

# The Journal of mHealth

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## *Digital Acceleration in Healthcare*

### INSIGHT

Using AI Safely & Quickly in Healthcare



### INTERVIEW

24/7 Wearable Blood Pressure Monitoring

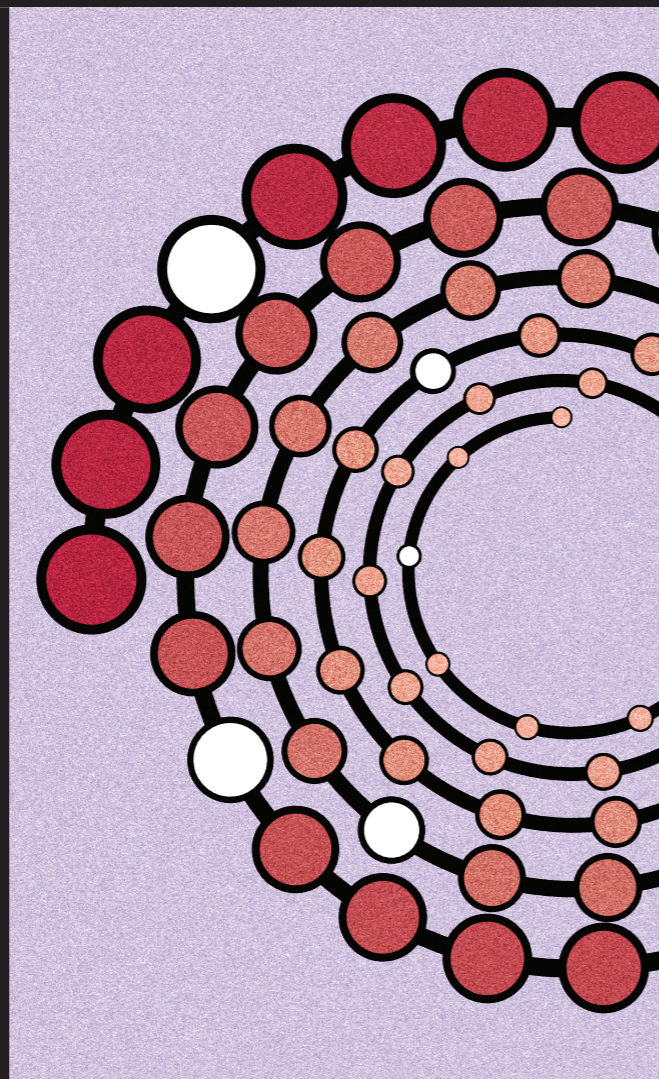


### TECHNOLOGY

How HealthTech is Adapting Fertility Treatment



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# Digital Technologies

## An Opportunity to Make Healthcare More Inclusive

2020 saw a huge increase in the adoption of digital technologies within modern healthcare economies. From the adoption of video-based triage and GP-to-patient consultations within primary care, to remote monitoring for shielding and vulnerable patients, as well as those discharged early from hospital – both within their own homes and a care home setting, digital technologies have driven wide recognition that there is an alternative way to manage clinical caseloads.

This is unlikely to be a permanent shift. Clinicians will – understandably – not want to manage their patients by video alone and there is no replacement for the face-to-face interaction within the privacy of a GP surgery. However, as Dr. Noel O’Kelly, Spirit Digital, outlines, digital has brought attention to the fact that there might be a better way of identifying and prioritising the patients we absolutely need to see. Moreover, it paves the way for long-term change in making healthcare more inclusive.

### What do we mean by digital inclusion?

As far back as 2017, the government’s digital strategy policy paper outlined plans to “build a stronger, fairer country that works for everyone”. Within the context of the NHS, this means having the infrastructure, connectivity, access, skills and confidence – amongst both those providing services and those receiving them – to make healthcare more equitable.

Indeed, as NHS Digital states, patients who are more likely to be digitally excluded include those who are amongst the more vulnerable: older people; those in lower income groups; people with disabilities; and those whose first language is not English, amongst others.

These are barriers that may be challenging to overcome, but they are not insurmountable, as the events of 2020 have shown. Indeed, there are many local

examples of where digital technologies, designed around the needs and abilities of the patient, have been successfully used to provide continuity of care to these patient cohorts.

From the virtual education programme for type 2 diabetes patients being delivered in not only English, but also in Gujarati, Hindi and Urdu; to care home residents receiving virtual ‘ward rounds’; patients with long-term conditions such as COPD, heart failure and asthma gaining access to digital Cardiopulmonary Rehabilitation services; and the remote monitoring of symptomatic COVID-19 patients post-discharge from hospital – these are all examples where patients and clinical & care teams have embraced digital technology to reconfigure traditional patient pathways.

### So where are we today?

COVID-19 has been a catalyst for extraor-

dinary change: the response proved what can be achieved with the right mindset and commitment. It has also shown the value of real-time collaboration between GP practices and an entire network of healthcare providers to ensure the right patients are treated at the right time. From the nurse practitioners and pharmacists that play a key role within practices, to the hospital consultants, care homes, opticians and dentists, the concept of working together as a team to look after patients – and how patients themselves can also contribute positively to their own care – is now firmly established.

But change has, so far, understandably been targeted at the most obviously vulnerable patients. To achieve true digital inclusion, there is still an infrastructure to be built. The priority for 2021 is to address the technology gaps revealed by the COVID-19 NHS response and to use that knowledge to achieve a wider adoption of a broad, effective community care model within local health economies.

### From reactive to preventative

With the right pathway in place, the opportunity presents itself to move from the current model of reactive care, to one where we can start to intervene early and prevent unnecessary exacerbations or avoidable hospital admissions. Being able to alert a patient with COPD on their local air quality on a daily basis, for example, allows patients and clinicians to make more informed decisions about how to better manage their condi-

tion. Having early warning that a vulnerable patient’s health might be deteriorating based on regular vital signs readings similarly allows appropriate intervention, be that through continued care safely at home or to facilitate an early, planned hospital assessment if there are concerning features.

Moreover, this model enables stretched primary care teams to identify and connect with patients who might currently be ‘hidden’ in the system. From the new widower suffering from loneliness, to shielded patients fearful of leaving their homes; or those with social interaction challenges or learning disabilities, by enabling a proactive model of care where we’re not constantly fire-fighting, digital technology can truly make healthcare more inclusive.

### What are the opportunities for tomorrow?

With a patient-centric, digital-first approach, the wider health economy will gain from a huge influx of data. Data that can be analysed, using machine learning and artificial intelligence, to help us predict the people who are more at risk, from either physical or psycho-social conditions.

It will enable us to look at trends; to better understand the side effects of medication on specific cohorts of patients. It will provide insight to help us better understand mental health, as well as making it much easier to carry out research and

develop therapies.

Ultimately, it’s about improving pathways, outcomes, access to medicines and reducing the cost of healthcare.

### Conclusion

Amongst the lessons of 2020 is the recognition that traditional ways of connecting to patients are at breaking point. There is an increase in patients with mental health conditions, an increase in the number of those with long-term conditions, an increase in older people with complexity and co-morbidities, and people are living for longer. This is a system that is struggling to cope with demand, even without the added pressure of a pandemic.

Yet the lessons of 2020 also give hope. Hope from the realisation that there is a new and better way of providing care. The trajectory for digital adoption is only going to increase. But it must be done at the correct scale and in the right way.

Key to digital inclusion is getting the right local stakeholders within a local health economy to work together. It is the cooperation of policymakers, front line clinicians and IT suppliers within a local area that will accelerate digital change and achieve a model of care designed to be truly inclusive.

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## What We Still Need to Use AI Safely and Quickly in Healthcare

Rachel Dunscombe and Jane Rendall examine what needs to happen to make sure extremely important algorithms can be introduced rapidly, and in a way that is clinically safe for populations.

When one NHS trust in the North of England started to introduce artificial intelligence several years ago, hospital clinicians needed to sit postgraduate data science courses in order to understand how algorithms worked.

Like most healthcare organisations, the Trust didn’t have a uniformed approach to onboarding algorithms and applying necessary supervision to how they performed.

It became a manually intensive operation for clinicians to carry out the necessary clinical safety checks on algorithms, requiring a huge amount of overhead and in turn significantly limiting the organisation’s ability to scale the use of AI.

### AI needs supervision

AI in many ways needs to be managed like a junior member of staff. It needs supervision. Hospitals need to be able to audit its activity, just as they would a junior doctor or junior nurse, and they need sufficient transparency of how an algorithm works in order to provide necessary oversight and assess if and when inter- ➔

vention is needed to improve its performance and ensure it is safe.

So, how can we do this in a scalable way? Expecting doctors to do a master's degree in data science isn't the answer. But developing a standard approach to managing the lifecycle of algorithms could be. In the UK, organisations like NHSX are making progress. But the real opportunity is to develop an internationally accepted approach.

If we are to adopt AI at the pace and scale now needed to improve care, and to address widening workforce and capacity gaps, we need to address the current absence of international standards on AI adoption. This could help to inform developers before they start to produce algorithms, and inform the safe application of those algorithms to specific populations.

Put simply, this is about what we need to do in order to make sure we adopt AI with similar diligence that we apply to safely adopting new medicines, but without having to wait the years it can take to get important medicines to patients.

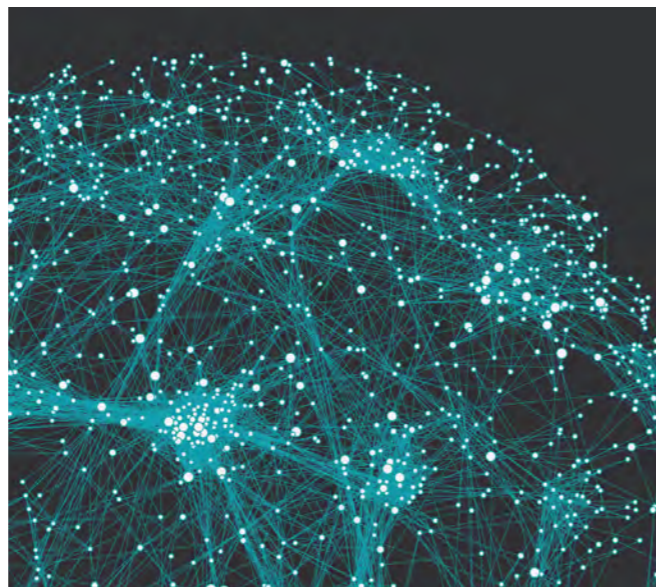
### A starter for 10 – thinking about an international approach to AI

Arriving at that international consensus will mean a lot of rapid progress and dialogue – and will most likely involve sharing lessons from across different sectors beyond healthcare.

But here are six suggestions of some of the components that could underpin a model and help healthcare to safely accelerate adoption:

**1. Clinical safety.** We need to embed AI into tools that can allow hospitals to examine the clinical safety of an algorithm. Healthcare organisations already have tools for clinical safety in their organisation – systems that gather data on the performance of doctors and nurses. Interfaces from AI algorithms should feed those same systems. We should report on AI in the same way as a doctor or nurse. There has been a lot of work from the Royal College of Radiologists about supporting junior colleagues to evolve in their career. Similar mechanisms could help to peer review the work done by the AI. This is about creating the same feedback cycles that we have for humans to understand where AI may have faltered or misinterpreted, so that we know where improvement is needed.

**2. Bias detection.** This is about examining demographics based on age, gender, ethnicity, other factors and determining where bias might exist. Hospitals need to understand if there are people for whom an algorithm might work differently, or not work as effectively. It might not be suitable for paediatrics for example. Skin colour, and a great many other factors can also potentially be significant. If a bias is detected – two options then exist: training that bias out of the algorithm, or creating a set of acceptable pathways for people with whom it won't work and continue to use it for groups where a bias isn't present. This could mean answering some big practical and ethical questions around access and equity. For example, is it appropriate to have a manual pathway for someone if the algorithm doesn't work safely for them, and to use the AI for the remainder of the population? But to even get to those questions requires transparency. Algorithm developers need to be transparent on the cohorts used to train the algorithm. As a



healthcare provider you can consider if this matches your cohort, or if there is a mismatch you should be aware of. You can then choose to segment your cohorts or your population, or capacity accordingly, or choose a different algorithm.

**3. New demographic validation.** One local geography might have two demographic minorities. Another, only a few miles away, might have a significant mix of ethnic minorities making up around half the population. Healthcare systems, like the NHS in the UK for example, usually buy technology before extending it over other geographies. This requires looking at new demographic validation. If the population in question changes – for example through immigration an extension of services, or something else happening: an algorithm needs to be validated against a new dataset. Something that can operate safely in the UK, might not operate safely in parts of South America, or China. Bias detection has allowed for validation in your original population, but you can't test it on day one against every set of demographics where it might be used. There are so many ethnicities and groups on this planet that this has to be done in stages. So, as you extend the algorithm across new demographics, you need to validate. If a service in Mersey extended out to Manchester, then it would need to be tested again.

**4. Explainable un-blackboxing.** Having to send doctors on data science degrees isn't practical. But we don't have a standard way of drawing pictures or writing words to say what an algorithm is doing at the moment. If you think about a packet of food, you get an ingredient list. We need a similar standardised approach for AI. We need to work towards explainable un-blackboxing that will include clinical terminology, but it will also include common measures we find across different industries in terms of performance. If you are going to get a CE mark or certification – it could be standard across health, nuclear, aviation and other sectors. The EU is early in its thinking on how that can work, but discussion has started.

**5. Clinical audit.** We need a clinical audit capability in algorithms. If a case is taken to a coroner's court, if there has been an untoward incident, we will have to show how an algorithm contributed towards care. This is something we already do with human doctors and nurses. We need to do it with algorithms.

**6. Pathway performance over-time.** In areas like radiology there is an opportunity to examine the performance of an algorithm compared with human reporting. This isn't about AI replacing humans, but it can help healthcare organisations to make decisions about where and how to make best use of the human in the pathway. For disciplines like radiology this is key, given the significant human resource challenge faced in some countries. We also need to think about this from the perspective of the patient. If algorithms can report a lot faster than humans, could humans delay the diagnosis, particularly when humans are being used for double reading? Could that impact the surgery or treatment? Are there opportunities to change that pathway, or to potentially use AI to help free up the human resource to focus on diagnosing more complex cases more quickly? This is about looking at the performance of the pathway and measuring outcomes where AI can make a difference. Playing that back to citizens at a time

when trust issues are still prevalent around algorithms, can help to demonstrate how AI is being used to improve healthcare.

Healthcare organisations are looking to AI to help to address a significant number of matters – from the ongoing pandemic to long established challenges. Not bringing AI will mean that we will otherwise hit crisis points – especially in areas like radiology, where in some countries demand continues to grow by around 10% year on year, whilst the number of trainees continues to decline.

But the situation is more complex than simply acquiring algorithms. A standard approach to managing algorithm lifecycle could make all the difference for successful adoption at the pace required.

Article by Rachel Dunscombe of Tektology and Jane Rendall UK Managing Director for Sectra ■

## Health Professionals Have to Ask

# “What's Next?”

'Applied Futurist', Tom Cheeswright in collaboration with Ludger Philippen, Director Healthcare Solutions Business Unit at Sony Professional Solutions Europe, discuss what challenges are ahead for healthcare...

The COVID-19 pandemic came as a shock but not a surprise. Bodies around the world have been warning for years of a novel disease that could wipe out millions and crash the global economy. In February 2019, Dr Jonathan Quick, chair of the Global Health Council, told Raconteur: “Our greatest fear is being blindsided by a new virus, most likely due to animal-human spill over, which then readily spreads from human to human, has at least a 5 to 10 per cent

fatality rate, does not respond to existing medicines, and for which an effective vaccine and accurate diagnostic test cannot rapidly be developed.”

We were confident this could happen. We just did not know when.

In many ways, COVID-19 was at the most optimistic end of forecasts. The death toll has been lower, and the economic impact smaller than worst case scenarios. This was our warning.

### So, what do we do next?

Perhaps the most important lesson we can learn is about readiness. While the pandemic threat remains, and there may

be future pandemics following similar patterns, these are not the only challenges on the horizon for healthcare operations. Looking beyond the current situation for other pressures and trends, we can begin to identify from where the next challenges will come and scope out a response.

### A Century of Change

The rest of the 21st Century looks particularly challenging for healthcare operations. We can already foresee clear pressure points arising from climate change, our ageing population and elsewhere.

### Climate

Our rapidly changing climate creates huge healthcare risks. From forest fires, as we saw recently in California or Australia, and their impact on respiratory diseases, to the potential for floods and droughts in other areas. Food production is likely to be disrupted, and there is already forced migration as some regions suffer the worst of the climate effects.

The greatest impact of climate change on healthcare operations is uncertainty. The instability and unpredictability in weather it creates can have a huge variety of impacts on the population, even ➔



in currently temperate climates in the UK and Europe. Considering the impact of climate change is the first of many signals that the future of healthcare operations will need to be extremely adaptable to a fast-changing situation.

### Ageing

As the latest research from the University of Washington shows, the global population is ageing faster than we previously understood. That the size of the population will peak lower and earlier than previously forecast is in many ways positive. It reduces pressure on the planet, and it is driven by rising freedoms for women around the world who, given the chance, are choosing education and careers rather than large families. But it also creates huge challenges. Countries like Italy are forecast to see their populations collapse by up to half this century.

In the UK, the Old Age Dependency Ratio, the number of people post-retirement age for every thousands of working age, is set to rise from 289 in 2017, to 360 by the early 2040s. But this rise will be very uneven. By mid-century, areas like West Somerset could have a 1-1 ratio of old age to working age persons. This not only places an enormous potential burden on the healthcare system, it creates enormous challenges in terms of funding.

### Globalisation

We live in an increasingly networked world. Products and people, services and ideas, flow around the world more easily than ever before. This is part of what makes the pandemic risk so great. One infected person can board a plane on one side of the world and a dozen carriers disembark on the other. It is hard to isolate any country now without the risk of serious economic harm. These are competing challenges that leaders have struggled to balance through this pandemic.

Alongside physical movement there is digital travel as well. Information and collaboration are its positives, misinformation and attempts to profit from it, its negatives. While we may have a more informed public now, we also have a more misinformed public, and this creates its own health emergency.

All of this may contribute to critical point

in the progress of globalisation. While many have benefited from falling friction in international trade and travel, the tenor of international conversations has hardened in the recent past. Rancorous relations between the US and China, the UK and the EU, and increasingly nationalist and protectionist politics in many countries may see borders hardening.

This could create enormous challenges for healthcare operations in terms of the supply of drugs, equipment, and staff.

### Public Health

With a declining and ageing population, the challenge of maintaining a healthy populace becomes greater than ever. States need citizens to be living healthier lives if those lives are to continue to be extended, so that they minimise their reliance on the healthcare system and can remain economically active. But right now, we are facing several public health crises, not least in obesity.

In the UK, one in four adults and one in five children is obese. And the UK is not an outlier, with the WHO putting the proportion of obese adults across Europe at 23% for women and 20% for men. With obesity being a risk factor for a variety of health conditions – including the current pandemic – and levels rising rather than falling, the public health challenge in the next decades is enormous.

There is also the quieter challenge of mental health, the second largest source of burden of disease in England, and something that costs 4% of GDP across the Europe according to the OECD.

But there is some good news on the public health front. Two of the critical campaigns of the last few decades, on drinking and smoking, seem to be having an impact. While the reduction in smoking and alcohol consumption remains small today, the trends are both moving in the right direction.

### Acceleration and Efficiency

To understand how these global issues will affect healthcare operations specifically, we also must understand the macro trends that are transforming the way we live and work. The advance of technology in recent years has stripped friction from so many

activities: innovation, operations, communications. The consequences of these changes have a clear and visible intersection with some of the pressures facing healthcare, and perhaps present ways to ameliorate some of those pressures.

The most obvious application of technologies that augment and accelerate is in addressing challenges of staffing and funding. The ageing population, the risks to international recruitment, and the post-COVID weakness in the global economy, all point to healthcare systems having to find increased efficiencies in the coming years. Technology that augments each human in the workforce can allow organisations to do more with less, trading some capital investment for much lower operational costs.

These savings can, perhaps counter-intuitively, map to better health outcomes. For example, by improving the flow and management of diagnostic data, time can be saved that is reallocated to analysis and patient care. More patients can be screened, raising the prospect of early diagnosis and treatment – preferable by every measure to a later, more acute response.

Technologies can also improve the collection and sharing of information, as well as its analysis. At Karolinska University Hospital in Sweden, video feeds from cameras and instruments can be presented in the operating theatre, stored against patient records, or streamed anywhere on campus, for example to teaching rooms and lecture theatres, using Sony's NUCLeUS platform. Streamlining the flow of rich information to people allows wider expertise to be brought in on diagnosis, accelerates learning, and improves record keeping for future analysis.

Creating these digital flows also prepares the operation for perhaps the most discussed incoming technology, Artificial Intelligence. While the term itself is a little hyperbolic at this point, early applications of the more accurately titled Machine Learning have demonstrated the incredible capability of algorithms to analyse patient data and make fast and accurate diagnoses to assist healthcare professionals.

### Optimisation and Agility

What we must take from the observa-

tion of the pressures facing healthcare is not just the need for efficiency but the uncertainty on the near horizon. The challenge of foresight is frequently not in identifying what will happen but when – as it was with the COVID-19 pandemic. Bodies like the WHO were only beginning their preparations for such a virus when it struck. Looking at the varied issues on the near horizon and their many possible effects, it is nearly impossible to say which will strike first or how the different effects will combine to create new challenges.

In response to this uncertainty, what our healthcare operations really need, even more than absolute efficiency, is the capability to adapt to a changing environment and the intersecting impacts of these various risks. With the likelihood that future shocks will require rapid changes of direction, we need infrastruc-

ture that can be turned quickly to new challenges, allied with improved information gathering and accelerated decision-making.

The future of healthcare operations is about building structures, systems and processes that can operate efficiently, but adapt rapidly to face new crises. Leveraging technology to strip friction from the organisation can free people to do more with less. Building the right infrastructure today will ensure they have the tools they need tomorrow, whichever challenge they face.

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# Consent Technologies

## How Healthtech is Adapting Fertility Treatment

Tony Marven, Director at MD Consents

To say 2020 has been an unprecedented year is an understatement and a cliché. But the pandemic has changed things in our personal and professional lives forever.

Nobody could have anticipated the upheaval we were about to face and this meant many private and public health organisations faced challenges as they navigated the unknowns of Covid-19.

Patient safety was a concern and many practitioners had to make the difficult decision to postpone appointments and treatments while awaiting news and guidance on protecting staff and patients against the virus. This included fertility treatment.

Like with everything else, the pandemic has changed the fertility treatment process in the short-term and as with other industries, technology has been a huge help in ensuring services can still be provided.

Many patients have waited years to start fertility treatment and the delays and cancellations have been difficult for them to cope with. Although many clinics were physically closed to patients they continued to provide support and guidance via video appointments, alleviating patient concerns and keeping communication flowing.

### The new normal for fertility treatment

Clinics were subsequently able to reopen with additional safety measures in place, providing they adhere to Human Fertilisation and Embryology Authority (HFEA) guidance.

Minimising contact has been paramount and clinics have looked for ways to reduce in-person visits where possible. One element where this is possible is the consent process.

The forms required to begin fertility treatment are extensive and can take up to 45 minutes each to complete. These forms require thorough reading by the patient in order for them to provide informed consent, so the process should not be rushed.

It is important for patients to feel comfortable and supported when signing these consent forms and, although every effort has been made to make the clinic environment safe, might feel anxious spending prolonged periods of time in a clinic, under pressure to complete the forms as quickly as possible.

Providing the option to sign consent forms in the safety and comfort of their own homes can ease patient concerns while also reducing clinic visits.

The HFEA has issued guidance on consent form completion during the pandemic, stating: ➔



*Consent should be given at the clinic (with both parties present if a couple is being treated) or a documented process should be in place to ensure that consent forms signed outside the clinic are signed by the correct person, have been correctly completed and the consent is valid.*

*Therefore, if clinics have a documented process in place to ensure the identity of their patients, and to ensure the forms are completed correctly, consents can be signed outside of the clinic.*

The pandemic has accelerated a trend that has been growing in fertility clinics – digital consent. Many clinics have already adopted an electronic consent process as part of their digitisation initiatives. At a time when many clinic staff are working from home, having a centralised online record of patient information minimises the risk of error and enables clinics to continue to provide regular services and consultations.

#### Ensuring patient data is secure

In line with HFEA regulations, clinics need to ensure that electronically signed consent forms provide evidence of a valid, compliant signature, proving that documents have been signed by the correct person. The eIDAS regulation provides a set of standards for the use of electronic signatures across Europe.

A Qualified Electronic signature is compliant with HFEA's requirements for consent as:

- » It is uniquely linked to the signatory;
- » It is capable of identifying the signatory;
- » It is created using electronic signature creation data that the signatory can, with a high level of confidence, use under his sole control; and
- » It is linked to the data signed therewith in such a way that any subsequent change in the data is detectable

This ensures that an electronically signed consent form can be linked to the signer, provides evidence of when it was signed and will become invalid if it is tampered with. This form of electronic signature is as secure and legally binding as a 'wet' ink signature.

For NHS clinics, there is the additional requirement of compliance with NHS Digital Data Security and Protection toolkit standards, as well as GDPR and other data protection governance.

#### The future of fertility treatment

While it looks like this new normal is here to stay, fertility clinics have been quick to adapt and offer support to patients. The consent process can take a considerable amount of time but while fertility treatment is still facing delays, clinics can utilise technology to provide patients with online consent services.

What is important is that fertility clinics ensure that the technology used to provide patient services is secure, robust and compliant with HFEA regulations to avoid unnecessary disputes. ■



# INDUSTRY NEWS

News and Information for Digital Health Professionals

## Rapid Screening App Detects COVID-19 Infection Using Wearable Sensors

Despite mass vaccination programmes starting to provide a glimmer of hope on the COVID front, the impact that the pandemic continues to have on our day-to-day lives means that the need for new technologies to help manage COVID-19 remains critical.

NeuTigers, an Artificial Intelligence company spun out of Princeton University, has this week announced the launch of CovidDeep, a clinically validated solution that can triage those needing further testing for SARS-CoV-2/COVID-19 using physiological sensors data derived from wearable devices.

#### Clinical solution

CovidDeep has been shown in a controlled clinical study at San Matteo hospital to predict SARS-CoV-2/COVID-19 with upwards of 90% accuracy, almost twice as effective as temperature checks and visual symptoms checks, which NeuTiger's study and others have shown predict COVID-19 with around 50% accuracy.

Early in the pandemic, NeuTigers realized its StarDeep™ Smart Healthcare Platform, which delivers AI-powered solutions to augment healthcare professionals' productivity, could be used in the fight against COVID-19. CovidDeep was developed through rigorous clinical research and validation trials beginning at San Matteo Hospital in Pavia, Italy, during the acute phase of the COVID-19 pandemic in April 2020, with further expanded prospective field studies in hospitals in France and the United States to explore its robustness.

A powerful tool for businesses and healthcare facilities who regularly screen for COVID-19, CovidDeep is already deployed in B2B settings including multiple nursing homes and assisted living facilities in America and Europe. Designed to help keep work and



medical facilities safe, CovidDeep is effective in multiple industries and use cases, and today is being made widely available.

CovidDeep works by collecting physiological sensor data from the Empatica E4 wristband, blood pressure and blood oxygen levels from any off-the-shelf, standalone monitors as well as personal health symptoms from a brief questionnaire. As a potential game-changer in the rapid and cost-effective screening of SARS-CoV-2/COVID-19, it is already being adapted to work with connected health products from Fitbit, Withings, Apple, Samsung, and other devices. The CovidDeep consumer app is expected in early 2021.

#### Deep Neural Networks

COVID-19 affects people's biometrics and physiological markers in both obvious and nearly imperceptible ways. Using advanced algorithms of machine learning, CovidDeep is so sensitive it can detect changes in these physiological patterns even before ➔

they are felt by the patient and all with real-time analysis.

The solution is powered by cutting-edge AI deep neural networks that mimic how the human brain perceives, learns, and interprets the world. NeuTigers' research co-founders at the Department of Electrical Engineering at Princeton University used proprietary deep neural networks to learn from hundreds-of-thousands of digital health data points and a specific questionnaire in SARS-CoV-2-positive and healthy participants. They identified patterns in the sensor physiological readings such as Galvanic Skin Response (GSR), Skin temperature, Heart Inter-beat Interval (IBI), Blood pressure, and Blood oxygen saturation levels (SpO2) that are consistent with how COVID-19 impacts the body. CovidDeep can recognize the 'digital signature' of SARS-CoV-2/COVID-19 and quickly identify if a person is COVID-positive, even if they do not have symptoms (asymptomatic).

"Advances in machine learning and the proliferation of medical-grade sensors in everyday consumer wearables has led to a new era in which we can predict and identify the onset of a myriad of diseases," said Adel Laoui, CEO and founder of NeuTigers. "Before the pandemic, our teams were using predictive models in our StarDeep health platform to monitor and screen for diabetes and mental health conditions."

"Realizing our AI technology could be valuable in the fight against COVID-19, we quickly pivoted and developed a new solution after rigorous clinical research trials. Initially meeting the urgent need for mass screening in the business environment,

CovidDeep is set to expand to a wider consumer offering in early 2021," he continued.

**CovidDeep - How it Works**

CovidDeep brings forth groundbreaking science as an app that can predict SARS CoV-2/COVID-19 accurately, safely, quickly, and importantly by preserving people's privacy. Users simply answer a questionnaire regarding symptoms and health history (based on CDC guidelines) and input their health sensor's data.

Data is entered by connecting CovidDeep to an Empatica E4 Wristband as well as inputting blood pressure and blood oxygen readings using any off-the-shelf device. All data remains local to the device, is never shared, and stays securely and privately under the user's control.

The platform then analyzes the data and provides a prediction as to whether someone is likely to be negative or positive for SARS CoV-2/COVID-19. The process takes around 2 minutes, allowing one Empatica device, blood pressure monitor and pulse oximeter to screen unlimited numbers of people after being sanitized between usages.

"Whether helping frontline healthcare workers, employers keeping the workplace safe, assisting airlines in reestablishing consumer confidence in travel, helping students to stay in schools, or providing fast access to sporting and entertainment venues, the applications of CovidDeep are endless," concludes Laoui. ■

# Pilloxa and University of Oslo Collaborate to Validate Smart Medication Adherence System

Digital health company Pilloxa is to begin ASTORIA – a single-armed and multi-centre observational clinical trial in which their digital patient-centric adherence solution will be tested in patients with cardiovascular disease, namely newly diagnosed patients with atrial fibrillation.

The study, to be conducted as a multi-centre trial with the University of Oslo as lead, is funded by an EU-grant from the EUROSTARS program and is also financially supported by Bayer.

ASTORIA, standing for ASsessment of Adherence TO Medication in Atrial Fibrillation - an eMonitoring Drug Dispensing Device Study aims to further

validate Pilloxa's full suite of medication support services – including their adherence app enhanced with mobile communication and a digitally connected pillbox – to enable remote patient monitoring. This includes alerting the patient to take their medication as prescribed and relaying their adherence patterns for further analysis.

The data gathered will enable further development of the solution to increase the quality and effectiveness of drug treatment in both the healthcare setting and during clinical trials. In total, 200 patients will be recruited and results from the trial are estimated to be reported in 2022.

The primary endpoint of the study is to

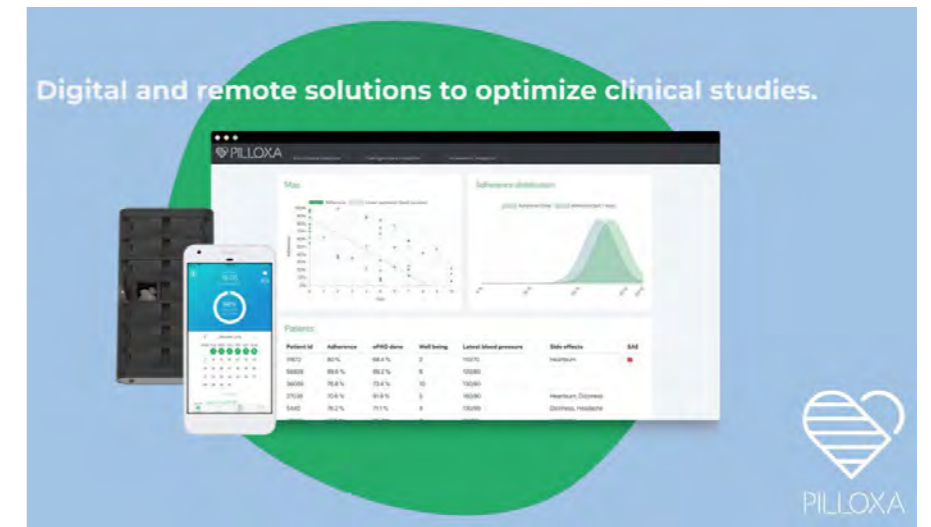
measure patient's adherence to rivaroxaban as measured by the Pilloxa adherence solution.

The principal investigator of ASTORIA, Dan Atar, Professor of Cardiology at the University of Oslo, comments: "Patients with atrial fibrillation carry an increased risk of developing serious and life-threatening events, a stroke being the most common. Fortunately, modern oral anticoagulant medicines have been shown to lower this risk, but it is of utmost importance that the patients take their medicine as prescribed. In the current trial, patients will be reminded when they need to take their medicine and relevant information around the treatment (e.g. time when the medicine was taken)

will be automatically documented. Data documenting whether patients have taken these medications as prescribed provides a good overview in realtime of patient adherence to medical treatment. It is anticipated that this knowledge will provide reassurance to the patient, relatives, and to the prescribing doctor. We also hope to learn how we can improve the quality of future clinical trials, a field in need of improvement when it comes to documenting the intake of drugs."

High adherence to anticoagulation treatment in atrial fibrillation patients is important for the prevention of thromboembolic complications and to reduce the risk of side-effects from the medication. Despite this, data has shown that patient adherence to their new oral anticoagulation (NOAC) medication gradually drops to 60% when evaluated after the first 12 months of treatment. Ensuring that patients take their medicine as prescribed is crucial as the effect of this new medicine on coagulation in the blood cannot be measured.

"That adherence to treatment is fundamental for any therapy to be successful is easy to accept but our research has shown that in practice, adherence is poor in many cases. The advantage of our technology, which we have developed



and documented over the last 5 years, is that it can be added as a new layer without changing the organization, running intensive training programs or making new, expansive investments", says Francesco Mazzotta, CEO of Pilloxa.

"Another advantage is that using our system does not bring any burden onto the patient. Contrary to being a burden, it helps the patient to carry out the treatment in an easier and more efficient way. Patients also tend to be more engaged, and the automatic documentation enables efficient feedback with minimal administration between healthcare providers and the patient, a truly patient

centric solution." continues Mazzotta. "If the study shows improved adherence rates with the use of Pilloxa, this would provide a strong argument for such devices to be implemented routinely for atrial fibrillation patients with an indication for use of long-term treatment with oral anti-coagulant. Furthermore, a positive result would also speak in favor of using Pilloxa's solution in conjunction with treatment with other drugs where adherence rates to medication is central for enhanced outcomes. Given the importance of adherence to treatment for reliable testing of drug effects in early phase clinical trials, we are continuously exploring such investigations with industry partners." ■

# Continuous Monitoring of Proteins a Game-changer for Patients with Rapidly Deteriorating Conditions

In a world-first, Australian researchers have developed an antibody as a biosensor that could become a game-changer for patients at risk of rapid health deterioration, such as heart complications, stroke, sepsis and cancer.

The research team, led by Dr Simon Corrie from Monash University's Department of Chemical Engineering and the ARC Centre of Excellence in Convergent Bio-Nano Science and Technology, took an antibody that binds EGFR (epidermal growth factor receptor) proteins and engineered it to monitor the concentration of EGFR proteins in serum solutions over time.

An inability to detect the growth of EGFR proteins in humans can be associated with the development of a number of tumours, including cancer, as well as the onset of diseases like Alzheimer's.

Using an independent detection mechanism developed by the research team, involving fluorescent dyes, researchers created a biosensor from a well-known antibody that was able to 'read out' changes of the EGFR protein in real-time by monitoring detectable changes in the fluorescence spectra.

The ability to monitor protein biomarker concentrations in body fluids in real-time is invaluable for tracking patients at risk of rapid deterioration, including those requiring personalised drug monitoring or those at high risk of complications arising from critical conditions, like sepsis, heart attack or tumour response to treatment.

No one has been able to engineer an antibody for continuous testing until now. ➔



“All the diagnostic tests that we are familiar with involve sampling something (blood, urine, tissue) at a particular point in time and taking the same to a lab to interrogate it. But for patients suffering from acute conditions, in which time to diagnose and rapid treatment are very important, this traditional diagnostic process is not good enough,” Dr Corrie said.

“Monitoring dynamic changes in proteins, for example protein levels increasing or decreasing over time, is likely to provide much more detailed information about a disease or treatment process, but the sensors required to do this don't exist outside of continuous glucose testing for diabetes.

“Our capacity to create antibodies, which bind reversibly to targets and can be ‘read out’ using fluorescence, means we can develop in vivo sensors. These sensors can monitor the levels of critical biomarkers as they change over time in response to a disease or treatment, rather than just sending a sample to a lab and getting a snapshot in a day or two.

“These biomarkers could include the amount of surface proteins on a cancer cell and whether or not a drug causes them to reduce in size, therefore testing the efficacy of treatment. It can also be used to monitor the concentration of potentially toxic drugs, like some antibiotics.”

This discovery was able to engineer an antibody fragment capable of reversibly binding to a protein analyte (scFv) in a chemical solution, while retaining the specificity of the original antibody sequence.

Through their efforts, continuous in vitro monitoring over multiple hours was successfully recorded.

“Work is underway to employ dyes that are much better suited to medical applications,” Dr Corrie said. “In future, we expect that this process will be used to generate a range of biosensors that can monitor protein concentration continuously inside the human body, through a biopharmaceutical process, or in the environment.”

Co-authors of the paper, published in ACS Sensors, are Dr Christian Fercher, Dr Martina Jones and Professor Stephen Mahler from The University of Queensland and the Australian Institute for Bioengineering and Nanotechnology. ■

## Stockholm Procures Gnosco's Teledermatology Platform for the Efficient Management of Skin Changes

Gnosco is to supply a teledermatology platform for 220 GPs in Stockholm. GPs, allowing them to document and photograph skin changes with a mobile phone and send them securely to skin specialists for remote expert assessment and diagnosis.

The Region Stockholm has signed a six-year agreement with Gnosco to deliver a broad introduction of the region's new care process for teledermatology for more efficient management of patients with skin changes.

Region Stockholm is one of Europe's

largest healthcare providers covering a patient population of 2.2 million. The region plans to use Gnosco's Dermicus platform to introduce a comprehensive standardized, operating system that will provide a user-friendly, secure and modern IT support for teledermatology.

The implementation will start during the Spring of 2021, with health centers gradually receiving training and go live on the teledermatology platform. The objective is to facilitate the communication and collaboration between primary and secondary care to enable efficient, safe and secure diagnosis of skin diseases.

The award decision regarding the procurement of the teledermatology platform, was made by the Healthcare Provision in Region Stockholm, which stated that, “Broad introduction of teledermatology is part of the development of the care process for skin cancer and means that the region can offer better care at a lower cost as well as increased safety and accessibility for patients. A prerequisite for the working method is access to adequate IT support.

“We are delighted to have met Region Stockholm's requirements for the introduction of their new care process for teledermatology. The agreement with the

Stockholm Region is now be the second tender we have won with an entire Region in Sweden. Stockholm has been working for several years to develop its care process in teledermatology and together with our platform Dermicus, an extremely efficient care process has now been created. Stockholm will have one of the most advanced platforms, taking teledermatology to a new level, together with future proofed AI-based functions being integrated,” said Daniel Eliasson, CEO of Gnosco.

### Dermicus and teledermatology

Dermicus is a digital decision support that consists of a smartphone application, dermatoscope and web application. Patient information and images are collected in primary care and then assessed by one or more dermatologists in the region at a distance. They provide feedback with a description, diagnosis and recommendation on how the patient is best treated.

Dermicus enables patients to be diagnosed with shorter lead times and also contributes to raising the level of knowledge of GPs in particular by first documenting a structured history and taking pictures and then relatively quickly receiving structured descriptive consulting responses from dermatologists, enabling optimized learning with direct support from dermatologists.

In sparsely populated areas and on islands, there are additional benefits to the Dermicus decision support system. Patients and staff do not have to travel to the same extent to get a diagnosis or



education and lead times are shortened.

In 2019 Region Skåne was the first region in Sweden to procure Gnosco's Dermicus teledermatology platform, and now Region Stockholm is the second. A third of the population in Sweden, 3.4 million, lives in these two regions.

### Implemented in the UK NHS

In the UK, the Isle of Wight NHS Trust with a population of 144,000, is first to implement the Dermicus teledermatology platform for the early diagnosis of skin cancer. Since May 2020 all the 14 GP practices on the island is using the platform.

Dr Amy Poyner of the Lighthouse Medical, the dermatology service provider for the Isle of Wight and who is responsible for the implementation of Dermicus, said: “It was clear before COVID-19 how effective the new service had been in improving care for our patients, but the pandemic has

demonstrated additional benefits of the remote technology and online collaboration that we couldn't have predicted when we started this initiative. Without Dermicus, we would have had to temporarily stop some of these services and rapidly plan alternative work arounds.”

“It's why we think it's so important to continue to scale the use of technology in our health services and will be looking to extend the teledermatology service further to all dermatology needs on the island. We are also considering introducing Gnosco's telemedicine service for wound care, so that a much wider part of our community can benefit from these vital services, and importantly, we can continue to safeguard these services now, and in the future. The decision by regional health care providers in Sweden to implement teledermatology with scale, proves that this can be achieved, even with the challenges that COVID-19 brings.” ■

## SOC Telemed Launches New telePulmonology Service

SOC Telemed has launched a new telePulmonology consultation service designed to provide U.S. hospitals with access to board-certified intensivists with pulmonary expertise through its on-demand telemedicine platform, Telemed IQ.

Amid COVID-19, the increase in acuity of conditions for patients, combined with saturated emergency rooms and intensive care units, has amplified the need for pulmonary expertise nationwide. In response, SOC Telemed will leverage its team of industry-leading specialists who bring years of experience working with complex hospital patients across the hospital environment, including aiding

in the COVID-19 response. The addition of telePulmonology care is possible due to the expertise of SOC Telemed's veteran physicians enabled by the robust Telemed IQ platform.

Through the company's offering, pulmonology consults are available in both routine and emergency settings. SOC Telemed specialty physicians work as a team with local clinicians, anywhere in the hospital, allowing personalized care to improve patient outcomes.

“It's no secret, 2020 presented many new challenges to the healthcare industry. Staying true to our company's vision ➔

of increasing access to high-quality specialty care, we can now provide pulmonary expertise to communities in need,” said John Kalix, CEO at SOC Teled. “Furthermore, the addition of telePulmonology validates our commitment to both growth and operating as a continuously evolving and innovative organization that can meet healthcare demands through a combination of technology and medical expertise.”

SOC Teled’s telePulmonology services can be more cost-effective than a traditional boots-on-the-ground solution and offer a

backup plan for staffing shortages or surge coverage. Additionally, telePulmonology used in conjunction with standard hospital practice can help alleviate burnout by local pulmonology clinicians.

By bringing pulmonary expertise directly to communities, telePulmonology reduces the need to transfer patients, allowing them to stay closer to home. SOC Teled eliminates the geographic barrier through its battle-tested platform and processes, resulting in increased positive patient outcomes and improved continuity and consistency of care. ■

## Sensyne Health Launches First Digital Health Product in the U.S.

British company Sensyne Health has launched GDM-Health, its remote monitoring solution for diabetes in pregnancy, as the company’s first product in the United States.

Sensyne’s sales and marketing partner for the U.S., Cognizant, is now offering the solution to U.S. health systems and health plans via its sales force. Virtual care services powered by GDM-Health will qualify for reimbursement under remote patient monitoring codes introduced by the Centers for Medicare and Medicaid Services (CMS) in 2020.

Diabetes in pregnancy is a common condition that can increase the risk of hypertension and caesarean section in mothers as well as preterm birth, birth trauma and admission to neonatal intensive care for newborn babies. Over 20% of pregnancies in the U.S. are affected by diabetes every year. GDM-Health has the potential to significantly improve the way this treatable condition is managed by doctors in collaboration with their patients.

The U.S. launch of GDM-Health follows results from a randomised controlled trial conducted in the U.K. which demonstrated a reduction in caesarean sections, improvements in blood glucose monitoring adherence and higher satisfaction with care in women using GDM-Health.

GDM-Health has demonstrated strong demand in the U.K., achieving a 47% market share across NHS England. It has been adopted by 50 NHS Trusts across the NHS with a further 7 Trusts in the process of going live.



Sensyne is concluding a pilot of GDM-Health at Jefferson Health, one of the fastest growing health systems in the U.S., comprising 14 hospitals with 2,800 beds, 6,000 physicians and 7,000 nursing staff with 18,000 births a year. Results from the pilot are expected to be reported in a peer-reviewed journal in early 2021.

Lord (Paul) Drayson PhD, CEO of Sensyne Health, commented, “This marks another major milestone in Sensyne’s development. The launch of GDM-Health in the U.S. market was a key objective for the Company in this financial year. Entering the U.S. market will help pregnant women and clinicians in the U.S. manage diabetes in pregnancy, improving outcomes for both mothers and babies. We are very pleased to be partnered with Cognizant and benefit from their significant sales force behind our initial launch. We look forward to the publication of the study conducted by Jefferson Health to add further weight to the benefits of the GDM-Health product.”

The roll out of the product in the U.S. will be led and overseen by Derek Baird who was recently appointed as Sensyne’s President, North America, and is responsible for driving the commercial development of the Company’s North American operations, building Sensyne’s presence in the U.S. and recruiting a U.S.-based business development team to work in collaboration with the Cognizant sales force.

“There’s no debating the U.S. healthcare system must do better to support maternal and infant health. GDM-Health, as a clinically validated solution with proven results, will address one of the key issues: effective management of diabetes in pregnancy. Given the increased reimbursement support for remote patient monitoring and the desire for fewer in-person visits, the timing is right for launch now. We’re thrilled to make GDM-Health the first formal U.S. product launch and I look forward to more to come.” said Baird. ■

## X-on Develops ‘One Number’ Contact System to Support Primary Care Covid-19 Vaccine Efforts

UK cloud telephony specialist X-on is supporting wide regional networks of GP practices to manage Covid-19 vaccination programmes with a simple contact system for patients to book a vaccination.

X-on has rapidly developed a softphone version of its cloud-based Surgery Connect healthcare phone system to enable Primary Care Networks to provide patients with a single dedicated number and support process for booking an appointment at community vaccination hubs.

The number is being made available for patients contacting vaccination centres set up by local PCNs, and through softphone technology will immediately identify to GP practice staff the purpose of the call and help direct and manage it.

The X-on system, initially introduced by PCNs in Worcestershire, Warwickshire and areas of London ahead of wider roll-out, offers an automatic phone call or SMS function to send out appointment details and reminders. With many of the first cohort of vaccination recipients relying on landlines, this service ensures they receive necessary updates - which may be missed with SMS alone - and directly connects them to the appointment booking service so that they do not have to call back to book in.

Surgery Connect also integrates closely with EMIS Web and SystemOne clinical systems, resulting in a more efficient contact process between patients and practices.

Holly Johnson, Operations Supervisor at South Worcestershire GP federation SW Healthcare, said: “PCNs are starting to roll out vaccinations in parts of the UK in the knowledge that the demand will be considerable. As a result, we are doing all we can to ensure that they are equipped as best they can be for the inevitable influx of essential communication between GPs and patients.

“The software provided by X-on will play a key role in helping our staff to manage vaccinations throughout our local population. Booking patient appointments, for example, will form one of the earliest phases of the process. If we can ensure that communication is handled effectively at this stage, it paves the way for a much smoother and more effective system overall.”



Paul Bensley, managing director of X-on, said: “The nation is embarking on the largest vaccination programme for a generation, presenting significant challenges and pressures for every specialty within medical care.

“Our contact system has been designed based on our close work with GPs and the primary care sector so that it works to the advantage of those at the heart of organising the community vaccination programmes. Our approach also provides flexibility so in the event of high demand and call volume at one practice, another practice within the local network can take the call and manage the process.”

The development of a softphone version of Surgery Connect, which provides sophisticated cloud-based appointment and consultation systems to help manage the Covid-19 vaccination programme, is the latest enhancement to X-on’s support for primary care.

Earlier this year it announced that it was developing a new softphone app that would mean patient calls to their GP are free and in turn reduce the cost to GPs and practices for outgoing calls by around 75%. The app is due for roll out in February 2021.

Following this, X-on developed its GP@Home service at the start of the pandemic, enabling doctors to provide patients with the same level of phone and video care from their own home as they would from their surgery. It also developed technology for GPs to switch from phone to video consultation in a single click. ■

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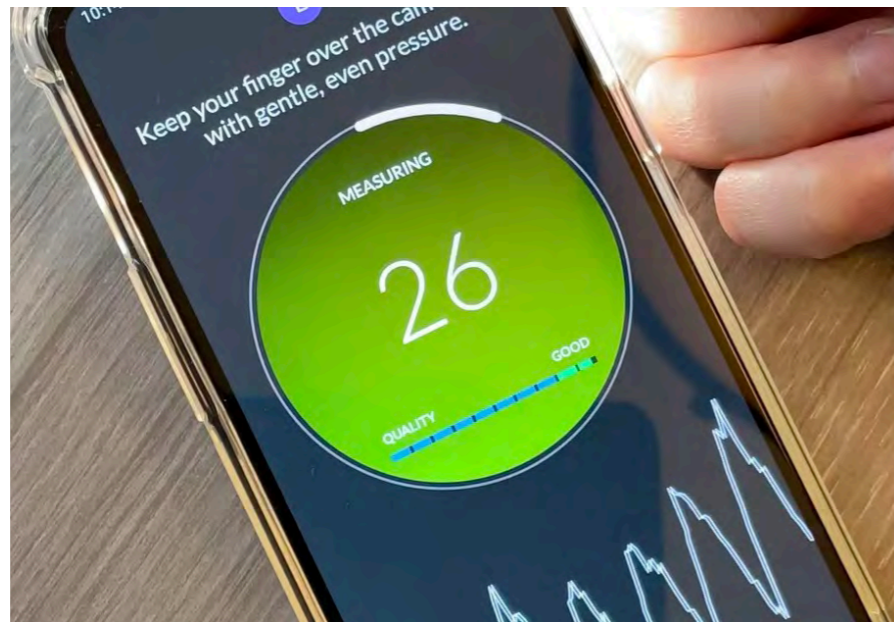
# Biospectal Launches OptiBPP™ Smartphone Blood Pressure Monitoring

Biospectal's OptiBP smartphone app and data platform empowers people worldwide with a medical-grade device integrated directly into their smartphone, enabling instantaneous blood pressure measurement and monitoring, anytime and anywhere.

Backed by grants from the Bill & Melinda Gates Foundation, Grand Challenges Canada and Innosuisse, Biospectal OptiBP empowers people worldwide with a medical-grade device that integrates directly into the ubiquitous smartphone already in their pocket, enabling instantaneous blood pressure measurement and monitoring, anytime and anywhere.

According to the CDC, hypertension affects nearly 46% or 100M US adults, while the World Health Organization estimates 1.13Bn people worldwide have hypertension. Dubbed the "silent killer," only one in five people afflicted with hypertension have control over the condition. People need an easy to use, digital means to accurately measure, monitor, track and share their blood pressure data with their doctors; a need that the onset of COVID-19 and demand for tele-health solutions has only amplified.

"Democratizing and providing easy access to blood pressure monitoring to people worldwide enables improved treatment and impacts medical outcomes. Biospectal OptiBP is a prime example of a broader transition toward remote patient monitoring that moves the clinical functions and capability out of the professional setting to the 'point of patient' where they live," said Elliott Jones, CEO of Biospectal. "Biospectal's patented OptiBP technology replaces the antiquated traditional blood pressure cuff and provides medical-grade blood pressure measurement and management at the 'point of patient' in the time it takes to download an app — without the need for yet another wearable device or additional bulky hardware. Health-conscious consumers and hypertensive patients worldwide can now contribute to and



be involved in their health outcomes in a way that hasn't existed previously."

## How Biospectal OptiBP Works

The Biospectal OptiBP app runs on a typical smartphone and uses the built-in camera to record and measure a user's blood flow via their fingertip quickly and easily. A measurement is rendered in approximately 20 seconds — half the time of a typical blood pressure cuff. Biospectal's proprietary algorithms and optical signal capture methods then transform the captured data into blood pressure values. With Biospectal's software solutions, anyone in the world with a smartphone can turn their device into a connected, smart, clinical-grade monitor in the time it takes to download and install an app. Additionally, the captured blood pressure data connects seamlessly with a user's clinicians to support treatment regimens that help improve health, longevity, and quality of life.

## Scientific validation

A recent large-scale, third-party clinical research study published by Scientific Reports in Nature validated the ability of the Biospectal OptiBP smartphone app to accurately measure blood pressure utilizing transdermal optical sensing and a

smartphone camera lens. No other blood pressure monitoring and management device on the market offers both the medical-grade accuracy and convenience of Biospectal.

"For low and middle-income countries around the globe, this type of technology is a game changer in the fight against non-communicable diseases, dominated by hypertension and cardiovascular disease," said Prof. Alain Labrique, Director of the Johns Hopkins Global mHealth Initiative and Associate Chair for Research. "For the billions of people living in remote, rural communities, having access to accurate blood pressure readings will enable early diagnosis and hopefully, treatment — preventing illness and loss of life."

Biospectal trained its software algorithm using over two million resulting invasively acquired blood pressure samples recorded in the operating room of the CHUV in partnership with the Swiss Center for Electronics and Microtechnology (CSEM), and then validated it with outpatients in the hypertension clinic CHUV. The company's patented technology represents 10+ years of non-invasive optical biosensing R&D led by Biospectal Chief Medical Advisor, Dr. Patrick Schoettker, M.D.. ■

# New Radar-based Technology Allows 'Contact-free' Vital Signs Monitoring

Scientists at Heriot-Watt University have developed a technique that monitors a patient's vital signs completely touch free.

By using a continuous wave radar-based system to sense tiny chest movements, the new method can accurately measure an individual's heart rate and respiratory rate without the need for wires, probes, wearable technology or other skin attachments. It could also identify early signs of heart disease like Arrhythmia while highlighting deterioration for those living with Dementia.

The new technique will benefit all ages as well as those with COVID-19 where the risk of cross-infection is high.

Dr Dimitris Anagnostou, Associate Professor and project lead, explains: "Continuous monitoring of an individual's vital signs can be necessary for several reasons. In hospital, it helps clinicians to determine which patients need urgent help, if someone is improving and can provide early warning signs of a more significant problem allowing quicker intervention.

"For infants and young children, extended use of electrodes and probes can cause skin damage as well as additional distress. Burn patients and those with compromised skin conditions are more challenging to monitor for long periods with wired devices. Our technology allows a patient full mobility while being monitored 24/7. Capable of working unmanned, the signal can also penetrate walls and protects privacy.

"Our approach has wide reaching applications for the treatment of COVID-19 and can allow the progression of the virus to be monitored long-term without increasing the risk of infection."

For many elderly people, monitoring is now necessary at home. Despite leaps forward in technology, such as wearable sensors embedded in watches, for individuals living with Dementia, remembering to put on a watch or wearing one continuously is problematic.

Dr Anagnostou continues: "While our technology is not designed to be a diagnostic tool, we are confident it can support those with assisted living needs to remain at home for longer with greater confidence that they have unintrusive, real-time, continuous health monitoring. This technology clearly demon-



strates what can be achieved through academic collaboration across disciplines and institutes."

Radars have been widely used for many years to determine the distance between aircrafts or the velocity of a vehicle by comparing the frequency or phase shift of the reflected and transmitted signals.

The new research works by detecting tiny physiological movements in the body of around 1mm even when an individual is asleep. The results of the research indicate excellent accuracy even if a relatively low frequency (2.4 GHz) is used, thanks to the novel system architecture and specialised components. It is believed this will aid its progression into home and clinical settings more quickly.

The team has designed a proof-of-concept prototype which can be built into a hospital headboard or mounted on the ceiling. Further applications could include its use in prisons, care homes and sheltered housing.

The team will now take the project a step further, utilising Wi-Fi signals to extract complimentary location and position tracking data that will further support those with assisted living needs to feel safer at home. The team will trial the technology which shows when a person has fallen or if their daily movements have significantly changed, highlighting the progression of several degenerative diseases. ■

# Volta Medical Raises 23 million Euros for Novel AI to Treat Cardiac Arrhythmias

Volta Medical, a pioneering French-based HealthTech startup, working on novel

artificial intelligence algorithms to treat cardiac arrhythmias, has raised 23 mil-

lion Euros. The new capital will allow the company to develop its revolutionary ➔

FDA-cleared and CE marked VX1 AI software solution as a new standard of care.

After developing the first commercially available AI software to help electrophysiologists improve management of cardiac arrhythmias, Volta Medical is now preparing to transform the way ablation procedures will take place in the future.

Theophile Mohr-Durdez, CEO and co-founder of Volta Medical said: “We are excited to be able to complete our highly ambitious medical program with the start of TAILORED-AF, a new randomized controlled trial. This trial aims to demonstrate how our AI software can help physicians optimize both efficacy and efficiency when performing complex procedures to treat heart rhythm disturbances.”

**The TAILORED-AF trial**

Recruitment for the TAILORED-AF, an international multi-center trial has already started. It is hoped that the results will provide a breakthrough approach for tackling one of the world’s greatest public health challenges in a more consistent and reproducible manner. Atrial fibrillation (AF) currently affects over 30 million patients worldwide.

The TAILORED-AF trial is designed to compare the VX1 AI software ablation strategy with currently used conventional anatomical ablation approaches.

According to Dr Tom De Potter, Head of Electrophysiology, OLV Hospital, Aalst, Belgium and one of the TAILORED-AF trial investigators, “treatment of the more severe forms of drug-resistant persistent AF remains a major challenge in our field, both due to the large number of patients affected and lack of therapeutic strategies that can offer predictable efficacy. Thanks to the software’s ability to identify signals that are relevant, from those that are less relevant, one of its greatest and most unique benefits is to allow for a more easily reproducible approach to ablation.” The results of the Ev-AIAFIB proof of concept study carried out with VX1 in 8 different centers will soon be published. They will provide data on why and how this new approach has the potential to provide electrophysiologists with a guidance tool that will optimize treatment of patients with AF in a lasting manner.

Conventional ablation methods, while useful for treating patients, who cannot tolerate or who are resistant to anti-ar-

rhythmic drug therapy, have so far been less precise than desired. Their results, even if significant in certain cases, remain sub-optimal. Localization and ablation of drivers perpetuating AF have been at the forefront of cardiovascular disease research but have not led to any radical changes to-date. Volta’s system is intuitive, user-friendly and shows promise to potentially reduce inter-operator variability in the analysis of procedural data without lengthening either the diagnostic or therapeutic procedures.

“We are eager to help new centers access and use our revolutionary tool during ablation procedures. This cutting-edge medical innovation enhances the efficiency and precision of the practitioners who are analyzing real-time data in the operating room. Its robustness will help physicians adopt a more efficient workflow and take the right decisions” – claimed physician co-founder, Jerome Kalifa.

Janke Dittmer of Glide Healthcare, which led the funding round, comments: “We are excited to support Volta’s team in bringing a unique solution to address one of the biggest unmet needs in the large and fast-growing electrophysiology market”. ■



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