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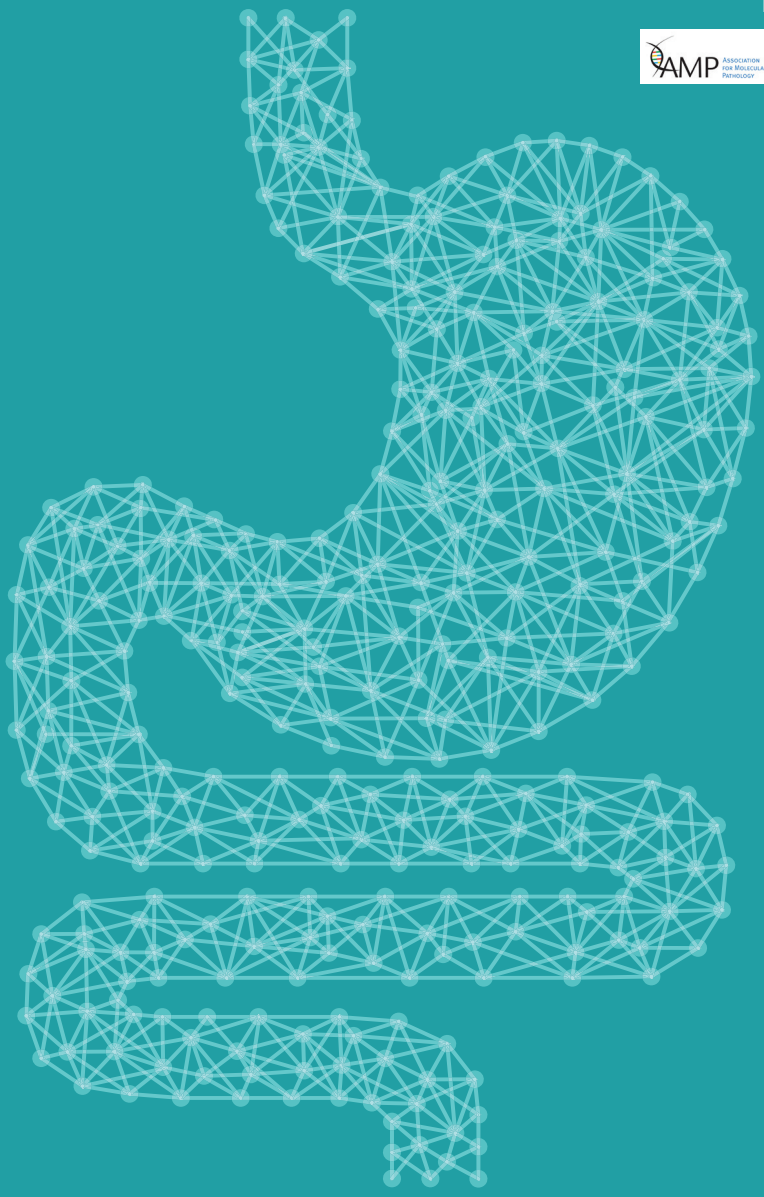

Join the dots

Gut bacteria opens up new possibilities in personalised medicine

On point
How technological advancements are shifting values in point-of-care testing

Artificial language
Is the healthcare industry ready for a move to AI diagnostics?

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Practical Patient Care
Issue 22 2018

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Emma Green
Editor

A well-oiled machine

The reach of technological innovation continues to grow at a rapid rate, radically changing all industries as it evolves. It's an exciting time for patients and healthcare professionals alike, with technology increasingly playing a role in almost all processes and providing an important tool that can be leveraged to support value-based care.

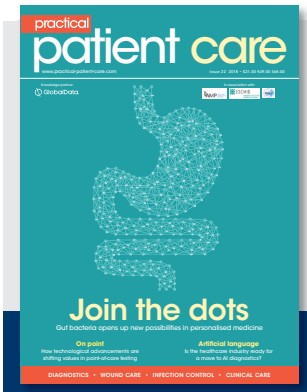
We're witnessing a dramatic shift from the current reactive model of healthcare to one based upon foresight, and a blend of the right technology and analytical knowledge, termed the 'predict and prevent' model. Of course, in healthcare and other industries, predictors are most useful when they can be readily transferred into action.

From point-of-care testing (POCT) and AI driving innovations in diagnostics, to augmented reality and apps changing the face of surgery and health monitoring, healthcare professionals are confronted with the unenviable task of implementing an array of solutions and techniques to improve the standard of care afforded to each patient. This must be balanced with the need to reduce the operational costs associated with providing this higher level of care. With increasing financial and resource pressures on medical practitioners and senior managers, this is certainly no easy feat.

Navigating tensions and opportunities within this landscape is clearly challenging, but with cross-pollination between parties, progress can be driven forward to achieve solutions that work for all. As the new editor of *Practical Patient Care*, I am hugely excited to stimulate these important discussions over upcoming editions. With a PhD in the field of diabetes, a passion for the field of healthcare, and a long-standing belief in the vital role publications such as ours play in providing a platform for exchanging and debating new ideas and sector developments, it is a responsibility I take seriously.

Under my watch, I want each and every edition to combine analysis of current and future trends with opinions and expertise of the industry's key figures in order to provide best practice and innovative solutions, helping our readers successfully evolve their patient care strategies for the better.

The care delivered throughout a healthcare facility is, of course, crucial to patient outcomes. All aspects of these services will be kept in mind in *Practical Patient Care*, ensuring that services can be optimised at all stages of the patient journey. I hope you enjoy this issue and I look forward to meeting with many of our readers to conduct these discussions in person.



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Cover story

How non-antibiotic drugs can effect the growth of bacteria in the gut and promote antibiotic resistance.

The slow shift towards AI diagnostics.

Why diabetic foot injuries must be addressed.

Contents

Faster results, less waiting.

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News

A new digitised system will help prevent NHS precsription fraud, despite vocal criticism from pharmacists.

PRESCRIPTIONS

UK Government to tackle NHS fraud

The UK Government is launching a new digitised system in an attempt to tackle prescription fraud in the NHS, estimated to cost £1.2 billion each year. Currently, patients either present an exemption certificate or sign the back of their prescription stating that they do not have to pay a prescription charge.

With the digitised system, pharmacists would be able to look up patients on the digital exemption database, before they hand over the medicine. "The message is clear: the NHS is no longer an easy target, and if you try to steal from it you will face the consequences," said Matt Hancock, health and social care secretary.

However, pharmacists have criticised the new system, suggesting that people with long-term conditions will be adversely affected. "Sometimes somebody has free prescriptions legitimately, they've got a medical exception – they're something like a diabetic – and they might forget to renew it and the computer says no. So I think this is potentially fraught with problems," said Sandra Gidley, from the Royal Pharmaceutical Society.

DIGITAL HEALTH

App launched that detects blood blockages in the heart

A recent study published in the *European Heart Journal* that included more than 5,000 patients in the US, Japan, Europe and Canada found that analysis using an app called HeartFlow led physicians to reconsider and change management plans for two thirds of their patients. Some patients who were originally scheduled to receive a coronary stent or bypass operation were able to avoid the procedure and be treated with medications alone, while others who would have received medications were redirected to stenting or bypass surgery.

Using deep learning and state-of-the-art data processing following a coronary computed tomography (CT) scan, the app creates a digital 3D model of a patient's heart using advanced algorithms, and then determines the impact of any potential blockages on blood flow.

The technology is being supported by the UK's NHS, as part of the Innovation and Technology Payment (ITP) programme to help physicians better diagnose coronary heart disease. "We will be working hard to ensure HeartFlow can help improve the overall patient experience, by helping physicians identify heart disease which may have otherwise been missed and delivering significant cost benefits to the NHS," said John H Stevens, president and CEO at HeartFlow.

COLLABORATIVE CARE

US pharmacy and health service to join forces

The US pharmacy chain Walgreens has struck a deal with McLaren Health Care, based in Grand Blanc, Michigan, to connect their pharmacy and health service offerings. The integrated health network will open new sites within Walgreens stores, and Walgreens will take over on-site McLaren pharmacies, buying up the system's prescription files and pharmacy inventory. Their strategic collaboration is part of efforts to compete in a rapidly consolidating market by making healthcare delivery more efficient.

"Consumers increasingly seek value and convenience when choosing a healthcare setting, and fewer – particularly younger adults – have a relationship with a primary care physicians, " said Philip Incarnati, president and CEO at McLaren. "Walgreens has a reputation for delivering outstanding service and customer experience, and we are proud to work with them to create these new clinics and give Michigan residents more options for quality, affordable care when and where they need it."

INFECTION CONTROL

Candidemia improved by hospital stay

A recent study from the University of Alabama found that patients with candidemia had improved mortality outcomes when infectious disease consultation (IDC) occurred during their hospital stay. This is a particularly significant finding in light of the high rates of mortality in this patient population. "Candidemia has mortality rates as high as 50%, and we wanted to better understand the impact that infectious disease consultation in hospitalised patients can have, specifically as it relates to survival rates and guideline adherence," said Rachael Lee, assistant professor in the University of Alabama's Division of Infectious Diseases.

The study, published in *Clinical Infectious Diseases*, looked at outcomes of 145

patients hospitalised with candidemia at the University of Alabama Hospital from over the course of one and a half years. Of these patients, 111 received IDC, while the other 39 did not.

Findings demonstrated that 30-day, 60-day and overall inpatient mortality rates were significantly lower in IDC patients, and there was an increased adherence to clinical practice guidelines. Patients with IDC were 66% less likely to die within 30 days compared with those without IDC. The research suggested that IDC may benefit even critically ill patients. Furthermore, early IDC can help its patients access antifungal therapy more quickly, which has been shown to lead to better outcomes.

Doctors experiencing burnout can be twice as likely to make mistakes and compromise patient care.

CLINICAL CARE

Doctors experience damaging burnout

Burnout in doctors has significant consequences on the quality of care they deliver, according to a large-scale systematic review and meta-analysis conducted by researchers at the respective Universities of Manchester, Keele, Leeds, Birmingham and Westminster. The researchers made their conclusions on the basis of 47 papers, which included responses from 43,000 doctors.

The study found that doctors experiencing burnout are twice as likely to make mistakes, such as making incorrect diagnoses or prescriptions. Burnout doubles the likelihood of lower professional standards. "We show conclusively that the provision of safe, high-quality patient care is severely compromised when doctors are physically, emotionally and mentally exhausted," said Dr Maria Panagioti, senior research fellow at the University of Manchester. Despite these worrying findings, researchers emphasise that doctors are not to blame. "Clearly, this is not the fault of doctors. It's caused by a combination of factors including high workload, the way teams work together and the absence of measures which improve well-being," said Panagioti.

DIGITAL HEALTH

Video-based system gets patient approval

Patients are satisfied with a novel, video-based telemedicine system, according to researchers from Kaiser Permanente, who wrote a letter to the *New England Journal of Medicine* about recent survey results. 93% of surveyed patients were satisfied with their doctor visit after using the platform. Researchers suggest that video-based telemedicine can increase patient access to care. However, there has been little evidence so far to support implementing it into clinical care.

The study looked at 210,383 scheduled video visits with 152,809 patients from 2015–17. Researchers then surveyed 1,274 of the patients about their experience of the visits. Video visits were only a subset of total visits with patients, with over 60% of clinicians using them with less than 5% of patients. For early adopters, video visits were helpful in extending the physician-patient relationship. The findings showed that 93% of patients surveyed said the video visit met their needs.

However, only 66% of scheduled visits were successfully connected due to patients either changing their mind or opting for an alternative method of communication with their doctor. "Further research is needed to examine continued adoption over time," researchers said. "Still, together with positive patient-reported experiences, our findings show the feasibility and growing adoption of video visits integrated with continual clinical care."

CLINICAL CARE

Reducing costs, optimising healthcare

In the face of escalating costs of medications and technology, healthcare patients and providers in the US continue to search for opportunities to reduce overall costs while optimising healthcare outcomes. At the Mayo Clinic Comprehensive Stroke Centre Practice, a project was recently conducted to design and deliver care that was more customised to the needs of individual patients while reducing cost and resource constraints.

The Mayo Stroke Practice used time-driven activity-based costing (TDABC) to determine costs associated with different protocols for stroke care. TDABC uses a bottom-up approach to identify the clinical processes and resources used to care for a patient over a period of time. It works from a process map of a patient's care pathway, attributing costs to the time of each resource used at each step of the pathway. With this information, clinicians learn how to make more efficient use of higher price resources, resulting in lower total costs while achieving the same or better patient outcomes. Although used for stroke patients, this model could be used in a variety of medical conditions to achieve these benefits.

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ECCMID, as the world's premier Clinical Microbiology & Infectious Diseases event, brings together experts from many fields to present their latest findings, guidelines and experiences to an expected audience of 13,000 colleagues. This year, the Programme Committee has developed a multi-faceted program incorporating keynote lectures and oral sessions, as well as interactive workshops, meet-the-expert sessions, and a wide range of symposia.

Resistance is futile

Dr Maria Daniela Angione of Trinity College Dublin has developed an electronic chip intended for use as part of a disposable diagnostic tool. Now undergoing preclinical trials, it could quickly detect bacterial infections and help address the growing problem of antimicrobial resistance. Here, its potential impact is discussed with Abi Millar.

Antimicrobial resistance is one of the defining healthcare challenges of our time. As more bacteria become resistant to the drugs designed to treat them, we face the possibility of a return to a pre-antibiotic age of infectious disease.

Already, 700,000 deaths each year are being attributed to antimicrobial resistance, a figure that could surge to ten million by 2050 if the situation is not rectified. We are seeing the likes of drug-resistant hospital infections (such as MRSA and *C. difficile*), multi-drug-resistant pneumonia, and a barely

treatable strain of gonorrhoea. This is clearly a complex problem, with no straightforward solution. However, one key piece of the puzzle will be minimising inappropriate antibiotic use. At present, antibiotics are prescribed far more than they ought to be. The Centers for Disease Control and Prevention (CDC) estimates that up to half of antibiotic use in humans, and much of antibiotic use in animals, is unnecessary and inappropriate. Improving 'antibiotic stewardship' – being responsible about how they're taken – would make everyone safer.

Unfortunately, the issue is compounded by a lack of rapid diagnostic tests. Since traditional culture-based tests can take days to return results, antibiotics are often prescribed before the patient has a definitive diagnosis. Often, this means they end up taking antibiotics for non-bacterial infections.

As Dr Maria Daniela Angione, a researcher at Trinity College Dublin, explains, rapid detection is important for several reasons – not just for reducing antimicrobial resistance, but also for controlling the further spread of disease.

"The current tests to identify bacterial infection require cell cultures, or they are based on immunoassay tests or PCR, which are extremely time consuming and require access to specialist facilities," she says. "In the primary care setting, the gold standard for urinary tract infections, for example, is still cell culture, which takes three days for the bacteria identification."

Financial issues

While there are currently a few techniques available for rapidly detecting infections, their use is hampered by price.

"They are based on an antigen detection test, but they are quite expensive and require specialised equipment," she says. "So there is a clear need for rapid detection of viruses and bacteria. Ideally this should be low-cost and applicable at the point of care, or without the assistance of highly trained medical personnel."Angione is currently working on a device that could dramatically improve the situation. Specifically, she has developed an electronic chip that will be integrated into a sensing platform and used as a disposable diagnostic tool.

"I'm trying to develop a rapid and accurate test to detect and identify bacteria," she explains. "The active layer of the chip is a molecularly engineered biopolymeric material with specific functionalities in a multiarray setting. It will enable clinicians to determine the appropriate antibiotic therapy in multiple infections and diseases, potentially improving the clinical outcomes for patients and reducing the inappropriate use of antibiotics."

With a background in electronic device development, advanced materials development, and biomolecules, Angione is drawing on an interesting blend of expertise. The upshot is that her device is like nothing else on the market today.

> "In the primary care setting, the gold standard for urinary tract infections is still cell culture, which takes three days for the bacteria identification."

Incredibly, she thinks the tool could one day be available for purchase, enabling a DIY approach to diagnosis. "In ten years time, what I'd love is this technology to be available not only in the hospitals, not

Developing the perfect rapid diagnostic test

The perfect new diagnostic would answer four key questions, which could inform diagnosis and treatment with the correct antibiotic, before any antibiotics are given.

Is the infection causing the illness bacterial or viral?
A diagnostic test able to indicate whether a patient has a bacterial infection could dramatically reduce unnecessary antibiotic prescription for viral infections, particularly in the primary care setting. In most countries, around 80% of antibiotics are used in the community, rather than the hospital, with around half of this use thought to be inappropriate.

If bacterial, what type of bacteria is causing the infection?
A diagnostic that could not only detect a bacterial infection, but also quickly confirm the type of bacteria causing it, would allow doctors to tailor treatment, and potentially decrease reliance on broad-spectrum drugs.

Are the bacteria that are causing the infection resistant to available antibiotics?
Diagnostic tests that detect resistance can direct doctors away from potentially inappropriate antibiotics and towards those more likely to be effective. In acute settings, ruling out even one or two therapies can save a patient's life.

Are the bacteria that are causing the infection susceptible to existing drugs?
A diagnostic that could rapidly measure the susceptibility of the infecting bacteria to existing antibiotics would be even more useful than one that detects resistance, because it gives the doctor greater confidence that the drug they choose will be effective. This would help to minimise inappropriate use of antibiotics.

There is a need for diagnostics that can be deployed widely throughout both the developed and developing world. These might be used at home, or in pharmacies, primary care clinics or hospitals. These diagnostics have three important functions.

Firstly, they will improve patient treatment by getting the right drug to the right patient quickly. Secondly, they will allow existing drugs to go further and last longer. Thirdly, they may reduce the need to develop new 'broad-spectrum' drugs, which are often the hardest drugs to find.

In order to achieve these aims, it is necessary to have diagnostics available in the right settings, which may differ by country as well as ensuring that financial rewards, culture and systems support their use.

Ultimately, what is needed is high-quality, affordable rapid diagnostics that can be rolled out as widely as possible.

Dr Maria Daniela Angione has developed an electronic chip housed in a sensing platform, to be used as a DIY diagnostic tool.

only to be used by doctors, but also available for everybody in the pharmacy," she says. "Anyone who needs it could go and buy a disposable chip in the same way as we currently buy a pregnancy test, and would be able to use it at home. Then if needed, they could get an antibiotic prescription or an antiviral therapy prescribed by the GP."

While this goal may sound like a pipe dream, it could become reality in the not-too-distant future. Angione's work has already reached a good stage of maturity and is beginning to generate respectable commercial interest.

"We are running some preclinical trials, working in collaboration with clinicians and talking to many companies here in Ireland," she says.

"The technology is performing quite well so far. While we were running the market feasibility study we got in touch with a few world-leading pharmaceutical companies and they expressed a huge interest."

Of course, she does not anticipate that bringing the device to market will be an easy ride. Since it is so unlike the others out there, and the underlying technology is so disruptive, it may be harder to convince pharmaceutical companies of its competitiveness.

Break the walls down

On top of that, there are societal barriers to dismantle before the technology is widely accepted.

"The first barrier that I see is related to the patients – they may have some expectations when they go to the GP, and clinicians might be reluctant to update their traditional approach that has been in use for so many years," she says. "Also, the pharmaceutical companies need to produce new antibiotics but they have little funding to invest in this area. So it's not just the development of the technology that is a challenge." All this said, she holds high hopes for the future, pointing out that the device's advantages speak for themselves. As it uses integrated circuits and low-cost electronic components, it is not only sensitive but cheap and easy to make. This means it could be suitable for use in remote, low-income settings – not to mention available in the pharmacy.

"It could facilitate diagnosis and enable a targeted therapeutic plan at an early stage of bacterial or viral infection, reducing the healthcare cost," Angione explains.

In the short term, she is hoping to work together with industry and clinicians to source more funding.

> "It could facilitate diagnosis and enable a targeted therapeutic plan at an early stage of bacterial or viral infection, reducing the healthcare cost."

"Of course it's a long process, but there are a few opportunities so I'm hoping to develop tools to validate the technology, bringing it to the market as soon as possible," she says. "We hope that growing interest will generate the support required to a point of commercialisation." ■

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From Flu Season to Fusion Season

Last flu season, molecular diagnostic labs across Europe switched their diagnostic instruments to Hologic's Panther Fusion™ system. The scientists who made the change tell their stories.

Meeting the Challenge

A long flu season with multiple strains of influenza heightens pressures and increases specimen numbers for virology labs. Ease of diagnostic use is crucial for dealing with a busy flu season, and the Panther Fusion system has proven capacity to deliver, with fast turnaround times as well as random and continuous access to samples and reagents.

Dr Albert Heim, from the Institute of Virology at the Hannover Medical University, started using the Panther Fusion system in December 2017, explains his reasons for switching to using the Panther Fusion system as their sole instrument for respiratory virus testing: **"We wanted a random access machine because it greatly reduces turnaround time between sampling and report of the result compared to batch testing. Currently the Panther Fusion system is one of the very few machines that has this option."**

Also in December 2017, the Medical Microbiology laboratory at Jeroen Bosch Ziekenhuis, Netherlands, adopted the Panther Fusion system in place of their previous molecular diagnostics instrument. Jeroen Schellekens BSc. wanted high throughput and random access capabilities after a limiting capacity of only 24 samples proved unproductive. **"It was very welcome to our lab. Random access and hands-on times of only 2 minutes per sample are great advantages,"** Mr Schellekens, a key user of the Panther Fusion system in the Jeroen Bosch Hospital, observes.

In October 2017, labopart - Medizinische Laboratorien in Dresden, Germany, made the decision to change their molecular platform from r-BioPharm-Assays to the Panther Fusion system with the Panther Fusion Influenza A/B/RSV assay by Hologic. **"The switching process was relatively easy, and it's very convenient to use,"** describes Dr Thomas Zimmermann, Head of Molecular Biology at the Medizinische Laboratorien Dresden.

Anne Kailow, Department Biomedical Laboratory Scientist at Herlev and Gentofte Hospital, Denmark, and her team analysed 11,000 respiratory samples from October 2017 to April 2018 using the Panther Fusion Influenza A/B/RSV assay on the Panther Fusion system. **"It was very easy to learn and use. Our technicians new to the Panther® system had five days training and after that they were capable, whilst our experienced Panther users had just two days training,"** Mrs Kailow says on adopting the Panther Fusion system for last year's flu season.

> *Dr Heim recalls his experience with testing growing sample numbers with the Panther Fusion system:*
>
> **We had a very rough influenza B season last year and we tested about 4,000 specimens for Flu and RSV, which is roughly twice the number we had to test the year before. It was easily achievable with the Panther Fusion system; without extra personnel and without stress."**

Excellent Assay Performance

Performance is key to any molecular diagnostics assay and instrument to ensure reliability of every result. Regarding the Panther Fusion Influenza A/B/RSV assay performance on the Panther Fusion system, Dr Zimmermann states: **"It is, in my opinion, very good. We can trust the results."** Dr Heim also praises the performance of the Panther Fusion Influenza A/B/RSV assay on the Panther Fusion system. After comparing 1,500 samples from the 2016/2017 flu season with an assay developed in-house by the Robert Koch Institute, he concludes: **"The performance of the Flu/Respiratory assay on the Panther Fusion system is excellent. Concordance was 98.4% after initial testing, and 99.4% after re-testing."**

In the Herlev laboratory, the Flu/Respiratory assay was validated to have an improved performance on their previous method. **"We will need further testing by sequencing before we can say for sure, but our initial testing found improved sensitivity and specificity compared with the method we used before, so that's really great,"** says Mrs Kailow.

Be Ready

With a broad Flu/Respiratory menu on a single molecular instrument, the Panther Fusion system has the capability to run increasing specimen numbers for a wide range of respiratory viruses, with no addition to workload. Dr Heim believes the Panther Fusion system managed the influx of respiratory samples during the 2017/2018 flu season, without needing additional technician support: **"In spite of growing numbers of specimens, we can use the same number of personnel."**

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RSV, respiratory syncytial virus.

A more contemporary test for TB

Doctors have made huge strides in fighting tuberculosis, but challenges remain when it comes to testing methods. *Practical Patient Care* talks to Dr Martin Dedicoat, an expert on the disease, about how research by companies like **Oxford Immunotec** might help stamp out the disease for good.

Though it tends to be thought of as a quintessentially Victorian disease, all dusty garrets and penniless writers, tuberculosis (TB) has remained a threat through to our own time. A full 25% of the world's population has latent tuberculosis infection (LTBI), and 5–10% of these cases will become active, endangering millions of lives.

In developed nations, where active TB is more or less eradicated, doctors focus on hunting down cases of LTBI. This focus makes sense, says Dr Martin Dedicoat, a consultant in infectious diseases at the Heart of England NHS Trust. "If you can find these people, and treat them for their LTBI, they will not progress to active TB," he explains. "That means no one else can catch it, and TB will ultimately disappear."

On target

In practice, though, things are not so simple. Because testing entire countries for LTBI is too time-consuming and expensive, doctors hone in on particularly vulnerable groups. At its most basic, this includes people who have come into contact with confirmed TB cases. More broadly, Dedicoat and his colleagues encourage the testing of HIV patients, people with kidney disease and those about to start taking biologic drugs. These patients can be up to 40 times more likely to develop fully fledged TB than the general population. Individuals with "social risk factors" are another target, adds Dedicoat, pointing to "heavy drinkers, homeless people and drug users."

Within limits

For over 100 years, doctors have tracked the aforementioned cases by using a tuberculin skin test. If the person has been previously exposed to TB, a lump will form. But as Dedicoat emphasises, this method has serious limitations. "It has operator variability," he explains. "You might inject it wrong or people's skin is different." This can create false positive results in some cases. Given treatment for TB can cause side effects of its own – notably liver disease – old-fashioned epidemiological tests risk cutting the life expectancy of patients who have never had TB.

Spot the difference

One solution is the so-called interferon-gamma release assay (IGRA) method. Rather than messing around with patients' skin, IGRA testing is done in vitro. "What the IGRA test involves is that you take a patient's blood, isolate their T-cells and stimulate them with TB proteins," Dedicoat explains. "If the patient's lymphocytes have been exposed to TB before, it'll react and release interferon gamma, which can be detected with a colour change or by looking at spots on the bottom of a 96 well plate. You can count the spots and quantify how much interferon gamma is released."

Two IGRA tests are currently available. One is called T-SPOT.*TB*, developed by Oxford Immunotec. IGRA has improved TB diagnostics, for example by preventing cross-reactivity to the BCG vaccination.

> "A quarter of the world's population has latent tuberculosis infection (LTBI), and 5–10% of these cases will become active, endangering millions of lives."

Although IGRA can accurately inform doctors if someone has TB infection, alone it cannot distinguish active from latent disease, nor predict the risk that latent TB will develop into the more dangerous form of the disease. However, Oxford Immunotec is working assiduously to improve the T-SPOT.*TB* test, and Dedicoat notes that tests predicting risk have already been done "experimentally".

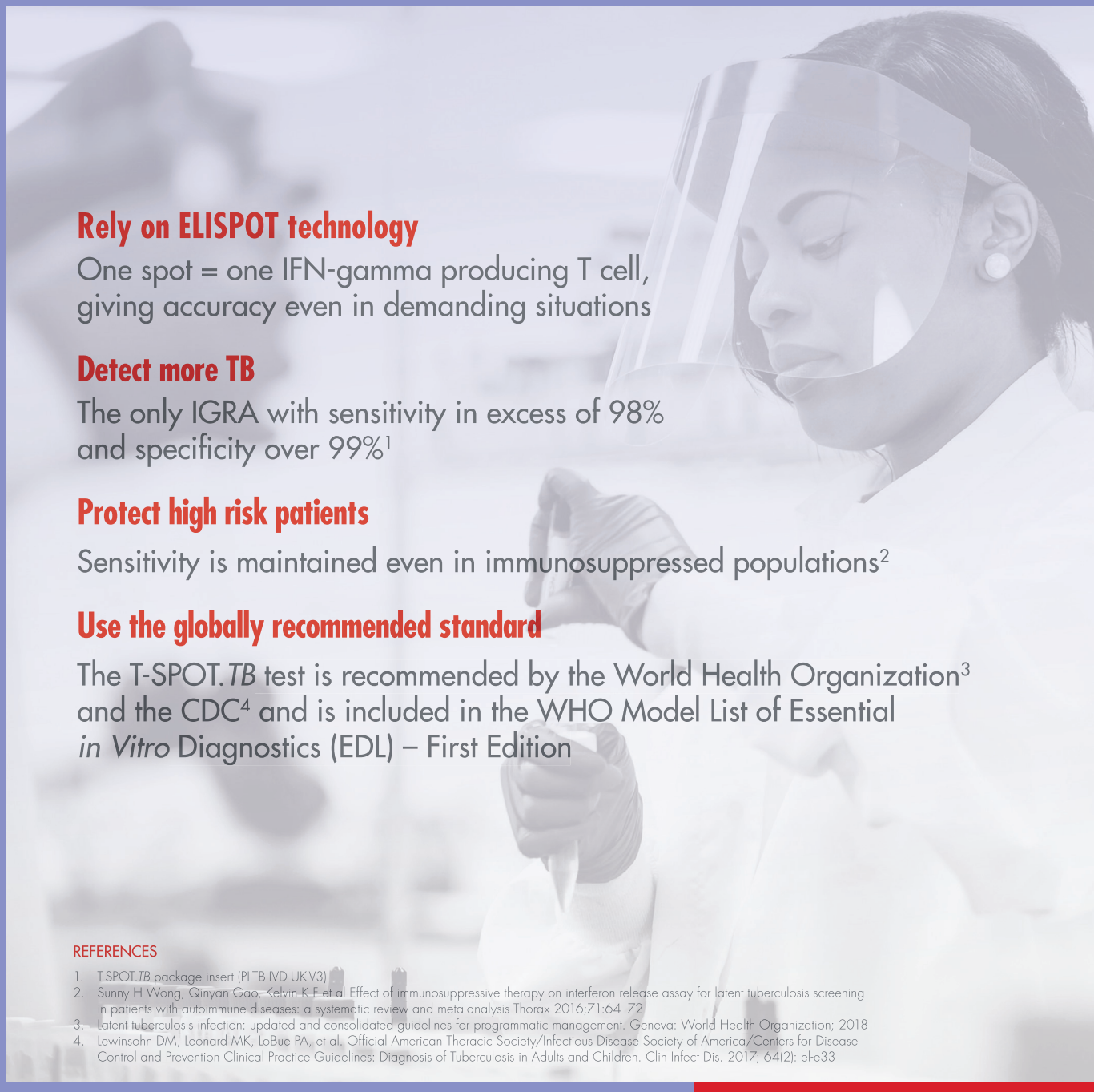
Raring to go

Given its successes already – the T-SPOT.*TB* test was licensed by FDA in 2008 – there is every reason to hope that Oxford Immuntec can offer a risk-prediction test soon. For his part, Dedicoat is enthusiastic about what the future might bring. "A test with inbuilt risk prediction would help us prioritise who we treat," he says. Combine these time-saving advantages with the cost-effectiveness of better testing and it appears there is every reason to share his excitement. ■

Further information
Oxford Immunotec
www.oxfordimmunotec.com

T-SPOT.*TB*

Use the T-SPOT.*TB* test to detect TB infection



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Detect more TB

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Protect high risk patients

Sensitivity is maintained even in immunosuppressed populations[2]

Use the globally recommended standard

The T-SPOT.*TB* test is recommended by the World Health Organization[3] and the CDC[4] and is included in the WHO Model List of Essential *in Vitro* Diagnostics (EDL) – First Edition

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2. Sunny H Wong, Qinyan Gao, Kelvin K F et al Effect of immunosuppressive therapy on interferon release assay for latent tuberculosis screening in patients with autoimmune diseases: a systematic review and meta-analysis Thorax 2016;71:64–72
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Oxford Immunotec

TB-UK-AD-MPN141-0001 V1

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DIAGNOSTICS

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Performing labs deliver results that drive better patient outcomes and improve healthcare value

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Realising a lab's true value

Running a medical lab is hard work, and inefficiencies are common. But with the right expertise, labs can vastly improve their services. *Practical Patient Care* finds out how **Abbott** is recommending a 'total value of ownership' approach to brilliant effect, sharpening efficiency, and saving lives and money along the way.

The rising cost of healthcare means that labs are being pushed to save money by reducing reagent costs and headcounts – all in an effort to avoid consolidation of services. However, by focusing on a total value of ownership (TVO) approach, labs have a chance to improve operational efficiency and the overall performance of an organisation.

Five-step programme

What is the TVO approach exactly? In short, it seeks to widen the scope of value beyond direct and indirect instrument costs, taking into account further benefits such as time and space savings. In brief, the process can be broken down into five steps. First, stakeholders need to establish goals and baseline metrics to steer the overall process.

Then they need to measure the direct and indirect instrument-related costs – including reagents, consumables, labour costs, maintenance and utilities – as well as audit lab workflow. The next step is to calculate and validate the benefits of a particular operational change, then implement measures that improve efficiency and productivity. The last step is to monitor ongoing performance, and also be ready to continually sharpen the process going forward.

> "Overall, incorporating TVO into daily work can be hugely beneficial for healthcare organisations and laboratories. After all, it is much more than a methodology."

Partner up

Not that any of this is easy. Labs need expert help to adopt TVO, something Abbott has demonstrated time and again. An excellent example would be its partnership with Christus Health Santa Rosa (CSR), based in San Antonio, Texas. The core lab at CSR offers a broad range of cardiac, infectious disease, transplant and paediatric services. Yet to meet the scope and demand of its testing portfolio, the lab was operating 14 diagnostic platforms from four vendors, creating an unnecessarily complex situation.

Clearly, the hospital had to find a way to maintain its high-quality service, while improving efficiency and creating capacity for growth. Important goals included improving turnaround times (TATs) to meet key performance indicators, consolidating and standardising platforms across campuses, and implementing better quality control processes. Its TVO analysis, and resulting improvements, far exceeded CSR's expectations, including reducing its immunoassay TATs from 59.5 to 46.2 minutes.

Abbott achieved similar results at Citilab, the second-largest medical diagnostics lab in Moscow. Before working with Abbott, it was under pressure to improve efficiency, reduce cost and demonstrate its true value. Using the TVO approach, Citilab compared the performance of Abbott and Roche instruments, and assays for its top 20 immunoassays and top 20 clinical chemistry assays. At first glance, the results indicated that the Roche solution was the winner, as the combined reagent and instrument costs were 17% lower. But once indirect costs were taken into account, it became clear that the Abbott platforms offered 33 and 26% savings for immunoassays and clinical chemistry assays respectively, adding greater overall value to the organisation.

Trial by TVO

In South Korea, meanwhile, Abbott proved its worth at the Korea Clinical Lab (KCL), a research-oriented medical foundation in South Korea. TVO analysis helped KCL determine optimum staffing levels and improve the quality of testing. Implementation of the recommended Abbott instrumentation led to a 12% increase in EBITDA (earnings before interest, tax, depreciation and amortisation), with a further 10% increase expected after putting into practice the additional TVO workshop recommendations.

Overall, incorporating TVO into daily work can be hugely beneficial for healthcare organisations and laboratories. After all, it is much more than a methodology. Instead, it is a complete change of mindset. But the benefits of adopting TVO far outweigh the challenges associated with organisational change and the risk of consolidation. In short, TVO is a win for everyone, from managers to staff to patients. Improved operational efficiency and a realistic understanding of costs support better decision-making and, ultimately, achieve better healthcare performance. ■

Further information
Abbott Diagnostics
www.corelab.abbott
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www.qlinea.com

Q-LINEA

The fight against sepsis

Sepsis is one of the world's biggest killers, but doctors have been limited by slow and laborious testing methods. *Practical Patient Care* talks to Dr Gorm Lisby from the Hvidovre Hospital in Copenhagen, and Jonas Jarvius, CEO of **Q-linea**, about how the medical profession is fighting sepsis and how the Swedish company is helping to save lives.

How big a problem is sepsis, from a health and economic point of view?

Dr Gorm Lisby: Sepsis is a severe clinical syndrome. A large number of different invasive bacteria and fungi can facilitate development of a cascade of immunological events that leads to clinical sepsis. There are an estimated 30 million sepsis cases annually, with six million worldwide deaths per year. It is a leading cause of mortality in the US associated with an annual cost exceeding $20 billion. In Europe, 300,000–500,000 of reported severe sepsis cases a year cost a total of around €20 billion annually.

What are the downsides of fighting the illness with broad-spectrum antibiotics?

GL: Although empirical antimicrobial regimens are considered to be broad-spectrum, the coverage rate is only 60–80% against sepsis-causing microorganisms. Thus, currently 20–40% of patients with sepsis will initially be without antimicrobial coverage. Using even more broad-spectrum antimicrobials empirically would not be a sustainable solution, as the literature clearly has demonstrated the direct relationship between antimicrobial use and emergence of antimicrobial resistance. Moreover, as the pipeline for new antimicrobials has almost dried out and as resistance has developed against all new antibiotics so far, overcoming antimicrobial resistance by developing new antimicrobials is not considered to be a potential successful strategy.

What benefits do targeted antibiotics offer instead, and how is speed of the essence in the process?

GL: Currently, less use of broad-spectrum antimicrobials – in other words, targeted antimicrobial treatment – is considered the only sustainable strategy for ensuring efficient antimicrobials for future use. To implement this strategy, faster microbial identification and susceptibility testing will be necessary, which will allow the clinicians to faster optimise the individual patient treatment. Faster optimisation will allow faster escalation of antimicrobialtherapy where needed as well as faster de-escalation of antimicrobial therapy where possible. Escalating antimicrobial treatment for the patients not covered by the empirical antimicrobial treatment will improve individual patient outcome. This is important, as the literature has documented that or every hour a covering antimicrobial treatment is delayed for septic shock, the survival decreases significantly.

Faster microbial identification and susceptibility testing will also allow clinicians to de-escalate antimicrobial treatment for patients receiving too broad-spectrum antimicrobials, thus reducing future antimicrobial resistance.

How do Q-linea's diagnostic systems improve on traditional platforms?

Jonas Jarvius: Currently, the time to receive information from an antibiotic susceptibility test (AST) is usually two to three days. This is due to slow traditional technologies involving several manual steps. In response, Q-linea are developing ASTar™, a system that can perform a fully automated phenotypic AST analysis using a dedicated instrument and single-use consumables. This means that the user at the microbiology laboratory only needs to load the sample and consumables in the ASTar instrument, then press start to receive a comprehensive AST report within three to six hours – more than 24 hours quicker than the traditional technologies. Meanwhile, ASTar has been developed to run up to 50 tests every day, with the capacity to analyse up to 48 different antimicrobials in each.

> "Faster administration of effective antimicrobial treatment could dramatically improve survival of septic patients."
>
> **– Jonas Jarvius**

What advantages does using Q-linea's expertise offer patients and doctors?

JJ: ASTar enables doctors to administer targeted treatment more than a day faster than today. Faster administration of effective antimicrobial treatment could dramatically improve survival of septic patients.

For the hospital, more accurate treatment increases efficiency and saves money. For microbiology laboratories, increased automation enable them to increase the number of tests performed with the same staff. A fully automated system enables less experienced personnel to perform analysis, for instance, during nightshifts. ■

Further information
Q-linea
www.qlinea.com

Enabling rapid care decisions

Diagnosing sepsis can be frustratingly slow when traditional techniques are employed, and lives can be saved by speeding up the process. We talk to Dr Natalie Whitfield, director of scientific and medical affairs at **GenMark Diagnostics**, about how ePlex technology is improving patient care.

Can you provide background on GenMark Diagnostics and the ePlex system?

Dr Natalie Whitfield: GenMark Diagnostics delivers molecular diagnostic solutions, designed to impact patient outcomes and reduce cost-of-care. The ePlex system integrates the entire process from order-to-report, and offers unique solutions designed to improve antimicrobial stewardship (AMS) and infection control in the delivery of patient-centred, value-based care. The ePlex software provides bidirectional LIS, epidemiological tracking, auto-filing of results, external quality control management and the new Templated Comments (TC) module.

How does the TC module work?

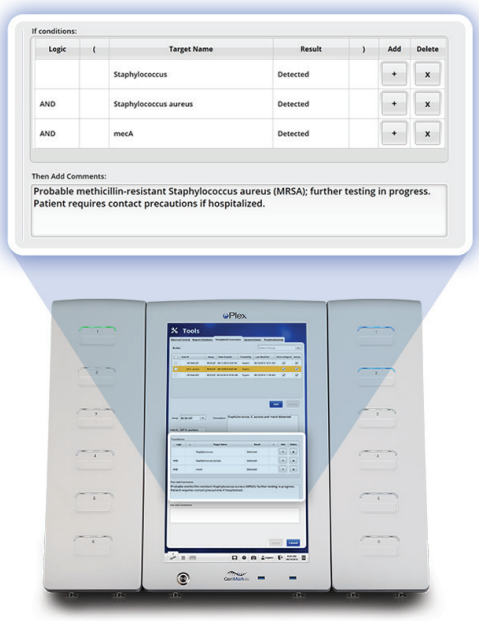
The availability of rapid, multiplexed technologies for comprehensive detection of infectious diseases is creating a paradigm shift in the role labs play in impacting patient outcomes, infection control and AMS. The drastically improved turnaround time from test order to reported result removes the laboratory as a bottle neck in patient care. The new capability has created the need for enhanced synergy between the lab and the rest of the care team.

The ePlex TC module provides a rules-based engine that enables users to customise conditions based on the ePlex Blood Culture Identification (BCID) Panel results to communicate interpretive comments on the result report and through to the LIS. Users can define specific rules for organism and antimicrobial resistance gene combinations in a logical structure. The TC module allows pharmacists to translate the antibiogram, formulary and their expertise into an action plan, empowering physicians to more quickly and efficiently treat patients and improve patient care.

Could you run through a case study of how it might be used in practice?

A patient arrives at the ED with suspected sepsis. Blood culture bottles are collected while the patient is started on broad spectrum antibiotics. Blood bottles ring positive later that day, triggering pathogen ID and resistance testing. Using the ePlex system, pathogen ID and antimicrobial resistance gene results are available within 90 minutes. Alternatively, traditional subculture and AST results take 48 hours.

If the laboratory has implemented the ePlex TC module, customised results can be transmitted from the instrument into the LIS, providing guidance on how to use these rapid results, eliminating the need to wait for consulation from specialists.



ePlex delivers solutions for lab workflow, safety and data management.

How does your ePlex system benefit laboratories, patients and clinicians?

Laboratories benefit from an easy-to-use system, that can be performed on all shifts. The test requires less than two minutes of hands-on time and the results can be automatically released to the LIS. Clinicians benefit from rapid results that can provide institution-specific guidance for optimal treatment.

The ePlex system has the broadest BCID panels available, delivering more information faster than non-molecular identification methods and AST so clinicians can make treatment decisions days earlier than for AST results, potentially improving outcomes.

In general, how does this approach distinguish GenMark in the market?

Recent studies have shown that rapid results for bloodstream infections have a significant impact on patients and the cost of care when the results are combined with an AMS.

The bidirectional interface, from order-to-report, with new customized Templated Comments helps hospitals provide quality patient care and keep compliance with their AMS metrics. ■

Further information
GenMark Diagnostics
www.genmarkdx.com/int

Gut feeling

New research has found that one in four non-antibiotic drugs affect the growth of bacteria in the gut, which could promote antibiotic resistance and greatly impact the way in which healthcare professionals diagnose and treat disease. Lucy Evans speaks to **Nassos Typas** of the European Molecular Biology Laboratory about the capacity to harm as well as heal.

In recent years, the human microbiome has become an exciting field of study. Spurred by advances in sequencing technology, along with disciplines like epigenomics and metabolomics, we know more than ever before about the 100 trillion or so bacteria in the gut.

While much remains to be explored, it seems clear that each person's microbial make-up can profoundly affect their physiology. In a healthy person, the gut plays host to a diverse bacterial community with an important range of functions. When the gut bacteria fall out of balance, various chronic conditions can result.

This in turn has implications for the way we think about antibiotics. While antibiotics have saved millions of lives, they are something of a blunt instrument in that they kill 'good' bacteria as well as 'bad' ones. To put it more scientifically, they disrupt the delicate intestinal ecosystem, wiping out useful species of

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[1]*Kalorama United States Market for In Vitro Diagnostic Tests*, 2017, pg. 878.

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†References available upon request.

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bacteria while allowing other, opportunistic species to thrive.

Supporting the resistance

A question that has not been asked so widely is whether other types of drug might also affect the microbiome. Could certain non-antibiotic classes of drug – especially those with gastrointestinal side effects – inadvertently damage the gut bacteria, in much the same way as antibiotics? And if they work like antibiotics, might they contribute to antibiotic resistance too?

A team of researchers at the European Molecular Biology Laboratory (EMBL) have been attempting to find out. In their latest study, published in *Nature* earlier this year, they screened more than 1,000 marketed drugs against 40 strains of gut bacteria. A surprisingly high proportion (24%) affected the growth of at least one bacterial species.

> “By getting resistance to non-antibiotics you might, as collateral damage, be building resistance to antibiotics.”

“How much damage drugs do to the microbiome is undecided, even for antibiotics, but more so for non-antibiotics,” says Nassos Typas, a group leader at EMBL and one of the study authors. “People expect that because these drugs are developed to target human proteins, they wouldn’t affect bacteria. But we found that the effect of non-antibiotic drugs on the gut microbiome is much more extensive than expected.”

Typas and his colleagues are not the first to explore this topic. Over the past few years, a number of different drugs – anti-diabetics, proton pump inhibitors, NSAIDs and antipsychotics, to name a few – have been associated with changes in microbiome composition. One recent paper, for instance, pointed out that atypical antipsychotics are often associated with metabolic disease, and suggested that ‘gut dysbiosis’ – imbalances in the gut ecology – might be why.

However, the literature to date has left several questions hanging. It has not explained, for instance, whether the drugs impact the microbiome directly, or whether there are additional factors at play. Nor has it determined whether this is a widespread phenomenon, or confined to just a few classes of drug.

Effects on gut bacteria

Typas’s team decided to systematically profile the interactions between drugs and individual gut bacteria, with a view to generating a comprehensive resource of drug actions on the microbiome. This resource would add an extra dimension to clinical studies and ultimately improve drug design. ››

Microbiome as a biomarker

Gut microbiome has emerged as a particularly useful biomarker for disease phenotype, prognosis and treatment response, according to Purna Kashyap, gastroenterologist at the Mayo Clinic and co-author of 'Microbiome at the Frontier of Personalized Medicine', who states:

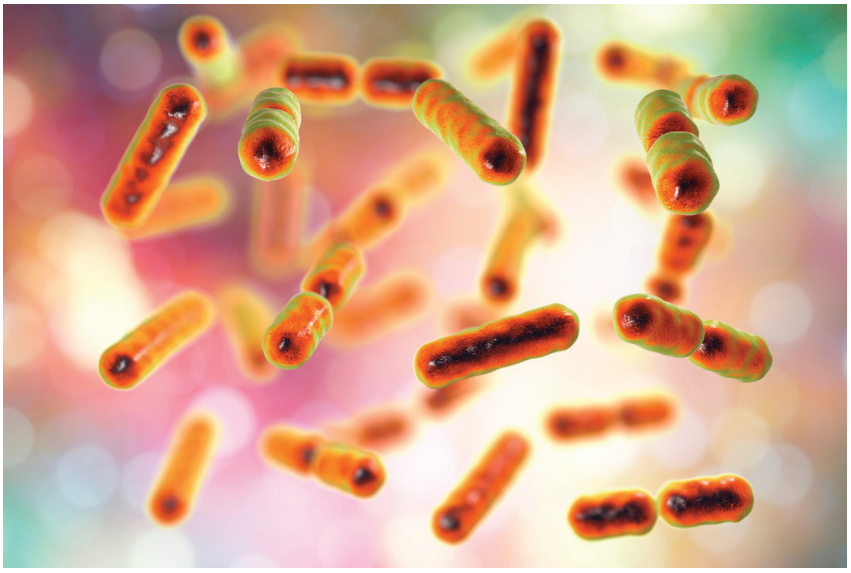
“The genomic revolution promises to transform our approach to treat patients by individualising treatments, reducing adverse events, and decreasing healthcare costs.

“The early advances using this have been realised primarily by optimising preventive and therapeutic approaches in cancer using human genome sequencing. The ability to characterise the microbiome, which includes all the microbes that reside within and upon us and all their genetic elements, using next-generation sequencing allows us to now incorporate this important contributor to human disease into developing new preventive and therapeutic strategies.

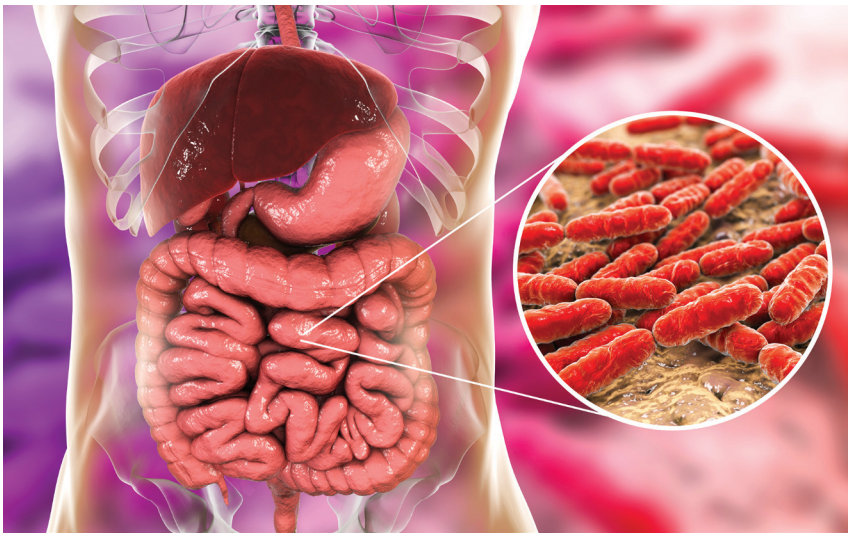
“In 'Microbiome at the Frontier of Personalized Medicine', we highlight the importance of the microbiome in all aspects of human disease, including pathogenesis, phenotype, prognosis and response to treatment, as well as their role as diagnostic and therapeutic biomarkers. We provide a role for next-generation sequencing in precise microbial identification of infectious diseases, and characterisation of microbial communities and their function.

“Taken together, the microbiome is emerging as an integral part of precision medicine approach as it not only contributes to inter-individual variability in all aspects of a disease but also represents a potentially modifiable factor that is amenable to targeting by therapeutics.”

Source: Mayo Clinic



Despite huge advances in the study of the human microbiome in recent years, new studies have shown the effect of non-antibiotic drugs on gut bacteria to be far greater than expected.



Microbes that are resistant to non-antibiotics also tend to be resistant to antibiotics, raising the possibility that resistance to the latter might be gained without taking them.

Their findings were striking – 203 of the drugs in their sample were active against certain bacteria (including 14 not previously reported to have antibacterial activity), with 40 of them affecting ten strains of bacteria or more. What is more, for reasons explored in the paper, the 24% figure is very likely an underestimate.

"Another very interesting finding is that the microbes that tend to be resistant to non-antibiotics tend to be resistant to antibiotics too," says Typas. "This made us think there might be a common underlying resistance mechanism for the two classes of drug."

Keen to pursue this line of thinking, the team conducted a few preliminary experiments. They found there was indeed an overlap between the resistance mechanisms against antibiotics and against human-targeted drugs.

This raises a galling possibility – in principle, you might be able to acquire antibiotic resistance even without taking antibiotics.

"By getting resistance to non-antibiotics you might, as collateral damage, be building resistance to antibiotics, and that's something we definitely want to look into further," says Typas.

While this finding may seem troubling, he points out that we do not currently know enough to assess the degree of risk. On top of that, where cross-resistance exists, we might also see a related phenomenon – 'collateral sensitivity'. In other words, when bacteria become resistant to one drug, they might simultaneously become more responsive to another.

> "It might enable us to optimise drug choice for individuals depending on what microbes they have. It might also help us reduce side effects, or maybe even optimise the drug function."

"The general trend is that the resistance mechanism might be common for non-antibiotics and antibiotics, but for every pair of drugs you might also have the opposite situation," says Typas. "In this case, developing resistance to non-antibiotic drugs – let's say to a proton pump inhibitor – might make you sensitive to an antibiotic. This would give us room to exploit collateral sensitivity to drive off antibiotic resistance. So in a way it's not only bad news – it also gives us a window of opportunity."

Look forward

At present, the EMBL team is pursuing a number of different directions. Firstly, they are further exploring the risk that non-antibiotics might foster antibiotic resistance. Secondly, they want to look beyond individual microbial species, and see how drugs affect the complex communities actually found in the gut. Finally, they want to assess whether drug-microbe interactions might inform more than just the side effects.

"Antipsychotics, for instance, have an extensive effect on our gut microbes – we want to explore whether this effect on the gut microbiome extends only to side effects like weight gain, or whether it might also translate to the mode of action of the drug," says Typas.

He feels that, sooner or later, both drug developers and front-line clinicians will need to pay more attention to these kinds of interactions. This would give them more control over the treatment's side effects and even its primary mode of action, as well as better understanding the appropriate dosage.

"There's a second aspect, which is how microbes might be changing the concentration of the drugs in the human body. So it's not only drugs affecting microbes – it's microbes affecting drugs," he says.

Further down the line, he thinks this work might help researchers design optimal drug combinations, as well as leading to new possibilities within personalised medicine. Although the microbiomes of healthy individuals have a lot of similarities, in that they all carry a common set of species, they often carry very different strains.

This means one person might carry a strain of bacteria that is resistant to a drug, and the next person might carry a strain that is sensitive. If it can be known which is which, it might become possible to pick the medications that best suit their microbiome.

"It might enable us to optimise drug choice for individuals depending on what microbes they have. It might also help us reduce side effects, or maybe even optimise the drug function," Typas concludes. ■

Identifying the problem

Get the precision technology to identify carbapenemase-resistant bacteria using lateral flow rapid tests developed by **Coris BioConcept**.

The surveillance and control of resistance to beta-lactam among Gram-negative bacteria remains a big concern for microbiologists worldwide. Descriptions of bacterial infections associated with the oxacillinase OXA-48 are increasing, revealing a huge impact on antimicrobial treatment and patient morbidity.

For clinical laboratories, OXA-48 and its variants represent the most challenging resistance mechanism to detect infections that are often under-detected by routine diagnostic methods. OXA-48 exhibits a weak hydrolytic activity on carbapenem and broad-spectrum cephalosporin, and is not inhibited by clavulanate or tazobactam.

Today, multiple allelic variants of OXA-48 have been described, with diverse hydrolytic profiles. As an example, the single amino acid substitution and four amino acid deletion described in OXA-163 confer an increased hydrolytic activity against cephalosporins, coupled to a loss of resistance to carbapenems and an inhibition by clavulanate and tazobactam.

This particular hydrolytic profile confuses its correct detection at the laboratory level and control at the clinical level. Treatment failures can impede patient recovery and favour the selection of new resistant strains.

For a long time, efficient identification of OXA-163-expressing strains relied on gene sequencing, which is not practical for a clinical laboratory's daily routine. The recently available immunochromatographic lateral flow test developed by Coris BioConcept to specifically differentiate OXA-163 from OXA-48 proteins replaces costly and lengthy genotypic methods.

This phenotypic test is an easy-to-use and instrument-free test that provides a fast (15 minute) and accurate (100%) identification of variants. Today, precise detection of other carbapenemases will be included in the test to reach a five-parameters assay. This up-coming RESIST-5 OOKNV test, commercialised by the same company, is the ideal tool to precisely identify the most prevalent carbapenemase-mediated resistance mechanisms on a single phenotypical assay. Its use on a daily routine in healthcare facilities will enable a broader surveillance of worldwide-disseminating new carbapenemase variants and help clinicians in the daily care of patients. ■

Further information
Coris BioConcept
www.corisbio.com

Antimicrobial stewardship

Significant challenges are posed to global health by the overuse of antibiotics and a corresponding rise in antimicrobial resistance. François Lacoste, executive vice-president of the clinical unit at **bioMérieux**, explains how the in vitro diagnostic company provides benefits to its customers through lab efficiency and medical value.

Antimicrobial resistance is recognised as an increasingly grave concern. The ability of microorganisms to change when exposed to antimicrobial drugs such as antibiotics, rendering them ineffective, threatens the effectiveness of a huge range of treatments for infectious diseases.

What is required is antimicrobial stewardship: increased knowledge and understanding of microorganisms and a corresponding refinement in the prescription of antibiotics to counter their overuse. This is facilitated by bioMérieux's diagnostic solutions in the daily routine of the lab. Microorganism identification is conducted by the VITEK MS mass spectrometry microbial identification system, and susceptibility testing by the VITEK 2, both part of an integrated solution that provides lab managers with precise and relevant information, which is then collated and reported in real time by the lab information solution MYLA.

The VITEK MS's database is continually updated to include new and emerging pathogens.

> "To keep pace with evolutions and remain clinically relevant, this database is constantly improved to include new and emerging pathogens."

The extremely comprehensive VITEK MS database

"We have over 1,300 strains and more than 40,000 spectra, which highlights the magnitude of the completeness of the database," says François Lacoste, executive vice-president of the clinical unit at bioMérieux. "To keep pace with evolutions and remain clinically relevant, this database is constantly improved to include new and emerging pathogens." The most recent update, the VITEK MS V3.2.0, is the first CE IVD database to include the bacteria *Brucella* and the fungus *Candida auris*. "*Candida auris* is an emerging pathogen that is responsible for very severe bloodstream infections in patients," reminds Lacoste. "Previously, it could be misidentified, and it requires specific treatment – so being able to precisely identify it brings high medical value compared with existing solutions at the moment."

The new database also allows more exact identification. "With this new database, we are also able to provide meaningful information on the *Acinetobacter* complex, for instance," Lacoste explains. "Different treatments are required for different species of *Acinetobacter*, so it is an instrumental benefit for the patient to be able to identify the microorganism at the species level more than at the genus level is really of added value," adds Lacoste.

The commitment to research at bioMérieux facilitates this constant improvement to the VITEK MS database. "In response to evolving medical needs, innovation is key. 13% of revenue is invested in research and development, and we have close to 1,600 people working in R&D for different applications," informs Lacoste.

Pushing boundaries

The VITEK MS allows five technologists to prepare samples simultaneously, and bioMérieux goes further still in helping labs to work effectively. "In terms of lab efficiency, we provide a service to organise the workflow within the lab," specifies Lacoste. "We conduct workflow assessment with the lab, for instance, in order to help customers to optimise the way their lab is organised, in terms of equipment, workflow and resources."

In addition, bioMérieux provides round-the-clock customer support. "One of the strengths of the VITEK MS is the support provided by the company. This translates into the ability to assist the customer remotely in case they need troubleshooting, or to perform a software update," points out Lacoste. "All these innovations, whether databases, gains in efficiency, keeping instruments working, for example, have one aim in mind – equipping healthcare teams to fight against antimicrobial resistance and sustain antibiotics for future generations, illustrating that bioMérieux is committed to serving public health." ■

Further information
bioMérieux
www.biomerieux.com

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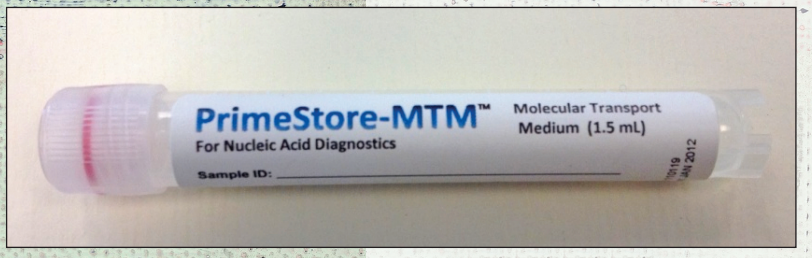

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Rapid inactivation of pathogens significantly improves safety at the collection site, throughout transport, and during every phase of testing. PrimeStore® MTM has improved testing results in laboratory samples and those collected in some of the most remote villages in the World.

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Pictured above: 3.0 mL vial with 1.5 mL of solution.
Also available: 2.0 mL vial with 1.0 mL of solution.

LONGHORN VACCINES & DIAGNOSTICS LLC

www.lhnvd.com

Sample collection for microbial molecular testing

As FDA clears the first microbial sample collection product for RNA and DNA, president of **Longhorn Vaccines and Diagnostics** Jeff Fischer explains the benefits of PrimeStore.

PrimeStore MTM has been demonstrated to be effective in published peer-reviewed clinical studies under the most challenging conditions. Why did you seek FDA clearance?

Jeff Fischer: Longhorn Vaccines and Diagnostics (LHNVD) developed PrimeStore MTM over ten years ago to provide better RNA and DNA for molecular testing. Peer-reviewed studies conducted using the leading molecular platforms to include next-generation sequencing have demonstrated that samples collected in PrimeStore MTM provide high-quality quantitative polymerase chain reaction (qPCR) and next-generation sequencing results. Whether the sample is collected and tested on-site or shipped at ambient temperature thousands of miles, clinical studies have generated highly sensitive microbial detection results without the need for pathogen containment or special handling procedures.

Over the past three years, several high-profile diagnostic companies have made outlandish, unsupported claims about their technology. Sample collection was and continues to be a field plagued with questionable technology. LHNVD approached FDA and worked closely with the agency to define a new category of device through PrimeStore MTM, setting a high bar for future products.

Your first indications focused on influenza and *Mycobacterium tuberculosis* (MTB). Why did you choose these pathogens?

PrimeStore MTM was originally developed to protect RNA in samples suspected of containing the influenza virus. Extensive work has been done in the developed and developing world, demonstrating samples shipped in PrimeStore MTM generate highly sensitive results for influenza viruses, and a wide range of respiratory pathogens in a variety of qPCR uniplex and multiplex tests.

After PrimeStore MTM was initially FDA-reviewed and authorised as part of the 2009–10 H1N1 pandemic, LHNVD shifted to systematic validation of PrimeStore MTM as part of the World Health Organization's urgent call for new products to combat the epidemic of MTB infection in the developing world. PrimeStore MTM's inactivation characteristics are ideal for MTB and the developing world. Collecting and transporting samples in PrimeStore MTM has two key advantages compared with handling raw sputum: safety and sensitivity. Many laboratories and near-care facilities lack containment facilities for handling highly infectious samples. Samples in PrimeStore MTM require no containment for safe handling. MTB can be a challenging pathogen to fully lyse. For samples containing low levels of MTB that aren't fully lysed, crucial DNA is not released, and cannot be detected. Samples in PrimeStore MTM are fully lysed, and the DNA is released and protected for highly sensitive molecular testing.

How can PrimeStore MTM be used to improve clinical outcomes?

Current respiratory samples are collected in universal transport media/viral transport media (UTM/VTM), which is a legacy media designed for culturing microbes. Studies have demonstrated that UTM/VTM inhibit molecular detection, reducing sensitivity of tests. Influenza drugs are most effective when the infection is detected early. Peer-reviewed studies demonstrated enhanced detection of the influenza virus in pre-symptomatic family members of symptomatic patients using qPCR with samples collected in PrimeStore MTM.

For MTB, PrimeStore MTM provides highly sensitive disease detection using a fraction of standard sputum volume required for other tests. Samples that test positive can be further tested for drug sensitivity by a number of molecular technologies to include next-generation sequencing. Rapidly determining effective treatment protocols is essential to cure rates.

PrimeStore MTM has allowed you to develop a new product that will dramatically improve MTB drug sensitivity testing (DST). What can you tell us about PrimeSeqMDR?

PrimeSeqMDR is a game-changing DST kit for MTB. It can be used with the highly sensitive, clinically validated open platform PrimeSuite MTB qPCR assay, or after MTB detection by a wide range of tests to include smears, culture or molecular detection. For non-molecular testing, a portion of the smear sample or culture sample can be added to PrimeStore MTM. Samples for molecular detection can be immediately placed in PrimeStore MTM.

PrimeSeqMDR provides timely and cost-effective DST for key MTB drugs, which include pyrazinamide (PZA). It is designed to be used with the industry-leading Illumina MiSeq instrument. ■

Further information
Longhorn Vaccines and Diagnostics
www.lhnvd.com

Difficile measures

A missed diagnosis of *Clostridium difficile* infection can cost a hospital tens of thousands of dollars, Dr Glen Hansen, associate professor at the University of Minnesota, says. Now, with physicians still struggling to accurately spot and treat patients suffering from this difficult-to-detect illness, a pioneering detection method developed by immunodiagnostics company **Singulex** may offer healthcare professionals a better weapon in their battle against the disease.

Clostridium difficile infection (CDI) is a type of bacteria that infects the bowels and causes a wide range of symptoms, including fever, loss of appetite, a rapid heart rate, abdominal cramping, nausea and diarrhoea. The disease most commonly affects people who have recently taken a course of antibiotics in a hospital or care-home environment. What's more, CDI is difficult to detect accurately without testing, precisely because of the number of ways the illness can manifest.

Medical company Singulex is now claiming a significant breakthrough in the fight against it. The business is pitching its investigational Singulex Clarity C. diff toxins A/B immunoassay as a way to perform rapid ultrasensitive precision measurement of specifically chosen biomarkers, which quickly reveal whether or not *C. difficile* toxins are present in patients' samples. According to Dr Glen Hansen, an associate professor at the University of Minnesota, and the director of Clinical Microbiology and Molecular Diagnostics at Hennepin County Medical Center in the US, the new device should be seen as a powerful addition to a hospital's arsenal.

Hansen explains that the history of CDI testing has been marked by two problems that persisted into the modern era. The first is the battle to correctly identify the malady before an outbreak scenario occurs, particularly among at-risk groups, which is especially pertinent as the current generation of commercially available diagnostics tests are lacking in sensitivity to the infection. The second issue is the struggle to prevent the pendulum swinging too far in the other direction and overdiagnosing every case of diarrhoea as a symptom of the disease.

Who is at risk?

Although it is believed that CDI is largely confined to hospitals, there is some evidence that more people from the community may be at risk of catching *C. difficile* than was previously thought. Meanwhile, a number of different groups in the clinical space remain particularly vulnerable to the infection, including patients who have received previous courses of antibiotics. CDI also tends to show up in cases concerning transplant patients, acute illness sufferers and people who are on the polar extremes of age.

Diagnosing CDI is based on the premise that it is a toxin-mediated disease. Scientists say the organism behind the illness produce a number of toxins capable of causing gastrointestinal disease, typically classified as either toxin A or B. Each can disrupt the integrity of the mucous membrane, often leading to diarrhoea in the patient. However, as previously mentioned, the symptoms of the illness can manifest across a wide spectrum of disease, ranging from mild diarrhoea to life-threatening colitis. Moreover, there are also cases of individuals who can appear asymptomatic, while still having been colonised with toxigenic *C. difficile*.

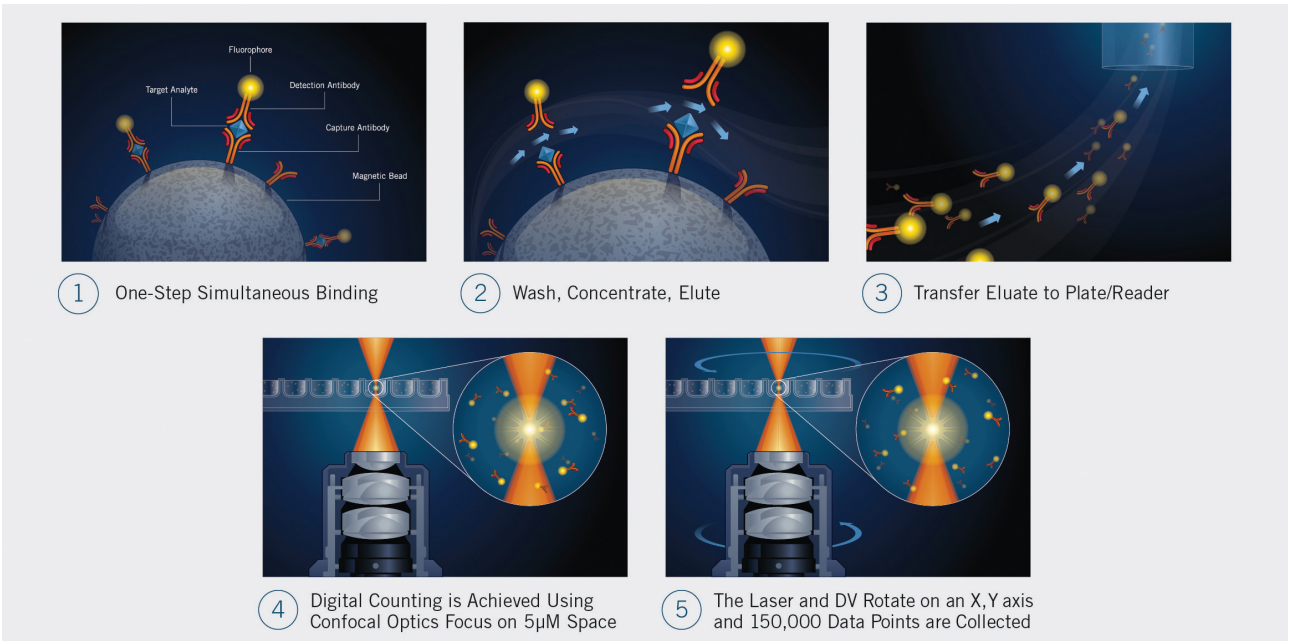
> "There are a number of high-profile studies, one in the UK and one in the US, showing that free toxin detection is more closely associated with the disease than not."

"Earlier generations of *C. difficile* tests relied exclusively on toxin A as their primary target," Hansen explains. "Many of these were early immunoassay antibody tests, and we have come to learn now with outbreak scenarios that there may be a small percentage of the population, around 5–15%, that carry only toxin B," he reveals. "Most cases of CDIs involve organisms that express both toxin A and B together, so most commercial assay demarcate toxin B as their primary target. The risk of missing toxigenic cases by targeting only toxin B is very small – less than 1%. So, most commercial laboratory-based assays demarcate toxin B as their primary target."

According to Hansen, there is still a debate within the medical community over whether or not the detection of a gene on a molecular assay – toxin A or B – is more likely to spot an infected patient than testing for the by-products of that gene.

"There are a number of high-profile studies, one in the UK and one in the US, showing that free toxin detection is more closely associated with the disease than not," Hansen says. "The reason that those findings come out that way is that we tend to see acute disease associated more with higher levels of toxin. It's not always that simple, but certainly if you have higher levels of toxin, you are at higher risk of having significant levels of infection. So, free toxin testing is the idea of testing the actual production of the toxin, which we detect via antibody to the toxin (free toxin), in a diagnostic specimen versus the detection of the gene itself."

Testing for *C. difficile* has gone through a number of different iterations. Since the discovery in 1978 that the



Single molecule counting technology is 100 times more sensitive than existing technologies.

bacterium was associated with human disease, several generations of tests to identify it have fluctuated in popularity. However, Hansen is enthusiastic about the abilities of Singulex's new development to improve staff detection rates of the malady in health institutions.

> "Free toxin testing is the idea of testing the actual production of the toxin... in a diagnostic specimen versus the detection of the gene itself."

"Detection is at the heart of what makes CDI such a contemporary issue, because the illness associated with CDI can range from very mild asymptomatic diarrhoea, that presents as a couple of bowel movements in a 24 hour period, to a life-threatening sickness," Hansen declares. "So, the spectrum of disease that we see with CDI is much larger and wider than we deal with in other infections," he continues. "Normally, we rely on laboratory testing, but it needs to be in conjunction with the clinical perspective of whether or not a treating physician believes that a patient's diarrhoea could be attributable to CDI, because there is a wide spectrum of symptoms that we see with patients."

Hansen's general perspective is that Singulex's new device could provide busy doctors with a rapid multifunctional assay that allows them to investigate incidents of CDI among hospitalised patients in a highly sensitive, specific and rapid fashion. Anything that can reliably detect free toxin levels at a level of sensitivity that matches molecular-based testing is an improvement over current standards – and an advancement in fighting *C. difficile*.

Indeed, the Clarity C. diff toxins A/B assay specifically aims to be the first ultrasensitive enzyme-linked immunosorbent assay test on the market that offers physicians and laboratorians the specificity intrinsic to toxin tests, but comes with a level of sensitivity that rivals molecular methods. The company says that findings in previous studies have demonstrated that, when compared with other currently available testing options, the Singulex system offers its clients quicker results, better sensitivity and enhanced specificity in the detection of both types of toxins associated with the presence of *C. difficile* in stool samples.

Getting it done

Hansen stresses how important a contribution to the field of *C. difficile* detection he hopes the Singulex Clarity C. diff toxins A/B immunoassay could make. It can bring together the sensitive testing required with the ability to tie free toxin-based tests to patients' samples, providing physicians with a test result that better correlates with the disease.

"This is a very unique assay that allows us to be able to interrogate the ability of a diagnostic specimen at a single molecule level, to look for more reliable clinical markers, which are free toxins, at a level in which the sensitivities can now match molecular-based testing," Hansen says. "When hospitalised patients have true signs of symptoms of CDI, we don't want to run into a scenario where we are missing these diagnoses." ■

Further information
Singulex
www.singulex.com

Point-of-care testing in emergency departments

The use of point-of-care testing in hospitals is on the rise across Europe. Emergency departments in particular are adopting rapid flu tests, such as **Sekisui Diagnostics**' OSOM Ultra Flu A&B Test, to speed up the time to diagnosis and address the burden on departments during flu season.

Rapid influenza diagnostic tests (RIDTs) are immunoassays for the identification of influenza A and B viral antigens in respiratory samples. In Europe, influenza generally occurs in epidemics between November and April each year.

Rapid tests are not as widely used in Europe at the point of care as they are in the US, primarily due to cost and performance issues. While using rapid tests does incur some additional cost, the savings provided by proper patient management can help offset the initial expense of the test.

Current challenges in testing for influenza

During flu season, emergency departments (EDs) must keep up with high demand for testing and diagnosis. While the duration of illness is often short, influenza brings with it a heavy economic and healthcare burden.

The European Centre for Disease Prevention and Control's fact sheet about seasonal influenza states that flu "causes 4–50 million symptomatic cases in the EU each year, and 15,000–70,000 Europeans die every year of causes associated with influenza".

Because flu-like symptoms occur in many other infections besides an influenza virus, care must be taken to accurately pinpoint the diagnosis. In Europe, there has always been a preference for making a clinical diagnosis based on symptoms.

As antibiotics are not effective against viral infections, flu testing supports effective antibiotic stewardship – helping conserve the supply of antibiotics available to treat life-threatening infections. In some cases, antiviral treatment can effectively lessen symptoms, speed-up recovery, and reduce complications like ear infections in children and pneumonia in adults.

Significant benefits of rapid tests for flu in EDs

Rapid testing is a viable solution that is especially well suited to the demands of accident and emergency departments and can:

- support clinical decision-making and treatment
- improve bed management
- be used by non-laboratory staff
- decrease unnecessary testing
- provide results in 15 minutes or less.

In addition, positive test results allow the immediate implementation of infection control and prevention techniques – minimising the spread of the virus in the ED or in other clinical settings.

Emergency departments could benefit greatly from effective point-of-care testing, such as that given by the OSOM Ultra Flu A&B Test.

Sekisui Diagnostics OSOM Ultra Flu A&B Test provides EDs with an advancement in flu rapid-test technology, and is cleared for sale in the US and Europe.

In a recent study of 500 patients published in the *Journal of Clinical Virology*, the OSOM Ultra Flu A&B Test was proved to perform well in EDs. The authors noted, "Given the diagnostic performances, even among elderly patients, and reading of the results by ED personnel and the speed of obtaining the result, the OSOM Ultra Flu A&B Test can be considered a decision-making tool adapted to the ED context.

"We evaluated the capacity of ED personnel, nurses, and physicians to perform and read the RIDT. Our results indicate excellent consistency in reading the test with external personnel at the virology laboratory. These results allow us to envisage the use of the OSOM Ultra Flu A&B Test at point of care in the ED after training nursing and medical teams. Currently, in some EDs, suspected or compatible cases of influenza are not isolated or treated. Providing a test is performed early in the ED process, near to the patient, by an ED staff member and with a result available in less than 20 minutes, this should allow us to set up a quality programme aimed at reducing the risk of influenza nosocomial transmission." ■

Further information
Sekisui Diagnostics
www.sekisuidiagnostics.com

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*Theocharis, George. Vouloumanou, Evridiki et al. "Evaluation of a direct test for seasonal influenza in outpatients", European Journal of Internal Medicine, Vol.21 (2010) 434-438

Listen to your heart

Spells of light-headedness, dizziness or palpitations can often occur. Monitoring the activity of the heart after such a diagnosis is vital in ensuring that the symptoms are not attributed to an underlying health issue with the heart. Finding a practical way of doing so without infringing on the patient's daily life, however, is difficult. Kristi Larson, a marketing manager for **Medtronic**'s diagnostics and monitoring division, talks about how the company's new insertable cardiac monitor, the Reveal LINQ, is an advanced and straightforward solution to this problem.

How commonly are palpitations, dizziness or fainting spells connected to a patient's cardiac health?

Kristi Larson: 40% of the general population will have a fainting episode in their lifetime. The prevalence of the condition also increases with age, as 50% of the patients admitted to hospital for fainting episodes are 75 years and older. Atrial fibrillation (AF) is also a growing condition with devastating effects. Approximately 8.8 million adults over the age of 55 have AF in the EU, and this number is expected to double by 2030.

The Reveal LINQ is the size of a paperclip, and was designed to be as unintrusive as possible.

The Reveal LINQ monitors a patient's heart after a fainting episode or stroke.

How might long-term monitoring of patient heartbeats potentially improve their cardiac health?

Fainting and AF episodes are often infrequent and difficult to detect with short-term monitors. We see that 24-hour holter monitors may detect only 2% of fainting – or syncope – episodes, while a long-term monitor is likely to diagnose 50% of syncopal episodes. A long-term monitor has the ability to monitor a patient's heart for up to three years, which increases the likelihood of capturing these infrequent episodes of fainting and AF.

What conditions is the Reveal LINQ best placed to monitor, and how does it work?

The Reveal LINQ is designed to monitor fainting, dizziness, palpitations and AF (after a patient has experienced a stroke). It is an insertable cardiac monitor, which is small – about the size of a paperclip – and inserted by a doctor just under the skin of a patient's chest. It has a three-year battery that continuously monitors a patient's heartbeat. When the monitor notices an irregular rhythm, it stores the episode and sends a report to the patient's doctor. The doctor then reviews the report and calls the patient if medical action is required.

What technological improvements does the Reveal LINQ contain over previous heart-monitoring systems?

Reveal LINQ is 87% smaller than previous implantable monitors and has improved accuracy over previous models. The monitor has evolved with five generations of algorithms inside the device to ensure that the right data is detected and provided to the doctor in a timely manner.

The notion of a heart monitor as a long-term addition to a patient's life sounds impractical. How intrusive is the insertion of the Reveal LINQ on the day-to-day existence of the patient?

After insertion, the patient receives a transmitting monitor – the MyCareLink Patient Monitor – that sits by the patient's bedside to collect the data. This transmitting monitor automatically starts up every night without interaction required by the patient. The system is easy to use and has been widely accepted by patients. ■

Further information
Medtronic
global.medtronic.com

PATIENTS WITH LONG-TERM MONITORING GET ANSWERS

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Continuous and wireless monitoring – with Medtronic CareAlert™ notifications for FASTER diagnosis.[5]

RECOMMENDED

By the 2018 ESC Syncope Guidelines for arrhythmia monitoring of Syncope Patients.[6]

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Rise of the machines

The potential for artificial intelligence (AI) and machine learning to transform the healthcare field is huge, with studies already finding diagnostic platforms outperforming their future human colleagues in terms of speed and accuracy. Take-up has been slow, however, with relatively few examples of active AI tools on medicine's front lines. What is accounting for this delay, and to what extent are we currently witnessing a cultural shift? Patrick Kingsland investigates.

Machine learning has long been touted as the next big thing for healthcare. With countless start-ups investing in that promise, applications are emerging across everything from diagnostics to drug discovery.

Of course, artificial intelligence (AI) within healthcare has some way to go before it realises its potential. Since the costs of getting it wrong are so high, the medical profession has tended to approach this field with caution. However, machine-learning techniques are poised to hit the mainstream over the next few years.

There is a political momentum here as well as a scientific one. In May, UK Prime Minster Theresa May set targets for a

"whole new industry around AI in healthcare", stating that AI could prevent up to 22,000 annual deaths from cancer by 2033.

Her plans were described as 'pioneering' by Cancer Research UK, which added that advances in detection technology 'have the potential to save hundreds of thousands of lives every year'.

Accurate algorithms

So how are machine-learning techniques being used currently, and what kind of opportunities could be on the cards?

While human radiologists will not lose their jobs any time soon, deep learning computers are already beginning to outpace them in diagnosing certain cancers. This, at any rate, was the verdict of several recent papers, which explored machine-learning applications within oncology.

In one paper, published in the *Journal of Medical Imaging*, a team at Case Western Reserve demonstrated that machine learning might have the edge when it comes to picking out malignant lung nodules. Human radiologists have a tough job here – of all the 'suspicious' or 'indeterminate' nodules that are flagged up on a CAT scan, around 98% turn out to be benign. The study found that a computational imaging technique was 5–8% more accurate.

Another study, published in the *Journal of Magnetic Resonance Imaging*, found that machines were better than humans at diagnosing prostate cancer from an MRI scan. When a machine analysed the images, rates of false positives were around 50% lower, and rates of false negatives around 70% lower. (Israel-based start-up Ibex has also developed an AI system for diagnosing prostate cancer.)

In a third study, published in *Annals of Oncology*, researchers showed that a deep-learning conventional neural network could diagnose skin cancer better than dermatologists. The network was trained to tell the difference between benign moles and malignant melanomas. Compared with the control group of dermatologists, it missed fewer melanomas and misdiagnosed fewer moles as cancerous.

"When I came across recent reports on deep-learning algorithms that outperform human experts in specific tasks, I immediately knew that we had to explore these AI algorithms for diagnosing melanoma," said study author Professor Holger Haenssle, of the University of Heidelberg in Germany.

AI is also being used to analyse molecular information from cancer patients, identifying people who may respond to certain therapies despite falling outside the target demographic. A recent study used machine-learning techniques to find 'hidden responders' – patients who slip through the net when using conventional sequencing strategies.

In May, scientists from Imperial College London and the University of Edinburgh announced they had used machine learning to detect a common cause of strokes and dementia. Their software could identify cerebral small vessel disease (SVD) with unparalleled accuracy, as well as estimating its severity.

SVD is a progressive neurological condition, in which blood flow to the white matter regions of the brain is reduced. Over time, brain cells die, which can lead to dementia or stroke.

While CT scans can be used to diagnose the condition, it can be hard to estimate exactly how far the disease has spread. Knowing that could be hugely helpful, as it could help flag up patients who are unsuited to certain medications, as well as assessing their dementia risk.

The software learned to detect SVD by analysing more than 1,000 CT scans from stroke patients. According to results published in the journal *Radiology*, it was 85% more accurate than an MRI scan (the 'gold standard' of diagnosis) in predicting the severity of the condition.

"This is a first step in making a scan-reading tool that could be useful in mining large routine scan data sets and, after more testing, might aid patient assessment at hospital admission with stroke," said Professor Joanna Wardlaw, head of neuroimaging sciences at the University of Edinburgh. ››

Applications in healthcare

Growth opportunities are hard to come by without significant investment, argue consultants at Accenture, but one major opportunity is a self-running engine for growth in healthcare: artificial intelligence (AI).

According to analysis by the company, when combined, key clinical health AI applications can potentially create roughly $150 billion in annual savings for the US healthcare economy by 2026.

At hyperspeed, AI is rewiring our modern conception of healthcare delivery. AI in health represents a collection of multiple technologies enabling machines to sense, comprehend, act and learn, so they can perform administrative and clinical healthcare functions.

Unlike legacy technologies that are only algorithms or tools that complement a human, health AI today can truly augment human activity – taking over tasks that range from medical imaging to risk analysis to diagnosing health conditions. With immense power to unleash improvements in cost, quality and access, AI is exploding in popularity. Growth in the AI health market is expected to reach $6.6 billion by 2021 – that's a compound annual growth rate of 40%.

In just the next five years, the health AI market is predicted to grow more than ten times over.

Top ten AI applications

Application	Value
Robot-assisted surgery	$40b
Virtual nursing assistants	$20b
Administrative workflow assistance	$18b
Fraud detection	$17b
Dosage error reduction	$16b
Connected machines	$14b
Clinical trial participant identifier	$13b
Prelininary diognosis	$5b
Automated image diagnosis	$3b
Cybersecurity	$2b
Total	**$148b**

Source: Accenture

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Synthetic speed

It is not the first time this year that machine learning has been used in the service of stroke patients. In March, a team from the Medical University of South Carolina and the University of Tennessee Health Sciences Center studied a device called the Cerebrotech Visor that can detect a stroke within seconds. Since the device can tell the difference between minor and severe strokes, it could enable a personalised approach to treatment.

Meanwhile, a team at the Boston University School of Medicine has used machine-learning techniques to identify risk factors for dementia. Through mining retrospective data, they found new combinations of factors that could make people more susceptible in later life.

Machine learning has also been used to predict epileptic seizures. Researchers at the University of Sydney are working towards a portable, affordable device that could be used by people with treatment-resistant epilepsy.

This device uses an algorithm that reads a patient's EEG data. It predicts if they will have a seizure to 81.4% accuracy, giving them a 30-minute warning and time to find somewhere safe. The system learns as brain patterns change, and will become more sensitive over time.

Meanwhile, researchers in Massachusetts have developed machine-learning models that can predict patients' risk of contracting *C. difficile*. This widespread infection is a huge problem for hospitals, and kills around 30,000 Americans every year. The model was able to generate daily risk scores for each patient, classing certain people as high-risk well before their actual diagnosis.

Machine monitoring

Machine learning also has its uses within mental health, with a number of start-ups developing apps that detect symptoms of depression. Cogito, for example, merges a number of AI techniques to analyse communication patterns. Its Cogito Companion app, trialled on patients at Massachusetts General Hospital, uses voice analysis tools as a gauge of well-being.

A further use for machine learning lies in monitoring heart disease. Most recently, researchers at the University of Southern California developed a new predictive model for this condition. The person uses an app on their smartphone to measure their pulse, and a machine-learning model detects their arterial stiffness.

"That's how you go from an $18,000 tonometry device and intrusive procedure to an iPhone app," said Niema Pahlevan, one of the inventors.

As should be clear, this rundown is far from an exhaustive list. New ideas and applications are emerging all the time, with powerful implications across the med-tech sector. As machine-learning techniques grow more sophisticated, we will surely start to move beyond speculation and into the realm of everyday applications.

Foot the bill

Diabetic foot injuries remain one of the most acute conditions of diabetic patients, typically caused by pressure ulcers. Amid a global diabetes pandemic, more needs to be done to ensure patients receive preventative and timely treatment. *Practical Patient Care* presents an edited extract from a joint paper in which the European Pressure Ulcer Advocacy Panel (EPUAP) and the European Wound Management Association (EWMA) outline how healthcare professionals can fight fatal complications and improve patient quality of life.

Diabetes is an important battlefield for better health for EU citizens. According to the latest WHO statistics, about 422 million people worldwide have diabetes, a number almost as high as all the EU population put together, and a figure likely to more than double in the next 20 years.

Looking closely at the EU population, in 2010 approximately 9% of the adult population (20–79 years old) was diabetic, with around 33 million in 2010, which will rise to 38 million by 2030. With the growing diabetes incidence, healthcare professionals and planners are encouraged to pay further attention to the major complications of this disorder.

Diabetes can lead to debilitating and acute complications with a serious impact on people health, including cardiovascular diseases and stroke, kidney failure, amputations and blindness. The complexity of this

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New smart detection system study

Researchers at the Manchester Metropolitan University tested a commercially available early warning system on clinical trial participants with diabetes who have a high risk of developing foot ulcers, and found it reduced the incidence of foot ulcers emerging or recurring by more than 70%.

One of the complications of diabetes is nerve damage, known as diabetic peripheral neuropathy, with the resulting loss of sensation making it more difficult for individuals to feel when their foot is at risk of skin breakdown, often caused by friction or foreign objects in their footwear.

Led by Neil Reeves, professor of musculoskeletal biomechanics, the research team equipped trial participants with shoe inserts that use ultra-thin sensors to monitor the pressure on the underside of the foot and provide feedback via a smartwatch worn on the wrist.

Whenever the pressure-sensing inserts detect clinically dangerous foot pressure, a vibratory and audio alert is transmitted wirelessly to the smartwatch prompting the device user to offload the pressure from a particular region of their foot.

These warnings allowed trial participants to learn which activities or times of day were most problematic for them – such as while driving – and which areas of their feet were the most prone to harm. The trial volunteers could then use the information to change their behaviour and immediately relieve the pressure, thereby avoiding harmful damage to their feet.

chronic illness requires continuous medical care with multifactorial risk-reduction strategies beyond glycaemic control. Patient self-management education and continuous training for health workers are critical to preventing fatal complications.

A number of studies have demonstrated that, due to diabetic complications, people with diabetes have hospital admission rates between two and six times higher than people without diabetes. Over 50% of people with diabetes suffer from at least one complication that, most of the time, requires hospitalisation. This is reflected in targeted patient safety.

Poor circulation and infection are among the most common complications that effect diabetic patients. These conditions demand treatments for providing a holistic medical approach while ensuring patient safety.

Drop the pressure

Pressure ulcers are the origin of diabetic foot injuries. Diabetic complications eventually affect every part of the body, but they frequently involve the feet, as diabetes can impair blood circulation.

It can prevent injuries from healing by narrowing the arteries that carry blood to the legs.

> “Evidence shows that more than half of all foot ulcers will become infected, requiring hospitalisation, and 20% of lower extremity infections will result in amputation.”

Practices have to be developed, as certain harm may occur in the delivery of care to diabetic patients.

Adverse events and errors in diabetes care can cause significant morbidity and, too often, disability and even death. In order to avoid adverse events and their dramatic outcomes, healthcare workers need to identify key and common complications.

This leads to peripheral neuropathy, a major cause of mechanical stress. A non-healing wound or pressure ulcers on the foot can develop into a deep sore that quickly becomes profoundly infected. This makes diabetic foot injuries one of the most serious and costly complications of diabetes.

Throughout their study recommendations and practice-oriented guidance, EWMA and EPUAP have constantly stressed that prevention and prompt treatment of foot injuries are vital for the safety of diabetic patients and for avoiding possible subsequent limb amputation. Evidence shows that more than half of all foot ulcers will become infected, requiring hospitalisation, and 20% of lower extremity infections will result in amputation.

As the diabetes pandemic progresses globally, so too does the problem of foot ulcers. Achieving control of diabetes relies not only on blood glucose levels and proper nutrition, but on proper footwear, adequate blood supply to extremities and pressure ulcer prevention. To avoid amputation becoming an inevitable outcome for many patients, a paradigm shift is urgently needed. Adequate training for healthcare workers, patient education, early assessment, and aggressive treatment by a multidisciplinary team represent the best approach to reduce complications and to ensure limb preservation.

Due to the high morbidity and mortality rates associated with diabetic wounds and infections, wounds and pressure ulcers must be treated holistically in order to identify underlying issues and reduce risk factors that are causing wounds in the first place.

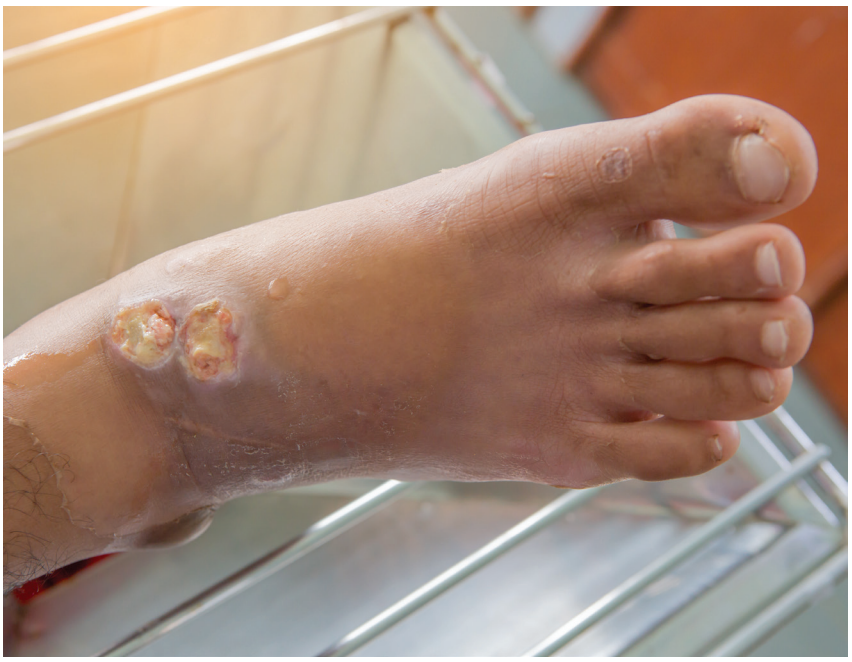
A holistic approach means, in practice:

- optimal diabetes control
- effective local wound care
- infection control
- pressure-relieving strategies
- pulsatile blood flow.

Unfortunately, treatment and patient safety measures are often not so methodical and quite varied across hospital settings. In Europe, diabetic foot care has been described as fragmented and unsystematic, and largely depends on which practitioner the patient happens to be seeing and which resources are available locally.

A call to action

To tackle the challenge of jeopardisation, many stakeholders have



Pressure ulcers are the most common origin of diabetic foot issues.

called on the European Commission to present an EU strategy on diabetes in order to gather further evidence on the prevention and management of its complications on which to base treatment strategies, and to promote the development of common clinical guidance.

In this frame, through a written declaration voted in during May 2016, the European Parliament called upon the Commission and Council to prioritise diabetes as a major European health, social and economic concern.

In order to ensure better wound and pressure ulcer prevention and care across Europe, programmes should pay particular attention to diabetic foot injuries as one of the most dangerous and common complications in diabetic patients. Any EU strategy should include recommendations on national guidance on the understanding of prevention.

This is likewise with comprehensive management and treatment of the diabetic foot, currently lacking among healthcare providers.

> “In Europe, in 2015, there were over 266,000 deaths due to diabetes. It is time for the EU and its member states to prioritise diabetes and its complications in the health strategy, and treat it as a major disease representing a significant burden across the EU.”

And also for the EU to develop strategy for diabetes prevention,

The declaration, signed by over 400 MEPs, aimed to encourage member states to establish national diabetes plans and to develop uniform diabetes management programmes based on best practices and evidence-based treatment guidelines.

Below are key recommendations to keep in mind while developing national guidelines on diabetes management:

- In diabetic foot control, achieving safe diabetic care requires active attention at all levels, starting from promoting a healthy and active lifestyle: numerous studies have shown that blood glucose levels are improved by increasing physical activity, which has a direct impact on blood circulation, wound healing and pressure ulcer prevention. Exercise has been shown to improve blood glucose control, reduce cardiovascular risk factors, and increase mobility among overweight patients with diabetes.
- In addition, any future national guidelines on diabetes should deal with this chronic disease holistically – this means that any effective and modern diabetes care should be done in a setting in which teamwork is ensured. Well-trained doctors, dieticians, physiotherapist and other non-medical professionals must work together more cohesively in the care of diabetic patients. With this in mind, nursing ratios should be higher when patients with diabetes are hospitalised, to guarantee that any complication or adverse event are prevented or promptly treated.
- Last but not least, a no-blame reporting system is likely to encourage paradigm change, providing less focus on who is at fault and more about how to prevent adverse events and errors caused by the system in which healthcare professionals work.

Kept on their toes

In Europe, in 2015, there were over 266,000 deaths due to diabetes. It is time for the EU and its member states to prioritise diabetes and its complications in the health strategy and treat it as a major disease representing a significant burden across the EU.

With the lifetime incidence of foot ulcers occurring in up to 25% of patients, we need to pay far more attention to the diabetic foot and its consequences. Keeping diabetic patients on their feet, walking and mobile, is fundamental in preventing the regression of health condition and in guaranteeing a long-term quality of life. ■

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Supreme saline

Winchester Laboratories' Saljet technology, a device used to irrigate and cleanse non-complex wounds, has appeared on the popular television medical drama *Grey's Anatomy*. More importantly, it has proven results in the world of non-fiction. Dr Harriett B Loehne, a certified wound specialist and the owner of her eponymous wound-management consulting company, shares her views on best practice in wound treatment and what differentiates Saljet from other treatments on the market.

What is Saljet and how is it administered?

Harriett B Loehne: Saljet is a disposable polymer vial with a twist-off top for single use containing 30ml of sterile normal saline (NS) 0.9%. It has no preservatives, surfactants or buffering. When firmly squeezed, it delivers 4–8psi of NS to the wound, with a maximum of 10psi. The vial and its top are recyclable or can be disposed of in regular waste.

The product is FDA-approved and licensed for use in dressing changes. It does not have to be dated or timed during a procedure. Saljet also has a CE mark. Licensed as a device and not a pharmaceutical, it does not have to be kept under lock and key, and can be used whenever a physician has ordered saline for a dressing change. The MSDS indicates no hazard, no cytotoxicity and no carcinogenicity. The vials are packed four to a strip and each box contains ten strips, with six boxes in a shipping case. It has a 36-month shelf life.

How does using Saljet surpass some of the shortcomings of current treatment methods?

Many wound and skin cleansers are cytotoxic: the dilution that is required to be non-cytotoxic renders their efficacy essentially nil. With few exceptions, NS should be used for cleansing and irrigation. For complex wounds requiring debridement, and those with deep tracts and tunnels, pulsed lavage is the intervention of choice. For all other wounds, NS can be delivered in several methods.

To be safe and efficacious, irrigation must be between 4–15psi. Pouring NS from a bottle does not provide the adequate psi, nor does a bulb syringe with impact pressure of 2psi. A syringe with a 19-gauge needle delivers 8psi, but requires a sterile basin, and raises safety concerns for the patient and clinician. Aerosolisation spray cans, in addition to being cold, decrease in pressure during use. Saljet moistens dressings for easy removal to avoid damage to granulation tissue, and eliminates concern for the contamination of opened bottles being reused, or the danger and cost of syringes, needles and basins.

What is best practice when it comes to cleaning and irrigating wounds?

To prevent delayed healing, wounds should be irrigated with sterile NS to remove debris, necrotic tissue, purulent exudate and biofilm initially, and at each dressing change. It is important to warm the irrigant, which can be easily done by body heat in the clinician's lab coat or scrub pocket. It can also be placed in warm water or given to the gloved patient to hold while dressing changes are being prepared. Thermocline – the principle that the wound must remain at least at body temperature for optimal healing – is often overlooked by wound-management clinicians. It takes approximately four hours for a wound exposed to air, and longer when exposed to cold, to begin the healing process.

How does Saljet decrease the volume of saline needed?

Pouring saline from a bottle is not efficacious and it often ends up wasted. Once the bottle is open, the saline is no longer sterile and should be discarded within 24 hours; and rarely is the bottle empty by that time. Saljet delivers a unit dose with no concern about storage or sterility, and subsequent waste with increased cost.

> "Saljet is an ideal method of cleansing all non-complex wounds and I would like to see it made available to the consumer over the counter."

In what contexts is Saljet currently being used?

Saljet is appropriate for use in hospitals, home health, long-term care, nursing homes, urgent-care centres, emergency room and emergency services, workplace employee health departments, the military and veterinarian offices.

How do you see this kind of device evolving over the years?

Saljet is an ideal method of cleansing all non-complex wounds and I would like to see it made available to the consumer over the counter. It has a place in the offices of school nurses, at camps and activity organisations, and in homes. ■

Further information
Winchester Laboratories
www.saljet.com

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EWMA 2019

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EUROPEAN WOUND MANAGEMENT ASSOCIATION

Experts converge in Gothenburg

The 29th conference of the **European Wound Management Association** will take place in Gothenburg, Sweden, on 5–7 June. It is organised in cooperation with the Swedish Wound Care Nurses Association, and is the ideal platform for experts in the field to exchange knowledge and experiences, and for showcasing the latest products on the market.

The theme of this year's European Wound Management Association (EWMA) conference is 'Person-centred wound care: Who is in charge of the wound?' A wound is always part of someone's body because they have to live with it. The patient therefore qualifies as an important member of the team when focusing on wound healing. When all professionals, with their specific competencies, work together with the patient, progress can be made, and clinical knowledge and competencies can be developed and shared. A multidisciplinary, inter-professional team and person-centred wound-care approach will support the wound-healing process, increase the patient's quality of life and prove to be cost-effective.

EWMA 2019 includes a mixture of new topics that are important to the European wound community and topics that have had enormous appeal during previous EWMA conferences. The sessions deal with the advancement of education and research in relation to epidemiology, pathology, diagnosis, prevention and the management of wounds.

Key sessions:

- Person-centred wound care: Who is in charge of the wound?
- Pressure ulcer prevention
- Translational science and clinical opportunities
- Catastrophe and war wounds
- Patient involvement and patient safety
- Multidisciplinarity and organisation
- Atypical wounds
- Surgical treatment of chronic wounds
- Economics of wound management
- Burns
- Surgical site infection
- Managing and preventing birth-related wounds and post-caesarean section
- Infections

EWMA streams:

- Pressure ulcer prevention
- Infection, prevention and control stream
- Diabetic foot ulcers
- Debridement day

Workshops:

- Debridement
- After debridement
- How to read a paper – understanding the basics
- Diabetic foot – assessments, offloading and footwear
- Managing wounds after discharge – case studies discussion workshop
- Eczema in leg ulcer patients
- Regulatory workshop
- Patient repositioning and the properties of the patient support surfaces used

Focus sessions:

- Skin necrosis in wounds
- Malignant and fungating wounds
- Pain assessment
- Lesions in patients
- Regenerative medicine in the treatment of chronic wounds

Abstracts for oral presentations, electronic poster presentations and paper poster displays may be submitted in the following categories: acute wounds, antimicrobials, basic science, burns, devices and interventions, diabetic foot, dressings, education, e-care, health economics and outcomes, home care, infection, leg ulcer, negative pressure wound therapy, nutrition, pain, pressure ulcer, prevention, quality of life, wound assessment, case studies (e-posters only) and professional communication (e-posters only).

Important dates:

- **Conference dates:** 5–7 June 2019
- **Registration opens:** November 2018
- **Abstract submission opens:** 1 October 2018
- **Abstract submission deadline:** 1 December 2018
- **Early registration deadline:** 3 April 2019

The EWMA conference offers high-level scientific presentations, networking activities, and an excellent opportunity to exchange knowledge and experiences with international colleagues. ■

Further information
European Wound Management Association
www.ewma2019.org

Diabetic foot ulcers can kill

Inotec AMD's NATROX oxygen wound therapy is a simple device that helps diabetic foot ulcers heal.

Patients with diabetes are twice as likely to have peripheral arterial disease (PAD) as those without diabetes.

In the case of wounds, PAD and diabetes will impact the outcomes of treatment, leading to:

- a significantly lower probability of healing
- longer healing times
- higher probability of recurrence
- more chance of wound infection
- greater risk in minor and major amputations
- potentially higher mortality rates.

An obvious way to improve clinical outcomes is to improve blood flow; however, many patients with DFUs are not good candidates for revascularisation surgery due to complications arising from comorbidities, late presentation or chronic ischaemia associated with irreversible tissue injury.

Emerging evidence suggests that topical oxygen therapy may provide a novel solution. The clinical evidence generated so far illustrates that NATROX has a positive effect on healing challenging or non-healing wounds, showing that:

- after eight weeks of treatment for DFUs, 30% of the control group healed, while 90% healed with NATROX
- after less than 25 days of NATROX, 57% DFUs and arterial ulcers healed
- a 53% reduction after eight weeks of NATROX, with seven out of ten DFUs on healing trajectory.

NATROX oxygen wound therapy provides 98% pure humidified oxygen 24/7 directly to the wound bed, while allowing patients to carry on with their everyday life. ■

Further information
Inotec AMD
www.natroxwoundcare.com

Take a shot

Injectable bandages are hugely promising for quickly administering materials to prevent fatality from excessive blood loss. **Dr Akhilesh K Gaharwar**, assistant professor in the Department of Biomedical Engineering at Texas A&M University, talks to Emma Green about this potentially transformative advancement in wound care.

There are a number of materials that can stop bleeding, but these can generally only be used for surface wounds and require pressure to promote clotting, which makes them unsuitable for high-risk situations, such as internal wounds. Many of these products also have further limitations, such as the need for pre-processing, batch variability and a lack of shear thinning properties. In addition, none of the current materials are biofunctional, meaning that they cannot interact with the body to produce the desired clotting and healing outcomes.

One of the most serious types of injuries that require quick and effective treatments are those obtained from shrapnel by soldiers on the battlefield. Statistics have shown that soldiers critically wounded in combat often pass away within 60 minutes, often referred to as the 'golden hour', In order to prevent fatalities from excessive blood loss, materials that can be self-administered are vital. Similarly, it is essential to be able to stop uncontrolled bleeding during surgical procedures in order to improve patient outcomes.

> "We were trying to build an injectable bandage that can stop bleeding without applying pressure, so that we can use it for internal wounds."

Against the flow

A number of researchers have begun to investigate the benefits of injectable bandages for these purposes. As part of a 2014 project commissioned by the US military, a team of researchers developed a syringe that could create a sealed barrier made up of small pill-sized sponges after being injected into a large wound. The antimicrobial clotting agent chitosan was used to create the material. This allowed the sponges to expand by soaking up excess blood while simultaneously speeding up the clotting process.

During testing, it was found that it took only 15 seconds to stop all excess blood flow. Although such technology is a big step forward for wound care, it has been challenging to create materials that can aid healing in addition to stopping bleeding. ››

Injectable hydrogels are promising materials for promoting healing and halting blood flow, as these biomaterials can be introduced into a wound site using minimally invasive approaches. Hydrogels are a 3D water-swollen polymer network, similar to gelatine, which are able to simulate the structure of human tissues. Ideally, an injectable hydrogel should solidify after injection in the wound area and promote the natural clotting cascade.

An emerging approach to improve the functionality of hydrogel networks is to incorporate bioactive nanoparticles. A range of synthetic nanoparticles have been used for this purpose. Two-dimensional nanomaterials are a recent development that have unique structural and surface characteristics. These nanoengineered ultrathin materials, with sheet or disc-like morphology, could generate major therapeutic advances in the field of regenerative medicine and biomolecule delivery.

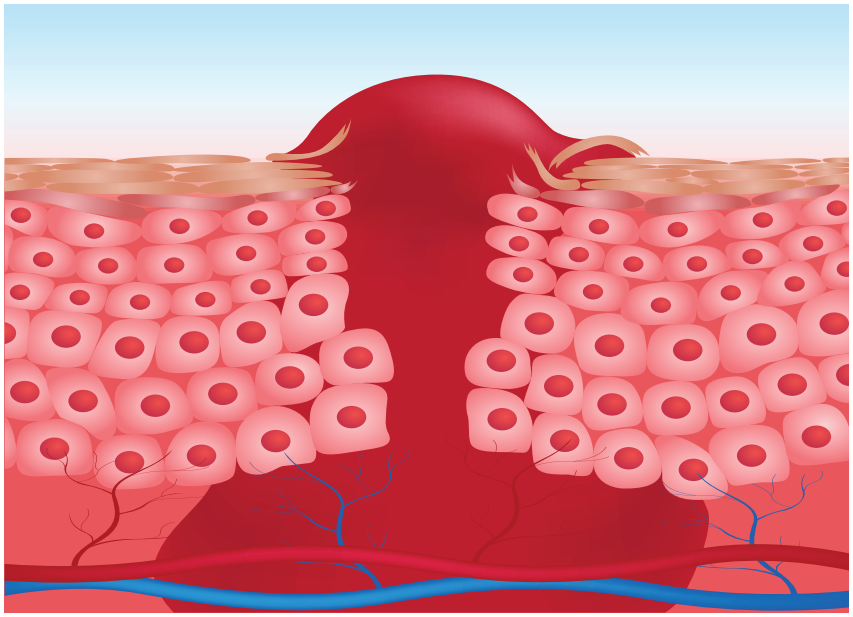
Food for thought

An injectable hydrogel has been created by Dr Akhilesh K Gaharwar and researchers from Texas A&M University using kappa-carrageenan, a common thickening agent for pastries, and synthetic two-dimensional nanosilicates. "We were trying to build an injectable bandage that can stop bleeding without applying pressure, so that we can use it for internal wounds," explains Gaharwar. "We also wanted to initiate wound healing and inject a material than can degrade over time to have a therapeutic effect."

When kappa-carrageenan is mixed with clay-based nanoparticles, this forms an injectable gelatine. The hydrogel is biofunctional because it is made from materials that we consume or are already found in our bodies. It is also particularly valuable because the components are readily available and affordable, and can be stored at room temperature for long periods of time.

Combining these materials creates a hydrogel that changes form depending on the pressure applied. "By combining kappa-carrageenan and nanosilicates, we can make injectable materials, with a texture similar to toothpaste," explains Gaharwar. "When you apply pressure they flow through, but as soon as you remove the pressure they solidify to stop bleeding."

Researchers found that clotting time using the hydrogel was less than three minutes. This can literally be the difference between life and death. The clotting ability was the result of the negative charge of the nanoparticles in the hydrogel. However, achieving this outcome was not without challenges. "It was difficult to find materials that could stimulate clotting," says Gaharwar. "We tried different materials, polymers like hyaluronic acid, but because they did



Materials that can stop bleeding only work on surface wounds and require pressure to promote clotting.

Carrageenans: not just a food additive

Carrageenans are a group of similar sulphated polysaccharides that have been used around the world for centuries as a gelatine and a home remedy. They have been made at home since 600BC but their commercial production did not begin until the 1930s. Carrageenans are used for a variety of purposes in the food industry, including as a stabilizer, thickener and emulsifier. They mimic the texture of fat in low-fat dairy products and help prevent non-dairy milk alternatives from separating. Carrageenans are also found in some packaged foods, luncheon meats, nutritional supplements and medications.

Edible red seaweed is the main source of carrageenan. The seaweed is harvested, dried and baked before being ground, sifted and washed to remove impurities like sand. It is then soaked in an alkaline solution, such as potassium hydroxide, and heated to remove the carrageenan. Filtration and centrifugation are used to remove cellulose mechanically. The remaining solution is evaporated to remove the water, and the powdered carrageenan is ground to meet final specifications.

Carrageenans are classified into three categories, depending on the amount of sulphation. The disaccharides in kappa-carrageenan have one sulphate, the disaccharides in iota-carrageenan have two, and the disaccharides in lambda-carrageenan have three. There have been some health scares about carrageenan, due to proposed links to problems such as chronic inflammation, insulin resistance and gastrointestinal issues. However, many of these studies used poligeenan, a form of degraded carrageenan, which is molecularly very different to the form of carrageenan typically used as an additive. Food-grade carrageenan has been declared safe by the Food and Drug Administration, The European Food Safety Authority and the World Health Organization.

not have a negative charge we were not able to achieve those properties. We screened all of these materials until we got this combination."

In addition to the rapid clotting mechanism of the hydrogel, researchers took advantage of special properties of the nanoparticle component. They used the electric charge of the nanoparticles to add growth factors that adhered to the particles to begin the body's natural healing process. This is particularly valuable as other approaches rely on the body's own ability to heal.

Researchers attached vascular endothelial growth factor (VEGF) to the nanoparticles and then tested this combination in a cell culture test to mimic the healing process. The test uses a petri dish with a layer of endothelial cells on the surface that create a solid skin-like sheet. This is scratched down the centre, creating a hole in the sheet resembling a wound. When the hydrogel was added to the damaged endothelial cell wound, the cells were induced to grow back and fill in the scratched region, essentially mimicking the healing of a wound in the body.

Injectable hydrogels are meant to solidify in the wound area and promote natural coagulation.

> "During the transportation, they will lose a lot of blood, and because of that loss of blood they will die. We are hoping this technology can stop bleeding on the spot, before getting these soldiers to a healthcare centre."

War against wounds

Gaharwar envisions two key uses of this technology. The first of these is on the battlefield, where effective and quick treatments are needed to treat wounds, because soldiers are typically a long distance away from healthcare centres. One of the valuable aspects of this technology is the ability for the injection to be self-administered, so soldiers can kick-start the wound treatment themselves before their journey to the hospital. "During the transportation, they will lose a lot of blood, and because of that loss of blood they will die," says Gaharwar. "We are hoping this technology can stop bleeding on the spot, before getting these soldiers to a healthcare centre."

The second implication of this technology is the operating room. Researchers are currently developing new technologies that are able to stop bleeding and promote healing in real-world clinical settings. "Right now, we are trying to develop second-generation materials that are adhesive to tissue," says Gaharwar. "When a surgeon is conducting any procedure, if they see any uncontrolled bleeding, they can use this material to seal tissue and stop bleeding. This material will also stimulate wound healing because it will be bioavailable."

Although these implications are exciting, the current technology does have limitations. "We cannot release growth factors at different rates," explains Gaharwar. "Now we can release growth factors for three to four weeks but if you want to add other growth factors to stimulate wound healing, it's not easy." Overcoming this barrier will be a key focus of Gaharwar's future research.

While researchers were encouraged by these results, they note that more testing is required. Gaharwar and his team are planning to conduct preclinical trials of the injectable bandage before proceeding to clinical use on human patients. The outcome of these trials is a little uncertain because of the higher blood pressure in humans, which will really test the strength of the hydrogel. If these tests go well, Gaharwar hopes the material will soon be able to be used in hospitals.

Researchers are also keen to embed other biologics into the hydrogel to speed up the overall healing process. Other experimental materials delivering drugs to wounds release a burst of medicine, requiring multiple injections, whereas this hydrogel can achieve a much slower release. The team believe they can include almost any type of small molecule drug or large molecule protein for sustained release from the gel. It is clear that hydrogels have immense potential, for wound care and beyond. ■

Need for speed

The demand for point-of-care testing (POCT) is growing due to the value shift in healthcare and increasing technological advancements. The rising prevalence of lifestyle and infectious diseases, early detection of diseases, and management of multiple chronic conditions is also fuelling growth of the market. **Dr Kay Roy**, consultant physician in respiratory and general internal medicine, and honorary senior lecturer at the University of Hertfordshire, outlines a new POCT for viral infections that can reduce unnecessary antibiotic use and hospital admissions, providing major cost savings.

The driving force behind point-of-care testing (POCT) is to bring the test conveniently and immediately to the patient. This increases the likelihood that the patient, physician and care team will receive the results quicker, allowing more rapid clinical management decisions to be made. A recent survey in five countries (Australia, Belgium, the Netherlands, the UK and the US) indicates that practitioners would like to use more

The rise of POCT

The popularity of point-of-care testing (POCT) has steadily increased over the 40 or so years since its widespread introduction. That growth is likely to continue, driven by changes in healthcare delivery aimed at providing less costly care closer to the patient's home. POCT technologies can be divided into two categories. The first of these is small handheld devices, such as glucose biosensor strips and lateral flow strips, which use immobilised antibodies to determine a range of parameters including cardiac markers and infectious pathogens. The second category of devices consists of larger, often bench-top devices that are essentially laboratory instruments reduced in size and complexity. These include critical-care analysers and, more recently, small haematology and immunology analysers. Together, these devices provide healthcare professionals the ability to obtain vital care management information at near instantaneous speeds, potentially resulting in numerous benefits to downstream clinical efficiency.

Key design components

It is possible to identify a number of key design components that are incorporated into all POCT devices. With the growing miniaturisation of devices, it is becoming increasingly possible to make smaller and smaller devices that incorporate all of these key design features, which include:

- operator interface
- barcode identification system
- sample delivery devices
- reagent storage and availability
- reaction cell
- sensors to detect the measurement reaction
- control and communication systems
- data management and storage
- manufacturing requirements.

Future developments of POCT devices

In light of the speed of technological development, and the benefits in efficiency and quality of care offered by POCT, it is likely that these devices will be increasingly used within healthcare. New emerging devices include those that are using molecular techniques to provide infectious disease testing in a sufficiently small device to be used at the point of care. Government initiatives, along with a high incidence of time-sensitive medical conditions, already provide strong incentives for the expansion of POCT in hospitals. In the community, financial incentives and trends towards increased patient involvement in their own care will likely continue to drive the expansion of POCT outside hospital centres.

POCTs. Despite the desire for POCTs, technological developments have often not been capable of creating the simplicity required for these tests.

> "We found that when patients had point-of-care respiratory viral testing soon after they were admitted to the emergency department, bed flow improved and fewer bed closures were required due to viral infections."

New research, presented to the European Respiratory Society International Congress (ERSIC), has demonstrated the value of a new POCT for viral infections, launched at Watford General Hospital in the UK earlier this year. The test, which takes 50 minutes to obtain results, could save hospitals an estimated €2,500 per patient not admitted to hospital, helping to relieve winter pressures on available beds, and may help to reduce the development of antibiotic resistance.

A key advantage of the test is the ease in which it can be performed. It involves inserting a swab into the patient's nostril to collect a sample of secretions from the back of the nose, which takes one minute. The sample is then prepared and inserted into a compact machine in three to five minutes. The machine analyses the sample and then generates a printout within 43 minutes. "The whole process from obtaining a sample from the patient's nose to getting a result should take under 50 minutes, which has a potentially enormous impact on quality of care, improving the patient journey by allowing earlier, informed decision-making about patient management," says Dr Kay Roy, consultant physician in respiratory and general internal medicine, and honorary senior lecturer at the University of Hertfordshire, UK.

The short turnaround time is particularly impressive considering that the POCT uses the same technology as laboratory tests. "This is the same test and technology as used in our microbiology laboratory, but we have brought the equipment to the patient's bedside. Results from samples sent to the microbiology lab can take more than two days," Roy explains.

Trial run

So far, results from the test have been promising. "Initial results on the first 1,075 patients show the potential of this service. We were able to identify 121 patients who had viral infections, lacked any evidence of bacterial infection, had a normal chest X-ray and only modest indicators of inflammation," says Roy. "Of these, hospital admission was subsequently avoided in 25% and unnecessary antibiotics were avoided in 50%. None of the 30 patients who avoided hospital admission and who were not prescribed antibiotics experienced adverse clinical outcomes, which is reassuring."

Of the patients in the trial, 61% had one or more viruses, of which 56% were influenza. The remainder consisted of other viruses such as rhinovirus, coronavirus, metapneumovirus and adenovirus, which can cause just as many respiratory and other problems as influenza or a bacterial infection, particularly among patients with chronic obstructive pulmonary disease (COPD). »

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Point-of-care testing allows early influenza diagnoses, helping improve infection control.

The results of the tests were combined with other important clinical indicators, such as chest X-ray findings, in 387 patients. In these patients, 121 were identified as being potentially suitable for avoiding hospital admission and antibiotics, helping to alleviate the annual winter burden experienced by the UK's NHS. "We found that when patients had point-of-care respiratory viral testing soon after they were admitted to the emergency department, bed flow improved and fewer bed closures were required due to viral infections. This is extremely valuable during winter bed pressures, especially during an influenza epidemic," says Roy.

Cost cutting

The expense of POCT is offset by avoiding the costs associated with laboratory testing and admitting patients to hospital beds. "We could make a significant saving for national health services by avoiding unnecessary admissions in patients who may have otherwise been admitted and given antibiotics while waiting up to two days for results from the lab. Patients in whom antibiotics were avoided also contribute to cost savings, as do the beds and wards that remain open," says Roy.

> "We could make a significant saving for national health services by avoiding unnecessary admissions in patients who may have otherwise been admitted and given antibiotics and given antibiotics while waiting up to two days for results from the lab."

The test can also improve infection control due to the ability to make early influenza diagnoses. "In the first two weeks of this new service, we diagnosed 50 cases of influenza: 22 by testing in the emergency department and 28 after patients were admitted," Roy explains. "There were no bed moves in the former group but there were 14 in the latter; demonstrating that earlier bedside testing in the emergency department improves infection control, thereby avoiding bed and ward closures and reducing the risk of spreading infection to vulnerable groups. Infected patients with POCT-based early diagnosis of influenza can be admitted to appropriately designated beds if admission is required."

Roy is about to start a randomised controlled trial in the community, in which primary care physicians/general practitioners (GPs) will be able to refer patients to a community hub for POCT, with respiratory physicians available to support the GPs. This collaborative approach can help facilitate improved antimicrobial stewardship, which is key in winning the fight against antibiotic resistance. "The frequent underestimation of the role of viruses in respiratory admissions, both in previously well patients and those with chronic underlying diseases such as COPD, has hindered good antimicrobial stewardship," says Roy. "This has sometimes led to other health problems for patients from inappropriate antibiotic use and hospital admission. We hope that quality of patient care can be improved with POCT for respiratory viruses, as well as helping to reduce the development of antibiotic resistance."

POCT has been well-received by other researchers in the field. "As European populations age, there is increasing pressure on the availability of hospital beds. Having to close a ward because a patient has been admitted with a viral infection that could spread to other patients and is not treatable with antibiotics places even more pressure on hospitals, as well as being expensive. [POCT] could make a significant difference not only to hospitals but also to patients, whose quality of life will be much improved by avoiding unnecessary antibiotic use and admittance to hospital," says Professor Tobias Welte, from Hannover University in Germany and president-elect of the European Respiratory Society (ERS).

Although further research is needed to confirm its usefulness in clinical practice, the results obtained so far are highly encouraging. POCT for viral infections has clear potential to provide significant time and cost savings, and helping to combat the ongoing global threat of antimicrobial resistance. ■

We are by your side today,

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From the beginning we have been deeply inspired by a mission to protect lives against infection. Partnering with you over the years has only strengthened this mission and you can continue to rely on us to provide innovative, sustainable solutions. We are committed to delivering quality in everything we do and we have a strong set of values that guide our daily actions to deliver results that our company and our customers can be proud of.

Take cleanliness to the next level

It has been more than 25 years since the arrival of STERRAD systems in the sterilisation world. Produced by **Johnson & Johnson**'s Advanced Sterilisation Products (ASP), the systems use hydrogen peroxide gas plasma technology to sterilise instruments at low temperatures, including heat and moisture-sensitive devices. Petra Stößer-Pfefferkorn, central sterilisation department manager at the HELIOS hospital in Aue, Germany, explains how the transition to the latest ASP steriliser contributes to even better safety, efficiency and compliance in their daily work.

What must you consider when reprocessing heat and moisture-sensitive devices?

Petra Stößer-Pfefferkorn: Heat and moisture-sensitive devices today are often equipped with high-tech features, like optical, ultrasound and electrical parts, and are, in most cases, extremely expensive. For this group of instruments, the challenge is to provide not only protection of the material but at the same time a fast reprocessing turnaround. The need is to ensure short cycle times for low-temperature and steam-sterilised devices to enable intense and flexible use for all groups of instruments in the operating room.

How has STERRAD with ALLClear Technology helped you address these challenges?

The innovative STERRAD system from Advanced Sterilisation Products.

STERRAD technology works at a low temperature (approximately 50°C) and under absolute dry conditions (<5% moisture) – so we reach an optimal level of material protection without any corrosion of metal parts or damages due to thermal tensions, and reach a sustainable elasticity for all synthetic materials. That's why all our high-tech instruments, like ultrasound scanners and transducers, 3D optics and flexible endoscopes, are treated safely and gently in the STERRAD 100NX with ALLClear Technology.

Four different cycles offer the optimal adjusted options for our complex and sensitive instruments, with various H_2O_2-concentration levels, program sequences and cycle times.

> "All our high-tech instruments, like ultrasound scanners and transducers, 3D optics and flexible endoscopes, are treated safely and gently."

Has STERRAD with ALLClear Technology helped you balance safety and efficiency?

Yes, absolutely. With STERRAD, we can rely on a safe and material-protective sterilisation process on hand. At the same time, we benefit from short cycle times – the planning flexibility of surgical procedures is much higher, and we can use the devices with maximal efficiency. Moreover, the level of investment regarding the necessary number of instruments can be reduced, considering the fast instrument turnaround. Gentle process conditions significantly extend the lifetime of instruments, so expensive repairs can be delayed or completely avoided – these are important when talking about efficiency and cost savings.

In terms of safety for our healthcare staff, we must underline that the biggest advantage of the STERRAD sterilisation process is working without hazardous substances. Despite a concentration maximum of 59% hydrogen peroxide in the cassettes, the user does not come into direct contact with the agent. Because of the final plasma phase, the sterilisation process ends with only non-toxic residues.

How has the new STERRAD with ALLClear Technology, released in 2017, as opposed to the older STERRAD 100NX, benefitted you in your daily CSSD routine? Why did you upgrade to the latest ALLClear Technology?

The central sterilisation department (CSSD) of the HELIOS hospital in Aue, Germany, has worked with the STERRAD 100NX technology since 2015. Before that time, thermo-sensitive instruments were sterilised with a formaldehyde steriliser with cycles lasting several hours. The short cycle time of STERRAD suddenly allowed a much faster instrument cycle from the operating room to the CSSD and back.

> “Complementing the disinfection step with a final sterilisation is absolutely welcomed to maximise patient safety, and a challenge for the future.”

At the same time, the pool of identically constructed instruments could be reduced in the hospital. After exchanging information and negotiating with the central headquarters of HELIOS AG and ASP, it was agreed in mid-2017 to exchange the STERRAD 100NX for the new-generation STERRAD 100NX with ALLClear Technology. A smooth transition from the heritage machine to the new one was enabled through the same release method of the sterilised load based on the STERRAD sterility guide and the independent monitoring system.

What is your experience with ALLClear Technology, compared with other heritage machines? Which new functionality gives you the greatest benefit?

The new preconditioning phase before the start of the actual sterilisation cycle helps to organise the reprocessing process, especially for flexible optics, in a more stable manner.

After being used on the patient, the flexible optics are cleaned in the decentralised endoscopy department, disinfected, dried and stored in trays.

The treated flexible optics are then transported within the hospital to the CSSD, where they are packed into sterile barrier systems and sterilised in STERRAD with ALLClear Technology.

An inherent risk of this process is naturally, the residue moisture that could occur. Also, the temperature of the instrument is hard to control as it varies due to the in-house logistics of the hospital. Those risks are minimised with the new adaptive preconditioning cycle. In addition, the newly designed user interface and the bigger display compared with the heritage STERRAD 100NX system received praise from the CSSD team.

To which degree does your documentation system deliver information on the efficiency and capacity use of the STERRAD system?

The HELIOS hospital of Aue uses the documentation system instacount by Invitec. This documentation system has functions that include a packing assistant with various user interfaces, media support (image, sound, video, PDF), the use of barcodes or transponders for set identification and barcode-based steriliser loading, and load release for sterilisers. Other functions include detailed load tracking and sterile item tracking, powerful production statistics on item and set level, and individual instrument tracking by data matrix recognition. With this information, we can also follow and understand the efficiency, reliability and capacity utilisation of our STERRAD units.

Do you think that developments in maximising patient safety will lead more often to the final step of sterilisation of flexible bronchoscopes after therapeutic use?

Complementing the disinfection step with a final sterilisation is absolutely welcomed to maximise patient safety, and a challenge for the future. However, this cannot yet be practically realised in the hospital in Aue for a number of different reasons, which include personal, spatial and device-related factors. Flexible endoscopes are currently reprocessed in the endoscopy department.

When adding a sterilisation step, these processes must be integrated into the CSSD. Lots of reconstruction and renovation works would be necessary to create the conditions to realise the change in the reprocessing process of flexible bronchoscopes.

What is the benefit of using ASP technologies for compliance?

Compliance and documentation are highly important parameters for all our workflow processes in the CSSD. With the STERRAD sterility guide database, ASP offers a helpful tool for releasing instruments after sterilisation in the STERRAD. Thus, the user has the assurance that the material compatibility is given, as well as that the geometric properties of the instrument are suitable for the STERRAD method.

That is why the ASP technology makes it easier for us to evaluate and implement the instruments in our own quality management and instrument-tracking system. From a technical point of view, the monitoring and measuring equipment – H_2O_2 measurement and independent monitoring system – in the STERRAD helps to parametrically evaluate the sterilisation process and ensure the release of sterile goods for use. ■

Further information
Advanced Sterilisation Products
www.emea.aspjj.com

Injection of truth

The administering of injectable biologic therapies and wearables is rising. These treatments present several challenges for healthcare professionals and patients: the large size of the molecules means that administration is not as straightforward, an effective dose may be highly viscous and patient compliance is not ensured. Patrick Kingsland asks **Dr Olivia Merkel**, professor of drug delivery at the Ludwig Maximilian University of Munich, how these problems can be addressed.

Injectable biologics and wearables are used to treat a vast array of conditions, ranging from arthritis to colitis and cancer. These therapies have become the go-to option in many cases because of their ability to meet a plethora of needs.

Take Humira, AbbVie's anti-inflammatory drug, which was the top-selling pharmaceutical in the world prior to the expiration of its patent in 2016. This drug is administered by subcutaneous injection, and has been approved for several indications. Other widely administered products in this category include Enbrel for rheumatoid arthritis, Lucentis for macular degeneration and Lantus for diabetes. Each of these medications surpasses $1 billion in annual sales.

The main advantage of these drugs is their precision focus. Rather than affecting the entire immune system, biologics work by interacting with very specific targets.

"Often, the target is a protein-protein interaction, which can be hard to interrupt with a traditional drug," says Dr Olivia Merkel, professor of drug delivery at Ludwig Maximilian University of Munich (LMU Munich). "For example, with inflammatory diseases, such as colitis, there are antibodies that are supposed to either capture cytokines and neutralise them, or block a receptor where the cytokine would bind, causing a strong inflammatory cascade. Biologics have been hugely advantageous in cancer. For example, Herceptin is now the standard therapy for patients with HER2-positive breast cancer and has greatly improved survival rates."

While these success stories speak for themselves, injectable biologics present a number of challenges. Injections are far less convenient for the patient than taking a pill and this causes problems with adherence. Non-compliance has been estimated at around 10%.

"I would say 90% of biologics have to use a parenteral vial," says Merkel. "Lots of them are injected, either systemically or subcutaneously, and some can be inhaled, but really you need a parenteral route."

This delivery route is forced by the size of the molecules involved. Unlike traditional small-molecule drugs, biologics cannot easily cross cell membranes, making them harder to administer.

"Most biologics are proteins, so they are very large, and they really have to be delivered to wherever the site of action is," adds Merkel. "Because they are so large, they can be easily degraded, and if this happens they lose their activity. So you can't give them orally because they could be degraded in the acidic environment of the stomach."

In fact, when proteins and peptides are delivered orally, their bioavailability generally lags at under 2%. Although it

is not for want of trying, the industry has largely failed to deliver biologics in a pill.

Upping patient convenience

Inhalable biologics have seen limited success, with the best-known example being MannKind's inhalable insulin, Afrezza. Despite its quick-acting formulation and radical promise, the drug has faced reimbursement issues and has not sold particularly well.

While the quest for other delivery methods is not over yet, it seems likely that the biologics market will be dominated by injections in the years to come. As the market for global injectable drug delivery devices and wearables continues to grow, the question remains: how can the industry maximise patient convenience as much as possible, while ensuring that they receive the correct dose?

As Merkel explains, the delivery method that patients use depends on the disease. "Compliance really is a problem if IV injections or infusions are necessary, and I think that this is the biggest challenge for translating biologics that are used in a non-cancer field," she says. "If you look at a patient with asthma, they're not exactly willing to go to hospital for infusions or even an injection. Patients with Crohn's disease are maybe a bit more willing to do this, but they still find it very invasive. And if you have cancer, you'll do anything to get better and survive."

This means that biologic drugs for cancer are typically delivered via infusion. It is unlikely that any issues with non-compliance will arise.

> "Even though we've now managed to deliver proteins quite efficiently, we're still struggling with nucleic acids. Maybe over the next ten years, we'll really translate things into clinical practice."

Other drugs, specifically those that need to be taken systemically, might be given by a nurse or doctor at regular intervals. These drugs take the form of intravenous or intramuscular injections and would be hard for the patient to administer themselves.

For other conditions, self-management may be more appropriate. Such injections are easy to administer, do not require specialist training and reduce pain.

The obvious example here is insulin, which has been used with great success for nearly a century. Unfortunately, other biologics are not so easy due to their large-molecular size and high viscosity. "If you have a high molecular weight, a low concentration of such a macromolecule can cause viscosity increases, meaning the it can be painful," explains Merkel.

"You can dilute it, but then you may have solubility issues and need to do an infusion. Someone with asthma is probably not going to be thrilled if you tell them that they have to come in for a two-hour infusion for their asthma every one or two months."

It has fallen to manufacturers to develop auto-injector devices that overcome these viscosity challenges. Recent years have seen great strides being made in this field, with a new

For certain conditions, traditional administration of injections may be on the way out, as self-management becomes the norm.

A chitin microneedle patch tested on human skin.

wave of products designed to deliver the drug safely, comfortably and with suitable force.

"Most of these biologics are sold as pre-filled syringes and auto-injectors that are similar to insulin pens," says Merkel. "They can be easily handled, and you have a very defined dose."

Orencia has three delivery options: intravenous infusion, a syringe and a ClickJet auto-injector pen.

Other than auto-injectors, another promising route of delivery is microneedle patches. These involve shrinking the needle to micrometre dimensions.

> "Compliance really is a problem if IV injections or infusions are necessary, and I think that this is the biggest challenge for translating biologics that are used in a non-cancer field."

Humira, for instance, is a highly complex protein with a molecular weight that is around 25 times higher than insulin. Andy Fry of Team Consulting has described the delivery challenge as comparable to injecting golden syrup.

The next big thing

Patients have two choices for auto-injection: a pre-filled syringe or a pen that hides the syringe from view. The latter makes the injection as straightforward as possible, producing a click once the injection begins and a visual indicator to show that it is complete.

Enbrel is administered via a SureClick auto-injector that follows a similar principle, while the arthritis drug

At this size, it is possible to deliver proteins through the skin, but not large enough to cause any pain. Hundreds of them can be placed on a single patch and can be applied as easily as a plaster. Merkel feels that these have potential to become the "big thing" over the next few years.

"Lately, there have been a lot of interesting approaches to microneedles, especially for vaccines," she states. "For a lot of vaccines, you don't really want them to go to the systemic circulation – you want them to be subcutaneous, where a lot of the immune cells are. With microneedle patches, you can deliver it to exactly where it's needed to get the immune response you want."

While microneedle technologies are still in the early stages of development, they are showing promising results so far. For example, a team from Georgia Tech and Emory University is working on a dissolving microneedle patch for flu vaccinations. Their phase-I clinical trial results – described as 'gratifying and exciting' – were published in *The Lancet* in June 2017.

Delivering refurbished genes

Beyond microneedles, Merkel feels that the next few years are likely to spell interesting changes across the board.

"We will see new vaccines, especially for cancer. And then, obviously with all the inflammatory autoimmune diseases, there's still a lot of room for improvement. Even though we currently have biologics that can treat those diseases, I think there's a need for better administration routes, better devices and better patient compliance," she adds.

Merkel points out that new gene-editing methods, including the CRISPR-Cas9 tool, involve biologics, and that they raise similar questions about delivery.

"Gene therapy has been a big wish for many years, and it has a lot of promise, but the delivery is the biggest problem," she explains. "Even though we've now managed to deliver proteins quite efficiently, we're still struggling with nucleic acids. Maybe over the next ten years we'll really translate things into clinical practice."

Ultimately, improved patient compliance means reduced healthcare costs, particularly in situations where patients feel empowered to manage their own conditions. Because biologics are predominantly used for chronic diseases, which require long-term treatment rather than a one-off cure, the potential savings are significant.

The industry will continue to invest in new delivery mechanisms and wearables, asking how biologics delivery might one day become as simple as taking a pill. While there are no simple answers for now, many patients will be relieved to know that the question is being asked. ■

Prevent nosocomial infections

MoveoSiphon by **MoveoMed** acts as a microbial barrier, effectively controlling the spread of nosocomial infections caused by contaminated sink traps.

Nosocomial infections are a major threat to patient safety. They require an efficient analysis, effective control, and most importantly, sustainable prevention measures. While implementing hand hygiene strategies is important, it is time to focus on additional vectors of infection. Important areas of infection, such as wastewater disposal, have been underestimated so far. Many publications have reported that healthcare-associated outbreaks are often linked to colonised sink traps.

Wastewater systems have to be considered as a potential source of pathogens in case of healthcare-associated outbreaks caused by multidrug-resistant Gram-negative (MDRGN) bacteria. Wastewater and biofilm in drain systems provide ideal conditions for colonisation and persistence of MDRGN bacteria such as *Pseudomonas aeruginosa*, *Acinetobacter baumanii*, *Klebsiella pneumoniae* and *Escherichia coli*.

Water flowing into the sink trap produces aerosols, emiting the bacteria in the sink trap up to a distance of 1.5m around the sink where they can come in contact with the staff and the patients, leading to healthcare-associated infections. Numerous clinical investigations have proved that conventional sink traps do not fulfil the high hygiene standards needed in invasive intensive care.

The sono-thermal disinfection device MoveoSiphon ST24 by MoveoMed meets those standards. It replaces the standard sink trap, acting not only as an odour trap but also as a microbial barrier.

The MoveoSiphon uses a dual approach: thermal disinfection that meets at least the standards of the technical process of pasteurisation, and electromechanical cleaning to prevent the development of biofilms on the inside walls of the trap. MoveoSiphon achieves a seven-log stage reduction in bacteria. Several studies have proved its effectiveness in controlling the spread of nosocomial infections caused by contaminated sink traps.

MoveoSiphon is not only beneficial for the patients, but also for the environment as continuous disinfection of the sink trap is carried out without using chemicals. ■

References available upon request.

Further information
MoveoMed
www.moveomed.com

Headset healthcare

Augmented and mixed-reality platforms are helping surgeons prepare for and carry out increasingly complex procedures. Abi Millar hears from **Dr Hans-Jürgen von Lücken**, senior physician at Hamburg's Kath. Marienkrankenhaus, and **Jakub Wlasny**, lead developer at apoQlar, about the potential for adding a new layer of reality to the surgical theatre.

Could augmented reality (AR) be the next big thing within the healthcare field? Over the past few years, there has been a wave of start-ups in the field, focusing on everything from neuro-assistance for autistic people (Brain Power) to easier blood transfusions (AccuVein). Perhaps most excitingly, it could change the face of surgery, replacing many of the tools necessary today with a single, wearable piece of equipment.

The possibility first emerged in 2013, when Dr Rafael Grossmann became the first person to use Google Glass during a surgical procedure. Since then, many new players have entered the field with a view to developing AR for the operating table.

These have included Medsights Tech, which uses image-reconstructing technology to give surgeons 'X-ray vision', and EchoPixel, which offers advanced medical visualisation software. Most recently, Touch Surgery, a London start-up developing holographic surgery headsets, raised $20 million from the backers of the Oculus headset.

"New applications – some that we can't even imagine yet – will help transform surgery and the surgical experience," said Grossmann, presciently, in a 2013 interview.

Surgeon simulator

One of the leaders in the field is the German company apoQlar, which is developing a software tool named Virtual Surgery Intelligence (VSI). It uses artificial intelligence to render MRI and CT images in 3D. When a surgeon puts on the AR headset, the 3D images merge virtually with the patient, giving the surgeon a new level of anatomical detail. This scan can be controlled with gestures and speech commands.

"It displays medical images in a 3D hologram, which the user can freely manipulate around the physical environment," says Jakub Wlasny, lead developer at apoQlar. "Those images are automatically fixed onto the body of the patient. This means doctors can slice through those holograms in order to explore the patient's internal structures, without having to look at any specific devices or screens."

Live streaming surgery – the first AR procedure

Dr Rafael Grossmann was the first practitioner to use Google Glass during a surgical procedure. Here he recounts the experience:

"Obviously, one of the main concerns regarding the use of Google Glass during surgery, with live streaming of data, would be to take every measure and to ensure the privacy of the patient's health information (PHI).

"That's exactly what I did. Not only did I obtain informed consent about what we were going to attempt (and documented it), but most importantly, I made sure that no recording or transmission of any identifying information was done. The streaming of video and photos, to myself through Google Glass, did not reveal any PHI, or even show the patient's face.

"By performing and documenting this event, I wanted to show that this device and its platform were intuitive tools that have a great potential in healthcare, and, specifically for surgery, could allow better intra-operative consultations, surgical mentoring and potentiate remote medical education, in a very simple way.
The patient involved needed a feeding tube and we chose to place it endoscopically, with a procedure called percutaneous endoscopic gastrostomy (PEG). Since it was the first time, I wanted to do this during a simple and commonly performed procedure, to make sure that my full attention was not diverted from taking excellent care of the patient.

"I arranged for a Google Hangout (HO) between my Glass and a Google account I created ahead of time for this very purpose. The connection is remote. The iPad used as a receiver was just yards away, but it could have been thousands. Before starting the operation, I briefly recorded myself explaining the planned event, and once again, talked about the importance of not revealing any PHI.

"I had Google Glass on at all times, with the HO active throughout the procedure. The live video images that I saw through Google Glass were projected in the iPad screen, remotely. We kept the volume down on purpose. We tried to keep it very simple and straightforward. As I said, even the procedure was a simple one. I was able to show not just the patient's abdomen, but also the endoscopic view, in a very clever, simple and inexpensive way.

"The whole thing was fairly quick and went very well. We used homemade techniques, so the pictures and video were not optimal, but I think the point stands: We demonstrated Google Glass streaming during live surgery, by a glass explorer surgeon, was possible."

Source: Rafaelgrossmann.com

Alongside its surgical uses, the tool can be used preoperatively to prepare for upcoming surgeries, and post-operatively to evaluate the surgical progression. The company is also developing two related tools: VSI Patient Education (for informing patients about their condition) and VSI Education (for training surgeons).

it as a post-operative and preoperative assistant.

"We have found [the tool] gives us a much deeper and more detailed insight into the anatomical structures," says Dr Hans-Jürgen von Lücken, senior physician at Hamburg's Kath. Marienkrankenhaus. "But the VSI is also a big help for our interns. This way, they can orientate themselves more quickly and the more experienced doctor can better communicate their surgical approaches and procedures." ››

> "VSI is a big help for our interns. This way, they can orientate themselves more quickly and the more experienced doctor can better communicate their surgical approaches and procedures."
>
> **– Dr Hans-Jürgen von Lücken**

After extensive testing, VSI has recently been introduced to a hospital in Hamburg, where surgeons in the head and neck department are using

AR looks set to enhance surgery in the coming years, helping surgeons to achieve the best results.

AR technology involves 'augmenting' the real-world environment with various pieces of computer-generated input (sound, images or information), by way of a screen or headset. Although it is related to virtual reality (VR), there is one key difference: VR places the user in a completely immersive world, detached from reality, while AR overlays information onto the physical setting.

> "While the technology can't replace the skill and experience of the clinical team, it could potentially help to reduce the time a patient spends under anaesthetic and reduce the margin for error."
>
> **– Jakub Wlasny**

Although AR is only beginning to make its way into the healthcare space, its potential is significant. From a medical standpoint, one key advantage is that practitioners don't need to take their focus off the patient. Currently, surgeons need to switch between various reference points – from the person on the operating table to the medical images and patient data displayed on various screens. With applications such as VSI, they can access all the information they need while the patient remains in their field of vision.

"We want to deliver a more immersive and friendlier way of working with medical images, helping doctors navigate around the surgical site and orientate those anatomical structures. This makes it quicker for them to proceed with surgeries," says Wlasny. "We also want to eliminate as many of the other tools that are now used as we can, and put everything in one simple device."

Holographic helper

As with many other technologies in this field, the VSI uses Microsoft's headset, HoloLens. This device, which creates blended environments based on mixed reality, enables a live broadcast of the surgery from the surgeon's perspective, meaning less experienced doctors could receive remote assistance.

Having already been used in many industrial settings, the HoloLens is just now beginning to make waves in surgery. In December, a team of French surgeons used HoloLens to livestream what they called the 'world's first surgical intervention performed with a mixed-reality collaborative platform'. And in January, a team at Imperial College London demonstrated how surgeons can use HoloLens headsets while conducting reconstructive lower limb surgery.

"The application of AR technology in the operating theatre has some really exciting possibilities," said Jon Simmons, who led the Imperial College team. "It could help to simplify and improve the accuracy of some elements of reconstructive procedures. While the technology can't replace the skill and experience of the clinical team, it could potentially help to reduce the time a patient spends under anaesthetic and reduce the margin for error. We hope that it will allow us to provide more tailored surgical solutions for individual patients."

At the time of writing, apoQlar is waiting to receive medical certification for VSI, which will enable surgeons to use the tool in the operating room. The company is also working to develop it further, adding new functionalities and areas of application.

Since the tool uses machine-learning algorithms, it will continuously learn and improve, recognising more tissue types and acquiring more knowledge with every operation.

"I hope that in the long term it'll be a full medical product presented in many different medical facilities, and we hope to deliver as many useful functionalities for different kinds of specialities as possible," says Wlasny.

It is early days still, but in a few years' time AR-enhanced surgery could well become the norm. According to a recent review in the *Journal of Healthcare Engineering*, applications in this space are developing rapidly (albeit with various teething problems that need addressing). The authors concluded that, in the future, AR "will likely serve as an advanced human-computer interface, working in symbiosis with surgeons, allowing them to achieve even better results."

From apoQlar's standpoint, there is no doubt that AR will revolutionise current surgical options.

As the company's founder Sirko Pelzl recently told the *Hamburg News*, "It's not a question of whether this will happen, but whether we will lead this revolution." ■

The missing piece

Effective 2D DataMatrix code readers have long been a missing element in completing the instrument-traceability triangle. The SurgiScan product range from **2DSurgical** promises to provide the missing piece.

The three basic elements of a successful instrument traceability system can be considered to form a triangle. Every element is essential in achieving an effective system, which works in the real world. The first element comprises of excellent software systems and has long been available. Many systems have been optimised for Central Sterile Services Departments (CSSDs), and offer benefits over and above a reliable traceability solution. The second element consists of laser and other code marking techniques, which are available from many manufacturers. Smaller and clearer codes can now be marked quickly and cost effectively. Historically, the final element – effective 2D DataMatrix code readers – have been absent.

Typically, generic readers have been used. These have often been handheld and, therefore, difficult to aim and focus. Difficulty in reading codes makes the whole traceability process slower and impractical, creating resistance to the implementation of the process by users who are frustrated by poor performance.

SurgiScan readers provide the missing piece necessary to complete the instrument-traceability triangle. They have been designed specifically for instrument reading in CSSDs, providing quick and effective traceability. SurgiScans have several benefits:

- They are incredibly quick and easy to use, without any training or technique, so reading does not add time to the CSSD process.
- They reliably read any mark on any instrument regardless of its size or material. Codes less than 1mm² can be read, even though the human eye may struggle to locate them.
- They can work with any software system. SurgiScan readers can be supplied with any new traceability system or retrofitted.
- They facilitate cleaning with a sealed aluminium case that prevents the entry of water (IP65). They easily fit into the CSSD regime.

Time and again, their reliability and ease of operation has been proved at locations worldwide. ■

Further information
2DSurgical
www.2dsurgical.com

Procedure boxes for better patient care

For hospitals striving to reduce waste, improve efficiency and provide better patient care, procedure boxes offer an innovative solution. Laura Marquez, procedural solutions manager at **Medtronic**, discusses their benefits for inventory management, operational efficiency and standardisation in surgery.

As funding becomes stretched and patient numbers rise, hospitals come under pressure to reduce costs and improve efficiency – but this is not always an easy task, and the provision of instruments for surgery is no exception. Inventory management is complex and takes time, while the need to have the right equipment on hand results in overstocking. The selection and assembly of individual items are time-consuming, slow up surgeries and are an area open to possible errors.

Improved operational efficiency

Tailored procedure boxes by the healthcare solutions company Medtronic provide answers to these issues. Each box contains all the instruments required for specific surgical procedures, streamlining the process of ordering stock and managing invoices. This is supported by a survey conducted by Medtronic on the use of procedure boxes at a number of European hospitals: Great Western Hospital in Swindon, UK, found the time spent investigating invoices reduced by 91% when ordering boxes.

An easy ordering process also helps hospitals with financial efficiency. Each procedure box – and therefore each surgery – has one unique code for reorder. "Hospitals have to manage budgets, and kits are the perfect tools to control the specific expenditure per procedure," says Laura Marquez, procedural solutions manager at Medtronic. The use of procedure boxes allowed University Hospital Limerick, Clinical Institute Beato Matteo in Vigevano, Italy, and Great Western Hospital to reduce inventory volume by 30% and inventory value by 50%.

Tailored boxes mean inventory management is simplified and storage optimised. "You know exactly which products to use for every surgery, so you get rid of all the extra stock that may not be needed," Marquez explains. Improved efficiency in this area frees up space; furthermore, Medtronic reports that waste can be reduced by up to 50%, as extensive packaging for individual items is eliminated.

Enhanced surgical experience

The benefits of using procedure boxes extend into the operating room itself. Having all the required instruments together in one box cuts the time it takes to prepare for surgery, as nurses do not have to select instruments from a variety of locations. This is borne out in Medtronic's survey results: University Hospital Limerick reduced its set-up time by 63%.

This has knock-on effects on the overall efficiency of the hospital. "Because there's a reduction of time in several processes in the operating room, there is more time to treat more patients," Marquez says.

Each procedure box contains all the required instruments for a surgery, improving operational efficiency.

Having all instruments packaged together in a kit removes the chance of mistakes when picking products for theatre. Medtronic's survey found that error rates in this area were lowered by 16–20%, reducing the likelihood that nurses would have to leave the theatre to retrieve missing items and allowing a smoother surgical experience. Furthermore, the use of prepared kits is a significant step towards the goal of standardisation in surgery, with identical items used in each specific procedure. Standardisation reduces clinical variants, which is then associated with better clinical outcomes.

Medtronic's procedure boxes are customisable, allowing surgeons to specify the equipment they require for procedures. "They can choose whatever product they want to be included in this box, and so it's tailored to the customer's needs," Marquez says. The inherent efficiency of procedure boxes offers hospitals a tool to improve in numerous spheres at once: budget and inventory, waste reduction, procedure times and standardisation in surgery. ■

References available upon request.

Further information
Medtronic
www.medtronic.com

Medtronic Procedural Kits support **Healthcare professionals** become **more efficient** in managing daily duties while improving **quality of patient care.**

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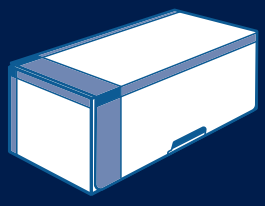

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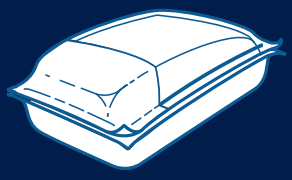

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Laser focus: increasing the safety of gynaecological laser therapy

As one of the most experienced developers of high-tech solid-slate laser systems, **Fotona** has used its expertise to create its latest innovation. Fotona SMOOTH is a minimally invasive outpatient laser therapy for various genitourinary conditions.

Symptoms of age and childbirth-related disorders, such as urinary incontinence and pelvic floor prolapse, affect hundreds of millions of women worldwide. Roughly 60–80% of women over 50 will experience atrophy in their lifetime. Almost 50% of parous women suffer from some kind of pelvic organ prolapse and 25–30% suffer from stress urinary incontinence. Conservative treatments such as pelvic floor muscle therapy (Kegel exercises) often fail because of the patients' lack of compliance. Surgical options, although effective, suffer from a high rate of adverse effects and are typically a patient's last resort. Due to the fear of risks and life disruptions associated with current surgical treatments, interest in lesser invasive treatment options is growing.

> "Almost 50% of parous women suffer from some kind of pelvic organ prolapse and 25–30% suffer from stress urinary incontinence."

Fotona SMOOTH is a minimally invasive, non-ablative Er:YAG laser procedure for functional strengthening of the connective tissue inside the vaginal wall. The treatment results in improved pelvic floor support and reduced symptoms of pelvic floor dysfunction. It is based on photothermal strengthening of the urethral wall and anterior bladder wall region as well as tightening of the vaginal canal through a process that involves the remodeling of collagen fibres as well as neocollagenesis, angiogenesis and proliferation of fibroblasts.

The therapy results in the return of normal continence function, a reduction of vaginal atrophy symptoms and tightening of the vaginal canal. The treatment is incisionless, without local anaesthesia and with little to no downtime.

Clinically validated indications for this non-ablative laser procedure include stress urinary incontinence (IncontiLase), vaginal atrophy and genitourinary syndrome of menopause (RenovaLase), pelvic organ prolapse (ProlapLase), and vaginal relaxation syndrome (IntimaLase).

Fotona SMOOTH mode treatment of the anterior vaginal wall. The product has been carefully designed to be minimally invasive.

Studies and outcomes

Since the introduction of the unique Fotona SMOOTH gynaecological laser therapy in 2012, a number of independent studies examining its safety and effectiveness have been published in the most highly respected, peer-reviewed international journals. To date, clinically proven results have been published in more than 35 SCI (high Science Citation Index) publications, providing a substantial base of evidence for the future of minimally invasive laser treatments for vulvovaginal disorders.

A compendium containing the abstracts of these published scientific studies is available for download on the official Fotona website. ■

All Fotona medical lasers are CE-marked and approved to be sold in the EU. For countries where specific national approvals or clearances are required, some of the products and applications may not yet have been approved. Prospective customers are advised to check with Fotona, their local Fotona distributor or a national regulatory body whether a specific product or application has been approved to be marketed and sold in their country.

Further information
Fotona
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An app a day

Non-adherence to treatment regimens costs healthcare systems hundreds of billions of dollars every year. Elly Earls speaks to **Jon Lee-Davey**, internet of things (IoT) health lead at Vodafone, to discuss how an IoT-powered solution could potentially save money and lives.

Anyone who has been prescribed a drug to take on an ongoing basis will remember a time they forgot to take their medication. Most probably, they didn't give it a second thought and are even less likely to have realised that their non-adherence is part of a multibillion dollar problem facing the healthcare sector, one that results in hundreds of thousands of deaths every year.

According to a recent Vodafone white paper, entitled 'The missing link in healthcare', the lack of medical adherence leads to 125,000 deaths per year in the US alone, accounting for 69% of all medical-

related hospital admittance and costing payers up to an estimated $290 billion each year.

For severe asthma, estimates suggest that the savings produced by optimal control would be around 45% of total medical costs, while improved medication adherence among patients with diabetes could result in over one million avoided emergency department visits and hospitalisations in the US annually.

The whys behind the problem are complex. In fact, there are over 700 identified reasons for non-adherence, ranging from concerns about side effects to bewilderment over complex treatment regimes. The only universal fact is that each individual patient is different, and therefore needs an individualised solution.

The good news is that a number of different factors are in the process of coming together to make a new approach to adherence – an internet of things (IoT)-enabled, and therefore much more personalised, one – not only possible but inevitable.

Data collection

IoT sensors are becoming smaller, more advanced and more affordable; connectivity is ubiquitous, fast and secure; cloud hosting is scalable and cost-effective; and the technology platforms that enable the development of novel solutions to measure patients' adherence and engage them in improving it are ready to go. Not only that, but patients are ready, too – the likes of Fitbits and sleep-tracking apps have opened their eyes to the value of being in tune with their physical performance and health, and therefore better able to improve it.

Smart adherence solutions work on the same principle. Data is collected by tiny sensors in pill packets or medical devices to be analysed and then shared with patients via apps on their smartphones. The idea is that showing patients that they're not following their treatment regime will provide a stronger impetus for them to do so.

"To engage, patients need to feel that they are part of the process," says Jon Lee-Davey, IoT health lead at Vodafone. "They also need to feel that the process is considerate of their own personal needs. By having a connected solution, we would be collecting pertinent data about that particular patient, making them feel like they have some ownership, and are empowered to be able to take control and begin to manage their own condition."

> "By having a connected solution, we would be collecting pertinent data about that particular patient, making them feel like they have some ownership, and are empowered to be able to take control and begin to manage their own condition."

For example, if a patient continued to miss their medication on Mondays and Wednesdays because of, for example, football practice, the technology could suggest they adapt their schedule to better suit their lifestyle. "It's about having that feedback loop that allows it to be put in the context of the patient. That's where it becomes that much more powerful," Lee-Davey says.

The benefits of IoT-enabled adherence technologies would extend far beyond an improved patient experience. Armed with better data, doctors could make better decisions, while payers could make significant

Delivering individualised healthcare: what do IoT-enabled adherence solutions mean for the future of healthcare?

More independence for patients
For patients, better adherence will mean better outcomes. They'll be more likely to live longer. They'll be less likely to suffer side effects from unnecessarily high doses. And with greater access to data on their own adherence and health, they'll be in a better position to take charge of their own health and live more independent lives. As data analytics becomes more sophisticated, it's possible that prescriptions could be changed automatically without the need for a clinical appointment.

More effective diagnosis and monitoring
But healthcare IoT technology doesn't mean patients are left alone. It will give clinicians access to data that will help them make more effective diagnoses and prescribe the best possible treatments for individuals. That data won't just be on adherence. They'll also have access to real-time data from connected health monitoring devices as well as medical trials. With this, they'll be able to aggregate data to develop stronger education programmes. And they'll be able to correlate adherence data with research results to help, for example, tackle the issue of antimicrobial resistance. Artificial intelligence (AI), machine learning and advanced data analytics could provide valuable new insights.

Better drug development
In research and development, the healthcare IoT value chain will mean access to more accurate information when running clinical trials and developing drugs. With better adherence data, there will be a greater likelihood of a clinical trial completing successfully. And by using smart devices to manage the delivery of medication, they'll be able to boost the success rate of their treatments.

Lower healthcare costs
For payers, better patient outcomes will mean lower costs. And the use of smart devices to improve adherence and measure health could prove a particularly attractive proposition for payers and health providers by helping avoid the need for stepped care.

Source: 'The missing link in healthcare', Vodafone

Why don't patients follow their treatments?

The picture is complex – there are over 700 identified reasons for non-adherence. That makes it difficult to develop a predictive model to suit all patients and situations. And that is why it is so important to have a means of accurately measuring and managing individual adherence.

Initiation

Across many chronic diseases, 20–30% of patients do not start their treatment or collect their prescription. That can be due to cost, lack of perceived benefits, and/or concern about side effects, as well as limited availability of medicines.

Implementation

Patients can simply forget to take their medication, or become overwhelmed by a complex dosing regimen – some patients may need to take many medications at different times of the day.

Persistance

Many patients stop treatment early if their symptoms have abated, they're suffering side effects or they do not perceive sufficient benefits. Nearly one third of heart-attack patients do not persist with their prescribed medications after six months.

Smarter approaches to adherence

Smart packaging
Opening a bottle or carton is a reliable indicator that medication has been taken. Sharing data with patients can improve behaviours and adherence.

Smart delivery
Sensors in devices, inhalers or syringges capture when medication is used. For example, they provide a measure of whether the full dose was taken, which can inform patient behaviour.

Smart pills
IoT-enabled pills can show exactly when medication is taken. These solutions can provide information on medication effectiveness.

Smart diaries
By keeping a diary, patients can become more engaged in the process of taking medication. Patients share information on how they're feeling with their doctor.

savings from a reduced need for stepped care.

"If patients aren't taking their therapy, it might be that their disease progresses or their doctor recommends them to move into a third or fourth treatment, which could be more expensive," explains Lee-Davey, who has been invited to speak to the European Parliament about the role the IoT could play in helping to share future European healthcare policy, evidence of just how seriously world leaders are taking this issue.

Plus, over time, an amount of data would be amassed that could be used to inform clinical research.

"One of the challenges of running clinical trials is that the data may be incomplete, and how do you test your hypothesis if you have an incomplete data set?" Lee-Davey asks. "Being able to gather accurate data during an expensive research process could lead to the development of better solutions and therapies."

The missing link

According to Vodafone's white paper, around half of patients being treated for long-term chronic illnesses such as hypertension, cancer or HIV do not stick to their recommended treatment programmes. Better approaches, those that connect the different technology dots in the treatment process, it claims, could bring 50% of the non-adherent population onside, potentially improving millions of lives and saving billions of dollars.

Personalisation is creeping into all aspects of modern healthcare – from tumour treatment and therapies for cystic fibrosis to voice assistants that can communicate with elderly patients in their own homes. Expanding this approach to medical adherence is the next logical step, and one Vodafone, as a technology and infrastructure provider, is working to help make a reality.

Already, the company, which connects 59 million 'things' via its Global Data Service Platform (GDSP) – more than any other company in the world – is helping to encourage adherence by providing connected solutions around sleep apnea and cardiac rhythm management devices.

Lee-Davey and his team see no reason why they cannot be the ones to bring together pharmaceutical and medical device companies, healthcare systems and technology companies to facilitate an industry-wide move towards individualised – and therefore much more effective – adherence solutions for drug regimens and other medical devices, too.

The excitement in Lee-Davey's voice when he talks about a future in which his company is helping to change and inform the way people live by using connectivity to improve their health outcomes is palpable. He hopes the rest of the industry sees it the same way. ■

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innovation you

Stay connected to what's vital

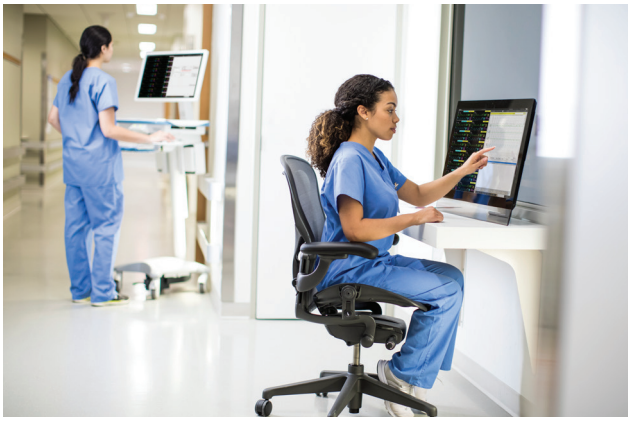
Dr Peter Ziese, business leader of patient monitoring at **Philips**, explains how the company helps hospitals provide patients with consistent patient monitoring and coordinated care.

As the healthcare industry adapts to a value-based care model and an increasingly complex environment, the pressure is on for health systems to rise to these new ways of working. They not only must deliver care efficiently and effectively at every level of acuity, but they must also focus on simplifying workflows, providing clinicians with fast and accurate information and making the most of existing IT systems. This all must occur while enhancing the patient and clinician's experience, improving health outcomes and lowering costs.

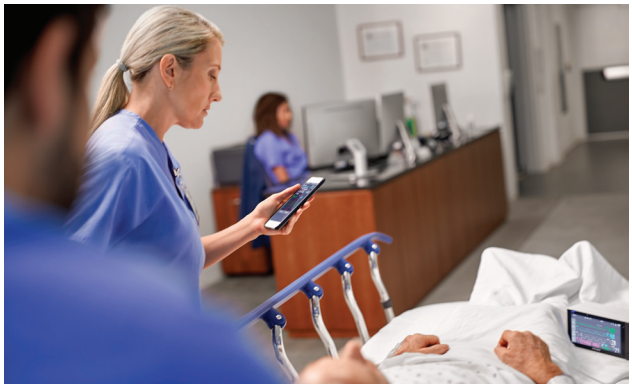
However, there are a number of challenges that providers face as they try to accomplish these objectives. For one, hospitals are never stagnant. With staff rotating in and out of departments for their shifts, patients being moved between areas and technology that is not fully integrated or updated in real time, there are many causes for variation in care, which can affect clinical performance and patient outcomes. Secondly, the problem of alarm fatigue is a huge concern for clinical staff. Sometimes, the monitoring and alarming systems designed to help patients can inundate clinicians, leading to alarms being disregarded because care teams cannot determine if they require action.

The importance of coordinated care

With the Philips Information Center iX (PIC iX) at the heart of the patient monitoring solution, the central monitoring system fits securely into a hospital's IT environment to help clinicians meet critical challenges. PIC iX provides visibility into a patient's clinical data virtually anywhere, anytime – at the bedside, during patient transport or via mobile apps and smart devices – to support clinician communications and streamline workflows. The system is highly integrated and securely feeds a steady stream of detailed patient data, such as vital signs, waveforms and alarms, into an electronic health record (EHR), enabling virtually gap-free patient records from admission to discharge – even during transport.



PIC iX provides visibility into a patient's clinical data virtually anywhere and anytime to support clinical decisions.



PIC iX enables clinicians to access a patient's clinical data virtually anywhere and anytime, even via mobile apps and smart devices.

Additionally, PIC iX includes technology that can help clinicians triage and prioritise alarms, helping them to reduce the level of non-actionable alarms. Alarm Advisor, for example, keeps track of how a clinician is responding to each patient's alarms and can make recommendations based on hospital policy, such as modifying alarm parameters. It also incorporates clinical decision support tools, advanced algorithms and early warning score trending to help clinicians identify a patient's deterioration early – something that is central to avoiding adverse events that require transfers back to the intensive care unit.

Philips' patient monitoring solution also includes PIC iX Data Warehouse Connect (DWC), which enables health systems to take advantage of the rich device data beyond the EHR. DWC is a continuous, high-resolution data-capture and storage solution that covers various devices, such as ventilators. Organisations can use this rich data set to execute quality-improvement programs, boost operational efficiency and conduct cutting-edge research. It also provides access to clinical expertise from Philips' Advanced Algorithm Research Center to extract and mine data, and assist in delivering algorithms and predictive analytics for specific clinical and operational outcomes.

Working together

With patient safety as a top concern, health systems need to see medical device companies not only as providers of technology solutions in patient monitoring, but also as powerful collaborators who transcend traditional box-selling and prepare them for the future. Philips works with hospitals to help them customise and standardise their protocols and people, while also providing the ongoing consulting, training, service, and support essential for enhancing outcomes and driving clinical performance – for life. ■

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Philips
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A newborn in patient-controlled analgesia

With the introduction of the Agilia SP Patient Controlled Analgesia, the latest innovative product from the Agilia Connect range of infusion pumps, **Fresenius Kabi** shows its commitment to supporting patient-controlled analgesia. This new-generation infusion pump features an ergonomic handset and a cybersecured hardware, providing patients with the safest way to administer analgesia.

The Agilia pumps from Fresenius Kabi have confirmed their success with more than 600,000 bases installed worldwide. Agilia SP Patient Controlled Analgesia (PCA) is a new syringe pump designed for the patient to self-administer a dose of analgesic drug with an ergonomic in-house developed handset. This allows more independency and safety in patients' self-administration.

Market trends show that the total revenue of this business is $86 million and the total units are forecast to grow at a compound annual growth rate of 4.7% until 2022. Growth in the market is driven by increasing demands for pain management due to the raising ageing population, improved cancer care, post-operative treatment and even treatment outside the hospital.

In the hospital, dealing with pain management for the patients in general therapies is central.

> "Agilia SP Patient Controlled Analgesia (PCA) is a new syringe pump designed for the patient to self-administer a dose of analgesic drug with an ergonomic in-house developed handset."

Cybersecured hardware

A long research was undertaken by Fresenius Kabi to gather input in order to build the main features that the patients and the clinicians are looking for.

This type of device is intended to deliver pain killers and they are often stolen from the hospital. Several questions concerning the level of protection needed around the device then arose. The decision for Agilia SP PCA was to completely lock the syringe part with a physical key as well as a four-digit code to prevent the patient from changing the dose, resulting in a safer overall product.

An ergonomic handset

A new device was developed to function on the Agilia Connect syringe pump with the integration of specific programs such as PCA dose, lock-out time, basal rate, cumulative limits, loading dose and more. The high-quality patient handset is an original in-house design that allows the patient to intuitively and effectively control the device. Fresenius Kabi has managed to harmonise the Agilia Connect family with this new pump and reorganised the hardware inside to perfectly integrate it into the rest of the portfolio – including Vigilant Master Med, the brand-new DERS (Dose Error Reduction Software) to help healthcare providers in their daily work.

Agilia SP PCA allows more independent but safer self-administration, promising to improve the quality of life of the patients.

The drug library Vigilant Master Med and the Agilia pumps work together to achieve dose error reduction with a high flexibility of customisation based on the different protocols that the clinicians use. Conscious of the safety issues in the hospitals, Fresenius Kabi offers 3,800 drugs and 19 profiles to further personalise and better adapt to the clinicians' practice in a continuous process of making a secured infusion system. The configuration of any type of parameters (drug or non-drug related) at the therapy level gives a high flexibility of customisation for every ward.

Agilia SP PCA is part of the Agilia family, a seamless program to integrate in any hospital information system. When used with the drug library, it enables a better clinical follow-up.

With a competitive price, an ergonomic handset and a completely protected hardware to administer analgesics in the safest way, Agilia SP PCA promises to increase the quality of life of the patients. ■

References available upon request.

Further information
Fresenius Kabi
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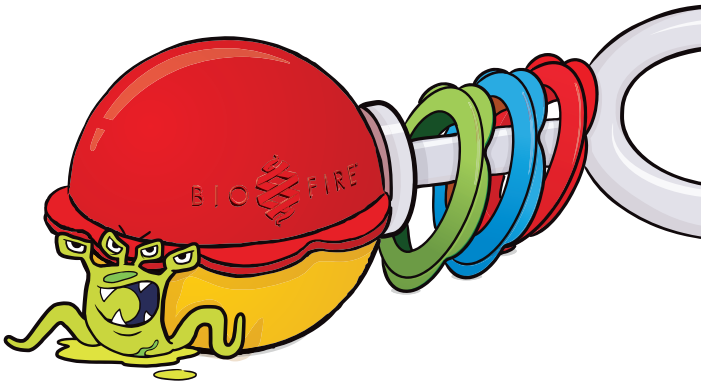

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