, 54.2% of study participants reported ease-of-use as a strength of the device. Though this study's average age of 38.2 appears young when compared to the expected age of patients with significant cardiovascular disease, it is comparable to the average age of the US population, which was 38.2 in 2018 (Rogers, 2019).

#### Use Data

A total of 28,449 ECGs were transmitted through the AliveCor Kardia mobile app during the study. On average, subjects submitted 59.7 ECG submissions over the six-month period. Nineteen



Figure 1. Average number of ECGs recorded per person over the 6-month study period by age group.

subjects submitted greater than 300 transmissions. The number of ECG transmissions increased with age (Figure 1). Subjects aged 70-80 transmitted approximately 4x more ECGs per subject (158.8 transmissions/person) compared to subjects aged 30-40 (38.6 transmissions/person). Subjects working in the technology industry recorded the highest number of average ECG transmissions (78.5 transmissions/person), and subjects working in academics transmitted the fewest number (34 transmissions/person).

By six-months, 68% of users had stopped using the device. This did not vary significantly by age, gender, or profession. Medical professionals were more likely to abandon the device earlier in the study (47% vs. 41% at one-month) and transmitted an ECG less frequently (every 12 days compared to every 7 days).

Amongst survey questions pertaining to context, the two most common settings in which ECGs were recorded were in social settings and with physical activity/exercise. This did not differ significantly between medical professionals and other subjects. Certain other settings appeared to be common reasons amongst users: 8.1% of transmissions were associated with caffeine intake, 3.9% associated with palpitations, 0.9% associated with dizziness, and 0.6% associated with chest pain. During the study, 77% of non-medical users endorsed using the device to investigate palpitations compared to 63% of medical users.

#### ECG Data

The average recorded heart rate (HR) was 74 beats per minute (bpm) (minimum 31 bpm, maximum 265 bpm). Bradycardia below 40 bpm was detected on 85 transmitted ECGs, and tachycardia faster than 150 bpm was detected in 255 transmissions. Mean HR declined with age as users aged 30-40 had a mean HR of 79 bpm whereas users aged 80-90 had a mean of 70 bpm (Figure 2). Male subjects had a lower average HR (70 bpm) compared to female subjects (73 bpm).

### IMPLICATIONS OF HISTORICAL FINDINGS ON FUTURE DESIGNS

In this predominantly young, non-medical cohort, the find-

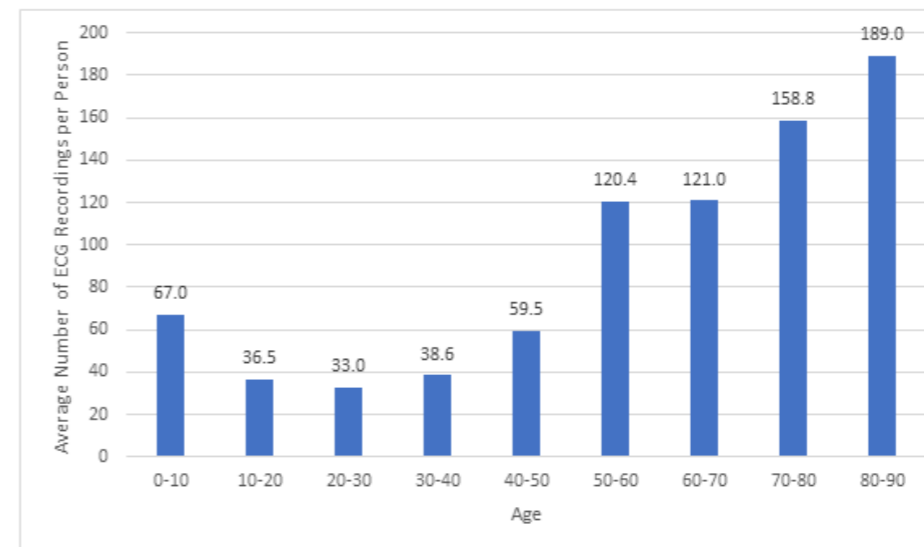


Figure 2. Mean heart rate seen in each age group.

ings demonstrate a tremendous appetite for on-demand ECG recordings. Subjects repeatedly used these devices to not only investigate medical symptoms, but more interestingly, used it in settings beyond the medical context such as in social settings and during physical activity. Health data has traditionally been in a silo; however, users demonstrated a collective interest in learning how their health interfaces within the greater social context.

Unsurprisingly, average ECG transmissions per person appeared to increase with age. One explanation may be that older users are more concerned about their health or may have a higher probability of symptoms that trigger a desire to record an ECG. Nonetheless, this demonstrates that older users have a significant ability to leverage technology to monitor their health. Though users in the 70-80 age group may not traditionally be viewed as technologically savvy, this study demonstrates that they are a prime audience for emerging healthcare technologies, and they deserve further studies to understand how to design experiences for them.

The results reinforced previously described "real-world" HR trends with age, as seen in previous large-scale studies. The study found an average HR of 79 bpm in subjects aged 30-40, which decreased to an average of 70 bpm in subjects aged 70-80. In the recently published data from the UCSF Health eHeart study (June 2019) with data from 66,788 subjects using smartphone photoplethysmography devices, their results found a similar average HR of 78.5 bpm in subjects aged 31-40, which decreased to an average of 73 bpm in subjects aged 71-80 (Avram et al., 2019). These results reinforce the consistency of such devices and reiterate their ability to capture meaningful data outside the clinic.

One of the challenges that came to light in this study is that 68% of users had stopped transmitting ECGs by six-months. Our interpretation of this is that despite an initial intrigue with the device and the ability to record ECGs, this novelty wears off. One possibility is that despite the device being easier to use than traditional 12 lead ECG recorders and Holter monitors, it does carry its own burdens (Barrett et al., 2014). At the time of this study, the AliveCor device was a standalone device separate from the smartphone. Perhaps carrying two devices became onerous. Another possibility is that capturing an ECG required the user to actively initiate a recording. Over time, as interest perhaps decreased, this barrier of actively ini-

tiating a recording perhaps outweighed the presumed benefit. Finally, another reason for progressively decreased usage may stem from the lack of a captivating user experience associated with recording ECGs. At the time of this study, the user experience was rather minimal – open the app, push the button to capture the recording, and then review it. In the future, a more engaging experience may be necessary to motivate users to continue recording.

The takeaways of this study are to leverage these findings to guide future designs of remote diagnostic devices. These findings indicate that devices should aim to streamline

use, which can be achieved by: (1) building these ECG abilities directly into the devices that people already use daily, and (2) designing them to initiate ECG recordings in the background without requiring active initiation. We have seen steps in this direction with Apple launching the ECG feature directly on the Apple Watch, thus leveraging a device that is already a part of peoples' daily lives. Apple has developed built-in algorithms to seamlessly detect bradycardia, tachycardia, and atrial fibrillation of these ECGs (Doshi et al., 2019). Finally, devices will need engaging experiences – which may come in the form of gamification or through improved education portals – to promote continued usage.

As these devices become more ubiquitous, these devices will change the way we manage cardiovascular disease outside the clinic. In today's care paradigm, we as a medical community manage diseases based on episodic clinic visits, which can often occur with months or years in between. Devices like this will help clinicians obtain better insights into patients' signs and symptoms outside the clinic, which can be leveraged to make meaningful clinical decisions and improve outcomes. These insights can also promote broadening the care model to a global, virtual care clinic where patients and physicians can make decisions together from any location (Shinbane & Saxon, 2016). It also allows for patients to learn about their clinical condition, for which, as this study shows, there is a growing interest.

### ON-DEMAND REMOTE DIAGNOSTICS IN THE COVID-19 ERA AND BEYOND

At the time of writing this article, we are in the midst of the COVID-19 pandemic. The medical community is facing new challenges of how to care for patients safely, and patients are facing new challenges of how to navigate their chronic diseases. Many clinics are closed and are relying on telemedicine visits. We are realizing the challenges of traditional healthcare models that rely heavily on in-clinic practices. Additionally, patients are concerned about exposure if they enter a clinical setting. In the author's experience, one patient had a history of intermittent palpitations, and was experiencing them during a telemedicine visit, but was hesitant to seek care. This patient is an ideal candidate to evaluate and triage using remote diagnostics. This pandemic has forced the medical community to re-evaluate each traditional in-person clinical interaction. It will accelerate the adoption of remote technologies, ➔

and we are beginning to see this as the HRS, EHRA, APHRS, LAHRS, ACC, and AHA are expected to release their upcoming “Worldwide Practice Update for Telehealth and Arrhythmia Monitoring During and After a Pandemic” guidelines (Varma et al., 2020). Additionally, the current COVID-19 clinical workflow involves self-monitoring at home and then presenting for care when needed. This model is well suited to permeate to other future workflows. In the future, patients may self-monitor cardiovascular symptoms at home with remote monitoring devices and then present as needed, as opposed to fixed-interval clinic visits.

As the global medical community is forced to learn how to treat this novel virus, these devices offer a rapid method to deliver care and conduct novel research. Initial studies have shown the importance of inpatient QT monitoring when treating COVID-19 patients with potential QT-prolonging or arrhythmogenic medications such as hydroxychloroquine and azithromycin (Chang et al., 2020; Roden et al., 2020). However, as more patients are deemed stable for continued care at home, there will be an increased focus on studying patients in the outpatient setting using mobile devices. In light of this, AliveCor received FDA clearance to use their mobile six-lead personal ECG device to monitor QT durations in patients outside the hospital (AliveCor Inc., 2020). As the global medical community studies this in parallel, a new large-scale decentralized approach to collecting research data will emerge leveraging remote diagnostics to collect data from any person in any location. Thus, remote diagnostics are quickly emerging out of necessity to become a key foundation in the way we do research and manage patients in an increasingly remote telemedicine-based healthcare paradigm.

## CONCLUSIONS

There is a growing demand for on-demand healthcare. In a time when consumers have on-demand from all other industries, yearly clinical check-ins are far from sufficient. Rather, devices like this will fill the gap and quench the demand for healthcare. Consequently, a new paradigm of continuous measurement and self-learning will emerge and drive the future of cardiovascular disease management, aided by the rise of remote diagnostic devices.

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to support care has always been very high on my agenda.

It has concerned me for a long time that we as a sector work in silos, and at times, I think we work in arrogant silos. We expect the patient to always come to us. At STHK, we have patients who travel some considerable distance to see us; from Anglesey, the Isle of Man, and the West Coast of North Wales, and up in Blackpool. I have had patients from Stoke-on-Trent travel for complex reconstructive work. We've always expected them to come to us. So, we decided to find out what we could do differently here.

### Shifting the patient mindset

A successful two-year pilot saw us trial video consultation technology, provided by Refero, with our Cancer Drains Outreach and Stroke Review Services. The pilot allowed patients to become digitally connected with our clinicians, and enabled continual engagement via video consultation and messaging through a web portal, smartphone or tablet.

Since the introduction of Refero's platform, we've already seen DNA rates drop from around 25% to just 10% in our six-month Stroke Review Service. We are now extending the programme to benefit patients attending a number of our outpatient clinics, from Speech and Language Therapy to Burns and Plastics.

Prior to the start of the COVID-19 pandemic, we were still very much in the process of changing the culture towards video consultation, particularly among our patients. People were used to travelling, and were very happy to go to a regional centre. Traditionally, patients prefer coming to the hospital to see their doctor, but that has completely, and understandably, all changed now. People are desperate not to come in, but they still need to see their doctor.

After a stroke, a patient will have their driving licence immediately taken away, so they become reliant on public transport, or family and friends to bring them into hospital for speech therapy or review appointments. Often, our patients will need to make a five-hour return journey from home to the hospital. Connecting a patient via a video consultation is an invaluable way of reducing their travel time, putting less strain on their recovery and helps us to assess how they are coping in their home environment, rather than after a strenuous and tiring journey into the hospital.

### Integrating old and new

As we continue to navigate this pandemic, STHK is currently looking at setting up clinics that have an initial face-to-face consultation, followed by two telehealth consultations, leading to another face to face, so that we can stag-

ger those people physically coming in. We are minimising footfall in the building, but still utilising that clinic's capacity. It's a perfect example of integrating tech with traditional treatment.

When it comes to video consultations, we're in a time where our clinicians are capable of using it, our patients are willing to do it, and providers can create systems that work across organisations which are properly linked to infrastructure, and are able to capture the information securely, while ensuring that all of the governance is in place to support it.

We have to embed this into the majority of our clinics across our healthcare sector for the foreseeable future. The world of healthtech is now very, very different than it was at the start of the year. And we mustn't go back to pre-crisis thinking.

Empowering patients through video consultation, giving them more control over their treatment and care, providing much more patient-centred care, not only aligns with the 10-year plan, but will help to ensure that the momentum gained from COVID-19 measures will continue long after the pandemic has passed. There has never been a better time for trusts to explore this technology.

Rowan Pritchard Jones is the Medical Director at St Helens and Knowsley Teaching Hospitals NHS Trust. ■

# Providing Patient Power Post-COVID

Covid-19 has provided an all-too real use case for video consultation in the NHS, but it's the power it gives patients over their own care, that will ensure it survives long after the pandemic, says Rowan Pritchard Jones.

Across healthcare, trusts are using all

sorts of different platforms for video conferencing. This year, the NHS has conducted more remote working than it ever has before. Perhaps an unintended consequence of COVID-19 has been the rise and accelerated adoption of video consultations at trusts, GP practices and clinics across the country.

Adopting video is something that we at St Helens and Knowsley (STHK), came to independently some time ago. Before I became Medical Director, I was our Chief Clinical Information Officer. I've stepped into my current role with a background and an interest in technology, and, in my heart, using technology

# INDUSTRY NEWS

News and Information for Digital Health Professionals



## Ocutrx Vision Technologies Receives Patents for AR Technology

serves to affirm our belief that the technologies we are developing will transform the future of augmented/extended reality and expand the bounds of optical technologies as we now know it,” said Michael Freeman, CEO/CTO of Ocutrx Vision Technologies.

The Visual Field Test patent teaches that by using a display controller in the headset to provide a visual field test to a patient, using both static and kinetic perimetry testing processes to identify the area of damage, medically known as a “scotoma” on the patient’s retina. As a result, the digital headset creates a retinal map of exactly where the analog retinal scotoma is located in a patient’s eyes as if it was projected onto the Oculenz display screen.

To aid AMD patients, the Oculenz then activates its two 4K cameras mounted within the device, taking video of what the patient should be seeing from the real world: “real-reality” (RR). Then, the software controller combines and modifies the RR streaming video buffering the frame-by-frame video images with the retinal scotoma map of each eye of the patient. Then, when the original video frames are displayed to the patient in the headset the buffer “pixel-shifts” the RR video to outside the scotoma, so that none of the information is displayed to the part of the patient’s retina where the scotoma exists. This permits a patient with AMD to see what would normally be hidden by the scotoma in their vision.

Ocutrx Vision Technologies, an augmented/extended reality manufacturing company, has been issued its third and fourth awarded patents by the U.S. Patent & Trademark Office. The third patent, titled “System and Method for Correction of Vision Defects Using Augmented Reality Glasses” covers the company’s visual field perimetry testing technology. This eye examination takes place in the augmented reality (AR) head mounted unit (HMU) to detect damaged retinal tissue called “scotomas” existing in central and peripheral vision which may be caused by various medical conditions such as advanced macular degeneration (AMD).

The fourth patent covers what Ocutrx calls Dynamic Opacity™ titled “Wearable Image Manipulation and Control System with Dynamic Opacity Augmentation in

Augmented Reality Glasses” a technology which is essential to the broader application of AR beyond gaming, and important to the AR industry as a whole. The patent covers technology which solves a common AR problem of being able to see projected virtual images or video in an AR headset in high-lighting conditions or daylight settings. An alpha-matte layer containing pixels, which turn varying degrees of opaqueness, are controlled to match, much like an exterior “shadow”, the reflected image the person sees inside the headset. In other words, it puts “a sunglasses” type shade behind just the virtual image while leaving portions around that image see-through.

“We are incredibly pleased to add these important patents to our Intellectual Property portfolio and the value of our company. The allowance of these patents

The head mounted visual-field test is a huge step forward because previously a patient had to go to an Ophthalmologist’s office and take the same test on a machine that’s half the size of a refrigerator. Now, with the Oculenz HMU the test can be taken by the patient at home, as often as the patient needs to, with the results being instantaneously available to the patient’s physician for immediate interpretation and further diagnosis by the doctor. Alternatively, the algorithms measure each test and reports to the Ophthalmologist when the scotoma has enlarged, or a new area of defect is detected.

The fourth patent uses the method of putting an occlusive “shadow” behind the projected virtual image through controlled pixels which exist on an alpha-matte lens while the virtually displayed images are being reflected into the eyes. Each pixel can be controlled in varying degrees of opaqueness gradation which Ocutrx calls AR Dynamic Opacity

(ARDO). ARDO is included in all the Oculenz headsets for patients, and in the ORLenz™ AR/XR headset for surgeons. The ARDO overcomes bright-light conditions by making the virtual image more visible than the RR in front of it.

Another feature of the fourth patent is a particularly important feature to the AR sector as a whole and involves the application of foveated rendering to AR visualizations. The part of the invention leverages the natural operation of the fovea in the human eye, with mechanical and software applications in the AR/XR HMU’s to get the most out of the resolution of virtual images and graphics. The Ocutrx patent teaches a method where the optical engine mimics the attributes of the human eye concentrating the highest-resolution in the center of the eye-box and a lower resolution on the periphery. These elements work together to display a higher-than-native display resolution projected onto the

fovea and macula, where most of a person’s high-acuity vision exists, while the user sees the virtual images in the lens periphery in a lower resolution which matches more closely their own peripheral perceptual acuity.

“Ocutrx Vision Technologies is transforming the way AR/XR can be applied in medical devices for surgeons and patients, alike,” said Dr. Linda Lam MD, MBA, Chief Scientific and Strategy Officer at Ocutrx. “Being able to match the resolution of the human eye with a symbiotic resolution in the headset is a major step forward in making augmented reality the most usable for medical applications.”

The company plans to bring more pending patents to market once approved. Ocutrx currently has 4 patents awarded and 49 international patents filed and 20 US patents pending. Freeman, himself, has well over 60 patents awarded to his credit in seven different scientific sectors. ■

## NIH Commissions PhysiQ to Develop COVID-19 Digital Biomarker

The United States’ National Cancer Institute (NCI) and the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH), have awarded physiQ a contract to develop an AI-based COVID-19 Decompensation Index (CDI) Digital Biomarker to address the rapid decline of high-risk COVID-19 patients.

The new early warning system, under development, would allow providers to intervene sooner when a COVID-19 patient is clinically surveilled from home and begins to worsen. Rather than relying on point measurements, such as temperature and SpO2, that are known to be lagging or insensitive indicators of COVID-19 decompensation, continuous multi-parameter vital signs will be used to establish a targeted biomarker for COVID-19.

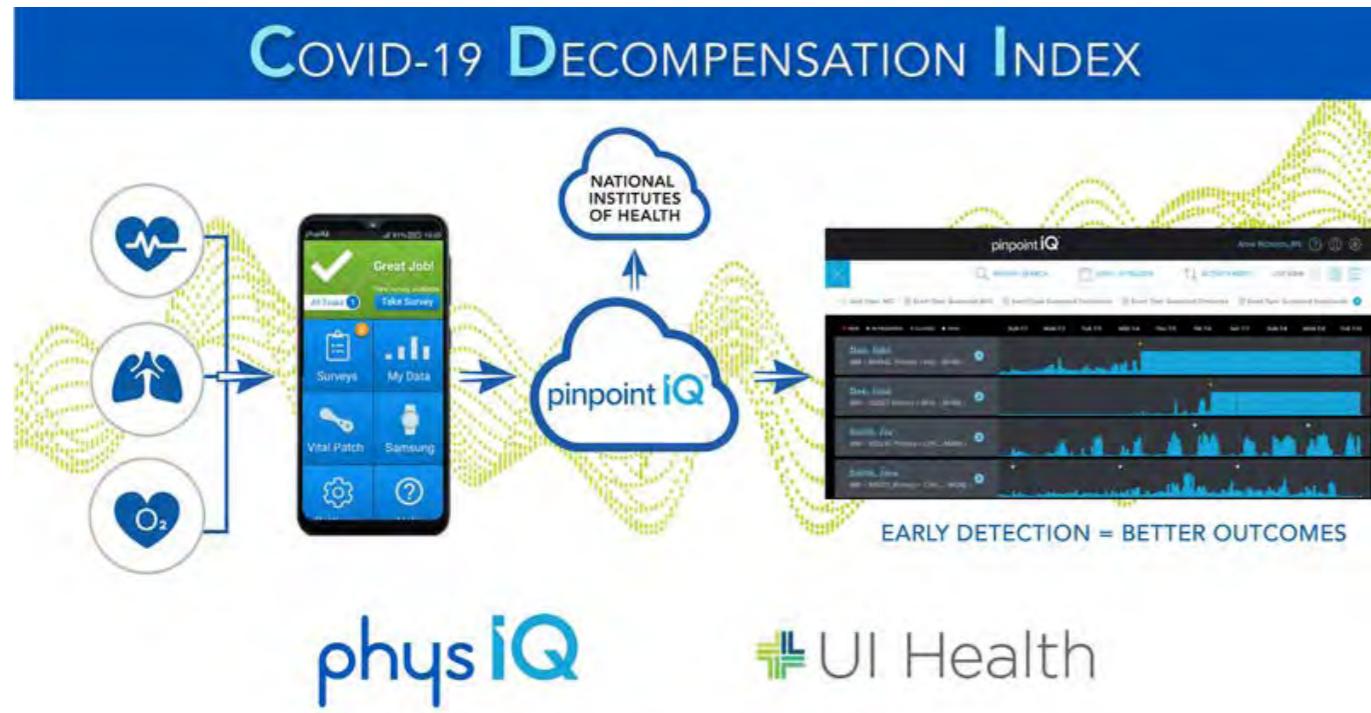
“Despite the technological advances and attention paid to COVID-19, the healthcare community is still monitoring patient vitals the very same way as we did in the 1800s,” said Steven Steinhubl MD, Director of Digital Medicine at Scripps Translational Science Institute (STSI) and a physiQ advisor. “With the advances in digital technology, AI and wearable biosensors, we can deliver personalized medicine remotely giving caregivers new tools to proactively address this pandemic. For that reason alone, this decision by the NIH has the potential to have a monumental impact on our healthcare system and how we manage COVID-19 patients.”

PhysiQ will develop and validate a CDI algorithm that builds off

existing wearable biosensor-derived analytics generated by physiQ’s pinpointIQ™ end-to-end cloud platform for continuous monitoring of physiology. The data will be gathered through a clinical study of COVID-19 positive patients in collaboration with University of Illinois Hospital and Health Sciences System (UI Health) and build upon work already in-place for monitoring COVID-19 patients convalescing at home.

For patients who participate in the program, physiological data will be collected before and after their admission to the hospital. “Since March, when the COVID-19 pandemic began, UI Health has been at the forefront of clinical research, patient care and community-based efforts to support the Chicago community. Working with physiQ is an opportunity for us to study and adapt new technology and potentially improve patient care and make a difference among the many vulnerable patients we serve, many of whom are experiencing COVID-19 disparities in their communities,” stated UI Health Chief Medical Officer, Terry Vanden Hoek MD.

In the development phase of this project, physiQ and its clinical partner will monitor participants who are confirmed COVID-19 positive, whether recovering at home or following a discharge from the hospital. During the validation phase, physiQ will evaluate lead time to event statistics, decompensation severity assessments, and the ability for CDI to predict decompensation severity. “The application of the CDI may provide a universal indicator of decompensation,” said Karen Larimer PhD, ⇨



ACNP-BC, study PI and physIQ's Director of Clinical Development. "Application of this technology could detect COVID-19 decompensation and prevent hospitalization or morbidity events in both scenarios."

The study is designed to capture data from a large, diverse population to investigate CDI performance differences among subgroups based on sex/gender and racial/ethnic characteristics. This project will not only enable the development and validation of the CDI, it will also collect rich clinical data correlative with outcomes and symptomology related to COVID-19 infection.

"We are honoured to have been selected by the NIH to pur-

sue such a worthy cause in such challenging times," said Gary Conkright, CEO of physIQ. "This is a culmination of many years spent in the pursuit of developing a clinical grade product to address serious medical conditions, without taking shortcuts, that has the ability to monitor the most complicated machine in the world, the human body."

This index will build on physIQ's prior FDA-cleared, AI-based multivariate change index (MCI) that has amassed more than 1.5 million hours of physiologic data, supporting development of this targeted digital biomarker for COVID-19. This will enable new research and further insight into using digital health to advance the public health response. ■

## GE Healthcare Unveils AI-Enhanced Women's Health Ultrasound

GE Healthcare has launched a new ultrasound system designed to help women's health clinicians expand diagnostic capabilities and improve patient outcomes. The Voluson SWIFT system features industry-first AI algorithms to support auto recognition in addition to an ergonomic design, impeccable image quality, and tools to improve efficiency.

A recent study found that obstetrics (OB) and gynecology (GYN) clinicians in the United States have some of the highest burnout rates among physicians, with the leading factor being bureaucratic tasks like paperwork, charting, and

patient data capture. In today's COVID-19 pandemic environment, these clinicians are now facing additional pressures to see more patients and perform exams quickly to limit possible patient exposure to the coronavirus.

To help combat these constraints and improve clinical outcomes, GE Healthcare gathered input from 200 women's health practitioners worldwide to develop the all-new Voluson SWIFT that is designed to help make clinician's daily work more manageable. New features allow users to customise the system to their personal preferences and the system

comes with guided workflows to help new users learn the technology faster and use it more effectively.

"The Voluson SWIFT is intuitive to use and comes with many options to personalize your preferences on the system and auto-measurement tools that allow you to focus on the examination rather than time-consuming adjustments," said Dr. Ralf Menkhaus, Gynecologist at Kinderwunschzentrum in Minden, Germany. "It's like the machine is helping do some of the thinking for you which has allowed me to seamlessly integrate it for any obstetric and gynecological exams I need to do."

logical exams I need to do."

The new ultrasound system features an embedded artificial intelligence platform, including the new SonoLyst application, the industry's first fully integrated AI tool that recognises the 20 views recommended by the International Society of Ultrasound in Obstetrics and Gynecology mid-trimester practice guidelines for fetal imaging, optimising the scan workflow by 73 percent when compared to manual 2D workflow.

"Voluson SWIFT has redefined one of the most essential tools obstetrics and gynecology clinicians rely on, delivering a contemporary design, intuitive user interface, and intelligent workflow supported by AI," said Roland Rott, General Manager of Women's Health Ultrasound at GE Healthcare. "In today's environment where cleanliness and time savings



opportunities are critical for clinicians, we're proud to offer a solution that makes our customers' work easier and gives them time back with their patients." ■

## B-LiFE Deploys Mobile Laboratory to Carry out COVID-19 Tests in Italy

As one of the most severely affected places by COVID-19, the Government of the Piedmont Region in Italy requested that the B-LiFE (Biological Light Field Laboratory for Emergencies) service was deployed in the area since June to carry out vital COVID-19 diagnostic tests. Using its advanced mobile laboratory, the mission of the B-LiFE department was to carry out a large number of COVID-19 tests for first responders, civil protection, health personnel, police and volunteers.



Mobile laboratories have become extremely important during the COVID-19 pandemic. B-LiFE is one of the most advanced mobile laboratories in the world and has been operational since 2014 when it was successfully deployed in Guinea during the Ebola outbreak. It is integrated and certified in the European Civil Protection Mechanism (EUCPM).

The deployment of B-LiFE is led by the Centre for Applied Molecular Technologies of UCLouvain (Catholic University of Louvain) with the support of ESA (European Space Agency), the Luxembourg Government and its Ministry of Defence. B-LiFE's partners in this humanitarian mission are Belgian companies Eonix and Nazka Mapps, Luxembourg companies' SES and GovSat, and French company ETELM.

B-LiFE was developed as part of the ESA Space Solutions programme (formerly known as IAP-ARTES 20), with the participation of Belgium and Luxembourg. The integration of satellite and terrestrial telecommunications, information management, earth observation, location management and real-time epidemi-

ological mapping allows B-LiFE to be deployed very quickly, autonomously and as close as possible to a crisis zone.

ETELM, a partner of B-LiFE, has made a critical contribution to the initiative in supplying telecommunications services. It has enabled the integration of TETRA and LTE terrestrial telecommunications capabilities into the satellite terminal provided by SES, GovSat and the Luxembourg Ministry of Defence. This work was necessary to ensure full autonomy during a crisis situation and to enable interoperability with local emergency services.

ETELM's 4GLinked Unified Mobile Platform has been successfully deployed and tested to support B-LiFE laboratory operations, including PMR TETRA and LTE base stations. ETELM's participation in the B-LiFE mission in the Piedmont Region, and the successful use of its equipment and service, ensures the company's ongoing partnership with B-LiFE. ■



# Hospital Becomes One of the World's First to Create Fully Digital Microbiology Lab

Bumrungrad International Hospital has used InterSystems TrakCare® Lab Enterprise to create one of the first fully digital microbiology laboratories in the world.

The digitisation of end-to-end process in microbiology follows Bumrungrad's go-live with the InterSystems TrakCare unified healthcare information system in October 2018 to support world-class care delivery throughout the hospital. The deployment included the digitisation of Bumrungrad's core laboratory handling 60-70% of the hospital's five million annual tests on around one million samples.

The hospital microbiology lab has now also gone fully digital with TrakCare Lab Enterprise, the only business management system for clinical labs. Currently, very few microbiology labs have fully digitised their operations. This is partly because of the complexity of their workflows. It is also due to a lack of electronic medical record (EMR) systems that support either end-to-end lab processes or integrated workflows across the best-of-breed systems used in microbiology labs.

Unlike traditional lab data and analytical management solutions, TrakCare

Lab Enterprise integrates patient data within the EMR for improved clinical support and patient-centered workflows, has built-in integration capabilities for interoperability with other systems, and captures comprehensive operational data for better lab decision making.

InterSystems partnered closely with Bumrungrad to understand its requirements and realise its vision. The complex nature of microbiology testing required extensive use of TrakCare Lab Enterprise's flexible configuration capabilities. With no product customisation needed, however, the configuration will continue to work with future, enhanced versions of TrakCare.

As a core function, microbiology labs culture and identify microbes and test their susceptibility to antibiotics to establish the best treatments for patients. They follow an investigative process with each step dependent on the results of the previous step. Bumrungrad, for example, identifies up to three organisms per sample and tests multiple antibiotics against each.

To digitise this process, Bumrungrad created a decision tree to map its microbiology workflows and TrakCare Lab

Enterprise was configured to support them. The product's interoperability capabilities were also used to integrate with the BD EpiCenter™ microbial identification and VITEK® antibiotic susceptibility systems via standard HL7 messaging. TrakCare Lab Enterprise now digitally manages the entire end-to-end testing process.

The benefits of this digital transformation include improved service delivery, increased patient safety, reduced turnaround times, and enabling the optimisation of robotics and automation. For example:

- » Clinicians at Bumrungrad can place microbiology orders in TrakCare and receive results within a patient's EMR, improving turnaround times and ease of use.
- » Reports delivered in a structured data format – rather than a PDF scan – enable clinicians to analyse results in context and make full use of decision support systems.
- » Patient safety is protected by eliminating manual transcription errors and validating sample and cultured materials using system-generated barcodes. This ensures that the right

test is performed on the right patient with the right result.

“Our clinicians are very happy with the digital transformation of microbiology,” said Jeremy Ford, Laboratory Research and Technology Director for Bumrungrad. “The primary outcome is improved service delivery – making it easier for clinicians to deliver care, having confidence in the results with no transcription errors, and reporting results in a much more timely way.”

“Longer term, the transformation will have a profound impact,” said Ford. “It enables accurate, real-time reporting for infection control, for example, which is very import-

ant for both patient safety and government reporting. It can take hospitals weeks to compile infection control reports using spreadsheets. In TrakCare, with digitised processes and an integrated EMR, you can run an infection control report every day.”

Bumrungrad will roll out further enhancements to TrakCare Lab Enterprise in its surgical pathology and referral laboratories later this year, with the blood bank following in early 2021, making all lab processes fully digital and paperless. “Each of the departments needs to be digital to allow high throughput robotics and automation,” said Ford. “It is no good investing in complex robotics if you have paper flowing around and you

cannot digitally optimise its use.”

“We are excited to be working with Bumrungrad to fully support the digital transformation of their laboratories with TrakCare Lab Enterprise,” said Martin Wilkinson, Product Director, Laboratories for InterSystems. “Clinical labs face growing demands for faster, more reliable, more accountable, and more comprehensive processing and reporting of results. Where they could once rely on manual methods, labs like Bumrungrad's are adopting automated methods of plating, identification, and susceptibility testing to meet those demands – and increasingly require digital technology platforms to drive that transformation.” ■

## Joint UK-US Research Team Use AI to Improve Diagnosis of Heart Failure

A research programme to use AI and machine learning to predict and detect heart failure, which can be difficult to diagnose and is often unrecognized, is being launched by a joint UK-US scientific team. The programme, a collaboration between pioneering UK health-tech company Ultromics and Mayo Clinic in the US, will apply AI to forecasting heart failure.

The team will use AI analysis of ultrasound heart scans to identify the markers of heart failure and develop an image analysis risk prediction model that can alert doctors to potential heart failure.

The aim is to develop a diagnostic and predictive tool that can rapidly identify heart failure, reduce misdiagnosis, and enable its earlier prevention. By supporting medical professionals, it will free-up their time to provide greater patient care and ease the pressure on care-teams. Ultimately, the ambition is to help save and improve the quality of patient's lives.

Heart failure is a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's needs for blood and oxygen. Globally it affects at least 26 million people and is increasing in prevalence<sup>1</sup>. Worldwide, it is the leading cause of hospitalisation in people over the age of 65. In the US it affects over 6.5 million adults<sup>2</sup>, with 550,000 new cases diagnosed each year.

CEO and co-founder of Ultromics, Dr. Ross Upton said, “This project is focused on a critical aspect of cardiac disease as it affects so many people every day. Using our pioneering AI technology stack, our objective is to map and scan databases of ultrasound images and develop detailed models to diagnose and hopefully even predict heart failure. Early intervention can make a huge difference to a patient's treatment and quality of life – so the sooner we can identify the condition, the better.”



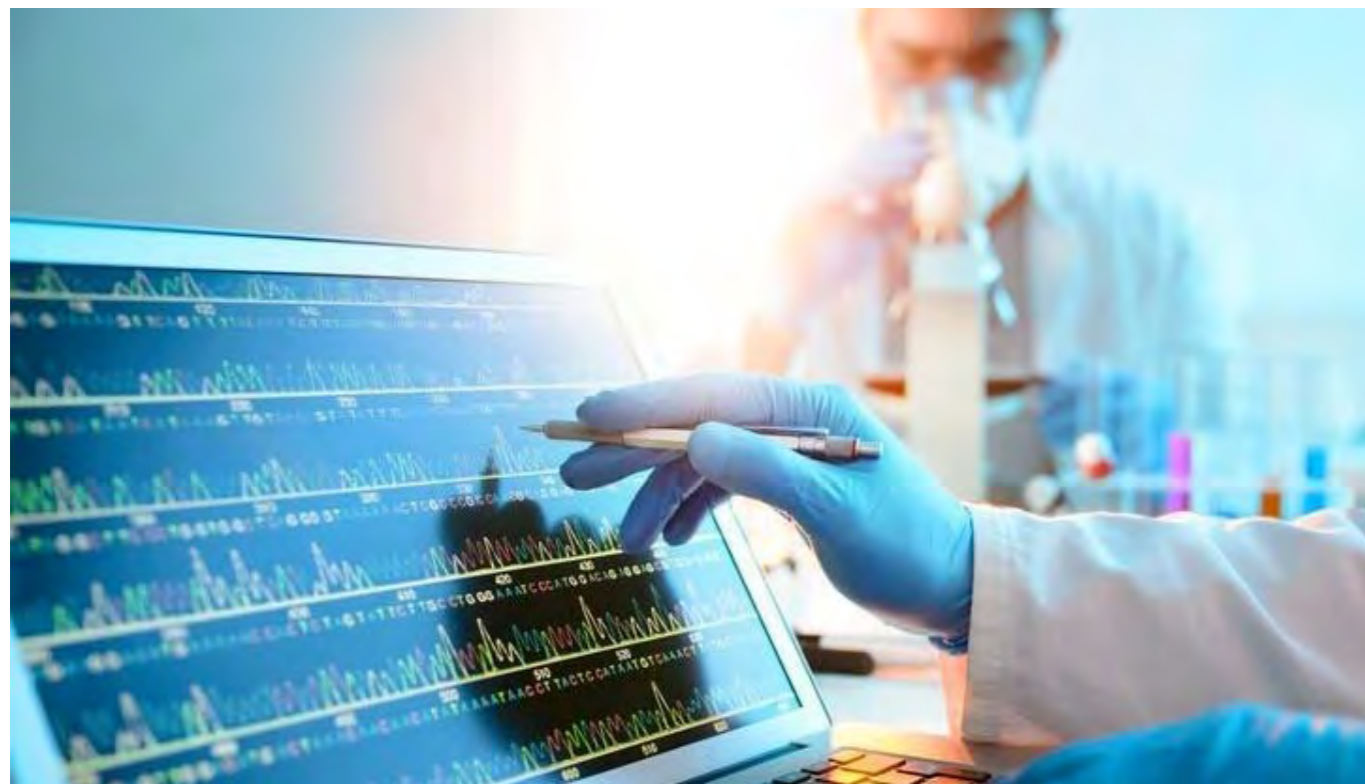
The research team will use the AI engine from Ultromics' first product EchoGo Core, to analyse 10,000 echocardiograms (echos). It will analyse 2D-echocardiograms, including assessment of systolic and diastolic information throughout the entire cardiac cycle.

Dr. Upton explained: “The study has two key objectives: the first is to identify novel biomarkers that can help identify early signs of heart failure. And the second is to develop a machine learning model using the novel biomarkers to provide an automated risk prediction of heart failure at the point of care.”

This project will be led by Gary Woodward, CTO of Ultromics and Patricia A. Pellikka, M.D., cardiologist, and clinical researcher at Mayo Clinic. It is the third collaboration between Ultromics and Mayo Clinic.

### References

1. CFR - Volume 3 Issue 1 Spring 2017 - Global Public Health Burden of Heart Failure
2. CDC data Dec 2019 ■



# Oxford University Hospitals Achieves 100% Digitisation of Surgical Histology Slides

Oxford University Hospitals (OUH) NHS Foundation Trust has become one of the earliest UK adopters of a fully digitised cellular pathology (histopathology) department. OUH is one of the first NHS trusts in the country to achieve the status of digitising all surgical histology and referral slides within the cellular pathology department.

OUH has worked with Philips to introduce their IntelliSite Pathology Solution, including three Ultra-Fast Scanners and one Ultra Versatile Scanner. This technology will reduce the pressure on the hospital's cellular pathology service, supporting the vision of digitally enabled care as outlined in the NHS Long Term Plan. The transition to digital pathology has been driven by the pathology and biomedical science teams working closely together to deliver on a joined-up ambition to fully transition to digitisation.

Introducing these solutions makes OUH better placed to lead the way in setting standards in multi-trust collaboration with regional partners. Its alliance with Milton Keynes University Hospital and Great Western Hospital in Swindon, which are also using the Philips IntelliSite Pathology Solutions, has allowed for multi-disciplinary team meeting cases to be reviewed digitally and for extra tests to be requested if necessary, expediting results and diagnostic decision-making.

Professor Clare Verrill, Associate Professor and Honorary Consultant in histopathology at OUH, commented, "We have seen a number of urgent cases where we have been able to provide a rapid opinion through digital solutions. In one case the digital platform enabled us to secure a crucial second opinion in a matter of hours, enabling the patient to start on life-saving chemotherapy treatment that evening. Although it is still early days, we have seen that the Philips IntelliSite platform has great potential to improve diagnosis quality through increased access to further opinions and to help us deliver faster results to patients."

In a recently published article in the *Journal of Clinical Pathology*, OUH Histopathology Consultant Dr Lisa Browning noted that as a result of the COVID-19 pandemic, there had been a 25% increase in uptake of digital pathology, with pathologists keen to fully validate digitally and provide remote training and ongoing support for this transition successfully via videoconferencing. By fully embracing digitisation, OUH have been able to continue with their medical education programmes, without any negative impact to quality of diagnosis. Through the first wave of the pandemic, the OUH team have not always been able to physically gather as a team

but the Philips IntelliSite platform has enabled continued teaching and training of junior histopathologists under remote conditions. Roles for biomedical science staff have also been able to be extended; for example, providing training and slide-viewing sessions for staff taking part in specimen dissection, a role previously undertaken by pathologists.

Professor Clare Verrill is leading the Oxford team for the Path-LAKE Centre of Excellence in Digital Pathology and AI of which Philips is the principal industrial partner. Her successful programme on digital pathology and artificial intelligence has been supported by the NIHR Oxford Biomedical Research Centre. The project will create a secure data-lake of tens of thousands of professionally annotated anonymous images for building deep learning algorithms that can automatically detect cancer. These images and tools will be made available across the consortium including a growing number of SME partners in this sector to develop artificial intelligence (AI) to overcome burgeoning workloads in the UK and establish a world-leading UK digital health industry.

OUH is a world-renowned centre of clinical excellence and one of the largest NHS teaching trusts in the UK. It provides a wide range of clinical, specialist services including cardiac, cancer, musculoskeletal and neurological rehabilitation, medical education, training and research. The cellular pathology department processes around 60,000 cases per year, resulting in approximately 300,000 slides. Over the years, OUH has invested significantly in the training of its 30 consultant pathologists and highly qualified teams in providing care to the members of its community. Many pathologists in the department have now completed their digital validation so cases can be reported digitally with the remainder of pathologists to follow in the near future. The team continue to work on refining processes, for example creating a 'one-stop' reporting portal with macroscopic images of specimens and scanned request forms. ■



# Caltech Sensor Rapidly Detects COVID-19 Infection Status, Severity & Immunity

University of California researchers have developed a new type of multiplexed test with a low-cost sensor that may enable the at-home diagnosis of a COVID infection through rapid analysis of small volumes of saliva or blood, without the involvement of a medical professional, in less than 10 minutes.

The research was conducted by Assistant Professor Wei Gao, at the Andrew and Peggy Cherng department of medical engineering. Previously, Gao and his team have developed wireless sensors that can monitor conditions such as gout, as well as stress levels, through the detection of extremely low levels of specific compounds in blood, saliva, or sweat.

The sensors are made of graphene, a sheet-like form of carbon. A plastic sheet etched with a laser generates a 3D graphene structure with tiny pores. Those pores create a large amount of surface area on the sensor, which makes it sensitive enough to detect, with high accuracy, compounds that are only present in very small amounts. In this sensor, the graphene structures are coupled with antibodies, immune system molecules that are sensitive to specific proteins, like those on the surface of a COVID virus, for example.

Previous versions of the sensor were impregnated with antibodies for the hormone cortisol, which is associated with stress, and uric acid, which at high concentrations causes gout. The new version of the sensor, which Gao has named SARS-CoV-2 RapidPlex, contains antibodies and proteins that allow it to detect the presence



of the virus itself; antibodies created by the body to fight the virus; and chemical markers of inflammation, which indicate the severity of the COVID-19 infection.

"This is the only telemedicine platform I've seen that can give information about the infection in three types of data with a single sensor," Gao says. "In as little as a few minutes, we can simultaneously check these levels, so we get a full picture about the infection, including early infection, immunity, and severity."

Established COVID-testing technologies usually take hours or even days to produce results. Those technologies also require expensive, complicated equipment, whereas Gao's system is simple and compact.

So far, the device has been tested only in the lab with a small number of blood and saliva samples obtained for medical research purposes from individuals who have tested positive or negative for COVID-19. Though preliminary results indicate that the sensor is highly accurate, a larger-scale test with real-world

patients rather than laboratory samples must be performed, Gao cautions, to definitively determine its accuracy.

With the pilot study now completed, Gao next plans to test how long the sensors last with regular use, and to begin testing them with hospitalized COVID-19 patients. Following in-hospital testing, he would like to study the suitability of the tests for in-home use. Following testing, the device will need to receive regulatory approval before it is available for widespread use at home.

"Our ultimate aim really is home use," he says. "In the following year, we plan to mail them to high-risk individuals for at-home testing. And in the future, this platform could be modified for other types of infectious disease testing at home."

The paper describing the research, titled, "SARS-CoV-2 RapidPlex: A Graphene-based Multiplexed Telemedicine Platform for Rapid and Low-Cost COVID-19 Diagnosis and Monitoring," has been published online and will appear in the December issue of the journal *Matter*. ■

# 94% of Care Environments Benefit from Going Digital amid COVID-19

One of the UK's leading providers of digital care systems is calling on the sector to be better prepared for the future by utilising agile technology that has been tried and tested throughout the pandemic - with 94% of users finding its coronavirus-spe-

cific features beneficial.

With the looming uncertainty of another UK outbreak of COVID-19, health and social care leaders are being encour- ➔

aged to consider going digital in a bid to better cope with the drastic changes brought on by lockdown.

Having already had to adapt its Mobile Care Monitoring system to better support staff in care environments during the first wave of the virus, Person Centred Software is appealing for others to follow suit as the industry remains in a precarious position, offering a solution that has helped 85% of paper-dependent care providers switch to digital in less than 24 hours.

Throughout the last four months, its software, which is used in over 2,000 care homes across the UK to evidence care interactions via innovative icons, has seen the implementation of eight new features to help protect the elderly and vulnerable.

These included coronavirus reporting, staff coronavirus auditing, track and trace reporting, and its Relatives Gateway video link. Person Centred Software's Care App was found to save each carer one hour per shift to complete administrative tasks, as opposed to how long it would take using paper, which is crucial at a time when staff absence and agency usage are on the increase.

A survey carried out by Person Centred Software on its customers in July found that 83% of care providers valued how well it had responded to sector and individual needs during the pandemic, with more than 87% of providers finding its coronavirus action icon useful. Furthermore, 88% of providers found its care monitor invaluable for real-time monitoring, especially as it can be accessed remotely if required.

One care group, Crabtree Care Homes in West Yorkshire, described how the Mobile Care Monitoring system's new features helped to prevent the spread of the virus and aided in the group's swift recovery and increase in occupancy.

David Crabtree, owner of Crabtree Care Homes, said: "Initially, the official symptoms released by the NHS did not include the different signs and symptoms in the elderly. Many of our residents who contracted coronavirus, for instance, said that they had pain in their legs. We discovered that this first sign was due to restricted breathing, so without accurate recording using the system, we would have missed three days of symptoms in our residents.

"If you want to protect residents and prove your service's quality of care to adult protection, CQC, and other external bodies, you've got to be recording at the point of care. Using technology



is the only way that this is possible."

Due to lockdown restrictions, Person Centred Software also made its Relatives Gateway feature - an online portal enabling relatives to stay in contact with their loved ones - free for sharing messages, photos and video links. This decision led to a 50% increase in usage of the feature, with over 5,200 people using it on a monthly basis at the height of the pandemic.

Heidi Thomas, Head of Marketing at Person Centred Software, said: "With the Government wanting us to be ready for the possibility of a second wave, as an industry, we must be prepared for the worst-case scenario. The flexibility of technology in care environments has equipped providers with the best tools possible to protect their residents - as circumstances drastically change, so does the technology. Unfortunately, those who still rely on paper can't be as agile and we encourage them to rethink their administration processes, especially if they were hit hard by the pandemic the first-time round."

During a recent webinar, Sue Howard, Deputy Chief Inspector of Adult Social Care at CQC, said: "Our guidance to staff is really clear; we are in a digital age. It is absolutely right and proper that care providers are using innovative, digital ways to improve their services."

Heidi concluded: "With technology currently being the largest contributor to innovation in the UK, and with winter and the pressures of flu season just months away, now is the time to go digital. We want to ensure everyone in care has the best chance to fight through this pandemic, and technology is going to play a key role in achieving that." ■

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# Moletest Aims to Revolutionise Melanoma Skin Cancer Screening with New Test

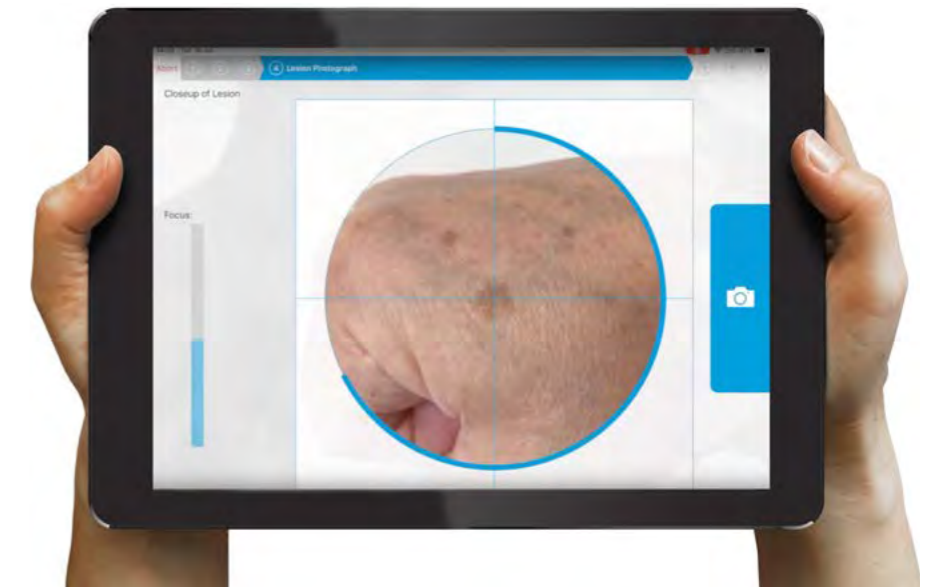
British medical technology company, Moletest (Scotland) Ltd, is aiming to substantially reduce the number of unnecessary dermatology referrals to secondary care using a new digital tool nomela®, the first and only professional medical rule-out screening test for skin lesions suspected of melanoma.

Since doctors lack a completely accurate way of screening out melanoma, the nomela® test has been developed to assist the process, fulfilling an unmet need and reducing the burden on the healthcare system. This is even more important now due to the COVID-19 crisis, where the NHS and healthcare professionals are looking to digital-first options and ways to reduce the need for patients to be managed and treated in a hospital setting.

GPs and other primary care professionals will be able to use a dedicated and secure nomela® iPad to take high quality accurate images of the suspect skin lesion, which are analysed against five algorithms to provide an instant result, either "No evidence of melanoma" or "Melanoma not excluded".

Joe Ferreira, Marketing Director at Moletest (Scotland) Ltd explains: "We are the only company to have developed a rule out test for melanoma. We have serious ambitions, especially in the current healthcare environment, where technology is king and there is a real need to provide innovative solutions that are sustainable and efficient. Following previous trials with NHS Lanarkshire, our latest trial with Addenbrooke's Hospital in Cambridge, aims to further confirm the accuracy of nomela®, which, as a test specifically for healthcare professional use, will fundamentally improve the patient pathway in dermatology care and provide substantial cost savings to health services."

Clinical studies with nomela®, in conjunction with NHS Lanarkshire, are due



to be published by the British Association of Dermatologists Annual Meeting in September 2020. These show that, with ranges set by nomela® at 100% sensitivity for melanoma, 53% of non-melanoma lesions may be assessed as "no evidence of melanoma". By extrapolation, if used by a GP, nomela® could therefore reduce the number of unnecessary dermatology referrals by more than 50%, potentially saving the NHS £125M per annum.

The company has now restarted its clinical trial with Addenbrooke's Hospital, Cambridge, which along with other trials was suspended by the National Institute for Health Research in March due to the COVID-19 crisis, aiming to further demonstrate the sensitivity and performance of nomela®.

Most skin lesions are harmless (benign) but some may be a melanoma, the most aggressive form of skin cancer.<sup>1</sup> Medical advice is that anyone who is concerned about a mole, especially if it is new or changing in size, shape, or colour, should visit a GP to have it examined.

If the GP is uncertain or suspects melanoma, then urgent referral to a dermatologist within 14 days for further

assessment is mandatory, though some 97% of such moles are found to be benign.<sup>2</sup> If the dermatologist or plastic surgeon remains concerned then a biopsy (removal of some or all of the affected skin) is recommended.


Bruce Murray, Technical Director at Moletest (Scotland) Ltd comments: "It is a challenge to identify which skin lesions are melanoma, whether by inspection with the naked eye or using technological advances, such as the dermatoscope. Our rule-out technology will help to identify which skin lesions do not require further investigation. nomela® uses the iPad Pro as a medical grade device which is centrally controlled so that it can be configured for each user and its operating system and software automatically updated following performance testing. The quality of its camera and screen ensure a clear close-up image with detailed edge detection. Our technical approach is to control all variable factors, including the type of device used to ensure reliable results. nomela® can deliver true innovation within this market, demonstrating the three dimensions of value that are critical in healthcare, including clinical benefit, patient quality of life and economic value." ■

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