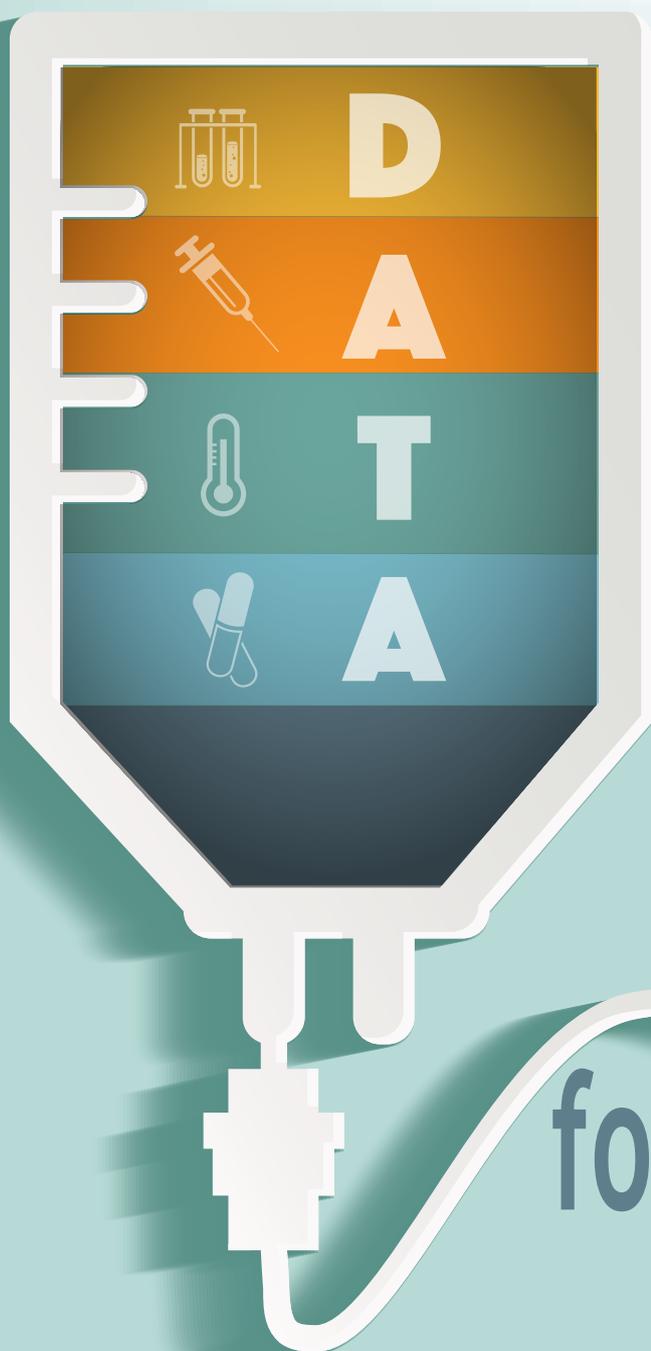


# The Journal of mHealth

The Global Voice of Digital Health

June / July 2017 | Volume 4 Issue 3



# DATA: The Latest Medication for Healthcare

## CUPRIS

New Model of Technology-Enabled Care



## TELEHEALTH

A Necessary Tool for the Future of US Healthcare



## MEDICAL IoT

From Clinical Trials to Drug Manufacturing

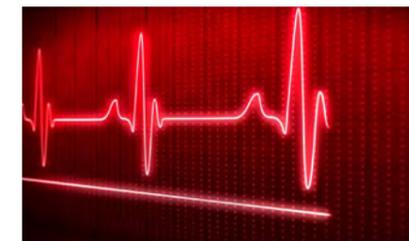


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...stand out from the crowd

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The most innovative companies  
in the field of digital health

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# Welcome



We have been to a range of fantastic healthcare events so far this year and it has been amazing to see how there is such a diverse interest in the growing use of digital technologies from across the healthcare ecosystem.

I think that we have probably all experienced frustration when it comes to the process of digital adoption in the healthcare industry, and as a sector we have definitely, at times, lagged behind many other industries. But this laboured approach is definitely changing. It has been especially interesting to discuss with delegates from all parts of the healthcare sector, and from around the world, their different visions for digital. A common theme that runs through all of these projects is data – *How can we provide better access to existing data? How can real-time data be used to improve decision making, drive efficiency and deliver better standards of care? How do we go about sharing relevant patient data with all the necessary stakeholders?*

These are just some of the questions that we consistently hear. Appropriate and timely access to information provides the potential to fundamentally improve the way in which health and medical care is delivered. Not by radically transforming the healthcare system – as some would have us believe – but by supporting existing processes and allowing them to be delivered in much more effective and relevant ways.

In this issue we delve into a range of projects to provide examples of where data is really having a profound impact on the way that care services are provided. We also ask a range of experts for their perspectives on the role of data in healthcare.

William Bolt of Unisys, discusses *How IoT is Transforming the Life Sciences Industry?*, Nicola Hall of Ingenica considers how in a commercial world where companies are looking towards artificial intelligence (AI), as the next generation of data management, healthcare organisations are still just understanding what digitisation could do for the organisation, and, Keith Nurcombe asks, *Is Data the New Black Gold for Healthcare?*

Also, it is that time of the year again where we launch the nomination process for our 2017 Global Digital Health 100. Year-on-year our Global Digital Health 100 continues to grow in popularity, and, with a global audience, it remains one of the most hotly anticipated events of the digital health calendar. Due to publish at the end of the year we have now opened up the nomination process. To nominate a digital health company, solution or project that you think we should consider visit [www.thejournalofmhealth.com](http://www.thejournalofmhealth.com). We look forward to reviewing your suggestions!

**Matthew Driver**  
Editor

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# Upcoming events

## July 2017

24-26

### International Conference on Diabetes, Nutrition Metabolism & Medicare

Vancouver, BC, Canada  
For more information visit  
<http://diabetesconference.alliedacademies.com/registration>

## August 2017

23-24

### Hospital Management Asia

Manila, Philippines  
For more information visit  
<http://www.hospitalmanagementasia.com/thejournalofmhealthguest>

## September 2017

12-13

### Internet of Health

Amsterdam, Netherlands  
For more information visit <https://internetofbusiness.com/events/internet-of-health-emea/register/>

14-15

### International Diabetes and Degenerative Diseases Conference

San Diego, CA, USA  
For more information visit <https://www.clytoaccess.com/international-diabetes-and-degenerative-diseases-conference>

18-19

### Artificial Intelligence Innovation Summit

San Francisco, CA, USA  
For more information visit  
<http://exlevents.com/artificial-intelligence/#JournalmHealth>.  
Get 15% off registration with discount code C932JM

27-28

### Artificial Intelligence in Drug Development Congress

London, UK  
For more information visit  
<http://www.artificialintelligence-congress.com/>

27-28

### 15th Annual Pharmaceutical IT Congress

London, UK  
For more information visit  
<http://www.pharmatechnology-summit.com/>

## Oct 2017

3-5

### IoT Solutions World Congress

Barcelona, Spain  
For more information visit  
[www.iotsolutionsworldcongress.com/visit/passes-and-prices/](http://www.iotsolutionsworldcongress.com/visit/passes-and-prices/)

## November 2017

8-10

### 4th European Congress on eCardiology & eHealth

Berlin, Germany  
For more information visit [www.e-cardiohealth.com/call-abstracts](http://www.e-cardiohealth.com/call-abstracts)

22-23

### Diabetes Professional Care

London, UK  
For more information visit [www.diabetesprofessionalcare.com/](http://www.diabetesprofessionalcare.com/)

# Data: The Latest Medication for Healthcare



*Nicola Hall, managing director at Ingenica Solutions (www.ingenicasolutions.com), the company behind the first GS1 certified inventory management solution in the UK healthcare market, explains.*

There was an article written in 1994 which concluded that healthcare was data rich, but information poor. Twenty plus years later, has it really changed?

In the last twenty years technology and data has changed the world we live in today, we are bombarded with data and information all the time. Technology has been disruptive and changed the fabric of our society, the next generation are referred to as “digital natives” yet despite this we are only just starting to see the seeds of change in the NHS.

The commercial world survives on the data to assist with decision making, and predicting trends, it uses data analytics to understand where their business is heading, the hot spots in the business, cost drivers and variations. The NHS is in effect running blind and dealing at an isolated micro level.

Today the commercial world is looking towards artificial intelligence (AI), as the next generation of data management, whereas healthcare organisations are still just understanding what digitisation could do for the organisation.

The NHS is one of the biggest organisations in the world, but it is not just one organisation it is thousands of organisations all with their own way of working. There is no standard operating process for the whole of the NHS, trying to put technology around multiple variations is difficult; as we saw with connecting for health.

There are three main areas where real information is needed to support the NHS, at the clinical level, managerial level and in the effective management of resources. The real goal is linking clinical choices to outcomes, whether that is a product or medicine used on a patient, to the length of stay or the clinical pathway they followed. To get to that point there is a real need for change.

## DATA STANDARDS

The GS1 program is often referred to as a “barcoding project”, but it’s not it’s about data standards. Without a common set

of data standards to identify a product, patient, caregiver and/or location, we are unable to use the data across the board. Providing a common data standard across these areas means that technology can be used to capture data, whether that is barcoding, RFID or other technologies. This project is focused on track and trace and improving the supply chain and procurement data.

Between the front-end patient facing systems and the back-end finance system there are a myriad of operational tasks that are run independently on disparate systems, or even excel spreadsheets, using different coding systems; systems that don’t talk to each other or are still purely manual. The interoperability program is set to try to alleviate this issue of systems integration.

I recently watched a documentary on the NHS, where every day thirty people met to tell one person if they had any bed available. The trauma of getting a bed available was the focus of the program, the inefficiency of the whole process was evident. The whole hospital was grinding to a halt around bed capacity, yet the only way the team allocating beds could get information was to have a daily meet-

ing to discuss this with the rest of the hospital, and others by phone.

The NHS has vast amounts of data, and through the effective application of data analytics, healthcare providers can drive efficiencies and cost savings. However, is that easier said than done in this challenging environment?

My focus has always been the management of resources in the NHS, specifically more recently the management of supplies and costing in the NHS. It is well known in commercial organisations that information flow is the lubricant of an effective supply chain, which in turn creates efficiencies. Data is crucial to fully understand and manage the flow of goods in and out of business, and this stands true whether in a public or commercial environment.

Although a world-class clinical organisation, the NHS is run on an inefficient and broken supply chain with procurement activity being undertaken without the necessary quality of data being available to ensure that best value for money is being obtained. Even when money has been spent well and good prices have been obtained, consumption is not managed and waste is often the result of poor inventory controls.

## ISSUES

To stay on top of gaining efficiencies and savings, up-to-date information is key. However there are a number of challenges to be tackled.

One of the issues in healthcare is that the competitive environment that has developed means that teams in the NHS are exclusive, protective of their data and often suspicious of national objectives and collaborating with other trusts and organisations. The collective power and influence here is not being harnessed to its best effect.

Lack of data, an inability to price compare (nationally and even with departments in a Trust), poor pricing history, limited purchasing history, no real supplier performance monitoring and poorly monitored purchasing control in the clinical workplace, alongside the lack of real accountability means that ingrained behaviour patterns and old processes can break local and national objectives, both

one by one and cumulatively.

Locally, most Trusts seem to suffer from a silo mentality, this means that mostly the procurement functions work in isolation from the clinical teams with a focus on price, and the clinical teams are focused on quality and outcome. At the moment those objectives are mutually exclusive. Those two objectives need to merge and these teams need to work more closely together. This will be easier to achieve with objective and informed data to support their decision making.

A further problem is the large variety available to the “on-line” clinical shopper has encouraged the lack of standardisation in product ranges, instead increasing the number of products and product ranges in use. Items not on catalogue are often “processed using free text”. This means a trust does not have a complete set of structured data, and products on the shelves are adrift from the Trust catalogues by up to 30%, even if the contract price agreement level is high. Trying to track some of these products as to where they came from and what they cost has proved time consuming and at times impossible. They have either been ordered on a previously deleted contract, or they were a free-text order, or the supplier no longer exists, the product retired or one supplier has been bought by another. It is this lack of coherent data that is a significant obstacle to effectively managing NHS procurement, and significantly improving efficiencies.

## TECHNOLOGY

One of the issues for healthcare organisations is how technology can be used to capture the data. Some technologies offer only limited functionality and are not configurable across multiple areas. Take NHS trusts as an example, many have hospitals across locations which require technologies to be configurable across different areas with different processes.

There are multiple areas within a trust where data is captured including manual screen entry, barcode scanners, RFID, cabinets, and mobile devices. The right solutions are needed to capture data and business intelligence; innovative tools can be used to dig deeper into data and analyse spend and usage.

Whilst data remains an issue, there are

examples of trusts that are breaking the norm. Portsmouth Hospitals NHS Foundation Trust for instance has the cleanest dataset in the NHS today (by external review). Ultimately improving systems and process is about improving the availability of data and information to make informed decisions.

The starting point for healthcare is therefore establishing effective inventory management to provide consistent and real data; inventory management solutions play a key role here.

The data generated by an effective inventory management system empowers today’s professionals working in healthcare, at all levels, by giving visibility, control and simplicity in a complex, fast-moving clinical environment.

As in other areas of the NHS, much of the focus of procuring goods is placed in a silo without looking at the cause and effect on the whole system. NHS procurement could be improved dramatically by ensuring the effective use of shared data, and crucially, by improved and simplified management of product within the NHS at the point of care.

## SECURITY

Data loss in the NHS is a huge issue, and many instances have surfaced over the inherent risk to highly sensitive information both as a result of human error and technology related. Recently ministers declared it was such a serious issue, that data loss has prompted five separate inquiries.

As well as confidentiality, another key issue is patient safety, which is also at risk during such instances, and as such review is looking into whether the mislaying of patient test results over a specific five year period may have contributed to the death of any patients.

Whilst this illustrates the human error, IT security breaches are also evident. Recently it was reported that further investigations are underway amid concerns that patient data, held by 2,700 GP practices in England, has been compromised.

## BEYOND TECHNOLOGY

Pure technical or hardware solu- ➔

tions alone are not the answer. Many possibilities exist for the effective management of inventory, but for this to really work within the NHS, any technical or hardware system needs to integrate fully into the operational processes of the Trust concerned, integrate technically with existing software/data systems, and be flexible enough to fit the wide range of operational activities undertaken within the NHS.

It is unlikely that any one form of data collection system or device would be suitable for use across all areas of a Trust. In all of this activity, the data recorded should also adhere to a common industry standard format, so that aggregation and analysis of data may be performed in a number of ways, whether this be for analysis of a regional cluster or for a national picture of a particular product or therapy.

In aggregating the data collected, and by utilising the management information from those Trusts with the enabling technology and processes - the NHS would be able to establish a more professional and equal relationship with its suppliers. This would improve the cost efficiency of these key areas of the NHS but would also help the suppliers plan their supply chain more effectively to meet the NHS needs. ■

## New Model of ENT Care Supported by Technology

*"Healthcare technology continues to advance and be implemented in healthcare organisations ... as new models of care delivery are being supported by technology" Coy S (2004).*

Ear Nose and Throat (ENT) hospital departments receive a large number of avoidable referrals. Many of these referrals are being treated in the wrong place (i.e. in an acute hospital), at the wrong time (i.e. often after a considerable wait) when they could be performed in the community. For example ear micro-suction can often be performed in a GP Practice with the appropriate equipment and does not always need to be performed in a hospital setting.

Cupris has developed an innovative technology that has the potential to dramatically reduce demand on secondary care ENT services. Through the use of digital examinations of the ear, nose or mouth, combined with innovative and secure software developed by Cupris, a new system of referrals and triage for ENT conditions is being used to deliver effective remote healthcare.

The scheme is taking forward one of the stated objectives of the Department of Health:

*"Better use of data and technology (in the NHS) has the power to improve health, transforming the quality and reducing the cost of health and care services. . . it is key to helping our NHS meet the efficiency, as well as quality, challenges it faces." (DoH, 2014)*

### Current pathway and new model of care

The current pathway for routine ENT referrals is as follows:

- i. Patient attends GP consultation.
- ii. If the GP feels a specialist ENT opinion is required, a referral form is completed or letter dictated/written.
- iii. The ENT Consultant is provided with a referral letter of varying length and content with which to prioritise the referral as routine or urgent, without any images.
- iv. Patient often has to wait two or more months for an outpatient review, which also requires travel to hospital.

The evidence<sup>1,2</sup> is that a significant number of these routine referrals could be prevented or treated by a variety of healthcare professionals in a setting closer to home. This new model is underpinned by a new system of sending images or videos of ear, nose or mouth examinations, with completed question-

naires to an internet-based ENT triage service.

Instead of referring patients to specialists, GPs will send images and videos of ENT examinations using the CUPRIS otoscope, alongside additional written information either directly typed, or collected through a customised skip-logic questionnaire that can be filled in at home by the patient or by the GP, practice nurse or carer. This dataset of information will be sent to the remote ENT team to confirm the need for a referral.

Advice and guidance can then be swiftly provided for most cases direct to the patient's GP or patient. Where appropriate, the patient can still be referred on to the specialist ENT facility or can be referred to another healthcare provider (such as a GP Practice with appropriate facilities).

The new model of care is as follows:

1. Patient attends GP surgery with ear, nose or throat problem
2. GP uses Cupris otoscope and platform with patients



- When the GP considers that advice or referral is needed
3. GP sends the case to the Remote ENT team through Cupris platform



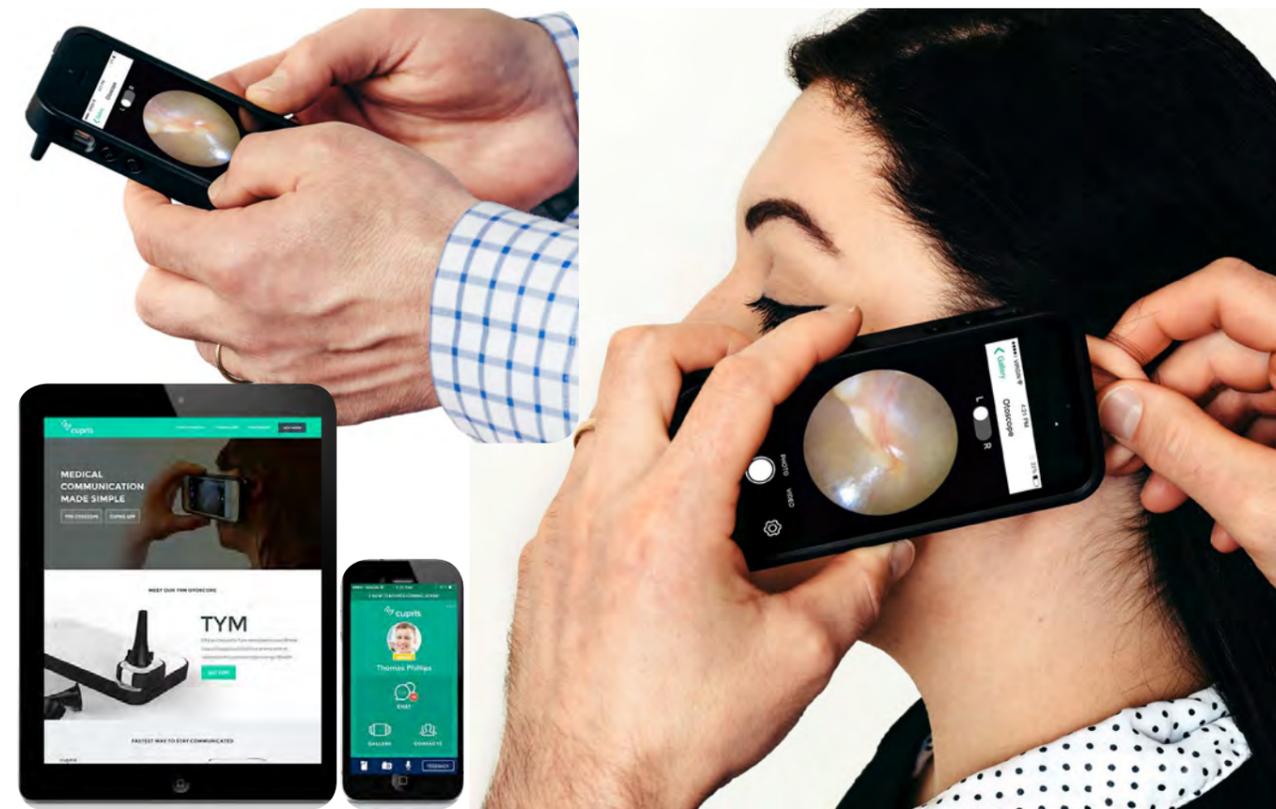
**Case:**  
- Clinical images/videos of the ear, nose or throat  
- Medical history information

4. The Remote ENT team gives advice to the GP on care and treatment management



#### Potential Endpoints

No further referrals needed > Expected for 60% of the patients  
Referrals to other healthcare providers > Expected for 40% of the patients  
Referrals to hospital needed



The medical history questionnaire can be completed by the patient themselves or their carers at home or in the practice waiting room. If an outpatient review is required, this requires less time, as the doctor already has most of the information he requires.

### Evidence based

This new service model has been assessed in a clinical trial at Medway NHS Foundation Trust. A report by the York Health Economics Consortium on the trial found that this new model of care could replace more than 60% of outpatient consultations and referrals by remote reviews. It also led to a subsequent reduction in the number of face to face consultations, and a reduction in the time taken for patient diagnoses.

This novel service model has been reviewed and found to be successful in several other research trials.<sup>1,2</sup>

### Benefits

The key outcomes and benefits of this new service model are to reduce avoidable outpatient consultations and make outpatient consultations more efficient. Crucially, the service for patients is improved with shorter waiting times and the avoidance of unnecessary trips to hospital.

Furthermore, the care and management of patients is focused on their primary care surgery, rather than their management being between the hospital and GP. This model is also likely to reduce 'Did Not Attend' (DNA) rates. Patients benefit from a quicker remote assessment by an ENT specialist. They may also avoid having to attend hospital altogether.

GPs benefit from quicker feedback from the ENT team and are empowered from second opinions received directly with associated images. ENT specialists' time is spent more productively.

GP Practices offering ear suction services benefit from redirection of patients to their facilities and CCGs benefit from the lower cost whilst offering a more convenient service for patients.

This approach to remote healthcare can easily be replicated in other specialties, using a combination of remote history-taking and examination.

### About Cupris

Cupris was co-founded by Jules Hamann (a Consultant ENT Surgeon), and Paul Thomas (an award-winning designer and entrepreneur) to improve healthcare communication by developing medical devices that exploit smartphone technology and a secure messaging platform.

Cupris is CQC Registered to provide the following regulated activities:

- Diagnostic and screening procedures,
- Triage and medical advice provided remotely
- Treatment of disease, disorder or injury

Further details about the company are at: <http://www.cupris.com/about-us/>

1. "Reducing unnecessary outpatient attendances." the Int J Health Care Qual Assur. 2010;23(5):527-31. Donnellan F1, Hussain T, Aftab AR, McGurk C.
2. "Substitution of outpatient care with primary care: a feasibility study on the experiences among general practitioners, medical specialists and patients" Sofie J. M. van Hoof, Marieke D. Spreeuwenberg, Mariëlle E. A. L. Kroese, Jessie Stevens, Ronald J. Meerlo, Monique M. H. Hanraets and Dirk Ruwaard, BMC Family Practice BMC series – open, inclusive and trusted 201617:108, DOI: 10.1186/s12875-016-0498-8© ■

# INDUSTRY NEWS

News and Information for Digital Health Professionals



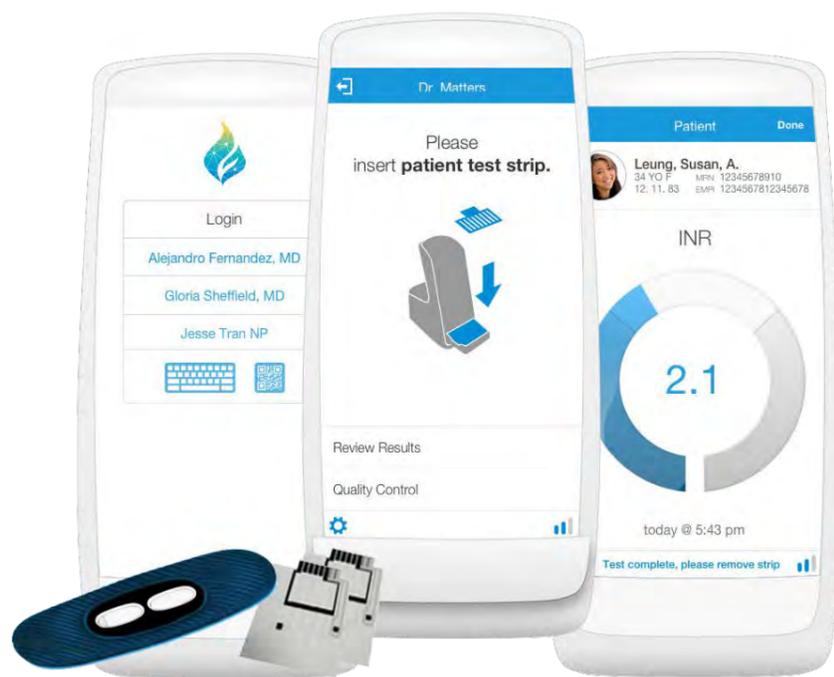
## Over a Million UK Anticoagulation Patients Can Now Access New Integrated Self-care Solution

LumiraDx Care Solutions, a dynamic health technology provider and part of the global LumiraDx group has launched an innovative new product, engage, which delivers seamlessly automated self-care for patients on warfarin therapy.

engage enables anticoagulation patients to self-test at home and send their INR details back to their clinic via an app. Dosing schedules are then automatically sent back to the patient. The whole process is fast and simple, providing convenience and freedom as the patient no longer has to undertake regular trips to the clinic but still remains under the supervision and guidance of the care team. In addition, engage reduces clinical risk and saves around £70 of nurse time per patient per year.<sup>1</sup>

The solution has been developed to fully integrate with the company's market leading anticoagulation management software, INRstar and has been successfully piloted at two clinical sites, where it is proving to eliminate data entry errors, improve patient health and reduce the risk of stroke.

For care teams, engage is simple and quick to set up with no additional work involved for the clinic other than recording the patient's interest and availability in the INRstar patient record,



which they register with the patient's consent and on their behalf (the patient cannot sign up independently of their clinician). Training and education on how to self-test and understand INR is included in the app as well as links to a dedicated technical support team.

engage interfaces with the Roche Coagu-check and also the latest Roche INRange device to eliminate human error while

carrying out supported self-care for anticoagulation.

Pernille Wood, Lead Practice Nurse at Three Spires Medical Practice says: "engage will make dosing much easier for patients. The engage app has a formal training programme and will offer freedom and flexibility to both patients and healthcare professionals. There will definitely be a cost saving [using engage] and

there will be less need to have clinics."

Clare Gardner, Marketing Manager at LumiraDx Care Solutions says: "engage is a game-changing solution for supported self-care: It is so simple and quick to implement for busy care teams and with full patient education and training included in the package, it means the patient's self-care is fully safe and supported, increasing clinic capacity which can then be diverted to other patients and services."

LumiraDx Care Solution's INRstar, is

the UK's leading software for anticoagulation management which is used in over 2,700 locations across the UK.

### References

1. From 2015 to 2016 the Isle of Wight CCG piloted self-testing with 78 out of 288 (27%) warfarin patients at a single practice. The figures below compare the 12 months before the trial started and the first 12 months of the trial. Time saving: On average 1.5 hours were saved per patient per year in clinic time. This

results in a saving of between £66 and £78 per patient per year based on the standard cost of £44 per hour for Band 6 and £52 for Band 7 nurse. (Source: PSSRU 2016 Report)

2. March 2013 Anticoagulation Europe: "It is estimated that in the UK, there are approximately 1.25 million people currently prescribed oral anticoagulant drugs" <http://www.anticoagulationeurope.org/files/files/Anticoagulation%20commissioning%20resource%20pack%20-%20March%202013.pdf> ■

## NHS Trust to Electronically Screen Every Patient Automatically for Sepsis

Nottingham University Hospitals NHS Trust (NUH) is the first Trust to roll-out a real-time, mobile sepsis screening application with integrated clinical alerts to get the right intervention from the right doctor at the right time.

Every adult patient across the 75 wards in Nottingham Hospitals is now being automatically e-screened for Sepsis using the latest software from Nervecentre. There are 8,500 sets of electronic observations taken each day at NUH, and all are automatically screened for sepsis and follow the latest NICE guidelines.

Evidence shows the chance of death from sepsis increases by 8% for every hour it remains untreated, therefore the real-time alerts generated to the 6,000 clinical users of Nervecentre at NUH can significantly help prevent deterioration, by reducing communication delays to zero.

During the first 24 hours of the sepsis e-screening 330 patients triggered as a potential risk for sepsis, causing immediate notifications to a registered nurse for confirmation of a source of infection, prior to escalation to a doctor. This then resulted in 178 automated 'real-time' escalations for sepsis to the relevant doctors. 39 patients were then confirmed by doctors as likely to have early signs of sepsis.

Roll-out of the Nervecentre software was instant with no 'downtime' needed in order for all staff to access the software on their mobile devices. Following a 2 year development project with Nervecentre, the Trust tested the Sepsis Software for 3 months in 'quiet mode' to ensure the parameters used for triggering were clinical appropriate. Then after a 5 week 'live' pilot in their busy admission wards, the Trust confidently applied the sepsis clinical rules to their electronic observations allowing all nursing staff and clinicians to instantly be able to use the life-saving application.

This measure was implemented as part of the Trusts 'Think, Stop, Treat' campaign aimed at significantly improving the early detection and response to Sepsis which has recently seen

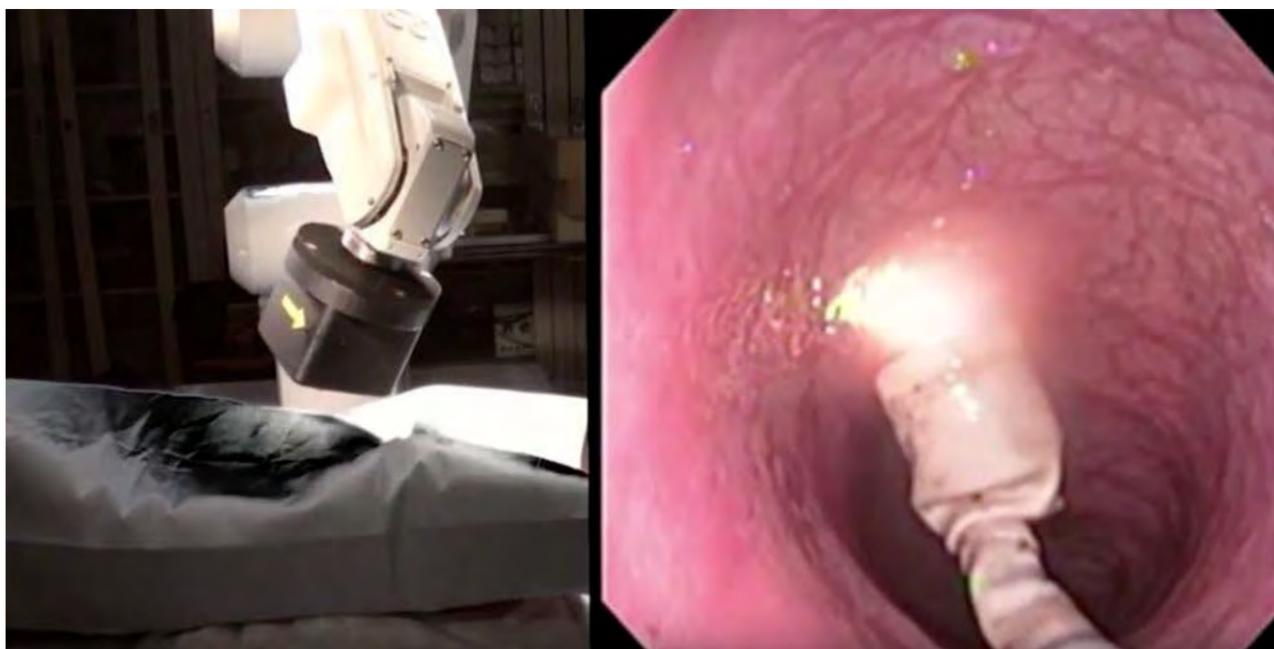


national coverage highlighting that over 45,000 die from Sepsis every year and that early diagnosis significantly improves patient outcomes. The e-screening will ensure that diagnosis of Sepsis is picked up rapidly and ensures an instant escalation and treatment action plan.

Paul Volkaerts, CEO, Nervecentre explains "The ability for NUH to 'turn on' sepsis screening for nearly 2,000 patients and 6,000 staff in one day demonstrates that the NHS is leading the world in next generation software. In a pager and paper based world, this could only be achieved through months of training and poster campaigns. NUH is well positioned to continue to adopt our innovative, patient safety improvements at a much faster pace than has been seen before in healthcare.

Early detection of sepsis is high on all NHS Trusts agendas and the rollout allowed NUH to be compliant with their agreed sepsis CQUIN targets. This Nervecentre e-screening tool is proving crucial to helping doctors and nurses alleviate the enormous range of human factors present in paper-based observations and screening. Other NHS Trusts are already piloting this patient safety focused software and will be rolling it out in the next few months, and NUH will be rolling out to paediatrics imminently. ■

## Colonoscopy Performed by Magnetically Controlled Capsule Robot



New research shows that an 18-mm magnetized capsule colonoscope, which can be paired with standard medical instruments, successfully performed intricate manoeuvres inside the colon while guided by an external magnet attached to a robotic arm. Researchers believe this technology will reduce the potential discomfort of colonoscopies and lead to more people undergoing the life-saving screening test.

This new study was presented at Digestive Disease Week® (DDW) 2017, the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery.

Researchers hope the capsule robot, which is inserted rectally, could be used safely and effectively in the future on humans to identify and remove precancerous lesions and tumours detected during colonoscopy.

"There's no doubt in the value of colonoscopies to keep people healthy through preventive screening for

colon cancer, but many individuals still avoid this procedure, because of fear of the test itself, perceived discomfort or the risk of sedation," said Keith Obstein, MD, MPH, FASGE, the study's corresponding author and associate professor of medicine at Vanderbilt University Medical Center, Nashville, TN. "We developed this capsule robot to make traversing the GI tract much easier, for both the clinician and patient."

Dr. Obstein and his team tested the capsule robot, which has a tether that is smaller in diameter than conventional endoscopes, 30 times in the colon of a pig. They reported that it successfully completed the manoeuvre of retroflexion, in which it bends backward to give the endoscopist a "reverse-view" of the colon wall, on its own (i.e. autonomously/autopilot) at the press of a button.

"Not only is the capsule robot able to actively manoeuvre through the GI tract to perform diagnostics, it is also able to perform therapeutic manoeuvres, such as biopsies of tissue or polyp removal,

due to the tether -- something that other capsule devices are unable to do," added Dr. Obstein. "Since the external magnet pulls the capsule robot with the tether segment from the front or head of the capsule, instead of a physician pushing the colonoscope from behind as in traditional endoscopy, we're able to avoid much of the physical pressure that is placed on the patient's colon -- possibly reducing the need for sedation or pain medication."

The team found that the autonomously-controlled capsule robot was successful in completing all 30 retroflexions. The capsule robot completed retroflexion in an average of 12 seconds, which was within the researchers' expectations.

Following the success of these tests in a pig, Dr. Obstein indicated that the team will be pursuing human trials, expected to begin at the end of 2018. In the meantime, his team will continue to optimize the algorithms that control the robotic arm to improve their performance in manoeuvring the capsule-based robotic system. ■

## Spry Health Unveils Clinical-Grade Wearable Loop to Deliver Continuous Vital Sign Monitoring

Spry Health, a Palo Alto, CA-based provider of remote patient monitoring solutions has unveiled their new clinical-grade wearable Loop that delivers continuous vital sign monitoring. Loop enhances timely care to chronically ill patients, with personalised analytics to improve patient outcomes, reduce hospitalisation and decrease spending by healthcare organisations.

Incubated at Stanford-affiliated accelerator StartX in 2013, founders Pierre-Jean "PJ" Cobut and Elad Ferber started Spry Health with a mission to help chronically ill patients receive proactive care and help them stay out of the hospital. Spry Health developed the clinical-grade wearable Loop to be a catalyst for both better care and lower costs.

"In a given year, over 28 million hospitalisations are attributed to chronically ill patients, resulting in an average bill of \$37,300 per stay with some patients winding up in the hospital three or more times per year," says Ferber in a statement. Empowering chronically ill patients is what drives the compa-



ny's dedicated team of experts in advanced health informatics, biological signals analysis, and medical research.

The Loop wearable continuously and non-invasively collects vital signs to assess the patient's baseline and monitor how their condition evolves. Loop's analytics platform pinpoints subtle physiological changes and

delivers relevant, actionable insights to healthcare organisations before new symptoms are noticeable to the patient. Healthcare organisations can then guide their most vulnerable members to the right care at the right time. The combination of an easy-to-use wearable with personalised analytics increases peace of mind and compliance for patients, improves their outcomes, and prevents costly hospitalisations.

To successfully validate the Loop wearable, Spry Health conducted comprehensive pre-market evaluations of a digital medical device according to Steve Steinhubl, MD, at Scripps Translational Science Institute. The evaluation had over 250 participants to prove the clinical equivalence of Loop against standards of care for blood pressure, heart rate, oxygen saturation, respiration, and CO2 monitoring.

Spry Health has submitted Loop for FDA (510k) clearance and is expected to gain clearance by early 2018.

Source: HITConsultant ■

## Giving Surgeons a Robotic Sense of Touch

Collaborative research between engineers from Heriot-Watt University and surgeons at NHS Lothian/University of Edinburgh has developed a method of mechanically palpating human soft tissue, using micro-mechanical probes to assess tissue 'quality', or stiffness. They focused particularly on diseases of the prostate and have shown that mechanical palpation or touch can differentiate between benign and malignant prostate tissue, a valuable additional tool for robotic assisted surgery.

Led by Professor Bob Reuben (Heriot-Watt University) and Professor Alan McNeill (Lothian University Hospitals, University of Edinburgh) the group has received funding from the Engineering & Physical Sciences Research Council, The Urology Foundation/John Black Charitable Foundation and the Medical Research Council.

As well as showing that their technology can indeed be used to diagnose whether prostate tissue is cancerous or not, the group is continuing to miniaturise it for use in robotic surgical platforms.

The group has now established a start-up company, Palpation Diagnostics Ltd, which has received Horizon 2020 Phase 1 funding to undertake a feasibility study and market research. This showed a real demand for a device to help in the diagnosis of men with prostate cancer and the company is looking for further funding to develop their device to market.

Professor Bob Reuben, of the School of Engineering and Physical Sciences at Heriot-Watt University, said, "Robotic assisted keyhole surgery is a tremendous tool, allowing sur-

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geons to work with great precision even at a remove.

“The current systems rely on surgeons working with purely visual information. Cancer changes the texture of the prostate and so touch can be very useful in helping surgeons be even more precise. The palpation tool uses micromechanical technology to provide the surgeon with more information about prostate tissue during an operation than they could get even if they could actually handle it.

“Our section of the team are engineers, not medics, and when we started work to develop this tool we were thinking of it as a purely diagnostic option. However it has paralleled developments in robotic assisted surgical tools, and now we are hopeful that we can join the two together to provide a really sensitive yet powerful device to support prostate operations.”

The recent introduction of robot-assisted laparoscopic radical prostatectomy by Professor McNeill and the team at the Department of Urology at the Western General Hospital presents a further opportunity for collaborative working between healthcare professionals, engineers and industry.

Professor Alan McNeill, Programme Lead for Robotic Surgery at the Western General, said, “Minimal access or keyhole surgery performed in high volume centres offers patients the best outcomes and a rapid recovery. Robot-assisted surgical systems help provide access to these undoubted benefits but currently lack the tactile feedback normally available to surgeons. Our experience of this type of surgery and collaboration with engineering colleagues at Heriot-Watt University provides us with an excellent opportunity to provide this missing element in robotic surgical systems.” ■

## Cyber Attack: For the NHS, a Simple XPlanation Misses the Point

*The WannaCry or WannaDecryptor virus was a world-wide phenomenon, but the NHS was badly hit. Dr Saif Abed, a founding partner of the health IT consultancy AbedGraham, says a forensic inquiry should be held into what went wrong; so the NHS can deal with the clinical and patient risk issues it exposed.*

Dr Saif Abed was driving when the first news of what was being called the #nhsyberattack came through. “I was using my phone as a sat nav, when suddenly it lit up with Twitter notifications,” he says.

“Initially, it was individuals saying: ‘I can’t get into my computer system’ and then it was news organisations saying: ‘It looks like there’s a large-scale attack underway.’”

By late afternoon, it was clear that at least 16 trusts and an unknown number of GP practices had been affected by the ransomware attack. Staff trying to log into their computers were greeted by a large, red screen saying their files had been encrypted and they would need to pay a ransom in the electronic money Bitcoin to get them back.

### WannaCry: one of the world’s biggest cyber attacks

Yes, it was also becoming clear that the NHS was not being targeted; it was



being affected by the release of a virus called WannaCry or WannaDecryptor (or variations of these names) that had already impacted a telco and banks in Spain.

Dr Abed trained in medicine but has specialised in IT strategy and security, founding the AbedGraham health IT and risk consultancy. And as such, he was not surprised that the NHS was caught up in something bigger.

“Ransomware tends to be widespread and opportunistic,” he says. “If you really wanted to launch a sustained attack against a particular organisation, then you would use something more specialist

and directly malicious than this.”

Even so, the NHS was hit hard. Some trusts, and boards in Scotland had to close their A&E departments or urge patients to attend only if they had life threatening conditions, as delays built up. There were numerous reports of appointments being cancelled and transfers and discharges delayed.

### For the NHS, a simple XPlanation misses the point

The basic advice to see off ransomware is always to have good perimeter security to stop viruses getting through, to train staff

not to click on suspect links, and to have good backup so systems can be restored without paying the ransom.

Perhaps inevitably, news organisations and social media commentators looking to understand why the NHS had been so badly affected by WannaCry focused on the first, technology layer.

Surveys, including the digital maturity assessment of trusts that NHS England conducted last year, have shown that a majority of trusts are still running computers running Windows XP.

This is a Microsoft operating system that has not been supported since 2014 (or, for the UK public sector, 2015) and is no longer ‘patched’ against the sort of known vulnerability that WannaCry exploited.

As the weekend’s general election campaign interviews kicked into gear, there were accusations that the outgoing government had allowed a deal with Microsoft to support XP to lapse, and that the NHS was too starved of funds to move onto more modern software.

### A national enquiry is needed

However, Dr Abed argues this misses the point. He says that WannaCry has exposed a bigger lack of investment in the NHS; in board level engagement in IT issues, in IT leadership, in basic infrastructure, and in staff training.

He also argues that a full investigation is needed to find out exactly what role

each of these played. “We need a forensic investigation into this, in part to avoid inappropriately blaming specific bits of software, or people,” he says.

“I have seen a lot of tweets apportioning blame: ‘It’s all the fault of the IT department’ or ‘how could people be so irresponsible as to click on a link’; but it’s not that straightforward.

“We have to ask why this software is still out there, why it is unpatched, why there hasn’t been the investment in clinical leadership to make people aware of the dangers, why there weren’t the people and processes in place to respond when it happened.

“Also, if we see this as only a technology issue, we run the risk of not seeing the situation for what it really is; a clinical risk and patient safety issue.”

This is not a tech issue, it’s a clinical and patient safety issue

Two days after WannaCry hit, on Sunday afternoon, NHS Digital issued a statement explaining that it was “continuing to work around the clock” to support NHS organisations hit by the attack; suggesting that it was going to take some trusts some time to recover.

It’s too early to say why some trusts and boards were hit by WannaCry, when others dodged it, or why some have recovered so much more easily from back-up than others.

However, Dr Abed says the dispari-

ties illustrate another, broader problem; NHS organisations have very different levels of digital maturity, yet funds for NHS IT tend to be announced for specific projects, and then delayed or clawed back before anything much is achieved on a wide scale.

“We need to invest consistently in infrastructure and people and processes,” he says. “That is why we need a forensic inquiry, and one that leads to immediate action, not one that takes two years and then issues a report.

“If we can pinpoint the problems, we can build a co-ordinated relationship between suppliers, the government and NHS organisations that addresses the problems in a way that meets clinical need.”

At various levels, then, the advice remains: have good perimeter security and apply all available patches, never click on a link about which you have the slightest doubt, sort out backup and have a plan for when things still go wrong.

But Dr Abed reiterates that this is not enough; the NHS needs to hold an enquiry into WannaCry and then get to grips with the fundamental problems that it exposed. “The part of me that is a clinician is hoping that this will not be siloed as a technology issue,” he says.

“This needs to be seen as a national challenge and as a board-level priority, because it is a clinical safety and a patient care issue. It just so happened that this particular point of failure was based on technology.” ■

## Stretchable Circuits Yield New Wave of Wearable Electronics

A team of engineers at the University of Wisconsin–Madison has created the world’s fastest stretchable, wearable integrated circuits, an advance that could drive the Internet of Things and a much more connected, high-speed wireless world.

Led by Zhenqiang “Jack” Ma, the Lynn H. Matthias Professor in Engineering and Vilas Distinguished Achievement Professor in electrical and computer engineering at UW–Madison, the researchers, published details of these powerful, highly efficient integrated circuits, in the journal of *Advanced Functional Materials*.

The advance is a platform for manufacturers seeking to expand the capabilities and applications of wearable electronics — including those with biomedical applications — especially since they strive to develop devices that take advantage of a new generation of wireless broadband technologies referred to as 5G.

With wavelength sizes between a millimetre and a meter, microwave radio frequencies are electromagnetic waves that use frequencies in the .3 gigahertz to 300 gigahertz range. That falls directly in the 5G range. ➔

In mobile communications, the vast microwave radio frequencies of 5G networks will accommodate a growing number of smartphone users and notable increases in data speeds and coverage areas.

In an intensive care unit, epidermal electronic systems (electronics that adhere to the skin like temporary tattoos) could allow healthcare staff to monitor patients remotely and wirelessly, increasing patient comfort by decreasing the customary tangle of cables and wires.

What makes the new, stretchable integrated circuits so powerful is their unique structure, inspired by twisted-pair telephone cables. They contain, essentially, two ultra-tiny intertwining power transmission lines in repeating S-curves.

This serpentine shape—formed in two layers with segmented metal blocks, like a 3-D puzzle—gives the transmission lines the ability to stretch without affecting their performance. It also helps shield the lines from outside interference and, at the same time, confine the electromagnetic waves flowing through them, almost eliminating current loss.

The advance could allow healthcare staff to monitor patients remotely and wirelessly, increasing patient comfort by decreasing the customary tangle of cables and wires.

Moreover, unlike other stretchable transmission lines, whose widths can approach 640 micrometres (or .64 millimetres),



the researchers' new stretchable integrated circuits are just 25 micrometres (or .025 millimetres) thick. That is tiny enough to be highly effective in epidermal electronic systems, among many other applications.

"We have found a way to integrate high-frequency active transistors into a useful circuit that can be wireless," says Ma, whose work was supported by the Air Force Office of Scientific Research. "This is a complete platform that opens the door to lots of new capabilities."

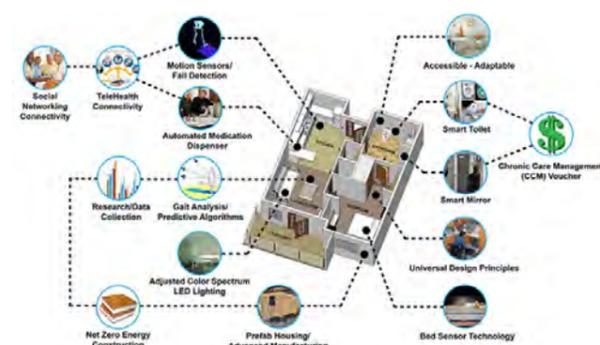
Ma's group has been developing what are known as active transistor devices for the past decade. This latest advance marries the researchers' expertise in both high-frequency and flexible electronics. ■

## What if Your House Could Help Keep You Healthy?

That's the notion that University of Kansas School of Architecture, Design & Planning Associate Professor Joe Colistra and his students will explore this semester through a couple of grants that aim to incorporate big data and sensing technology into the warp and woof of homes of the future.

In October, the American Institute of Architects awarded Colistra a \$30,000 Upjohn Research Initiative grant. In December, Colistra received word that Mozilla's Gigabit Community Fund had given him an additional \$21,000 grant. He is pooling those grant funds to build a housing unit – or at least part of one – that will feature embedded sensors to collect residents' biometric data, with the goal of monitoring their health. The project will be executed by fifth-year students in the school's East Hills Design-Build Center.

"With Kansas City having Google Fiber, you ask yourself: What would you do with unlimited bandwidth? So we proceed to the question of big data collected through the built environment," Colistra said. "What if your house could capture your heel strike, the number of times you left your apartment, the number of times you go to the bathroom, how much sleep you got last night? The idea with connectivity and the Internet



of Things is to link all that data together."

Colistra explained that the idea of a floor that could monitor heel strikes "can tell if someone has fallen, if there is a stutter in their step that is a precursor of Alzheimer's disease. These are not your normal sensors, but ones sensitive enough to use predictive algorithms on. They would be most useful to seniors, so we are working with scientists, including Jessie Huisinga at the Landon Center on Aging at the (University of Kansas) Medical Center, who work on Alzheimer's disease. They can already do gait analysis with a device like a Fitbit, but this would be in the

background. You would not have to turn it on. The monitor would be in the floor. It's an accelerometer, linked to GPS. There could be smart mirrors, smart toilets ..."

Smart mirrors, he explained, look for changes in the skin – moles, lesions, the effects of stroke. Smart toilets monitor hydration and evacuation.

"We are looking at the possibility of taking hydration readings that might lead to adjusting your diuretic or heart medication on the fly," Colistra said. "It could revolutionise geriatric medicine. Your housing unit could be like a medical device; it takes care of you."

Colistra said the project will be done with an eye toward creating a smart house with prefabricated components (e.g., walls, floor panels) so that such items become economically viable if implemented on a large scale.

Colistra said the project will be completed by the end of the

school year – with as many rooms as the funding will allow. The results will then be displayed at conferences, including Maker Faire Kansas City June 24-25 at Union Station.

"It grows out of the New Cities research initiative," Colistra said. "The question there is, 'How do we make lifelong neighborhoods?' That includes daycare, jobs, walkable streets, and, for seniors, rehab clinics and doctors."

Colistra said working with health insurance companies on creating such dwellings would be ideal. They might be motivated to do so with the idea of bringing down their own costs, he said.

"It's a possible new way to make smart cities," Colistra said. "We know all this stuff is coming. The question is how to build architecture to use it. It's all existing technology. It just hasn't been put together yet."

*Image: Diagram of senior living prototype unit, courtesy of Joe Colistra. ■*

## Clinical Industry on the Cusp of a Mobile Diagnostics Revolution

The healthcare sector is on the verge of a new era in mobile diagnostics, according to Novarum® founder and BBI Group Head of Mobile Dr Neil Polwart, who was speaking at the annual Diagnostic Marketers Association Global Marketing Summit (DxMA) in New Orleans, last month.

The annual DxMA summit brings together leading experts from across the clinical laboratory industry to discuss technological innovations, sector trends and changes in regulation, reimbursement and marketing.

UK-based Novarum is part of leading diagnostics and healthcare business BBI Group. A specialist in mobile reader solutions, Novarum's innovative handheld test reader app facilitates the reading and sharing of low cost disposable test results with multiple applications across human diagnostics, veterinary and the environment.

Speaking at DxMA, Dr Polwart said the convergence of mobile technology and Point of Care Testing (POCT) had the potential to unlock a mobile diagnostics revolution. Dr Polwart highlighted that the industry had reached a critical point where the accessibility, intuitive user-

interface and the inherent connectivity offered by smartphones can overcome the limiting factors of many point of care tests – creating new and exciting possibilities within the healthcare sector.

Dr Polwart commented: "It was great to have the opportunity to speak at this key industry event. POCT have long been heralded as a major revolution in healthcare that will transform the patient experience, accelerate diagnostic decision making and present new market opportunities for diagnostic companies.

"In reality, many POCT never progress beyond laboratory use because the challenges in using, interpreting and reporting the data devalue the benefits that the test may bring. Such issues are particularly apparent with patient self-testing.

"However, in contrast to the challenges associated with adoption of POCT, mobile technology has made unparalleled strides forward in the last ten years, with over three billion smartphones now in circulation, increasingly as the primary method of connectivity – this convergence means we're now operating at the vanguard of a new mobile diagnostics revolution."



Novarum's smartphone readers enable tests to be carried out remotely, in the field and in challenging environments, with instant access to accurate test results – using nothing more than a smartphone. The app has already been adopted by some of the diagnostic industry's biggest brands and Novarum continues to work directly with pharma partners, including smaller and more nimble specialists focussed on developing new approaches to target and treat infectious disease, toxicology and auto-immune disease. ■

# New Study Confirms Mobile Health Potential for Easier Asthma Control

It is widely recognised that mobile health has the potential to transform the self-management of chronic diseases. For asthma, a chronic disease affecting 30 million children and adults under 45 in Europe, self-management remains a challenge due to poor inhaler technique and adherence problems.

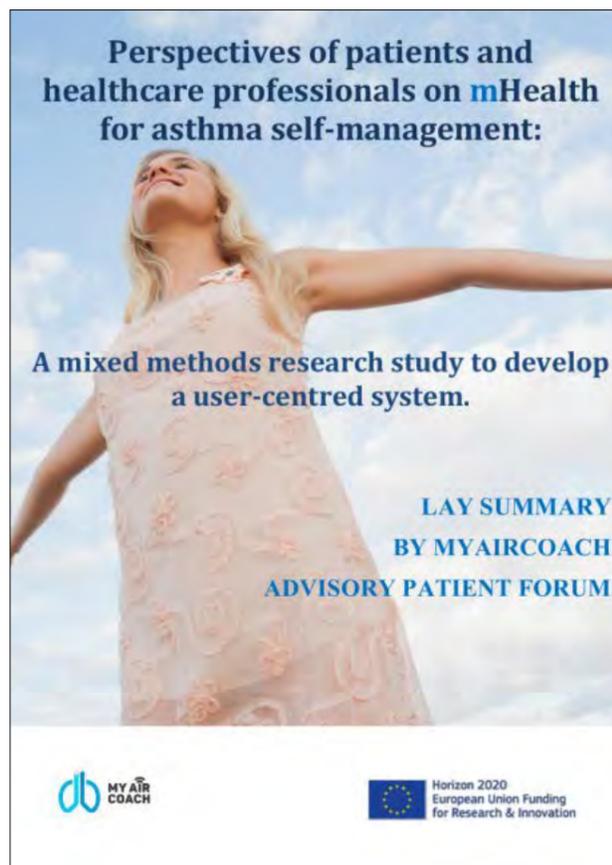
MyAirCoach is a mobile health system that, when connected to a multi-sensor based inhaler, measures not only the asthma patient condition and symptoms in real-time, but also provides patients and healthcare professionals with information about the environmental factors around the patient that could trigger asthma.

While patients are involved from the conception of the project, myAirCoach partners have gone further and asked people with asthma and healthcare professionals their opinion on the utility and efficacy of mHealth tools for asthma self-management. Their preferences and requirements have been put together into 'Perspectives of patients and healthcare professionals on mHealth for asthma self-management: A mixed methods research study to develop a user-centred system', a study published on World Asthma Day 2017<sup>1</sup>.

The study describes how patients and healthcare professionals are strong supporters of mobile health tools for the self-management of asthma, and how this technology helps monitoring the environment to avoid asthma triggers. However, patients are most frequently used to monitor and collect data, while healthcare professionals are more worried about a system alerting patients to deteriorating asthma control and advising them when to seek medical attention.

MyAirCoach Advisory Patient Forum is composed of more than 20 expert patients that participate and advise on the development of the project. The article below is a result of their work and summarises in lay terms the findings of the scientific study.

Giuseppe de Carlo coordinates the Patient Advisory Forum<sup>2</sup>: "Asthma is a tricky disease, many times patients do not know why they are getting worst. Just having the possibility to immediately evaluate their symptoms and assess what might be going wrong directly with their doctor thanks to an app can change



their life, as they will be really controlling their asthma and not the other way around".

MyAirCoach is a three-year EU research project funded by the Horizon2020 Research and Innovation framework programme.

1. 'Perspectives of patients and healthcare professionals on mHealth for asthma self-management: a mixed methods research study to develop a user-centred system'. European Respiratory Journal, 2nd May 2017
2. Giuseppe de Carlo from the European Federation of Allergies and Airways Diseases Patients' Associations and Erika Kennington from Asthma UK are the two myAirCoach partners coordinating the Advisory Patient Forum. ■

## DON'T MISS

our **Upcoming Events** section on page 3 to find out what's on across the mHealth industry

# Study Highlights Critical Security Deficiencies in Medical Devices

Survey of Medical Device Manufacturers and Healthcare Delivery Organisations Reveals Industry's Lack of Confidence and Alignment in Securing Medical Devices

Synopsis, has released the results of the study "Medical Device Security: An Industry Under Attack and Unprepared to Defend," which found that 67 per cent of medical device manufacturers and 56 per cent of healthcare delivery organisations (HDOs) believe an attack on a medical device built or in use by their organisations is likely to occur over the next 12 months. The survey also found that roughly one third of device makers and HDOs are aware of potential adverse effects to patients due to an insecure medical device, but despite the risk only 17 per cent of device makers and 15 per cent of HDOs are taking significant steps to prevent such attacks.

The Synopsis study conducted by the Ponemon Institute, a leading IT security research organisation, aimed at identifying whether device makers and HDOs are in alignment about the need to address cybersecurity risks. The study surveyed approximately 550 individuals from manufacturers and HDOs, whose roles involve the security of medical devices, including implantable devices, radiation equipment, diagnostic and monitoring equipment, robots, as well as networking equipment designed specifically for medical devices and mobile medical apps.

"The security of medical devices is truly a life or death issue for both device manufacturers and healthcare delivery organisations," said Dr. Larry Ponemon, chairman and founder of the Ponemon Institute. "According to the findings of the research, attacks on devices are likely and can put patients at risk. Consequently, it is urgent that the medical device industry makes the security of its devices a high priority."

Other key findings from the study highlight:

- » Building secure devices is challenging. 80 per cent of device makers and HDOs report that medical devices



are very difficult to secure. The top reasons cited for why devices remain vulnerable include accidental coding errors, lack of knowledge/training on secure coding practices and pressure on development teams to meet product deadlines.

- » Lack of security testing. Only 9 per cent of manufacturers and 5 per cent of HDOs say they test medical devices at least once a year, while 53 per cent of HDOs and 43 per cent of manufacturers do not test devices at all.
- » Lack of accountability. While 41 per cent of HDOs believe they are primarily responsible for the security of medical devices, almost one-third of both device makers and HDOs say no one person or function in their organisations is primarily responsible.

FDA guidance is not enough. Only 51 per cent of device makers and 44 per cent of HDOs follow current FDA guidance to mitigate or reduce inherent security

risks in medical devices.

"These findings underscore the cybersecurity gaps that the healthcare industry desperately needs to address to safeguard the well-being of patients in an increasingly connected and software-driven world," said Mike Ahmadi, global director of critical systems security for Synopsis' Software Integrity Group. "As we saw with the past two studies on the Building Security in Maturity Model (BSIMM), the healthcare industry continues to struggle when it comes to software security. The industry needs to undergo a fundamental shift, building security into the software development lifecycle and across the software supply chain to ensure medical devices are not only safe, but also secure."

A complete copy of the "Medical Device Security: An Industry Under Attack and Unprepared to Defend" report can be found here. ■

# Telehealth: A Necessary Tool for the Future of US Healthcare

By Alexander Myskiw, Business Development, Healthcare & Life Sciences Practice, DataArt

The results of the Health Affairs study begin to paint a truly interesting picture within the Healthcare industry. The study has discovered that telehealth will probably not be cutting costs as advertised because it will increase utilisation and therefore healthcare spending. Telehealth will however help patients gain access to medical care and allow hospitals to lower their occupancy rates providing an opportunity to focus on more immediate medical emergencies. In 2014 the Becker's Hospital Review published an article describing a healthcare environment that continues to have higher inpatient volumes and increased emergency department admissions at hospitals.

Northwell Health has taken great strides in alleviating the increased emergency department admissions by implementing a telehealth application called the electronic intensive care unit program. It allows emergency specialists to remotely advise EMT's on proper patient care. The program has a special sub program called Telestroke that allows neurologists to quickly evaluate the patient as soon as they are in the hands of the emergency medical team, essentially saving valuable time and patients' lives. Northwell's recent partnership with Azivia means that they see a bright future for telehealth and expanding its use to home-care patients will allow them to use technologies like wearables, tablets, and other Bluetooth devices to monitor vitals, record symptoms, and eventually allow specialists to predict medical emergencies rather than react to them.

Introducing technologies like telehealth, medication adherence apps, wearables, mHealth, and even robotics, hospitals and doctors will bring their medical expertise into the homes of their patients. Why not bring the operating room to your home? We have all seen the amazing Da Vinci robot that can stitch a grape. We know that robotics can be controlled via the internet. This idea might be slightly outlandish given the current investment into telehealth but technology is headed in the right direction and with a \$1.7 Trillion healthcare market annual revenue the numbers make this future a bit more realistic.

The telehealth market is projected to grow 18.4% from its current \$17.8 billion by 2020 and patients will soon enjoy access to any doctor in the world! In my opinion, this could revolutionise the way patients take care of their health. Bringing hospitals and doctors to the home will create an environment where the healthcare industry can provide their medical services and expertise to an extended network with ease. Patients can be monitored and professionally consulted, more often than not, saving the patient and the trip to the hospital, something that some hospitals might be weary of.

If the occupancy rates continue declining, how will hospitals still profit? Hospitals will need to get with the program. Although telehealth may not be a huge cost cutting tool, it is definitely an instrument that provides hospitals with the capabilities to provide higher quality care and at the same time increase their potential market, eventually reaching global markets.



Recently, Mercy Health invested \$50 million into a 24/7, 300 physicians, nurses, specialists, researchers and support staff facility, that is estimated to deliver healthcare services to 3 million people in 5 years (limited by Medical State Licensing). The USA physicians have a big hurdle ahead of them regarding individual state licensing requirements; however, I'm a bit surprised that the healthcare industry professionals have not demanded a nationwide license. For telehealth to grow the state licensing restrictions must be revisited and a solution regarding the problems relating to telehealth policy must be developed.

Telehealth looks like the "Gold Mine" the Healthcare industry has been waiting for. Freeing the hospital's services from the confines of a hospital or ambulance. Telehealth has a role to play in transforming the relationship between doctors and patients from an isolated interactions/touch point mindset to a relationship mentality where value shifts from urgent need-based encounters to building a relationship from prevention and education through to lasting support.

The typical Doctor-Patient Relationship, as described in the article from the US National Library of Medicine National Institutes of Health: "Whose doctor is it anyway?" which expresses one of the most critical problems inherent in managed care for the doctor-patient relationship. Patients correctly wonder if doctors are caring for them, the plan, or their own jobs or incomes (the latter is equally problematic in fee-for-service care)."

Now with telehealth everyone, especially in rural areas, can choose their doctor. He is just a simple video call away. Telehealth gives the hospitals and their doctors the opportunity to offer high quality care that focuses on patients, showing the patients that the hospital and doctor actually do care. It will take plenty of failures before telehealth finds its sweet spot, but it's a technology that will remove limitations within the industry, provide great opportunity for profits, and make a difference that saves lives.

Whether the industry is ready to fully commit to telehealth or not, the technology and the people's desire for accessible medical care, when it matters, will be the driving forces compelling hospitals' to develop a network of healthcare services that will reach a vaster network of patients and increase the quality of patient care. Healthcare costs might not be cut, but lives will be saved with telehealth. It is a medical lifeline that is available when you need it! ■



By Keith Nurcombe

Keith Nurcombe has worked in healthcare for over twenty years spending the last few years working with businesses in the health and technology space, most recently building O2 Health where he was Managing Director until the end of 2012, since then he has been providing consultancy services to businesses.

## What does this mean now?

Understanding, via the use of digital applications, where a patient started their journey, their interactions, and click-by-click, or screen-by-screen, allowing us to see exactly where they have been and what they did, or often more importantly where they stopped, and what they didn't do. This is data we could have only dreamed of a few years ago. When designing and delivering services this potentially allows us to make changes quickly, deliver new operating models in an agile way and really define patient friendly services.

As we have seen, elements help us design better services – but what about mass collection of patient data and what that can tell us. Well, we can find out about trends and usage of healthcare services much more quickly than before, thus educating us and helping us to manage our care and delivery better, and in a much more focussed way.

This greater access to data also presents new commercial opportunities, whereby we might take the collected data and with suitable permissions use it to deliver other non-healthcare related services which are personalised and appropriate for the patient - targeting the patient as a consumer.

Somebody said to me recently that "data in healthcare is the new black gold for providers, patients and the healthcare industry".

I'm not so sure, if I am honest!

It is a very powerful tool for so many aspects of what we are doing and what we could do, but I am not sure it's quite the new black gold.

So what are we doing with healthcare data, what should we be doing, and, more importantly - in an ideal world - what could we be doing with the data that we derive?

For a long time healthcare data consisted of manual qualitative and quantitative datasets that took a very long time to build, but delivered value through the potential insight they gave into many areas of healthcare, including: population health modelling, public health, hospital admission rates, in-patient readmission data etc.

Suddenly in the world of digital we have opened a rich vein of opportunity to get data at scale, with speed and in areas that previously we never dreamed of.

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## From Clinical Trials to Drug Manufacturing: How IoT is Transforming the Life Sciences Industry



William Bolt, EMEA Life Sciences Executive, Unisys

Ingestible pills equipped with micro cameras. Smart home devices connected to hospital networks. Wearable devices constantly tracking and recording patient data. Thanks to hardware innovation and improvements in IoT technology, we are on the cusp of a Life Sciences R&D transformation. It's a change fuelled by the growing demand for patient-centric care and the need to improve the bottom line.

However, pharmaceutical, biotechnology and medical device companies still face significant challenges. Generic competition, increasing M&A activity, blockbuster patent expirations, heavy compliance burdens and widening geographical disparity contribute to a complex and intricate operating landscape – one that is characterised by rising development costs and eroding margins.

In order to ensure sustainability, firms must embrace innovation. Fortunately, in this case, technology does not disappoint.

### Putting the patient at the heart of things

Pharmaceutical and biotechnology companies must reach

clinical outcomes faster. They need to harvest data in an efficient and effective way, while deploying analytics in a timely and secure manner. Technology can facilitate this change.

Today's clinical trials often require complex designs and demand significant involvement from healthcare staff. This is due in part for constant monitoring and communication during trials. Currently, this is done largely through patient anecdotes and physical appointments, resulting in an onerous, lengthy, and expensive process.

Having the ability to harvest data in an efficient and effective way, and being able to deploy analytics in a timely and secure manner, are two ways to simplify clinical processes, decrease development time, and rein in costs.

By combining medical-grade devices with IoT networks, pharmaceutical professionals will have the ability to monitor patients remotely. This includes keeping track of changes in body temperature, hydration levels, sleep cycles, and other daily activities – all collected passively and in real-time. This new method of data capture facilitates efficient and effective information transfer, while exerting minimal impact on the patient experience.

Solutions such as the recently launched Active Insights™ by

Unisys, a comprehensive and integrated medical device management platform, allow Healthcare and Life Sciences companies to effortlessly monitor all the medical devices within their organisation from a single point of contact. This means that it becomes easier to track device performance, monitor device maintenance and ensure regular compliance.

### Next generation drug manufacturing

Further down the development chain, pharmaceutical manufacturing is also heading towards a revolution. Wireless connectivity and state-of-the-art sensors are providing greater visibility across every step of the production process. This insight affords greater operational efficiency: wastage is minimalised, downtime remediation is done in near-real time, and compliance is more readily met through persistent and consistent monitoring.

However, these advantages also come with inherent risks. According to IBM, the Life Sciences industry is now the top industry for cyberattacks, ahead of more traditional targets such as Financial Services and general Manufacturing. The very nature of the data sought by hackers means that ramifications of any security breach can be quite severe and extensive. Theft, counterfeit, and unlicensed medicines within the supply chain are a huge problem that cost the industry billions, globally. Public exposures of patient information can quickly destroy brand and industry trust while putting patients, providers, and payers at significant risk.

Pharmaceutical companies need to enable connectivity, collaboration and information flows, but also need to protect them. This is especially critical for networks with third-party collaborators. However, unfettered data movement is crucial for insight and development to flourish. Meaning networks must be secured against attacks, but also protected in a manner that minimises the impact on their utility.

A three-step data security process can help. In this instance, the

data of interest is first isolated from the rest of the system. Second, it is encrypted, before it is transferred out of the network or networks. These steps are key to compliance with directives issued by various regulatory bodies, including the GDPR, EMA, FDA, PMDA and GPhC, among others.

Remember, complex devices aren't the only target. Smart scales, smart fridges, and any other devices connected to a critical network can be exploited to compromise sensitive data. According to Gartner, there will be roughly 20.8 billion IoT devices by 2020. Without proper precautions, the possible attack surface becomes absolutely enormous, growing at a frightening pace.

The IoT-powered Life Sciences revolution is still in its early stages. The resultant connected future is still clouded with security, privacy, and regulatory concerns. However, what is clear is that IoT technologies will allow pharmaceutical companies to extend their offering 'beyond the pill' with complementary services and products. This result is sure to improve the general satisfaction and safety of patients, and boost the bottom lines of both payers and providers. In order for this to happen, implementing proper security measures is essential. ■



## An NHS-wide Cloud for Diagnostics?



An NHS-wide cloud for sharing diagnostic images and intelligence across the health service could mean huge economies of scale, stronger collaboration, and rapid digitisation. Sectra's UK managing director Jane Rendall and chief technology officer Fredrik Gustavsson explore.



### One of the only places in the world that can fully exploit cloud for healthcare

Pressure to improve sustainability and reduce isolation in healthcare has renewed the hunger for a different approach to IT. Installing software in individual organisations, and then managing it locally

on hospital servers, is a resource hungry method that for many organisations is starting to reach its limits in the race to digital maturity.

The UK is in an almost unique position to accelerate its digital progress and embrace truly national economies of scale by exploiting cloud technology,

something that has already started to be seen in diagnostic disciplines.

Northern Ireland, for example, has one of the most effective and largest scale picture archiving and communications systems (PACS) in the world. By exploiting cloud, a single imaging system is now accessible by healthcare profession- ➔

als across the whole of Northern Ireland, allowing different disciplines to access a patient's radiology record from almost any location.

Large scale cloud deployment has also already been seen in England where more than 400 sites across the NHS are using the Image Exchange Portal (IEP) to make images rapidly available to the right professionals. Supporting regional working and new ways of delivering care across organisational boundaries, the IEP is used by NHS staff to exchange some 15,000 studies every day that would otherwise need to be burned onto CDs and sent via costly courier services.

But achievements so far are just the beginning. There is now greater potential than ever for the NHS to use cloud to leverage rapid expansion of digital technology across organisations and sustainability footprints.

Cloud has the potential to speed up the time in which all parts of the health service benefit from the latest innovation and software updates, to enable the collaboration demanded by evolving models of care, and to use the 'N' in the NHS to greatest effect, whilst still allowing specialist functionality demanded by the frontline.

### Ensuring the NHS spreads digital innovation quickly

NHS organisations can no longer afford to be working from IT systems that are years out of date. But the reality is that too often, hospitals can today be working with software that at best receives an update every one to two years, and at worst, isn't updated in closer to a decade.

Other industries do not work like this. Organisations ranging from Facebook to Google upgrade their applications almost immediately, and make those updates instantaneously available to users across the globe.

Whether it is the electronic patient record (EPR), or a vendor neutral archive (VNA), technologies are becoming so central to the delivery of care, that all healthcare organisations must have access to the latest innovations.

Professionals must not be denied the functions they need because of con-

tractual limitations or because internal datacenters or resources are not in a position to support the latest versions needed by staff delivering care.

Advances in care mean that software innovation is now a continuous cycle, where vendors must be responsive to the immediate needs of healthcare professionals. Cloud adoption could help all healthcare organisations ensure these innovations are available to their own staff, irrespective of the internal resource that might traditionally be needed to ensure continuous uptime, or the hardware to ensure compatibility.

Cloud now signals an opportunity to leap frog digital maturity, and beyond that to ensure rapid expansion, innovation and growth. The conversation needs to shift from which hardware to buy. Just as consumers can now instantly stream films to their home through online services like Netflix, without the need for a DVD or a DVD player, a clinician should not have to wait months or even longer to get the latest functionality, whilst upgrades are carried out to hospital servers, or whilst negotiations are completed with the software vendor.

### Security and other economies of scale

Security, often cited as a point of concern in cloud adoption, has the potential to be significantly enhanced, particularly at a time when resources are in high competition. Individual trusts trying to attract the right candidates with the knowledge and skills needed to safeguard their systems are not only competing against other trusts, but against wider public sector bodies, security services and high-paying private sector organisations, where cyber and IT security expertise are in extremely high demand.

Cloud driven economies of scale that allow better prices, apply just as much to security. Although NHS chiefs are quite rightly trying to encourage responsibility for cyber security at all levels of the healthcare enterprise, a collaborative approach to securing shared cloud systems, could provide the NHS with another boost.

Put simply, NHS organisations have a different primary purpose and different resources than large scale IT organisa-

tions. They are healthcare organisations. Expecting individual IT departments across more than 200 trusts to be self-dependent for security is an unnecessary burden that does little to leverage the economies of scale of the healthcare system.

Nevertheless, cloud does require a pragmatic approach when it comes to security. It would not be appropriate, for example, for the NHS to base its information in a public cloud, where other actors and other countries may share access to the same servers. A large scale private cloud could however be an answer for the NHS, allowing economies of scale across the country in everything from licensing to hosting, hardware, operations, monitoring and security.

### Creating an NHS-wide cloud for diagnostics

Just as Northern Ireland is already using a PACS to share radiology images across the entire region to relevant healthcare professionals, VNAs are now increasingly being seen by healthcare organisations worldwide as a way to share information from a full range of diagnostic departments.

VNAs will become as central to healthcare as the EPR, and cloud offers a chance to deliver such technology at pace. If done at a national scale across England, resulting economies could help ensure a robust and resilient, continuously up-to-date system.

At a time when the face of healthcare is in a state of flux, cloud means the potential for responsive and future proof technology in the NHS, supporting accelerated adoption followed by a forward momentum of innovation.

Collaboration and regional working is also intrinsically much easier to accomplish in a cloud environment by moving away from peer to peer networks. As the Image Exchange Portal has proven for hundreds of trusts, cloud can allow the rapid integration of different organisations' information.

This is about supporting all trusts, regardless of digital maturity, and removing complexity for local IT teams by paving the way for healthcare pathways where information really does follow the patient. ■

# Next Steps for Standards

The Next Steps on the Five Year Forward View reiterated the need for integrated care. The UK's NHS and the healthcare IT industry know that integrated care demands integrated data, if safe consistent patient care is to be provided.

Yet, says Andrew Meiner, the Managing Director of Stalis, that's not happening. To change things, we need national and industry action on open standards; and NHS service providers need to make sure they are used.

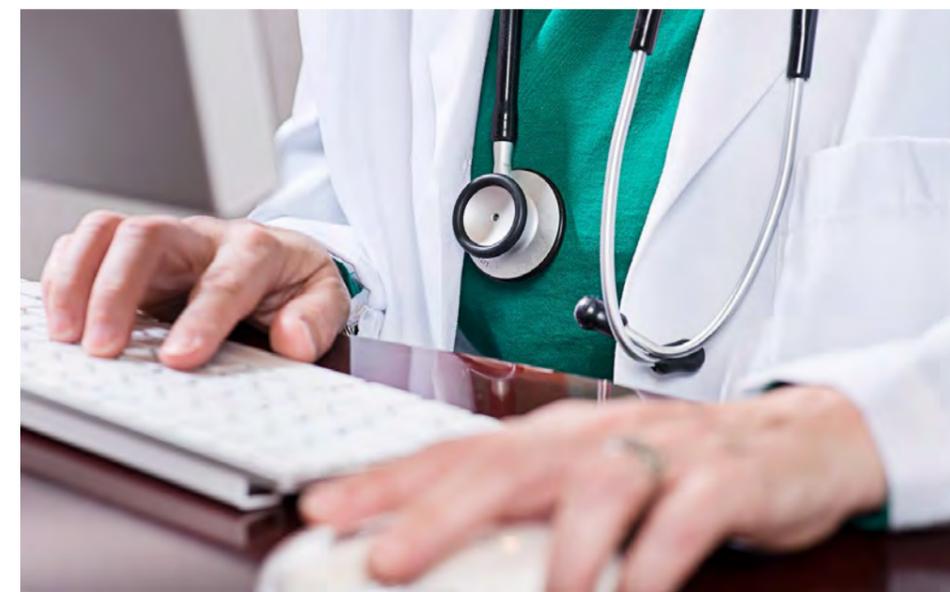
Just before the general election was called, NHS England set out the progress that it wants to see taken on the Five Year Forward View.

The Next Steps on the Five Year Forward View report reiterated the message that the key to closing the growing gap between funding, demand and cost is for health and social care organisations to do things differently.

It requires the integration of processes and services, and to integrate services you need to integrate their data. This seems obvious; and is generally accepted by those close to the task. Yet, in practice, it is not happening.

The GP vendors are contractually committed to releasing their data under GPSoC, but progress is extremely slow. And in the acute sector, the EPR vendors are still storing data in their own way, using proprietary standards.

It is extremely frustrating, because if you want data-driven change in healthcare, then you have to have open standards for how data is structured. So, the question is how we can make this happen.



### Well-known standards

We're certainly not short of standards organisations or open standards. There is Integrating the Healthcare Enterprise or IHE, which has led on Cross-Enterprise Document Sharing, better known as XDS.

There is Health Level 7 (HL7), which provides a framework and standards for the integration and exchange of healthcare information, and which is behind Fast Healthcare Interoperability Resources, or FHIR.

And there is the openEHR Foundation, which is co-ordinating the work on openEHR. But openEHR is more of an approach than a standard, because it separates information from its use, so it can be templated into useful tools.

These standards are different and not mutually exclusive. XDS is a proven way of distributing clinical documents using a pull mechanism and sharing those documents across large geographic regions.

FHIR is the logical evolution of HL7v2 and HL7v3, and al-

lows complex point to point integrations to be built quickly and cheaply. So, both XDS and FHIR can use the CDA, or Clinical Document Architecture, that defines the structure of some medical records, but their use cases would be different.

XDS is the better choice if you want to search for clinical documents for a patient, while FHIR makes more sense if you want to transfer care responsibility from one provider to another. FHIR also allows data from mobile devices and wearables to be integrated.

OpenEHR, meanwhile, is the most aspirational to deliver, but it promises to promote collaboration between clinicians and data analysts by providing a common language and tools for them to use.

### Setting things on FHIR is not enough

Until recently, though, these three main groups did not really talk to one another with any sense of a common aim to support integration. So, you could have two integration projects, doing great work in

different parts of the country that still couldn't talk to each other.

A good example is London, where there are something like 60 data exchanges. Some are built around proprietary standards and some around different open standards. London is trying to join them up, but only to share documents.

To really gain the benefits of integrated data and understand the health needs of a population through analytics you need to add a source of good quality standardised data based on something akin to openEHR.

### National action needed

The industry has taken some steps to bring these standards together, with the INTEROPen initiative. This is a forum for companies to collaborate on the design and application of technical interoperability standards; and almost 100 are now signed up.

NHS Digital is also focused in this area and has started to interact with INTEROPen. It has published an in- ➔

teroperability handbook and is working on further 'offers' for local bodies, including open interfaces, a business justification for integrated records, and help with the information governance issues they tend to throw up.

So, there are some good steps being taken at a national level, and there is industry buy-in. However, because there are different initiatives underway, there are different architectures being proposed to pull things together.

But, what we really need is for someone at a national level to say: 'this architecture, using these standards' – and also 'these companies can provide you with these components'.

#### Benefits of an open ecosystem

If that happened, and everybody followed the architec-

ture, then it would be possible to share information around and analyse it. It would be possible to retain existing suppliers. It would create new space for innovation.

If there was a truly open ecosystem for healthcare, in which data was separate from the systems that create and store it, then developers could come in and use it to develop new products using modern, mobile technologies.

Unfortunately, while the Next Steps document had some good things to say about approved systems and approved configurations for electronic patient records, it had much less to say about standards. From that perspective, it was a bit of a missed opportunity.

#### Customers: demand your data...

The other missing piece is cus-

tomers' input and demand. NHS organisations, after consultation with the public and taking into account Caldicott principles, really need to say: "This is our data, and we choose how to store it, who to share it with, and what to do with it."

When I travel around the country I see organisations at very different stages of their digital journey. Some providers are just trying to get off a burning platform and install a new patient administration system.

Some are focusing on functionality, but not thinking about the way in which the systems that could deliver that could also lock-in their data. Some are thinking about the integration piece, but not always looking at the bigger picture.

The challenge for the growing number of integrated care projects out there is the short term demand to deliver on a

particular initiative or to generate cash savings. That can make it tempting to go for an apparently cheaper, proprietary solution to 'fix' a problem or get a tick in the efficiency box.

It can make it harder to go for a more strategic option that will require more capital up front, but put the whole healthcare economy in a better place in the longer term.

Having that national steer on architecture and standards would help customers make better choices in the face of those pressures; but I think we will also need a few visionaries with exceptional leadership skills to show the way.

What we all need to remember is that this is the NHS' data. It is not the vendors' data. It should be structured so the NHS can do what it needs to do with it; because, in the end, we will all benefit from that. ■

# Are you Lost in the Maze of Health IT Standards and Regulations?

The world of health IT and app compliance can be an impenetrable and, at times, almost mystical field. The Information Governance Toolkit, Medical Device Directive and SCCI 0129/0160 standards are three very different beasts. And depending on precisely what your solution does, the various frameworks may or may not apply for a given product.

For start-up manufacturers and experienced developers alike the myriad of health IT standards and regulations can be overwhelming. What's more, get it wrong and it's not just sales that could be affected...you might well end up committing a criminal offence. At Safehand, we are specialists in health IT assurance. In addition to professional consultancy we provide some free straight-forward tools to help you along the way. In this article, we'll summarise the standards and regulation in three of the most important areas.

#### Medical Device Directive

The EU Medical Device Directive or MDD is the big daddy of regulation in this sector. Fail to comply with this one and the Medicines and Healthcare products Regulatory Agency (MHRA) have the powers to introduce you to the concept of the dawn raid. The MDD is woven into the UK's Consumer Protection Act and if your application falls within scope of the Directive, you may be facing some serious regulatory overheads. And make no mistake, waivers, warnings and other limitations of liability rarely cut the mustard with the MHRA.

Products which comply with the MDD proudly display a CE Mark, a legal and public declaration by the manufacturer that the requirements of the directive have been met. But this badge of honour must be earned through a combination of careful evidence gathering, validation and formal assurance.

Medical Devices are classified into four categories; I, IIa, IIb and III depending on the risk they present to the patient. Class I devices are at the lower end of the risk spectrum and compliance can be achieved through self-certification. One can, in theory, submit a simple form to the MHRA and for less than £100 receive approval to affix the CE Mark to a Class I device. But remember that to do so without completing the underlying assurance work (which can be substantial) is a criminal offence. In practice, getting at least some expert help is essential.

For other classes of Medical Devices, the manufacturer can expect audits and inspections by organisations called Notified Bodies. These sentries of the regulatory world put manufacturers through their paces and demand proof that devices are safe, clinically effective and appropriately risk managed. And of course, this must all be paid for by the device manufacturer ultimately raising development costs.

But here's the interesting catch, not all health IT products need to conform with the Medical Device Directive at all. On the

surface, the MDD tells us that if a product is for the diagnosis, prevention, monitoring, treatment or alleviation of disease, handicap or injury or for the control of conception then it needs to be CE Marked. But that's just the start of the story. Other guidance from the MHRA and steering groups clarifies that if a health IT system is only for the purposes of storing and retrieving information then the MDD doesn't apply. And let's face it, that's just what most health IT systems do; they allow one user to enter information and another (or the same user at a different time) to bring it back.

It's this quirk of MDD exemption which means that most health IT systems and apps we see in everyday practice are not CE Marked. But, if your system goes further than storage and retrieval, the regulatory position quickly changes. If a system makes a clinical decision, takes a measurement, performs a calculation, employs a clinical algorithm, makes a diagnosis or raises an alarm then it's likely that it needs to conform.

At Safehand, we've constructed a useful decision tree to help you decide whether your application might need to comply. You can access the tool by registering for our Members Area: [www.safehand.co.uk/members](http://www.safehand.co.uk/members).

#### SCCI 0129 and SCCI 0160

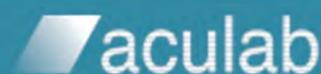
Just because your product isn't a Medical Device doesn't mean you can throw caution to the wind and forget about safe design. In 2012, NHS Digital issued their SCCI 0129 and 0160 standards to fill an assurance gap which was becoming increasingly visible. There are plenty of health IT solutions which could cause very real harm even though they are not Medical Devices. Electronic Medical Records systems, Patient Administration Systems, Result Management solutions, etc. all have the potential to adversely affect care delivery if they were to provide misleading information or become unavailable. SCCI 0129/0160 fill this void.

These standards are mandatory for suppliers and NHS organisations and, increasingly, it's just not possible for credible health IT vendors to do business with the NHS without implementing them. The appearance of bodies like NHS Choices, ORCHA and Our Mobile Health which review and endorse health apps are also driving the SCCI 0129/0160 conformance agenda. Providing health services with safe tools is in everyone's interest and the prospect of defending a legal challenge in court without compliance is an unenviable position.

SCCI 0129/0160 are similar to the risk management requirements of the Medical Device Directive but other facets of the CE Marking process such as clinical evaluation are not required in this lower risk arena. Nevertheless, there is no lack of rigour called for here and the need to formally appoint a Clinical Safety Officer underlines the needs for at least one clinical individual to put their neck on the line. Interestingly, the SCCI 0160 element dictates that the healthcare organisation needs to ➔

## White Paper

### Telephone-based Speech Analysis in the Healthcare Industry



#### Opportunities for Telephone-based Speech Analysis in Healthcare

Download your copy of this free white paper from leading communications provider, Aculab, and discover how healthcare providers can utilise a telephone-based voice and speech analysis system as a cost-effective means of contributing to the management of certain disorders and diseases.

[www.aculab.com/healthcare-white-paper/](http://www.aculab.com/healthcare-white-paper/)

play their part in operating the system safely, something which is conceptually less clear with Medical Devices.

But once again not every health IT system needs to comply with SCCI 0129/0160. If your product deals with data at the population level or the purely administrative functions of a health service like Estates or HR then you might not need to comply.

Safehand has developed a decision tree and detailed FAQs to help suppliers in this area too. Again, these can be accessed for free through [www.safehand.co.uk/members](http://www.safehand.co.uk/members).

### Information Governance Toolkit

Whilst SCCI 0129/0160 primarily deal with a system's potential to cause harm to individuals, Information Governance sets out to deal with the security and privacy of data. It's essential that BOTH these areas are considered by all suppliers.

The security of personal and clinical data is governed by a number of disparate UK/EU laws and NHS policies. Some time ago, the Department of Health acknowledged that even figuring out which of these applied to health IT suppliers was a mind-bending task. What was needed was a simple tool to bring together all the requirements in one place and to facilitate a self-assessment by a supplier. This essentially became the Information Governance Toolkit or IGTK which is available at <https://www.igt.hscic.gov.uk>.

The Department of Health states that "IG Toolkit assessments must be completed and published by all bodies that process the personal confidential data of citizens who access health and adult social care services." This pretty much means that any software organisation involved in the management of personal, social or clinical health data needs to provide a submission using the tool. This might seem an onerous and administrative overhead but comply here and you'll conform with most of the relevant Information Governance rules in the UK.

The toolkit sets out a number of requirements and asks users to score themselves from one to three for each element. Suppliers are expected to demonstrate that those who handle data understand their privacy and security obligations, that practical measures have been implemented to control access to data and that policies are in place to govern how data is transported and looked after.

In practice, organisations are expected to achieve at least level two compliance in each area and demonstrate continual improvement and vigilance. The overall result is publicly available on the IGTK website so it's worth putting in some thought before you make the submission. Without help, constructing the policies and templates from scratch is time-consuming so you might want to work with a partner to simplify the task.

### Summary

Standards and regulation in health IT are complex and with so much at stake it pays to tackle compliance from a position of knowledge. Working with an experienced partner such as Safehand not only gives you the confidence to go to market on the front-foot but also allows you to reach this position without diverting resources from other business-critical functions.

But whether you choose to benefit from the experience of others or to go it alone, make sure you operate in the health IT industry with your eyes wide open. Above all else, avoid the temptation to ignore compliance in the hope that it will simply go away. Embrace it, and leverage the assurance it brings to drive the quality of your product.

For more information about assuring health IT visit [www.safehand.co.uk](http://www.safehand.co.uk) or contact us at [contactus@safehand.co.uk](mailto:contactus@safehand.co.uk)

*Adrian Stavert-Dobson is a doctor, safety consultant, blogger and published author on the subject of managing clinical risk in health IT. He is the Managing Partner of Safehand Consulting. ■*

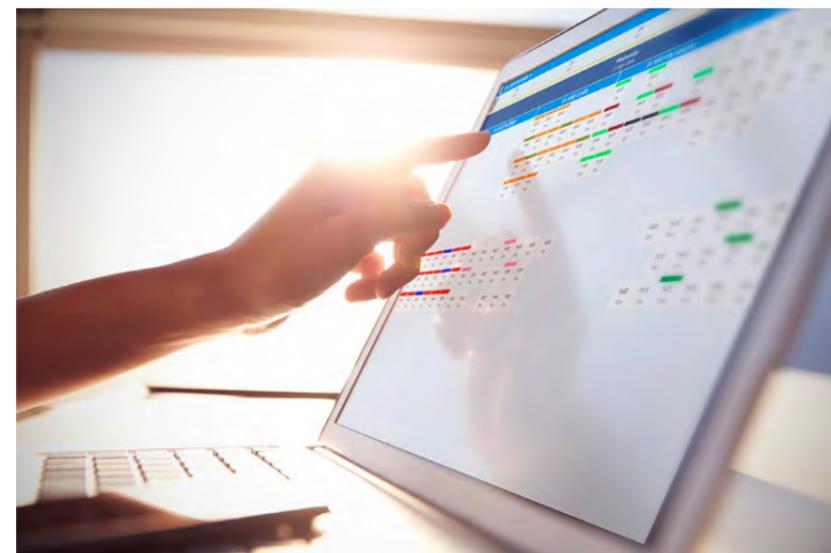
# Population Management Solution Enables CCG to Effortlessly Identify an Additional 4,000 Patients with Long-term Conditions

In 2014, Greenwich had the highest rate of years of life lost due to avoidable death in South East London. The CCG was aware, that compared to the national average, recorded prevalence rates for four key long term conditions were low across the area, meaning that there was a sizable group of local resi-

dents that were potentially undiagnosed and untreated. In addition, there was also a significantly high level of diabetes patients with a HbA1c of >75mmol/mol who would benefit from more intensive care and management. In June 2015, Greenwich CCG worked with Vision to build a simple, real-time and efficient

solution for identifying these patients.

In a cost-pressured NHS it was vital that the CCG identified these patients, not only to ensure that these patients received the most appropriate care as early as possible to avoid hospital admissions and any further complications



resulting from their condition, but also to secure the much-needed funds resulting from maximising available QOF points. Whilst the need to extract data was clear, in an environment where GP practices are under increasing pressure and time is at a premium, the solution needed to be easy to implement, require minimal input from GPs themselves and not add to the already heavy administrative burden experienced in primary care.

David James, Commissioning Project Lead, Greenwich CCG: "Like many CCGs in highly populated urban areas, our GPs are under extraordinary pressures to deliver high quality healthcare to an ever increasing diverse and aging population with a myriad of complex long-term conditions. With the aim of improving the quality of care for patients in our borough we introduced the Year of Care model following diagnosis. Limited time and resources however, mean that merely identifying those patients who would most benefit from this approach and avoiding unnecessary hospital admissions can be challenging. We needed a case-finding tool that was tailored to our particular needs in Greenwich, that could work across the multiple IT platforms in use and which would not contribute to the already stretched practice workloads. Having previous experience of Vision's decision support tools, we knew that it would deliver what we needed; a thorough, consistent, automated data analysis to identify those at risk and undiagnosed patients as well as provide the CCGs, GP syndicates and individual practices with the information they needed to monitor progress."

was available for me to review in one central dashboard enabling me to track progress on the identification and review of patients with long term conditions and ensuring accurate service payments were made. The tool was also really easy to implement, having a minimal impact on Practice workloads regardless of their operating system. There was great support in place from the Vision team and the initial teething problems you'd expect to experience with a project of this type were immediately resolved and efficiently dealt with. The results speak for themselves!"

### A measured increase in identification of patients with all targeted long-term conditions

In the first year alone over 4,000 patients were identified and diagnosed with one of Greenwich CCG's target long term conditions: diabetes, COPD, hypertension and heart failure. This is an increase in prevalence of 6- 18% across these conditions and the numbers continue to grow into year two. The clinical benefits of diagnosing these long term conditions earlier to reduce complications such as cardiac events and kidney failure, are well documented. Furthermore, avoidance of secondary care admittances reduces pressure on the already overstretched hospitals in the area and brings with it significant patient and economic benefits.

To deliver the CCG wide strategy, Greenwich needed an approach which would operate across its four GP syndicates with a total of 39 practices using a mixture of EMIS and Vision software. Prior to using Vision's tool, data extraction and analysis were considerably inefficient and time consuming, with CCG members visiting each practice to manually download and collect the entire data set. This would result in decision-making that was often based on months-old and potentially out-of-date, and therefore unreliable, data making it an extremely unsatisfactory approach.

### Development and implementation of an intelligent solution

Vision and the CCG worked closely to build and implement a tailor-made solution that truly delivered what was needed, both at a CCG level and at an individual practice level. The basis of Vision's state-of-the-art tool is to collect, process and analyse information from patients' records to offer healthcare providers and commissioners powerful insight. One of the key objectives of the project in Greenwich was to increase recorded prevalence of identified key conditions to provide patients with the best possible care and to fulfil and maximise QOF requirements. Once the technology solution was tailored to fulfil these objectives, prior to implementation, a local service agreement was signed with approval from each practice.

Jan Matthews, Directorate of Commissioning, Greenwich CCG: "I was really impressed with how up-to-date data from all of our 39 practices across the borough

Dr Jon Behr, Chief Medical Officer, Vision: "As a practising GP, I fully understand the daily pressures and busy workload experienced in primary care, however, this tool runs in the background of daily work so you hardly know it's there, but so useful when you need refer to it. It has the flexibility to be tailored to the specific clinical needs of any population and can be configured to look at and collect data for any group of patients, such as those with chronic kidney disease, atrial fibrillation or cancer, supporting practices to better care for their patients, and enabling the best use of available resources."

### Learning from Greenwich CCG's success and moving forward

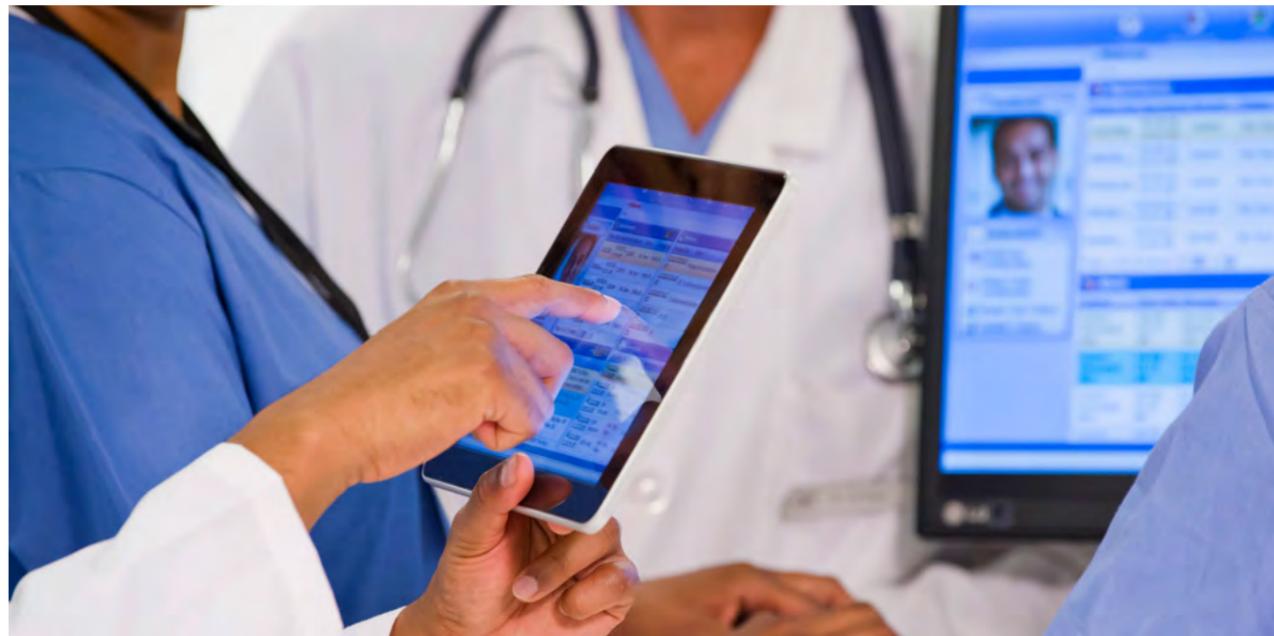
The tool gives a centralised, collated view of any number of practices and as it is truly interoperable, can be run in an area regardless of the GP software systems in use – this could be Vision software, that entirely of another provider, or a mixed environment, ➔

like Greenwich CCG which uses both Vision and EMIS systems. Integrating seamlessly with all existing data management systems, it identifies specific cohorts of patients, diagnosed or undiagnosed. To do this, it only collects the specific data set that is needed, which means the extraction and analysis can be completed overnight, giving CCGs a rapid view of accurate, up-to-date data presented in a meaningful way. The alerts can guide behaviour change to offer diagnoses or treatment, without overpowering the GPs' judgement.

Vision developed this population management tool to enable healthcare service providers to hit their clinical targets and maximise available funding with negligible disruption to their usual daily routine. The tool promotes consistency of read code entry which allows the CCG to effectively see a combined picture of the population, or compare the statistics across practices. It supports the implementation of the new GP contract by allowing GP practices to produce accurate data around elements that continue to be tied to QOF points and those

related to agreed indicators no longer in QOF. The tool is built to be flexible in order for Vision to work closely with clinicians to combat their specific needs and objectives, while providing durability through the changing healthcare environment. It offers a solution to the ongoing nation-wide focus to identify patients with long term conditions and patients with a high frailty risk. Using the solution, the numbers of adverse events which could be avoided with wide scale patient identification and informed care planning are exponential. ■

## Managing Digital Transformation: The Role of the CIO



Patients at Imperial College Healthcare NHS Trust are now able to receive their appointment notifications via email rather than traditional post, as part of a joint project with Xerox to improve how the Trust communicates with patients. In this interview, John Kelly, Deputy CIO at Imperial College Healthcare NHS Trust, explains the details of the project as well as explaining some of the challenges facing CIOs in the NHS.

### 1. How easy has the process been for transitioning to digital?

We are well on our way towards predominantly using digital channels to communicate with patients in 2017. We originally started our digital transformation journey by introducing self-service kiosks so patients can independently register for appointments when they arrive at the hospital. This reduces admin-

istrative costs and patients are invited to provide their consent to move away from paper-based communication in the future. We now have the biggest deployment of self-service kiosks in Europe.

Our partnership with Xerox will allow more than 75,000 patients to receive their appointment notifications and reminders via email rather than traditional post, streamlining the Trust's patient communication strategy and saving an expected £1 million over four years on postage costs.

### 2. Why do you think the paperless system for the Trust has taken so long to come into play?

The GP service is largely paperless and has been for a long time. However, across community social care and acute care, the cost of transitioning can be expensive. At Imperial College Health-

care Trust we're now well on our way towards achieving a completely paperless service and meeting our 2020 objective.

### 3. What challenges and opportunities do you face with the paperless system?

In terms of the challenges, patients can be concerned about email confidentiality – patients may worry that email is not as secure as sending a letter via the post. However, patient confidence is steadily starting to build and will increase over time.

In terms of opportunities, the Trust can make vital cost savings by streamlining its administrative processes. Many appointments require more than one letter which equates to somewhere in the region of 2 million items of correspondence per year. By switching to emails, patients get their appointment details more quickly and conveniently.

For patients still wishing to receive communication via post, our partnership with Xerox has streamlined the mailing process and provided additional cost savings for the Trust. Using its secure shared delivery centres, Xerox has created a centralised, digital resource for postal mail management to ensure that all patients receive correspondence without delay or error. By identifying incorrect or incomplete mailing addresses before letters are posted, Mailmark barcode technology tracks letters to ensure patients receive appointment details in time.

### 4. Cybersecurity is featured highly in the news recently. What are you doing as a CIO to protect the hospital from confidential information being leaked?

We have very strict security policies to ensure our network is secure. We are committed to making sure our operating systems provide a strong level of protection and we firewall as much as we can. Therefore, if there was an unexpected cyber-breach, we can manage and limit the threat very quickly. We are doing as much as we can to ensure patient data is protected.

### 5. Which technologies are making your personal life easier?

My tablet is my constant companion. I can access my work mail and calendar but I can also use it for personal activities such as shopping. It's changed the way I use technology and the way I interact. The size also makes it easy for me to transport. I always take notes on my iPad and store them in the cloud – I very rarely carry paper around these days!

### 6. How can a CIO improve collaboration in departments?

It is vital to have positive clinician engagement. At Imperial College Healthcare NHS Trust, our clinicians are very engaged with our digital transformation goals. We've moved rapidly from pushing technology to clinicians, to clinicians coming forward to request additional solutions. By creating a core EPR, we now have a basis for what we can build together in the future. A key part of my role is to integrate these systems so that we can exchange information to build workflows. This will help facilitate smoother

patient handovers at the end of a doctor's shift, for example.

As a Deputy CIO, it's also important to find new ways to use technology to allow the Trust to integrate more effectively with community GPs and other services so that the pathways continue to run smoothly.

### 7. How are you using social media to engage with new technologies?

We have a digital strategy of which social media is a part. It is an important tool to engage the wider community although it's still early days in terms of direct and meaningful interaction with individual patients.

### 8. Are you a part of any CIO network groups, if so which ones?

I'm involved in the London CIO Network, particularly those in North West London. I regularly meet with the IT leads and CIOs within the healthcare sector.

### 9. What are the biggest CIO challenges you face?

A key challenge is that the technology has not quite caught up to the standards clinicians and patients expect. For example, not all technologies and systems can talk to each other yet. We need to integrate these systems if we want to successfully transfer patients from hospital and provide appropriate follow up care.

Additionally, if we want our patients to begin to interact with us digitally, then we need to connect our internal systems. Not all of our systems are based on the same standards, particularly the way in which we standardise the coding of data and the way this information is shared. For example, we code diagnosis and allergies in a hospital but GP surgeries would need to translate the code in order to read it. This is not a good thing as important details can become confused in translation.

### 10. As a CIO, how are you delivering change through cross-functional teams?

As Deputy CIO, I ensure that we are working closely together and not operating in IT siloes. We ensure that across the various healthcare disciplines, we have somebody with an appropriate clinical and nursing background directly involved with the IT decision making and prioritisation.

### 11. What does the future hold for the Trust?

Our vision is to become fully digital and our partnership with Xerox will help us achieve this. Becoming truly digital will enable us to function more effectively as a broader service - paper records didn't previously allow for that.

We also want to use digital channels to communicate with our patients more frequently. This will help the NHS become less siloed and the Trust will be able to work more closely with GPs to become one truly integrated care team. Looking further into the future, we plan to provide care to patients through technology such as teleconsultation and telemonitoring. ■

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# Philips Brings Next Generation EMR Solution to the European Market

Philips is set to expand, its award-winning next generation EMR solution - Tasy, into the European market, following an agreement with Krankenhaus Düren. Together with this German public hospital, Philips will co-design and enterprise wide pilot Tasy. It will give the 450 bed institution, that treats 70,000 patients per year, an innovative EMR solution to meet the requirements and needs of the current and future local hospital market.

Philips already has a highly successful, leading position in the Latin American EMR market with about a thousand installations at healthcare providers in Brazil and Mexico. Tasy, a Best in KLAS award winner, has helped eight hospitals in Brazil receive EMR Adoption Model Stage 6 certification from HIMSS Analytics, meaning the hospitals are near-paperless and are driving integration, security and analytics to optimise patient care.

Traditional EMRs typically contain standard medical and clinical data about a patient. They were originally designed to use this information for administrative tasks such as billing. Philips Tasy takes a different approach and is developed to streamline workflows and optimise patient care. It offers a single integrated platform and database to enable centralised management of all medical, organisational and administrative processes. These range from patient care to inventory and supply management, revenue cycle management and financial reporting. Other processes Tasy covers are bed management and the scheduling of rooms and the right staff for appointments and medical procedures. It also adds to patient safety by featuring scientifically established protocols and advanced algorithms for rapid detection of sepsis and infections.

“We are excited to enter the European market with an innovative EMR solution that takes a more seamless approach to managing care and solves many of the challenges of traditional solutions,” said Yair Briman, Business Leader of Healthcare Informatics at Philips. “The single platform allows for standardisation of processes across the hospital with anytime, anywhere access to big data analytics. This will enable advanced real-time risk assessment and decision making, helping to continuously improve safety and patient outcomes.”



“In Germany, there is a clear need for a new generation of hospital information management solutions that actively involves patients and supports clinical and administrative decision-making,” said Dr. Gereon Blum, CEO of Krankenhaus Düren. “In order to streamline both clinical and non-clinical tasks we need to give everyone access to the same consistent data in real time. A patient-centric solution like Tasy aims to capture data, to aggregate and share relevant patient information, allowing better collaboration and faster coordination among medical professionals, for better and safer patient care within all the medical disciplines.”

There is a need for innovative EMR solutions that help hospitals become fully digitised, overcome administrative hurdles and streamline workflows across departments. Hospitals and care networks are dealing with a number of pressing business challenges such as changing population demographics, a growing demand for access to quality care and strained budgets. Advanced interoperability in health information exchange is critical for hospitals dealing with massive amounts of data coming from multiple disparate systems. In order to meet the demand for care while containing healthcare costs, doctors and nursing staff are challenged to work more efficiently and collaboratively across medical disciplines. Physicians often find that traditional EMR and EHRs add significant hours to their work day and interrupt the doctor-patient relationship. ■

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# Global Digital Exemplar:

## Taunton and Somerset open source success signals new era for EPRs

### Introduction

Taunton and Somerset NHS Foundation Trust (TSFT) achieved a significant milestone when it deployed the UK's first open source electronic patient record (EPR) from IMS MAXIMS. This landmark move was part of the reason TSFT was named one of 12 NHS Global Digital Exemplars. They will receive up to £10 million to pioneer digital excellence, share best practice and fast track its plans to help staff achieve higher efficiencies, enable better organisational workflows and deliver better patient care.

### The challenge

As the largest acute hospital in Somerset, the trust serves a population of over 340,000, and provides some specialist and tertiary services for the whole of Somerset with a catchment population of 544,000. It manages around 700 beds, 30 wards, 15 operating theatres, employing over 4,000 staff.

The trust's previous PAS system was not being used to full effect, as there was minimal clinical buy-in and engagement in the deployment and use of the system. This was having an impact on their ability to deliver safe and effective healthcare.

TSFT recognised that an effective IT system could achieve higher efficiencies, enable better organisation workflows and deliver vital information at the point of care. The IT team knew that any future investment and in particular the EPR had to deliver demonstrable benefits. This in turn defined the key priorities for the deployment of the new EPR. It had to have three core criteria:

- » **Safety** – enabling safer working to ensure that clinical staff have the latest information available at the bedside to aid good decision making
- » **Efficiency** – delivering care at the lowest cost possible
- » **Interoperability** – supporting inte-

grated care across the region, as part of the Five Year Forward View.

### The solution

IMS MAXIMS worked closely with TSFT to implement the first open source EPR system in the UK.

TSFT decided to use the open source version of the IMS MAXIMS EPR, openMAXIMS, due to it being a more flexible, cost effective option that the trust would have more control over. The fact that there are no licence fees made it a highly attractive option as the trust had free access to £45 million of software development. But it also recognised the future benefit to the NHS overall, from being able to develop, then share, changes or improvements to the software with other NHS trusts, so taking advantage of economies of scale. In other words, develop something once and share it many times, so achieving the same result as proprietary software but at a fraction of the cost.

Improving the patient experience was also an important driver for the project. With the new EPR the trust has been able to make processes for admission, transfer and discharge of patients more efficient and coordinated with the help of real-time bed management and discharge planning.

Due to the innovative nature of the project, NHS England became interested in the work and were incredibly supportive in helping the trust move forward and get the project up and running, endorsing the trust's approach as a sensible and rationale one. Their involvement also gave non-IT personnel at the trust added confidence it was the correct strategy to deliver long-term benefits.

Commenting on the use of open source technology at Taunton, Richard Jefferson, head of programme commissioning at NHS England, said: “This represents a landmark moment in the use of open soft-

ware in the NHS and validates the idea that open source can play a significant role alongside proprietary offerings. The growing number of open source communities such as those within NHS England's Code4health initiative are an exciting opportunity to deliver innovation, quality and value through collaboration and are putting clinicians at the heart of decisions. openMAXIMS is a great example of this, and essential to its success has been the dedication and true partnership between Taunton and Somerset NHS Foundation Trust and IMS MAXIMS.”

### The benefits so far

#### Greater clinical engagement

One of the main success factors is the partnership that has been forged between IMS MAXIMS and TSFT. In the past the trust struggled with clinical buy-in of the deployment and effective use of IT systems, however the collaborative approach to working, and by positioning the changes as system transformation rather than an IT project, ensured unprecedented levels of clinical ownership and adoption.

One of the largest events in the continual educational process was an open day, which had attendance from 500 staff. Clinical staff demonstrated the new EPR to their colleagues, which was very well received compared to when an IT supplier demonstrates its own products independently. The Taunton EPR team, building the system alongside IMS MAXIMS, also explained how they were going to create it, right down to the configuration of the drop down menus to meet the exact workflow needs of each clinical team. This has led to usability benefits such as fewer clicks being required to perform certain tasks, compared to the old system.

Once the 2,500 staff had been trained, the trust was also able to use a full replica of the software on the intranet and work through different scenarios. All of these →

factors meant that nearly every member of staff had seen the software before it went live, so there were no surprises.

Dr Chris Swinburn, clinical lead for the project at the trust, said: "Our clinicians have been involved right from the start, from influencing the procurement of the software right through to the design of the system to suit our clinical needs and processes. We wanted to work with IMS MAXIMS because its system has been created over a long time within an NHS environment and developed alongside clinicians. Following the go-live, we believe we have developed a robust EPR system that can be replicated in other hospitals. This can deliver wide reaching benefits across the NHS."

**Safer and more effective patient care**

Another measure of success is the impact of the system deployment on workflow and patient care. Eight million records were migrated into the new EPR and only seven needed to be manually loaded, with minimal disruption to service delivery. Moreover, processes for admission, transfer and discharge of patients is more efficient and coordinated, with the help of real-time bed management and discharge planning.

This first phase has also seen some new outpatients activity move to become

electronic, such as real-time outcoming of patients instead of completing forms. Clinicians are triaging letters online rather than printing them out and also making decisions online for each referral. All therapist teams have decided to use the software too, so physiotherapists and occupational therapists are working paper-lite, plus two specialties, cardiology and diabetes have also followed suit.

**Financial savings and the paperless NHS agenda**

Due to the nature of the software and approach to deployment, the cost of moving to openMAXIMS will pay for itself within three years. The open source EPR is also set to save the trust £600k a year by 2018 and has ensured TSFT is on course to achieve the paperless agenda set by government.

Malcolm Senior, director of IT at the trust, said: "With the NHS looking to reduce the projected £30bn a year funding gap by 2020/21, there is now, more than ever, a clear requirement to make the most of precious hospital resources. For me, openMAXIMS represents an affordable, flexible system that will deliver the functionality we need. Our clinicians have found it intuitive to use and have taken to it very well."

**Integration between care settings**

Almost all GP practices in the Taunton area use the EMIS system and work is under way to interface this with our EPR system so that by summer 2016 the hospital will have access to GP records of patient medication. This will be extended so that GPs are able to track what has happened to their patients while they are in hospital, both as inpatients or outpatients. In later phases, this interfacing will continue to spread, to include all NHS providers, social care and the voluntary sector, allowing seamless, safer care for patients who will not have to repeat their stories or details. The goal is to have patients themselves holding the record and sharing the information that they themselves wish to share.

**Financial savings and paperless**

Due to the nature of the software and approach to deployment, the cost of moving to openMAXIMS will pay for itself within three years. The EPR will also save the trust £600,000 a year by 2018 and has ensured TSFT is on course to achieve the paperless agenda set by government. The £10 million Global Digital Exemplar funding over the next two years will accelerate the delivery of its technology roadmap including paperless nursing, e-prescribing, clinical decision support, medicines management and integration with GP systems. ■

**Quality care without the paperwork**

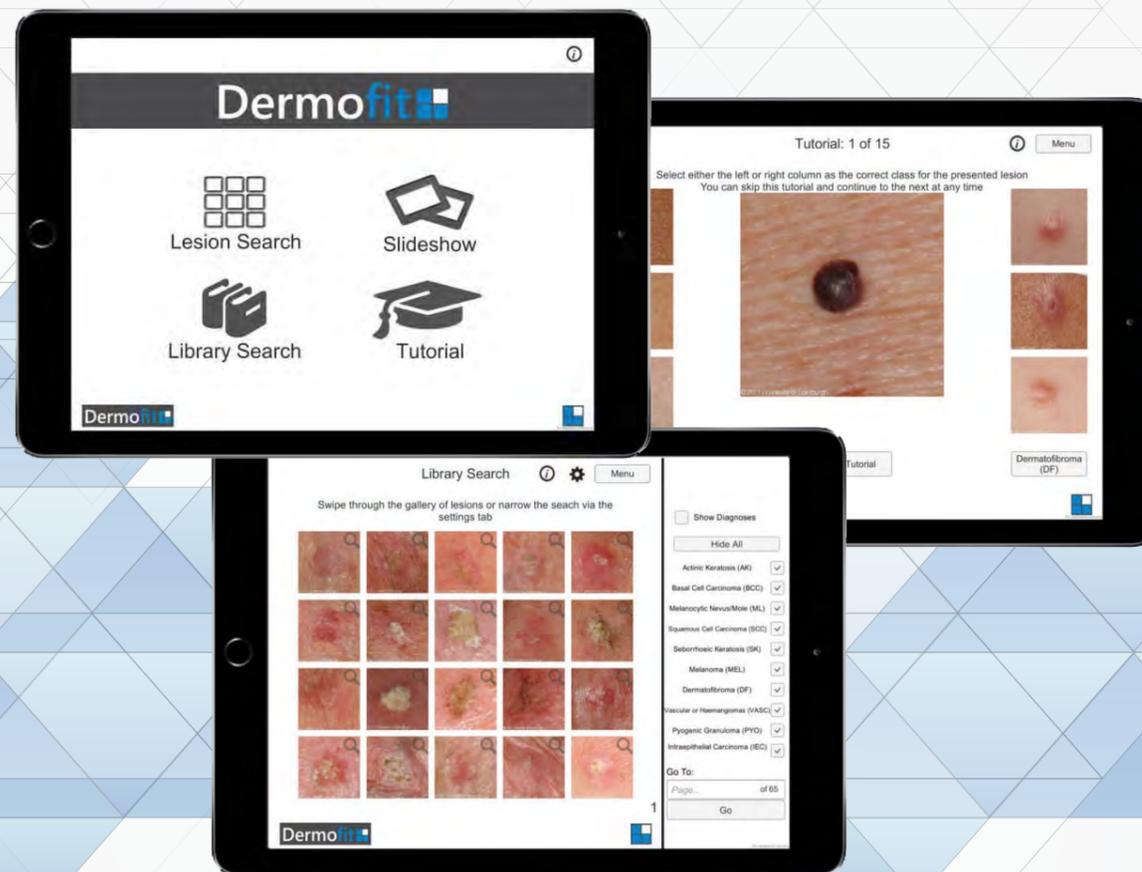
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