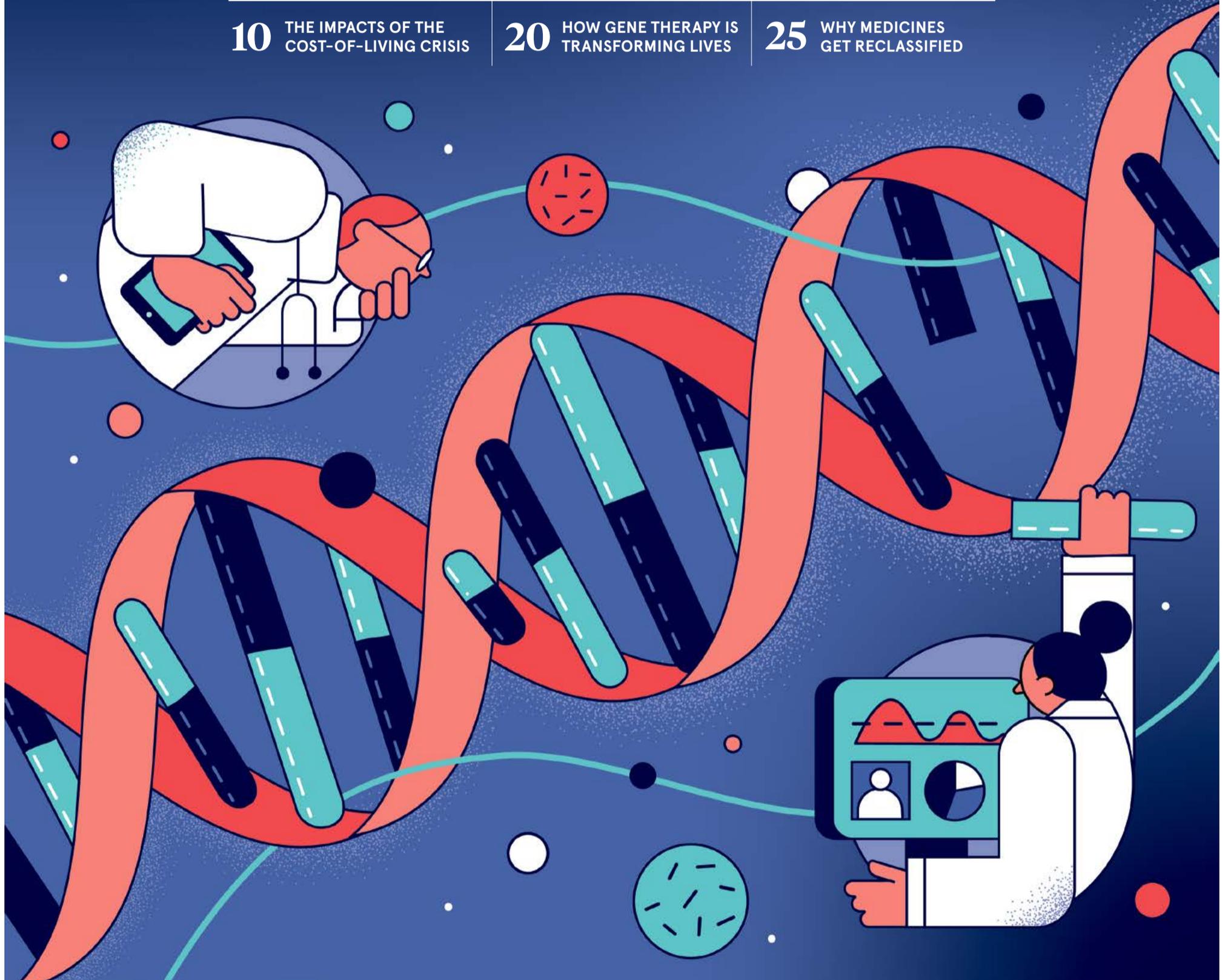


FUTURE OF HEALTHCARE

10 THE IMPACTS OF THE COST-OF-LIVING CRISIS

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25 WHY MEDICINES GET RECLASSIFIED



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[1] Milton Keynes University Hospital: Versius® Robotic Assisted Surgery Case Study February 2022

FUTURE OF HEALTHCARE

Distributed in
THE TIMES

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NATIONAL HEALTH SERVICE

Thrombosis surgery: why the NHS needs more than a stent

While Covid has been hugely disruptive, the service faces longer-term problems that have caused the waiting list to lengthen alarmingly. How can the blockages be eased?

John Illman

Many statistics lay bare the alarming decline of the NHS over the past decade, but none is starker than the backlog of patients awaiting non-emergency care. Even before the pandemic, there were about 4 million people on the waiting list – an increase of about 1.5 million in eight years.

By April this year, the queue had extended to 6.5 million would-be patients – nearly 10% of the UK population. Faced with this alarming figure, ministers are making a big play of the Covid effect. That has had a big impact, but the parlous state of the NHS was writ large well before anyone in government had heard the term 'Sars-CoV-2'.

In a prescient 2012 report, the Nuffield Trust predicted a decade of managed decline for public health-care provision. The independent think-tank observed: "The NHS in England is targeting efficiency savings of £15bn to £20bn by 2014-15... and it is likely that austerity will be required beyond this period."

Cost-cutting has played a large part in the NHS's failure to meet its main elective treatment target since 2016: that 92% of patients should see a consultant within 18 weeks of a GP referral. The waiting list comprises patients due to have consultant-led care, including outpatient clinic visits and non-surgical treatments. Once the NHS finally gets through the pandemic, reducing this list to an acceptable length may prove the organisation's second-biggest challenge in its 74-year history.

Many insiders fear that this task will prove even tougher than surviving the Covid crisis, because it's likely to take many years. The Institute for Fiscal Studies has predicted that the NHS waiting list is likely to lengthen until at least 2024, by which time it could contain up to 10 million names.

A report published in June by researchers at the University of Birmingham, *Forecasting the NHS*



Waiting List in England (2022-30), warns that there may be 3.3 million people on "a hidden waiting list" – that is, not officially counted because of Covid-related disruption. The government has promised "the biggest catch-up programme in NHS history". One of its new targets is for the service to deliver 30% more elective care than it had been doing before the pandemic by 2024-25.

Aneel Bhangu, senior lecturer in surgery and a consultant colorectal surgeon at University Hospital Birmingham, is a co-author of the research. He is not convinced that Westminster is being realistic with its aims.

"Eliminating the waiting list by 2030 would require an 8.4% increase in elective procedure volume per year," he says. "That equates to a 50% increase above pre-pandemic levels, which is unlikely."

Emergency admissions take over beds originally allocated to elective patients, but A&E patients are also facing lengthy – and sometimes life-threatening – waits. In 2004, the Labour government introduced a target stipulating that at least 98%

“Deaths arising from long waiting lists no longer make the news today, alas

of A&E patients should be admitted, transferred or discharged within four hours. This was cut to 95% in 2010 by the coalition government, which started a long-term austerity drive in response to the recession of 2008-09.

"No one takes notice of this target anymore – it has been missed since 2016," says a senior NHS insider, who asked not to be named. "The word is that it's going to be scrapped, because it's totally unrealistic."

The length of the waiting list has dominated the NHS debate ever since the highly publicised death of Ian Weir in June 1999. The 38-year-old father of two had been waiting seven months for coronary artery

bypass surgery in Darlington – the constituency of his friend, Labour MP Alan Milburn – when he had a fatal heart attack the day before he was due to meet a surgeon.

The tragedy did have a life-saving legacy, according to Jerry Murphy, professor of cardiovascular medicine at Darlington Memorial Hospital, who had been involved in Weir's treatment. It was "the spark that lit the fuse," he recalls. "It galvanised government investment in the health service."

In October 1999, Milburn became secretary of state for health. Among his first significant acts in that post was overseeing the publication of the NHS's first *National Service Framework for Coronary Heart Care* early in the following year. One of the outcomes of this 10-year plan was that the average waiting time for bypass surgery fell from 12 months to three.

But that was then and this is now. As Murphy notes: "Deaths arising from long waiting lists no longer make the news today, alas."

Summer is meant to be a good time in the NHS – illness and mortality

3.3million

The number of people estimated to be on a "hidden waiting list", due for treatment but not officially counted because of Covid-related disruption

University of Birmingham, 2022

rates soar in winter – but a new phrase has entered the healthcare lexicon. The NHS is in a condition that’s become widely referred to as ‘perpetual winter’. If the government is to clear the backlog, it will need to find effective solutions to the following problems.

Chronic disorders

Capital shortfalls

According to Health Foundation research published before the pandemic, the UK’s capex on public healthcare was 0.27% of GDP, compared with an average of 0.51% in 10 equivalent OECD countries, including the US.

The Conservatives’ 2019 general election manifesto promised “40 new hospitals” and eight other building schemes. Announced by Boris Johnson with a characteristic flourish, the £3.7bn package was to have been “the biggest hospital-building programme in a generation”.

The National Audit Office is conducting a value-for-money review of the programme, because the pledge is said to be unaffordable.

Moreover, many of the “new” hospitals are merely improvements to existing ones. The review underlines concern about the perilous state of the NHS capital budget for new hospitals and other critical equipment such as scanners.

Attempts to digitise the NHS over the past 20 years have largely failed – some projects spectacularly so. The parliamentary public accounts committee condemned the 2002-11 national programme for IT (cost: £9.8bn) as one of “the worst and most expensive contracting fiascos” in public sector history, for instance.

There has probably never been a worse period in which to introduce expensive new IT in the NHS than the 2010s. On several occasions during that decade, funds that had initially been earmarked for digital development were snatched back to meet more immediate needs. It seemed an easy target because of Westminster’s reluctance to invest further after the earlier shambles and because digital projects rarely delivered immediate returns, unlike giving hospitals more money to spend on staffing. But digital tech is now seen as a high priority (see “Why the NHS’s paper-ectomy is way more than a cosmetic procedure”, p26).

A brain drain from primary care

The NHS’s primary care services are treating 11% more patients with 5% fewer GPs, compared with five years ago. The government has admitted that the manifesto pledge to recruit 6,000 more GPs by 2024 is unlikely to be met. The number of fully

“**Nothing is more fatal to the spirit of our staff than the feeling that they cannot provide the service their patients need**”

Staff shortages

Five years ago, the NHS’s biggest problem was a shortage of cash. Now it is a shortage of labour.

The British Medical Association (BMA) has reported that there were more than 100,000 vacancies in NHS hospitals for healthcare professionals in March, including 39,000 for nurses and 8,000 for doctors. The average number of doctors per 1,000 people in the 22 EU nations that are OECD members is 3.7. In England, the figure is 2.9.

According to the BMA, England would “need the equivalent of an additional 46,300 doctors simply to put us on an equivalent footing with today’s OECD standard. High vacancies create a vicious cycle: shortages produce environments of chronic stress, which increase pressure on staff and in turn encourage higher turnover.”

Brexit has made it more difficult to put us on an equivalent footing with today’s OECD standard. High vacancies create a vicious cycle: shortages produce environments of chronic stress, which increase pressure on staff and in turn encourage higher turnover.”

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Critics noted that this was because he was a member of two successive Conservative governments that had been determined to restrict expenditure on the NHS as part of their austerity policies.

qualified GPs working full time fell by 1,737 between September 2015 and May this year.

Social care’s malaise

The NHS and the social care systems are supposed to work in harmony. When one doesn’t perform, the other suffers. In May, the Association of Directors of Adult Social Services reported that almost 170,000 hours of home care could not be delivered because of staff shortages.

“The cost-of-living crisis is worsening the situation, as local authorities are outbid by local firms desperate for staff,” says Matthew Taylor, CEO of the NHS Confederation.

Potential treatments

Integrated care systems

Established in July, ICSs mark a restructuring of the NHS, a revolutionary change of philosophy and the end of the internal market introduced by the Thatcher government in 1990 to spark competition among health authorities for NHS contracts. The new mantra is collaboration, not competition.

There are 42 ICSs, each covering populations of between 500,000 and 3 million people. The idea is to encourage joined-up care between GPs, hospitals, local councils and voluntary organisations.

So-called virtual wards are a key example (see “Doctor in the house”, p13). They emerged as a lifeline for hospitals that were running short of beds during the depths of the Covid crisis. Patients were sent home with a smartphone, a blood pressure monitor and a pulse oximeter. They submitted their vital signs on an app to the hospital twice a day, contacting staff immediately if necessary.

NHS England and other proponents of virtual wards think that these can shave a few days off hospital stays and also have the potential to avert admissions in the first place. But there are critics – including leading think-tanks such as the Nuffield Trust – that don’t see any evidence to support this belief.

About 12,000 NHS beds every day are occupied by medically fit patients who cannot be discharged because of staff shortages in care homes. Joined-up care could enable many such patients to obtain the care they need in their own homes, where they would far rather be.

About 12,000 NHS beds every day are occupied by medically fit patients who cannot be discharged because of staff shortages in care homes. Joined-up care could enable many such patients to obtain the care they need in their own homes, where they would far rather be.

Workforce planning: a whole host of headaches

Recruiting and retaining staff is a make-or-break issue for the NHS. Key problems to address include:

Pay discontent

The King’s Fund says that “more than £50bn is spent on the pay bill for the NHS, making pay a significant lever to attract, keep and incentivise staff. However, because pay is the biggest single cost in delivering healthcare, it is often one of the first ways in which costs are contained.”

The public sector’s austerity era meant, for instance, that NHS nurses’ average basic earnings fell by 5% between 2011 and 2021 in real terms, according to the Health Foundation.

“No nurse ever wants to take industrial action, but nothing is off the table for our members,” says Pat Cullen, general secretary of the Royal College of Nursing. “The pressure on nursing staff is unrelenting.”

Unequal opportunities

A 2019 staff survey indicated that one in six NHS workers did not believe that

their employer provided equal opportunities for career progression.

Absenteeism

Sickness absence in the NHS was found to be between two and three percentage points higher than in the rest of the economy, according to the *Interim NHS People Plan* published by NHS England in 2020.

Bullying

Along with other abuse, bullying is estimated to cost the NHS in England at least £2.28bn a year through sickness absence, high staff turnover and lost productivity.

Nearly half of NHS doctors feel that they work in a toxic environment with a blame culture that jeopardises patients’ safety and discourages reflection and learning, according to a survey published in the *British Medical Journal* before the pandemic.

Addressing healthcare leaders at an NHS Confederation conference in June, the body’s CEO, Matthew Taylor, said: “Nothing is more fatal to the spirit of our staff than the feeling that they cannot provide the service their patients need. This is what we face now. To deny it is an act of wilful blindness.”

Genomics

The study of genes enables treatment to be tailored to genetic profiles. It has been acclaimed as the biggest advance in cancer care since the introduction of chemotherapy at Yale University in 1942.

Genomics has the potential to save money and millions of lives by bringing a new level of precision to treatment. For example, DYPD, a gene mutation carried by about 10% of the UK population, can make chemotherapy harmful to the bone marrow, sometimes with fatal effects. Doctors now have a £50 genomics test to identify it.

Genomics can also identify women who will not benefit from chemotherapy, which can cause severe side effects, after breast cancer surgery.

Chemotherapy for breast cancer costs the NHS £248m a year, according to a study published last year by the Norwich Medical School.

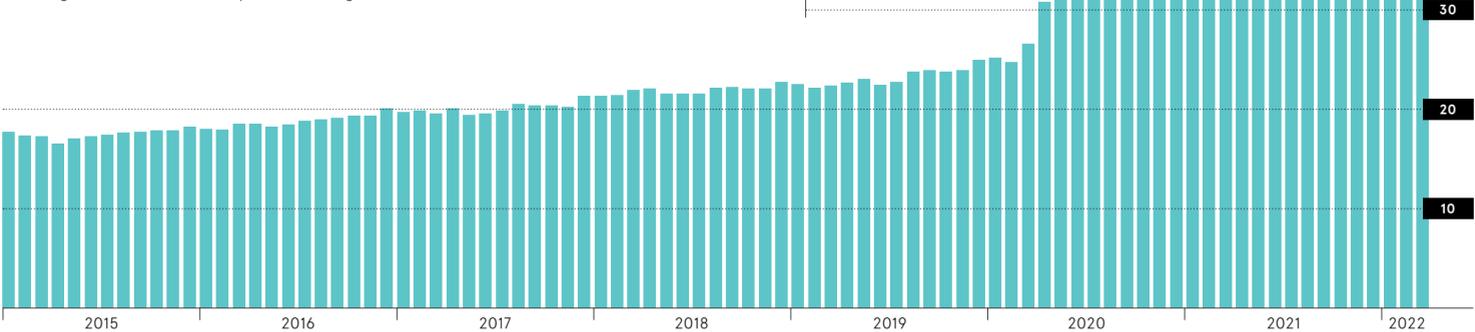
Surgical hubs

Defined as hospitals where Covid is not treated, surgical hubs are dedicated to performing planned operations to clear the waiting list. Nearly all elective surgery was postponed in the first wave of the pandemic.

“Surgery has to be available on the NHS all year round, not stop and start,” stresses Professor Neil Mortensen, president of the Royal College of Surgeons of England. “If a dangerous new variant takes hold, or another bad flu arrives in the autumn, we cannot allow surgery to grind to a halt again.”

WAITING LISTS HAVE SHOT UP OVER THE PAST TWO YEARS

The average number of weeks that NHS patients are having to wait for treatment after a referral



Manufacturing advances are improving gene therapy treatments

The technology and infrastructure behind gene therapy treatments has hampered its route to market. But the future is bright for patients

Medical science is racing ahead as it decodes complex genetics to reveal routes to therapies and cures to the most intractable diseases blighting society.

Cell and gene therapies are booming, with CAR-T cell treatments recognising and neutralising even the most shrouded cancers and Crispr gene editing techniques reaching landmark approvals to tackle rare, life-threatening conditions.

But the science – along with its lifelines to patients – stalls if the mechanics of testing and manufacturing the products at scale do not keep pace.

The scientists who discovered Crispr and its revolutionary ability to change the DNA of animals, plants and microorganisms were awarded the Nobel Prize in Chemistry and their work is leading to huge steps towards curing inherited diseases. However, the costs of enabling this discovery, and other

gene and cell therapies, is as daunting as the molecular complexity but contract testing development and manufacturing organisation WuXi Advanced Therapies – the advanced therapies business unit of WuXi AppTec based in the heart of the cell and gene therapy industry – has refined manufacturing platforms that accelerate these therapies to market.

The company’s innovation arm, Oxford-based Oxgene, specialises in discovery and biomanufacturing technologies that feed into an end-to-end service that ensures transformative science reaches the market and, ultimately, the patient.

“We are passionate about improving and accelerating patient access to the cell and gene therapies that could change, or even save, their lives, which we do through long-lasting and meaningful partnerships with our customers,” says David Chang, chief executive officer at WuXi Advanced Therapies.

He adds: “Manufacturing these products with consistency involves major challenges. It is one thing to have the bright idea, but it takes extra rounds of effort, expertise and ingenuity to make it commercially viable – and that is what we live and breathe.”

Research has identified the manufacturing challenge cell and gene therapy faces in clinical testing and

commercialisation with the implications reverberating from R&D through clinical trials to reimbursement. The manufacturing process involves living cells with inherent variability and high risk from contaminants.

Chang says: “We analyse the process, see the bottlenecks and innovate around them. It is a difficult and economically toxic process. Typically, a research institute or a spinoff company will have a great idea but no experience of how to take it to commercialisation.

WuXi Advanced Therapies has an end-to-end service which acts as a turnkey solution to help them realise their ambitions.”

The annual Mass General Brigham “Disruptive Dozen” report, which showcases emerging gene and cell therapy (GCT) technologies, this year identified breakthroughs such as restoring sight by mending broken genes, CAR-T therapies that take aim at autoimmune conditions, engineering cancer-killing cells that assault solid tumours and harnessing RNA to treat brain cancer. Even more recently, the European Medicines Authority (EMA) has approved the first gene therapy to be delivered directly into the brain for treatment of adults and children with severe aromatic L-amino acid decarboxylase (AADC) deficiency who have a genetically confirmed diagnosis, and the New England Journal of Medicine reported positive results from a phase 1-2 gene therapy trial in patients with hemophilia B.

“We are working with cells, which are difficult to characterise and very difficult to work with, in comparison to small molecules,” adds Cawood. “But, because they have all of those complexities, they have a huge amount of advantages; they can adapt, they can respond, they can interact with human biology in ways that small molecules simply can’t.”

WuXi Advanced Therapies is committed to being an influential partner on the journey from idea to transformative treatment. Chang adds: “Our platforms offer the ability to fine tune testing and manufacture in the shortest possible time and we pride ourselves on the opportunities our systems provide for industry. These techniques offer so much potential to scientists, new and existing companies and, most importantly, to patients. It means hope.”

“**We are passionate about improving and accelerating patient access to the cell and gene therapies that could change, or even save, their lives, which we do through long-lasting and meaningful partnerships with our customers**”

2-5% to 70%

the increase in full capsid production as a result of Tessa vectors

78%

the increase in active clinical trials for CAR-T cell therapies from 2019-2021

Oxgene, 2022

The US-based academic healthcare system is part of a global push to advance cell and gene therapy to transform cancer care and treat conditions that currently have minimal therapies and no cures.

“These are exciting times and we now have treatments for patients who previously had no option. Every cell and gene therapy that makes it to the clinic or commercialisation is a huge step forward,” says Dr Ryan Cawood, Oxgene founder and chief scientific officer at WuXi Advanced Therapies. “Ten years ago, there wasn’t the funding, the infrastructure or manufacturing capability. Now, we have the platforms to see if these products are viable at a much faster pace. We then have the technology and expertise to make them happen and take them to commercialisation.”

Oxgene has developed the Tessa system that allows for large scale adenovirus-associated virus (AAV) production that helps reduce the cost of cell and gene therapy manufacture without compromising on safety. It is part of a suite of technologies that are energising the sector and, crucially, attracting investors to support early-stage science because they reduce the once prohibitive costs of taking some products to commercialisation.

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To find out more, please visit advancedtherapies.com



INTERVIEW

Canterbury tales

David Meates overhauled New Zealand's Canterbury District Health Board so that it became a world-leading exemplar of integration. He believes that a similar approach could prove transformational for the embattled NHS



Oliver Pickup

The maxim "prevention is better than cure" is widely attributed to the philosopher Erasmus of Rotterdam, who died in 1536. Has this adage ever been more apposite for the NHS?

Analysis by the Health Foundation on 13 July found that up to 39,000 extra beds are likely to be required by 2030 in England alone if the service is to restore the level of care it was offering before the pandemic. Scaling up could cost the taxpayer as much as £29bn.

The day before, Public Health Scotland statistics revealed that only 65% of A&E patients had been seen in the week ending 3 July within the Scottish government's four-hour target time, marking the worst performance since weekly records began in 2015.

In the previous week, data from freedom-of-information requests to every NHS trust in England showed that almost 117,000 patients had died last year awaiting care – close to double the pre-pandemic figure. Meanwhile, a record 6.5 million people are awaiting non-emergency treatment.

So, when 42 integrated care boards (ICBs) were created across England on 1 July as part of an NHS shake-up, the fanfare was muted. New pathways, such as blood-pressure checks in betting shops, failed to quicken the pulse of some observers, while the drafting of children's mental health specialists into GP surgeries overwhelmed others. Yet these actions were designed to transform

how healthcare is provided and prevent avoidable premature deaths in the coming years.

But such seemingly mild doses of alternative approaches to medicine could, with injections of trust and collaboration, actually revive the fortunes of the NHS tomorrow. So says David Meates, a consultant on the ICB roll-out. By developing these ICBs and empowering local teams, communities and people, the potential of "precision health" – an approach to care that's integrated, efficient, highly personalised and designed to cut hospital stays and costs – can be realised, he argues.

Meates is well placed to comment, having led the transformation of the Canterbury District Health Board (CDHB) in New Zealand. His organisation came to be seen as a world-leading exemplar of integrated health pathways. (But even paragons aren't immune from being restructured out of existence: at the end of June, the CDHB and 19 other district health boards were merged into a new body called Te Whatu Ora Health New Zealand, which oversees the day-to-day running of the system for the whole country. 'Te whatu ora' translates loosely from Māori as 'the weaving of wellness'.)

As CEO of the CDHB in 2009-20, Meates was responsible for the health of about 600,000 people. He inherited an organisation in desperate need of reform. Indeed, when he arrived, there was "internecine warfare" between various stakeholders

– hospitals, GPs, care homes and pharmacies – according to Meates.

The divisions generated by these self-interested factions had led to a "complete breakdown of trust and confidence of the community. Frankly, the very broken system couldn't keep doing what it was doing," he recalls, pointing out that the CDHB had been unable to hit its targets and was "perpetually in deficit". Sound familiar?

Seeing so many functions pulling in different directions, he understood that there was "nothing binding them together and no shared sense of purpose – a common 'why?'"

Meates set about reasserting the core aim of the CDHB: to improve the integration between community and hospital care by rebuilding trust. He resolved to use relatable language and build a social movement that engaged various cultures and created a simple, user-centred vision for a better health service. His



We continue to see the impacts of fragmented care based on the organisation's needs instead of the person being at the centre of service design and delivery

12%

The proportion of New Zealand's population that was covered by the Canterbury District Health Board

Te Whatu Ora Health New Zealand, 2022

work aimed to make healthcare preventive rather than reactive, giving patients and communities the tools and knowledge to take better care of themselves.

First, he invited the factions to an open forum to try to understand their frustrations and rebuild trust.

"We involved people from outside the system to stimulate those conversations, because stakeholders in this sector often look at problems through an internal lens," Meates says. "Using other organisations as a part of the engagement also makes for a safer forum for conversations that otherwise wouldn't be held."

Through these discussions with medical and community leaders, and also interactive workshops that hinted at what could be possible, a clear vision of what stakeholders wanted Canterbury's health system to look like appeared: one that is connected, centred on people and

aims not to waste their time. Meates' objective was to empower people motivated by having "co-designed the vision" to take the actions required to realise that vision.

To illustrate and so simplify the vision, the team drew a one-page diagram showing Agnes, a fictitious 85-year-old in the middle, and the relevant health services around her. Using a persona helped to change the attitudes of those within the healthcare system and, crucially, the wider community.

"We had a large, ageing population, so this helped us understand what that typical person might look and feel like. This was different from the cold, hard way of thinking of things as outcomes or outputs," Meates explains. Having the core focus of serving Agnes better made decision-making easier, drastically improving cost-efficiency.

Using the persona of Agnes to articulate the new vision led to other "game-changing" benefits, he adds. "Coming from a person-centred view of the world enabled us to engage with our indigenous populations in quite different ways."

Almost 10% of the population that was covered by the CDHB is of Māori ethnicity, while just under 3% is of Pacific origin.

"We stopped talking about them as hard-to-reach communities and, after putting the lens back on to us, realised that we were a hard-to-reach health system," Meates says. "We flipped things around and



It is said that 'change happens at the speed of trust', yet so much of our health and social care system is built on distrust

made the community part of the solutions and ownership."

There was more engagement with churches – which are central to the Pasifika community – and hairdressers, who were encouraged to refer older customers if they were having trouble getting out of their chairs.

"We wanted to stop elderly people falling and ending up in a hospital, so we empowered people to refer anyone who seemed to be struggling to a strength-based programme. This resulted in a massive decrease in the number of falls," Meates says. "We've saved thousands of people from dying that way."

Meates stepped down as CEO of CDHB in late 2020 but was soon persuaded to travel halfway around the world to offer guidance on the ICB roll-out. From September 2021 to July 2022, via Lightfoot Solutions, he worked with various health systems in Wales and England.

Having recently returned to his homeland to contest the mayoralty of Christchurch, Meates offers some reflections on his time in the UK.

"It is said that 'change happens at the speed of trust', yet so much of

our health and social care system is built on distrust," he argues. "We continue to see the impacts of fragmented care based on the organisation's needs instead of the person being at the centre of service design and delivery. Funding and contracts dominate the discussions and are often the key performance metrics, with limited visibility regarding patient outcomes."

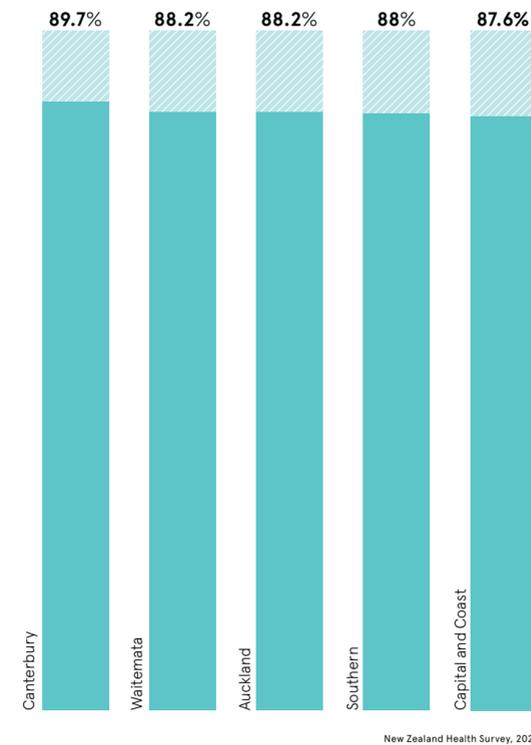
Meates believes that NHS leaders and strategic decision-makers in other sectors should be looking to the future rather than getting stuck in "crisis management" mode.

The temptation is to revert to what the system has always done to deal with crises. This means that the necessary system changes will keep getting "put into the 'too hard' basket". Without the will to focus on the future, the health and social care system will continue to be "overloaded and under siege".

He continues: "It's a fundamental shift of mindset. Most of what we use today is of limited value to tomorrow, yet we're still trying to use everything from yesterday to solve tomorrow's problems." ●

THE POPULATION OF CANTERBURY HAD THE HIGHEST SELF-RATED HEALTH RANKING IN NEW ZEALAND

The nation's top five health districts, ranked by percentage of the population that rated its health as 'good' or above in 2021



Commercial feature



Breakthroughs boost liver disease prospects

Primary Biliary Cholangitis (PBC) causes misery to thousands in the UK but medical research and the campaigning work of the PBC Foundation are improving diagnosis, treatment and disease management

Hope is on the horizon for people living with Primary Biliary Cholangitis (PBC), a long-term auto-immune condition that causes acute liver damage and reduced quality of life.

The condition, which results in bile acid inflaming, damaging and scarring the liver, has no therapeutic cure and symptoms are often overlooked or misdiagnosed, which has historically led to an average five-year wait before effective treatment.

But a series of clinical breakthroughs and campaigns by the PBC Foundation are encouraging drug development and improving condition management by raising awareness among the public and medical profession.

There are in excess of 20,000 people in the UK living with PBC, many of whom are believed to be undiagnosed. This is because their main symptoms, usually fatigue, an itch under the skin, joint and muscle pain, and brain fog, are often ascribed to other conditions.

"The result is that many people endure these symptoms unaware of PBC, and their personal and work lives can suffer when they could be getting the help they need," says Robert Mitchell-Thain, CEO at the Edinburgh-based PBC Foundation. "Their quality of life is impaired significantly and it is still taking too long for patients to reach a diagnosis."

"PBC affects nine times more women than men and many are told all sorts of nonsense before reaching a diagnosis, such as 'we are all tired' or even that they are going through the menopause. We are committed to raising awareness among the medical profession so they can make swifter diagnoses and patients can

take ownership of the condition and lead fuller lives."

The Foundation is a leading force for education and research around the condition. It is collaborating with pharmaceutical companies and regulators to improve the prospects of clinical trials and accelerate treatments and a potential cure.

"We need to highlight to healthcare professionals [HCPs] the extent of symptom burdens that people living with PBC experience," says Mitchell-Thain. "We also need to empower patients with the confidence to discuss their quality of life with HCPs so it can be prioritised in their treatment."

HCPs look to other conditions first to explain the fatigue, brain fog, and joint and muscle pain that characterise PBC but, when they do consider it, the standard antimitochondrial antibody blood test is 95% accurate at detecting the presence of PBC.

"That all said, disease progression is very different to symptom burden and we absolutely must tackle both aspects of this incurable disease," says Mitchell-Thain.

With no cure, an early diagnosis is essential in ensuring patients can try existing first- and second-line therapies, and develop an effective management of their condition. Early diagnosis and successful treatment can lead to a normal life expectancy, however if either of these aspects are missing it can lead to deterioration that can eat into both physical and emotional wellbeing.

The foundation is leading work to create a clinical methodology that measures symptoms in a way that works for PBC patients, clinicians and regulators. It involves adapting tests known as the Global Clinical Impressions (CGI)

scale, which measure symptom severity and are approved for other conditions.

The research work could lead to a stronger clinical trials framework that could see therapies developed at pace to provide effective management of the condition and its symptoms from an early diagnosis.

The foundation has supported research across the disease space, including developing a quality of life measurement tool and focusing on potential triggers that confuse the body's immune system and increase the impact of symptoms on quality of life.

"We have 15,000 patients from 80 countries using our services and, because of the unmet need, we have a huge responsibility and opportunity to make a difference to their and their families' lives," added Mitchell-Thain.

"GPs rarely encounter PBC and the time taken to reach a diagnosis can really impair the management of the progression of PBC, particularly in terms of their quality of life and the psychological impact. We are working hard to change that and, although there is a lot still to be done, the signs of change are promising."

For more information please visit pbcfoundation.org.uk

pbc foundation
support for life

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UK-NP-PB-0801, Date of Prep: July 22

The digital revolution in care: delivering the best outcomes for residents

Health providers are harnessing the power of technology to provide personalised, high-quality care services

Technology is at the heart of the government's new health data strategy, which includes a promise of the rapid digitisation of social care by 2024. Bupa is leading the way with a widespread digital transformation across each of its care homes and villages (around 130 in total) as it looks to overhaul healthcare in its care and retirement settings.

"We see digitisation as essential for the future," says Rebecca Pearson, general manager for Bupa Care Services. "Technology enables our people to spend more time on the most important part of the job; face-to-face, quality care for residents. By making our processes more efficient with technology, we can offer really personalised care. Our people form strong connections with our residents in our homes and villages and provide a life-enhancing experience."

One example of this is in dementia care. At first glance, Bupa's Richmond Villages Willaston looks like a modern flat development. But the six ground-floor neighbourhoods are in fact part of a specialist village for people in the early stages of dementia. It's one of the first of its kind in the UK, where treatment is tailored to the individual. 'Homemakers' are on hand to help residents continue doing chores and hobbies they enjoy, enabling them to maintain their independence whilst also being there as discreet support as needed round-the-clock.

But it's innovative technology that sets this model apart. At night, residents are acoustically monitored using technology inside their bedrooms that alerts staff if there are unexpected changes, indicating that someone is unwell or confused. Staff can act quickly if needed while otherwise enabling residents to get an undisturbed night's sleep, maintaining their independence and quality of life.

It's not just in dementia care where technology is changing the face of care services. Traditionally, staff in care homes have always filled out paper notes throughout their shifts including details about medication, wellbeing and feedback from the residents. It's a time-consuming process that delays the feedback loop required to implement change quickly. But most importantly, it reduces the time a carer can spend having a conversation with a resident and building a positive, trusting relationship.

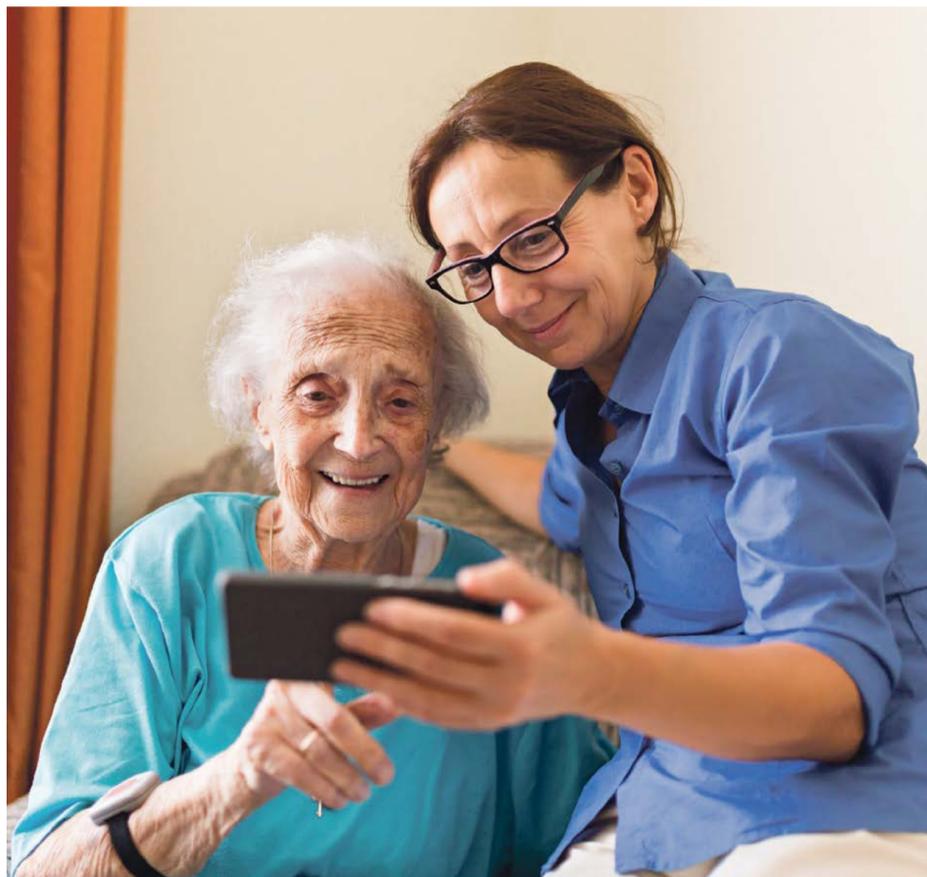
But a host of digital tools have been designed to change this and are now available to Bupa healthcare workers

via a handheld device. Using eCare, carers now record every interaction with residents in real time, freeing up capacity for the real relationship-building that's essential for high-quality care. April Parrott-Carter, home manager at Field House Bupa Care Home in Hertfordshire says: "We can now record notes on the go rather than afterwards in another room. This means that staff can record more detailed, up-to-the-minute accurate notes. They can also add more information about the resident's mood, what they chatted about or what activities they had been taking part in. We used to spend an hour a day on paperwork, but now it just takes minutes."

Another step-change is that the information recorded can be accessed by residents' families in real time. This helps build up a full picture of what life is like in the home and how their loved ones are doing day to day. They can also choose ideal times to visit based on real-time information about their mood and behaviour. "Relatives have told me that they now sign in a few times a day to see how their relative is and what they're up to, and especially the food they're eating. They really enjoy having that insight," says Parrott-Carter.

Attitudes towards technology in a care setting are changing, and expectations of standards are higher than ever. A recent study carried out by Bupa found that nearly 60% of those surveyed want to see more use of technology in care homes and feel it could provide more personalised and safer care. An overwhelming 75% also agree that tech could help carers to free up time.

"It's what families expect to see, and increasingly, it will be what our residents expect too as we all become more technology-savvy. So it's important that we lay the groundwork now," says Pearson. "And crucially for us, technology is helping our people



get back to what they love. Our people tell us they want more time to care. That's why they came into this profession. So it's up to us at Bupa to help make this happen."

Taking its digital transformation one step further, Bupa workers will soon be utilising an electronic medical records system. This is designed to reduce the time it takes to administer medications safely and improve clinical outcomes, by creating a joined-up service that all health professionals, such as physiotherapists and GPs, can access and input records into.

As well as adding notes in real time about changes to care plans and medications, this also makes it easier to refer back to previous notes to look for patterns and factors affecting residents' health, with residents' full medical history available in one place, at the touch of a button.

All of Bupa's quality monitoring processes are also now stored in a digital quality and compliance solution, which has been rolled out in each of its homes and villages. It helps care home managers to oversee and

manage the core tasks they need to do to carry out quality monitoring and then make swift changes to day-to-day processes if necessary. Stakeholders and regulatory partners can also be updated with the click of a button, so managers no longer sift through files. With high standards and infection control measures essential, this thorough record-keeping enables Bupa care teams to demonstrate the robustness of their standards to regulators and authorities.

It's not just about quality or compliance. A pilot project is underway trialling the use of a dementia memory game app which allows carers and families to play hundreds of personalised memory-provoking games with residents to enhance the quality of their time together.

Pearson says: "The use of digital tools and better data allows us to drive up quality standards and care outcomes for our residents. But ultimately, it's the human connection that is at the heart of our digitisation journey. As residents adjust to a new life and environment, or deal with

dementia, it's the people caring for them that bring fun and laughter back into their lives. Through the use of technology, we want residents to have more of this essential connection with our teams, so that they feel at home and enjoy their time with us." Technology was once seen as an interface that symbolised the physical distance of separated loved ones. Now, it's being harnessed to provide long-term solutions that keep families connected, improve the quality of care in care homes and villages across the UK and bring independence, meaning and happiness back into the lives of people in their later years.

For more information, visit bupa.co.uk/care-services



Technology enables our people to spend more time on the most important part of the job; face-to-face, quality care for residents

REPRODUCTIVE RIGHTS

What the reversal of *Roe v Wade* means for US employers

To give itself and its staff maximum protection, any firm seeking to help employees who need to travel for an abortion should ensure that it understands the legal implications

Sam Forsdick

In the aftermath of the US Supreme Court's ruling on *Roe v Wade*, which on 24 June revoked the constitutional right to terminate a pregnancy, several large companies rushed to pledge their support for employees affected by the landmark decision. Airbnb, Disney, Google, JP Morgan, Netflix, Patagonia and Starbucks were among the first to promise financial help for members of staff who could be obliged to travel out of state to access the reproductive healthcare services they required.

As this special report goes to press, Texas is set to enshrine the Supreme Court's judgement into state legislation. In effect, this will

place a near-total ban on abortions within its borders.

Canva is an Australian software firm that has offices in Austin, Texas. It has committed itself to covering the transport and accommodation costs of any US employee travelling to terminate her pregnancy, as well as those incurred by a companion of her choice.

"We are deeply concerned by the court's decision," says a spokesman for the company. "Canva is committed to creating an environment where our team feels safe and supported in the choices they make for themselves and their families."

The swift responses of these businesses indicate their commitment



to women's rights, while providing some reassurance to employees.

Employers can support their staff in myriad ways, including expanding healthcare plans and providing extra paid leave. That's the view of Amanda Monroe, a senior litigation associate specialising in employment at Michelman & Robinson, a law firm with offices across the US.

"Beyond that, we may see employers take on the risk of continuing to offer pre-existing travel and relocation benefits and/or expanding health benefits to include travel and lodging for those seeking abortions," she predicts.

But there are legal implications to consider. Monroe warns that many employers will need to look at "the extent to which specific state laws restricting abortion may affect leave accommodations, healthcare plans and employment practices".

Facebook's parent, Meta, is another company that has pledged to

The Supreme Court's decision generated a wave of protests (and counter-protests) around the country

fund out-of-state travel for employees seeking abortions. But it clarified in a recent statement to the *New York Times* that any support provided would be to "the extent permitted by law", adding: "We are in the process of assessing how best to do so, given the legal complexities involved."

Numerous Republican-controlled states have already clamped down on the act of expediting someone's access to reproductive care, including funding the costs of an abortion through insurance. In Texas and Oklahoma, for instance, any person or organisation deemed to be helping someone to obtain an abortion after the sixth week of pregnancy could be subject to a civil lawsuit.

Mahir Nisar, principal at employment litigation specialist Nisar Law Group, considers this aspect to be one of the biggest potential legal risks that employers will need to take into account.

Adding to the complexity is the potential for staff to challenge employers with a US-wide presence that don't apply their abortion policies universally, he says. Firms offering support to employees in states with laws against aiding and abetting abortions will be at risk of getting sued. But, equally, if their policies apply only to staff in those jurisdictions, these could be challenged on the grounds that they could be discriminatory.

"This makes it somewhat difficult for firms to navigate," Nisar says. The other key consideration will be how to protect an employee's privacy, according to Monroe. This "remains paramount", she stresses. "Companies, especially those that offer travel-related reimbursements for employees travelling out of state for care, will have to balance the need for employee privacy relative to medical decisions and treatment against internal policies requiring proper documentation for expense management purposes."

To preserve confidentiality, employers may have to revisit their

healthcare provisions and/or policies governing leave. Monroe suggests that they could consider expanding the list of treatments that are eligible for travel expense reimbursement and/or time off, to "avoid the potential exposure of private medical information".

To address this, organisations could consider including abortion-related care to their list of treatments – radiotherapy or chemo, say – that are automatically eligible for travel expenses to be paid. This would enable anyone to apply for reimbursement without having to specify the reason.

LaDawn Townsend, founder and CEO of consultancy VOS Group, offers some advice for employers whose healthcare plans don't offer such facilities.

"There needs to be a way for the employee concerned to talk directly to someone senior in HR, who can then communicate with their manager, without going into details, if a service has been provided," she says. "Organisations will really have to tighten up on their internal communications and HR standards."

Similarly, companies may consider removing the requirement on employees to provide a detailed justification when seeking leave to undergo medical treatment.

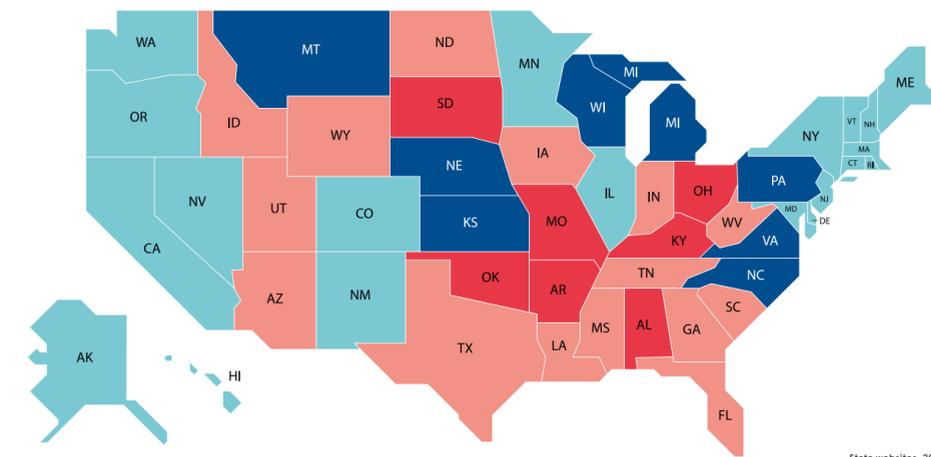
Nisar reports that "a lot of employers are saying that they don't need to know the reason for the medical procedure, but we're waiting to see how that works in practice".

He adds that, while firms have been quick to pledge their support for women's reproductive rights since the *Roe v Wade* reversal, their new policies have yet to be tested.

Nisar believes that many such declarations could be perceived as a "branding" exercise, undertaken by companies eager to be viewed as "on the right side of history". In his view, it's down to them to develop effective policies to support female employees – and so demonstrate that their actions are more than "performative allyship".

THE LEGAL STATUS OF ABORTION ACROSS THE US

● Legal ● Unclear or under threat ● Likely to be banned soon ● Banned



State websites, 2022

WELLBEING

From poorer to poorer

Covid may have battered the NHS and threatened the nation's health, but soaring inflation and concerns about the cost of living could prove just as detrimental to our wellbeing

Danny Buckland

The NHS has emerged from the depths of the Covid crisis battered, bruised and weighed down by backlogs. The forecast for its recovery is unlikely to improve any time soon, with the cost-of-living crisis set to have a profound and lasting effect on how the service functions.

The costs of basic essentials such as energy, food and fuel are soaring, the Bank of England is predicting yet more budgetary turmoil and there is talk of a looming recession.

As wages lag behind inflation, people are putting in longer hours, working through illness and taking second jobs to make ends meet. Many thousands of hard-up people are turning to the gig economy – clocking on for shifts as taxi drivers, delivering food, selling homemade crafts or completing paid tasks online, for instance.

None of this is good for the nation's health and wellbeing. A survey published recently by Totaljobs indicated that 17% of Britons had taken on extra work or a second job. Well over three-quarters of respondents (78%) said they were experiencing burnout as the stress of managing their shrinking funds hit home.

Research from Aviva also revealed that 38% of people who had started a

second job since the start of the pandemic were using these funds to cover day-to-day expenditure on rent, food and clothes.

As parents struggle to feed their families and heat their homes, doctors are concerned that the health of millions of children could be damaged by the cost-of-living crisis.

Dr Camilla Kingdon, president of the Royal College of Paediatrics and Child Health, has warned of a "generational impact", for instance. And William Roberts, CEO of the Royal Society for Public Health, says: "The tough times are getting even tougher, which is having a big impact on the public's health."

People are already doing all they can to earn more and spend less, he adds, yet households are having to make "increasingly difficult" daily financial decisions as the cost of essential goods continues rising.

Some people are having to skip meals so that they can afford to buy enough petrol to be able to drive to work, Roberts says. "These decisions are not only bad for your physical health but also really stressful."

Anecdotal reports from GPs confirm that patients are struggling both physically and mentally.

"It's clear that the cost-of-living crisis is deepening and is leading to



libphphoto via iStock

extreme stress and the worsening of mental and physical health," says a doctor at a busy Surrey practice, who asked not to be named. "Coming out of the Covid crisis, people seem to be less resilient than before. As patients are being exposed to common ailments again, their more fragile mental and physical health is rendering them less able to deal with these illnesses as resiliently."

“Employers have a fundamental duty of care to the health and wellbeing of their workforce – and it should be an absolute priority for organisations

He advises taking exercise, maintaining a good diet and seeking help, but acknowledges that this isn't always possible. "Healthier foods, gym memberships and exercise classes are luxuries that many more people won't be able to afford."

He stresses that it's important for people to be "proactive" and consult their GPs for advice on more affordable exercise options and healthy lifestyle choices, as well as speaking to employers for workplace adjustments or financial help.

Companies of all sizes are themselves facing pressures from all directions, with rising costs, skills shortages, supply chain disruptions and dwindling margins on top of the inflation spike and general economic uncertainty.

Ben Willmott, head of public policy at the Chartered Institute of Personnel and Development (CIPD), is all too aware of the effects that the cost-of-living crisis is having on

employers and workplaces. He says that problems caused by stress and the impact these can have on people's mental health should be at the forefront of managers' minds.

"Employers have a fundamental duty of care to the health and wellbeing of their workforce – and it should be an absolute priority for organisations," he says. "It's a very challenging environment in lots of workplaces. This is why people managers are talking to employees about their workloads, ensuring that their objectives are realistic and problem-solving so that people aren't under excessive pressure."

Willmott points out that many companies have strengthened their wellbeing offering and have added financial counselling to help employees solve money problems.

"This is where they can make a material difference to employees, their work/life balance and their health," he says, adding that the

CIPD is keen for the government to explore regulation on flexible working and employment rights.

Meanwhile, Totaljobs' research indicates that employers want the government to reduce energy bills, scrap the planned increase in national insurance contributions and introduce other measures to ease the cost-of-living crisis.

The CEO of Totaljobs, Jon Wilson, observes that the high level of open vacancies is placing an even greater burden on understaffed teams to the point that their workloads are becoming unmanageable.

"While employers are making good strides in offering wellbeing initiatives, skills shortages mean that many workers will continue to feel the pressure of empty seats in their teams," he says. "This factor, combined with the ongoing strain caused by the cost-of-living crisis, means that businesses need to create an environment where people feel their voices are heard and their mental health is cared for."

Changes at policy level are also needed to lessen the pressure of rising living costs, he adds.

Jonathan Portes is professor of economics and public policy at King's College London and a former chief economist at the Cabinet Office. He observes that the post-Brexit staff shortages have given many workers bargaining power. But, while flexible working has been financially rewarding and liberating for some, matters have been very different for those at the other end of the labour market.

"Zero-hours contracts give power to the employers rather than the employees – and people feel they don't have control of when they work and how," Portes says. "The pressures from the current cost-of-living crisis risk making that worse. Some people will feel they have to accept second jobs, or jobs where they don't have control over their hours and have a balanced work and family life."

The mayor of Greater Manchester, Andy Burnham, spoke to the BBC recently to point out that the anticipated energy price cap increase in October and rising food

“The cost-of-living crisis is deepening, leading to extreme stress and the worsening of mental and physical health

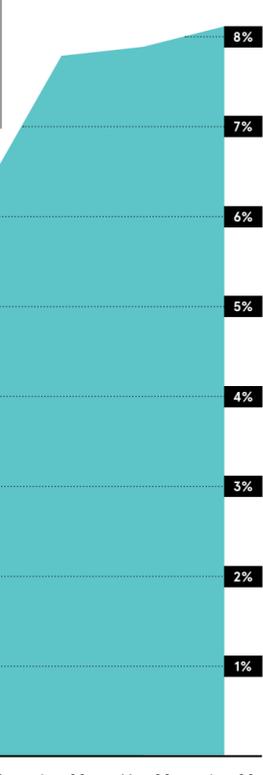
costs, caused partly by cereal crop failures in Ukraine, would only heighten the financial pressure on British families in the autumn.

"It is not just a health crisis; it is a mental health crisis," Burnham stressed, adding that it required "much more decisive action from the government right now".

Healthcare workers are not immune from cost-of-living pressures, of course. They too are taking on extra work to fund basic living costs or being tempted to move to higher-paid sectors, creating a potential NHS skills drain.

A survey by a campaign representing 13 NHS health unions found that the pressure of staff shortages was harmful to their wellbeing. The poll also revealed that 80% of health workers were thinking about quitting because their pay was being outstripped by inflation.

The turmoil that's engulfed Boris Johnson's government in recent months has added to the uncertainty. Finding ways to recalibrate the economy – and stabilise health and health – will surely be at the top of his successor's in-tray. ●



THE UK'S INFLATION RATE IS SOARING

Consumer prices index including owner-occupiers' housing costs

Office for National Statistics, 2022

May 20 Jun 20 Jul 20 Aug 20 Sep 20 Oct 20 Nov 20 Dec 20 Jan 21 Feb 21 Mar 21 Apr 21 May 21 Jun 21 Jul 21 Aug 21 Sep 21 Oct 21 Nov 21 Dec 21 Jan 22 Feb 22 Mar 22 Apr 22 May 22 Jun 22

Commercial feature

Q&A

The future of health testing

Jack Tabner, director of strategic partnerships at Thriver, explains how tele-diagnostics will transform healthcare for patients, businesses and the NHS



Q What diseases do Thriver's diagnostic tests target?

A Thriver offers blood tests that check for biomarkers that indicate risk for a wide number of chronic conditions, such as diabetes, dementia, heart disease, cancer, IBD and hypothyroidism.

Q How can consumers benefit from tele-diagnostics?

A Remote testing and monitoring could improve the health of millions of consumers, especially those managing long-term health conditions. Regular health checks lead to better health outcomes, fewer deaths, and a reduction in emergency admissions and amputations.

Patients can choose when and where tests are completed, what types of tests are done and the method by which a sample is taken.

Q What's the advantage of tele-diagnostics for practitioners?

A Activities currently taking up time and resources will be reduced, as certain patients are supported to regularly test themselves at home. This enables practitioners to know who to see, as is already the case with diabetes and NHS health checks. As technology advances, patients on clinical trials, for example, can be monitored remotely.

We believe routine testing at home and sophisticated use of biodata will enable people to proactively take care of their health – sometimes even before they get sick.

Q Tell us about your partnerships with healthcare organisations and private companies

A Thriver has reached more than 2 million people via at-home tests. We developed a Class I medical software device to help individuals understand and take action to improve their results. We also helped to deliver remote diagnostics for the government's Covid antibody testing programme.

Alongside our consumer devices, we've created a platform that enables healthcare organisations and private companies to scale remote diagnostics, bringing testing to people in their homes and on the high street. We can provide the infrastructure for remote testing at scale and integrate it with existing digital systems to deliver insights via a simple API.

Q How can Thriver testing help with disease prevention and why is this a key focus?

A The company's mission is to increase the time people spend in good health: their 'healthspan'. It is estimated that more than 20% of people's lives are spent in poor health. On average, males born today can expect to live 16 years in poor health. For females, it's 19 years.

Preventable long-term conditions cause most mortality and morbidity in the UK. The growing burden of chronic diseases relates to behaviour and physiology, which can be changed. We must build a public health system that supports people to make healthier, informed choices from a younger age, before it's too late.

number of chronic conditions, such as diabetes, dementia and heart disease, which are all linked to mortality. There's strong evidence that following effective lifestyle advice reduces risks.

Thriver tests clearly show what's happening inside a person's body now and indicate how healthy they can expect to be in future.

Health promotion can't be left entirely to overstretched NHS professionals. We believe lifestyle and prevention diagnostics will help to flatten the demand curve in 15 to 20 years.

Q How does Thriver's ethos fit in with NHS goals?

A Along with telemedicine and telepharmacy, tele-diagnostics helps individuals access care safely and conveniently. We see this with the demand for virtual GP appointments and the rise of patient-initiated follow-ups in hospital outpatient settings. And we'll see this more as virtual wards free up acute hospital beds.

By drawing lessons from sexual health and bowel screening programmes, leaps in data curation and analysis, and genetic testing, Thriver will play a key role in screening for diseases such as Covid, as well as cancers and hereditary conditions, providing integrated care systems with data to conduct research, plan and stratify risk.

The vaccine programme showed that certain demographic groups are at greater risk of certain diseases and, sadly, less likely to access healthcare. By offering convenient testing to these groups, we believe Thriver can reduce health inequalities.

For more information, visit thriver.co/solutions



“Routine testing at home and sophisticated use of biodata will enable people to proactively take care of their health

Q Can Thriver tests be used to prevent poor health?

A Yes. The biomarkers we test for can indicate risk for a wide

A dose of digital: what digitalisation means for healthcare

Janssen UK & Ireland managing director, **Gaëtan Leblay**, discusses digitalisation and innovation in the pharmaceutical industry and what this means for patients

Over the past decade, digitalisation of the pharmaceutical sector has progressed steadily. Automation, artificial intelligence (AI) and machine learning offer swift clinical data collection and analysis, and the streamlining of administrative tasks can release time for crucial research. In the past two years, we have all seen the step change that has occurred in healthcare and almost every other aspect of our lives.

I am a passionate proponent of digital transformation and regularly advocate for the value of data and innovation in healthcare. But while the advances we see today are exciting, we must remember that they cannot exist in a vacuum. Janssen UK's digital strategy, as a cornerstone of our business, recognises this point first and foremost. To this end, we have created an ecosystem of trusted partners that consistently create and deliver digital propositions. Together, our goal is to create value through collaboration, and deliver our joint industry goal to ultimately improve patient treatment and outcomes.

The next few years will see the ongoing ripple effect of the pandemic's surge toward digitalisation.² Pharmaceutical companies are in a strong position to guide this innovation in a patient-centric direction.

Janssen's innovation pipeline

At Janssen, we remain committed to a patient-first approach to innovation and have been developing and implementing our digital strategy for the past few years. Guided by our credo, we continue to recognise our first responsibility is to the people we serve. In every project we undertake, we look to innovate with purpose, to create change, and improve outcomes for patients and staff. To better understand our role and application of technology, we first ask the question: how will it improve patient outcomes?

This thinking led to the creation of our own J&J Innovation Centres. These

hubs – based in the UK, US and China – identify, develop and accelerate early-stage science to solve the greatest unmet healthcare needs of our time.³ The centres act as collaborative hubs where entrepreneurs and scientists can develop treatments, technologies and products that directly benefit the patient – and have seen tangible, promising results.

Beyond these centres, Janssen's digital pipeline has yielded real technological innovation that is already being integrated into our processes – one of the most exciting being an augmented reality (AR) application for patients.

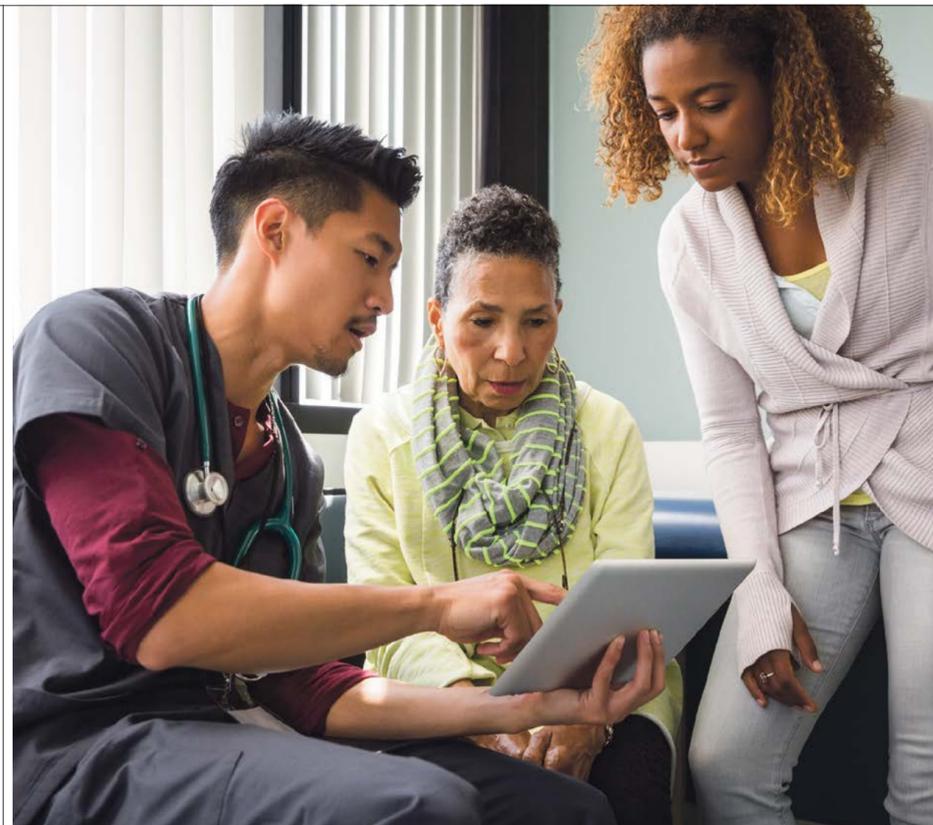
AR in action

When we look at the current landscape, a key area for improvement in both the US and Europe is adherence to treatment, which across disease areas and patient groups is still sub-optimal.⁴ Improved understanding of how such treatments work could make a difference and at Janssen we decided to tackle this challenge in a new way.

An example of this application of new technology is using AR to support patients with their administration of treatments; specifically an interactive AR experience, users of our app can view the treatment and the application instructions virtually, while also accessing further information for correct device usage. The app not only provides insights on device functionality, supporting adherence, but it can also encourage increased engagement between healthcare professionals (HCPs) and their patients.

Many industries are touting the use of AR; sometimes it feels as though we are talking "ambition" versus "reality". I believe that applying AR to tackle real-world problems and education will help empower patients to take greater control of their treatment and, in the longer term, hopefully improve outcomes.

AR is a promising new tool driving positive change for HCPs and patients



alike and I look forward to seeing how it will continue to advance the patient experience. In the meantime, we are also pursuing many other avenues to explore how this technology can be used in furthering medical education.

Crowd solving for patient resources

As technology continues to improve, at Janssen, we are ensuring these developments are harnessed into everyday processes, so we are able to focus our time and resources on projects that make the biggest difference to the lives of patients and their families. With that in mind, we recently reassessed a time-intensive process within the business – the review of educational content used by HCPs and patients.

As the proliferation of digital channels and content continues, reviewers have been facing increased demand to approve materials at a faster pace and on a larger scale. We partnered with Ernst & Young to develop Smart Reviewer, an AI-powered functionality that would streamline our content review process. The integration of AI allows for the swift identification of language or factual errors, and flags information that must be validated. Not only



To better understand our role and application of technology, we first must ask the question: how will it improve patient outcomes?

does this reduce review timelines while maintaining quality standards, it also allows for further efficiencies for the reviewer and frees up time that can, in turn, be applied to other complex tasks. Digital innovation that seemingly occurs invisibly, while still bringing out benefits, is still worth celebrating.

Another way we're looking to supercharge our patient content is via MED Select, a platform that supports the rapid creation of personalised content and patient education resources, to empower patients by providing relevant information tailored to them. MED Select also allows HCPs to develop individually selected resources. Together with our AR solution, these smart materials support patients in taking a proactive role to help manage their condition and to encourage more effective conversations with HCPs.

Developing a partnership ecosystem

Janssen's data and digital vision is bolstered by the infrastructure of strong tech and thought leadership partners. To enable our strategy, it is critical that we continue to source talented, experienced leaders – whether they are a part of the pharmaceutical industry or from unrelated sectors facing similar challenges.

Janssen's strategic partnerships include several world-leading pioneers in digital innovation, from Amazon Web Services to Rolls Royce Data Labs: each with a vision to help us solve business challenges with AI and data-driven solutions. Janssen is also part of the Rolls Royce residency, an incubation group of industry leaders collaborating to solve shared problems. This means we are guided by its Altheia framework – a toolkit to ensure ethics and trustworthiness in AI – so that as our

technology develops, data safety and security are equally focused all along the journey.

As the pharmaceutical industry moves inevitably towards a digitised world, I wholeheartedly believe that we must ensure new innovations work for everyone: for the people in our organisation and, more importantly, for patients and their families. Fortunately, the broader industry is already heading in this direction. I am inspired by the efforts underway at Janssen in championing a collaborative drive to reimagine technology in new ways and evolving healthcare to new levels.

For more information please visit janssen.com/uk



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EM-105676, July 2022

HOSPITALS AT HOME

Doctor in the house

The NHS has been using virtual wards in a bid to reduce its hospital treatment backlog. Has this been a worthwhile investment so far?

Joy Persaud

Waiting lists are rarely out of the headlines, with the number of people awaiting NHS treatment in England rising every month over the two years to this May, reaching a record high of 6.6 million. To help tackle the backlog, NHS England wants its 42 newly established integrated care boards to deliver a virtual ward capacity equivalent to 24,000 beds by December 2023.

The virtual ward has become an effective method of treating certain patients in their homes. The NHS's provision of tech-enabled remote healthcare has enabled people hospitalised by Covid-19 to be safely discharged earlier than they might otherwise be, for instance. It could help to protect the service against being swamped by a further wave of severe infections. And, as the UK's population ages, the demand for outreach care services for people with dementia is likely to grow too.

About 45 hospital-at-home services are in operation at the time of writing. Their shared objective is to care for people who would otherwise occupy acute beds. All the necessary kit is brought to the home, ranging from intravenous drips and breathing equipment to monitors and a touchscreen device with a web connection. Each patient is given clear instructions about what to do if they feel that their condition is worsening or their monitors give an early warning of deterioration. They are also given the contact details of a trained hospital-at-home medic who can triage them and send help if necessary.

"The goal is to provide evidence-based holistic care for acute patients and give them autonomy," explains Dr Chet Trivedy, research lead and consultant in emergency medicine at University Hospitals Sussex NHS Foundation Trust. "Patients fare better in familiar surroundings. They can sleep in their own bed, eat the food they like and have relations, friends and beloved pets

around them whenever they wish. This reduces the risk of hospital-acquired infections and also the risk of falls in people with memory impairments, who may not cope well in hospital. It helps the flow of patients into and out of hospital, allowing some to go home earlier with their medical needs met. It enables others to avoid hospital stays in the first place."

Remaining in a hospital bed for prolonged periods can cause frail patients to lose muscle tone and fitness because they are no longer doing routine activities such as bathing, getting dressed and making meals. Deconditioned patients become stiffer, creating a vicious circle of frailty – so serious that it prompted Professor Brian Dolan, founder of the End Pyjama Paralysis campaign, to describe it as the difference between going home or going into a care home.

With this in mind, Bromley, which is home to more older people than most other London boroughs, has embarked on a pilot scheme called Bromley at Home, under which adult patients are given intravenous antibiotics in their homes. This follows the recent launch of Bromley Children's Hospital@Home as a permanent service.

The project's leader, Elliott Ward, conducted a comprehensive survey of stakeholders beforehand, including Bromley residents and clinicians. He found that 91% of the respondents were in favour of home-based treatment and 89% had no qualms about its provision. The most common concerns centred on the adequacy of clinical training and the use of digital tech.

Ward is adamant that no one will be left behind because of an IT issue. Alternative methods, such as the third sector helping patients to settle at home with the technology, or telephone-based support plus visits, are under consideration.

"We've started a pilot pathway with intravenous antibiotics, with



ambitions for the service to be running across a few pathways before the winter," he says. "We'll gradually expand over the next couple of years if our data supports it."

The scheme is based on a collaboration that started during the pandemic, including planners and providers in the NHS, local government and the wider community. "We're not going to profess that we're there yet," Ward stresses. "There's a lot of work that can be done on how we refine pathways for patients. We're getting residents involved in those design elements through workshops and talking things through, because we professionals tend to see things through a certain lens."

Lorna Redpath is a district nurse and respiratory specialist who has been overseeing Bromley's hospital-at-home team. She ensures that its staff have enhanced clinical and respiratory assessment skills and can manage key processes such as cannulation and the delivery of intravenous medication.

The key benefits of the Bromley at Home approach are that it "provides



It helps the flow of patients into and out of hospital, allowing some to go home earlier with their medical needs met

45 hospital-at-home schemes are in operation

50 virtual beds per 100,000 patients by December 2023 is the target set for the new integrated care boards

NHS, 2022

choice to patients, improves their experience, decreases their length of stay in hospital and reduces complications", Redpath reports.

But, while many people undoubtedly benefit from being cared for at home, the method obviously won't suit all patients, particularly those who don't have a supportive household to rely on.

"For people living alone, we need to think about services from our third-sector supporters, including befriending and sitting services," Trivedy says. "We are clear that acute patients who wouldn't benefit from being home will be treated in hospital. But the holistic approach is a real shift – and we have seen positive results for those whose needs it has been meeting."

This has certainly been true for Rachel Ashley's 15-year-old daughter, Daisy, who has been regularly hospitalised with chest infections. Last year, she entered the care of Bromley Children's Hospital@Home.

"Daisy had bilateral pneumonia at nine months old and has suffered recurrent infections ever since," Ashley explains. "Previously, we'd have had to attend A&E and face an arduous wait to see anyone who had knowledge of her situation. She would often deteriorate quickly and go from seeming slightly unwell to very poorly, needing supplemental oxygen in a matter of hours."

Were there concerns about managing Daisy's condition at home?

"The service was fully explained to us," Ashley says. "It soon became clear that, other than being seen by a registrar or consultant on a daily ward round, she was getting the same care she'd have received as an inpatient. Her oxygen saturation would be read alongside her blood pressure when necessary and her chest would be listened to. If the team had any concerns, these would be fed back immediately to the clinician on duty. Hospital@Home has given us our lives back."

THE UK'S GROWING STRUGGLE WITH MENTAL ILL-HEALTH

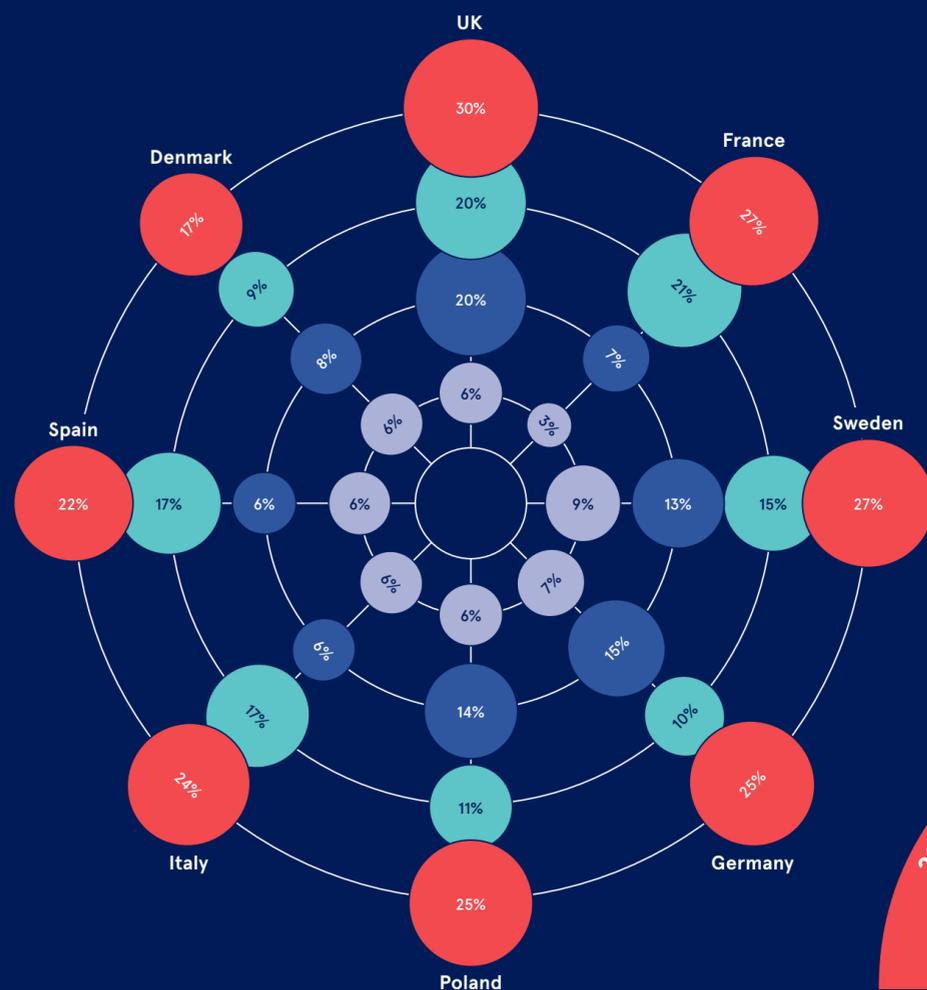
The nation's mental wellbeing has been on the decline in recent years. The consensus is that too many people – from workers reporting job-related burnout to patients seeking treatment for life-threatening disorders – aren't getting all the support they need. And, while the NHS's expenditure on mental health services is rising, the economic costs are growing too

THE UK HAS ONE OF THE HIGHEST RATES OF MENTAL ILL-HEALTH IN EUROPE

YouGov, 2020

Prevalence of mental illnesses in Europe

● At least one mental health condition ● Anxiety disorder ● Depression ● Something else



UK WORKERS ARE INCREASINGLY REPORTING JOB-RELATED MENTAL HEALTH PROBLEMS

Number of people reporting work-related stress, depression and/or anxiety (thousands)

* No data is available for 2012-13

Health and Safety Executive, 2021



THE NUMBER OF DETENTIONS UNDER THE MENTAL HEALTH ACT 2007 IS RISING

NHS Digital, 2022

Detentions on hospital admission in England

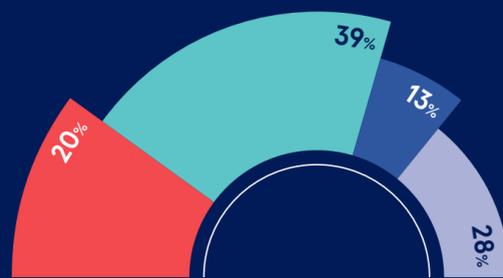


MENTAL ILL-HEALTH IS A LONG-TERM MEDICAL CONCERN FOR MANY PATIENTS

Duration of contact between patients and NHS mental health services in England

NHS, Care Quality Commission, 2021

● Up to one year ● One to five years ● Six to 10 years ● More than 10 years



THERE IS A SUBSTANTIAL BACKLOG IN MENTAL HEALTH SERVICES

NHS England, 2021

The following figures cover Q3 2021-22

1.1 million

people were referred to community-based mental health and learning disability services but were still awaiting their second contact

342,000

people with severe mental illnesses were eligible for all six components of a physical health check but were still awaiting them

77%

of British consumers believe that mental and physical health problems are equally serious
YouGov, 2020

81%

of mental health patients say that they are receiving medication for their needs
NHS, Care Quality Commission, 2020

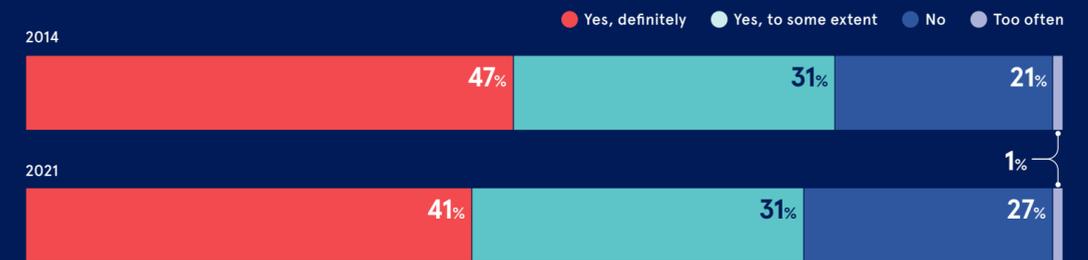
12,745
psychiatrists

were employed in the UK in 2020, up from 8,193 in 2000
OECD, 2021

PATIENTS' VIEWS ON THE FREQUENCY OF NHS MENTAL HEALTH VISITS ARE BECOMING MORE NEGATIVE

NHS, Care Quality Commission, 2021

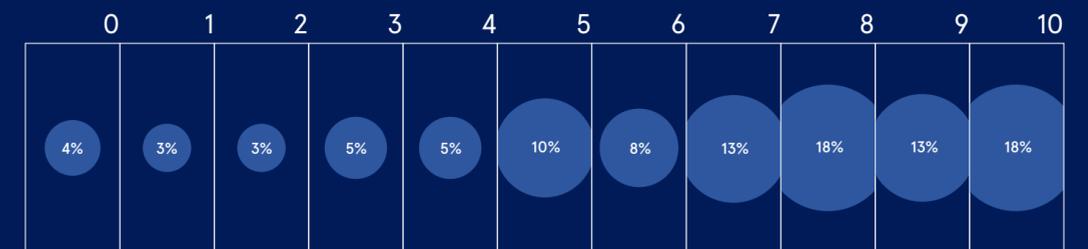
Responses of patients in England when asked if they have received enough attention from NHS mental health services for their needs



SEVEN OUT OF 10 PATIENTS RATED THEIR EXPERIENCE OF NHS MENTAL HEALTH SERVICES AS BETTER THAN AVERAGE IN 2021

NHS, Care Quality Commission, 2021

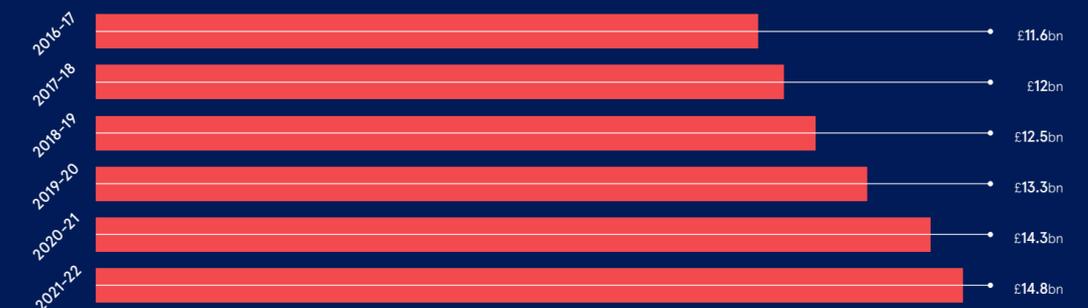
Patient ratings from 'very poor' (0) to 'very good' (10)



NHS EXPENDITURE ON MENTAL HEALTH IS RISING

NHS England, 2022

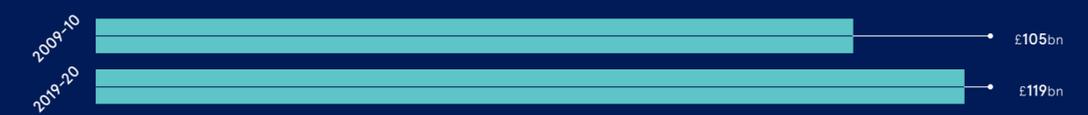
Annual spending on mental health services since 2016-17



THE COST OF MENTAL ILL-HEALTH TO THE UK'S GDP INCREASED BY 13% IN A DECADE

Centre for Mental Health, 2020

Estimated annual cost to the economy



Breaking new ground in the fight against cancer

With innovative cancer screening tests now available, care may be revolutionised for millions of patients

When a friend developed cancer some 20 years ago, biochemist Randy Scott began exploring the potential of genomics, the study of genes, to understand the disease. He developed the ground-breaking Oncotype DX tests designed to transform treatment decisions of certain cancers. More than a million people worldwide have now received the Oncotype DX test¹.

Breast cancer

Central to the genomics revolution transforming cancer care, Oncotype DX testing, among other things, identifies gene expression in cancer cells^{2,4}. Take breast cancer for example. So-called adjuvant, or additional, therapy is a key part of treatment. This can include chemotherapy after surgery when there may be uncertainty about whether or not the operation has totally eradicated the tumour⁵.

The problem is that not all women benefit from chemotherapy⁶. Dr Richard Simcock, who has been a consultant clinical oncologist at the Sussex Cancer Centre since 2004, says: "We can now more accurately predict which women are going to benefit. The Oncotype DX test helps reduce the guesswork. More importantly, I can identify those women who are not going to benefit, sparing them the toxicity of chemotherapy."

Chemotherapy side effects include fatigue, nausea and hair loss⁷. It is not only patients who benefit from this transformational advance. A recent study by the East Anglia Medical School reported that chemotherapy costs the NHS more than £248m per year⁸.

What surprised researchers and doctors was the scale of the impact

70%

of women with the most common type of breast cancer show no benefit from chemotherapy⁹

New England Journal of Medicine

of the Oncotype DX test. In a landmark trial with 10,000 patients in the US, Canada, Ireland and South America, reported in *The New England Journal of Medicine*, researchers found that 70% of women with the most common type of breast cancer show no benefit from chemotherapy⁹.

The Oncotype DX breast cancer test is not like a genetic test that maps a person's genetic profile. The National Institute of Health and Care Excellence (NICE) explains: "It looks at genes in a patient's breast tumour to understand how these genes interact and influence the tumour's behaviour."¹⁰ This is critical because every tumour is unique; the more doctors know about each one, the more likely they are to be able to treat it effectively.

Marketed by a world leader in cancer diagnostics, Exact Sciences, the breast cancer test is part of an extensive portfolio of tests aiming to enable the delivery of personalised care across the cancer continuum.¹

Colon cancer

Exact Sciences' products include Cologuard, a stool DNA-based colorectal cancer screening test for average-risk individuals who are 45 or older. Detecting disease at an early stage when it is easier to treat, Cologuard analyses stool samples for 10 genetic markers and blood in the stool. Reported to have been used by more than eight million people, the sample collection is carried out in the privacy of people's homes¹¹.

Minimal residual disease

Exact Sciences is developing a test to identify so-called 'minimal residual disease' (MRD), which are cancer cells that remain in the body after treatment. The number of such cells may be so small that they do not cause any physical signs or symptoms.

Any remaining cancer cells in the body can become active and start to multiply, causing a relapse of disease. Detecting MRD from a blood sample may indicate that the treatment was not completely effective or that the cancer cells became resistant to the medications used. Exact Sciences



“People do get ‘wowed’ by the science, but what we’re trying to do is to provide sufficient information to enable patients and physicians to make informed decisions about their treatment approach and likely outcome

estimates that such information may be used to guide adjuvant therapy decisions and/or to monitor cancer recurrence, in conjunction with other clinicopathological findings, providing more than 12m testing opportunities in the US alone.

Multi-cancer early detection

Too often, cancer is detected too late. Current screening can find some types of cancer – breast, colon, cervical and lung – but these make up less than a third of all cancers¹². Exact Sciences is developing a new kind of blood test, Multi-Cancer Early Detection (MCED), to detect cancer early, when it is at its most treatable stage.

In future, MCED tests may become as standard as routine blood pressure testing and identify cancer in millions of patients long before symptoms occur. They may even consign late cancer detection to history.

Exact Sciences is further developing the MCED test originally developed by Thrive Earlier Detection, one of eight companies it has acquired in the last three years to position itself as a leader in the rapidly expanding world of genomics cancer testing.

In 2020, Thrive and researchers from Johns Hopkins University announced

that a multi-cancer blood test used to screen more than 9,000 women had detected 26 undiagnosed cancers¹³.

Working across the cancer continuum

Transforming cancer outcomes requires a comprehensive suite of tests and treatments for all patients before, during, and after a diagnosis. Exact Sciences' vision is to fuel the future and advance cancer care for patients at all stages of the disease, working with others to put all these pieces together and into action.

Hereditary cancer assessments will give as many people as possible the power to know their personal risk for cancer screening tests for more cancers so they can be detected early when they are more treatable. Therapy guidance tests to help patients and health care providers select the right course of treatment for their specific cancer and to avoid over- and under-treatment.

Minimal residual disease testing is currently in development and is designed to assess whether a treatment has removed the cancer and monitor whether the cancer is coming back on a highly personalised, cancer-by-cancer basis.

Personalised versus precision medicine

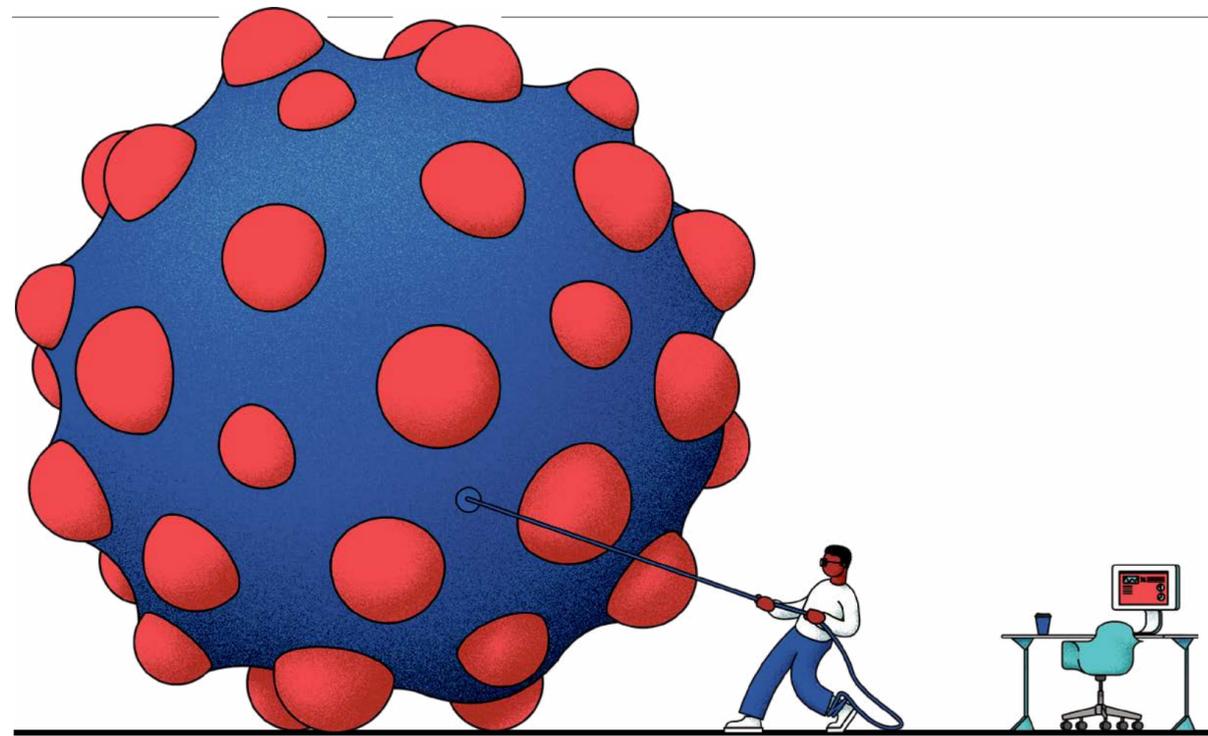
The pace of scientific progress is dazzling, but Simcock stresses that traditional holistic care is as important as ever. He says: "I think that some people conflate 'personalised' medicine' with 'precision medicine.' Making a clinical decision purely on the basis of whether a person has a particular mutation is not very personal. It should not distract us from the holistic care of that individual. The key here is not what is the matter with them but what matters to them. But we need precision medicine to deliver 'personalised' medicine."

Andrew Paramore, director of medical affairs at Exact Sciences, agrees. He says: "People do get 'wowed' by the science and references to 'personalised' and 'precision,' but what we're trying to do is to provide sufficient information to enable patient and physicians to make informed decisions about their treatment approach and likely outcome."

To find out more, please visit exactsciences.co.uk

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COVID-19

A legal tonic for chronic sufferers of coronavirus

An employment tribunal has ruled that someone with long Covid can be categorised as disabled under the Equality Act 2010. What does this mean for employers and employees?

Sam Forsdick

After catching Covid at the start of this year, William Pickthorn, an account executive at PR firm MikeWorldWide, was surprised by the length and severity of his illness. Even though he was a relatively healthy person – he'd run the London Marathon in October 2021 – his fitness declined alarmingly. He experienced regular bouts of breathlessness and extended periods of extreme fatigue.

"My whole body stopped working properly. I struggled to walk at all," he recalls. "My limbs constantly felt numb, I had difficulty breathing and my heart was beating like mad."

Pickthorn is among 1.8 million Britons who've experienced symptoms of long Covid, according to the Office for National Statistics (ONS). Two-thirds of sufferers claim that their ongoing condition is adversely affecting their day-to-day activities, with 19% reporting that their capacity to perform basic tasks has been "limited a lot". For many, this means an inability to do their regular work.

Long Covid is thought to be one cause of the UK's high rate of economic inactivity. ONS data indicates that 447,000 more people aged 16 to 64 were classed as economically inactive between February and April this year than there were between December 2019 and February 2020, just before the pandemic struck. While other factors, including the great resignation and a wave of early retirements, have played their part, it's estimated that long-term sickness absence has accounted for two-thirds of this increase.

It's becoming a problem for employers. In February, a survey of more than 800 enterprises by the Chartered Institute of Professional Development (CIPD) found that 46% of them had employees who'd experienced long Covid in the preceding 12 months. More than a quarter of respondents cited it as one of the main causes of long-term sickness absence in their organisations.

Rachel Suff is a senior CIPD policy adviser specialising in employee

relations. She warns that long Covid is "a growing issue that employers need to be aware of. They should take appropriate steps to support employees who have the condition. There's a risk that those who experience ongoing symptoms may not receive the support they need and could even fall out of work."

The survey also found that 26% of respondents were providing guidance to line managers on how to support staff with long-term health problems. But, given that a recent Scottish employment tribunal ruled

“There's a risk that those who experience long Covid symptoms may not receive the support they need

that an employee suffering from long Covid was disabled in the eyes of the law, this percentage will need to increase.

The landmark decision in favour of Terence Burke in his claim of disability discrimination and unfair dismissal against Turning Point Scotland means that people suffering Covid symptoms for an extended period can be deemed disabled under the Equality Act 2010 if these have a substantial impact on their daily activities. Employers must therefore be prepared to make reasonable adjustments to help such individuals in their work.

"Employers must apply the same considerations to employees with long Covid as they would to those with any other long-term medical condition," explains Helen Snow, an employment lawyer and partner at Geldards. "That means ensuring that they have in place comprehensive policies covering sickness absence and long-term sick leave."

Safeguards for employees under the act include the right not to be treated less favourably because of their disability; the right not to be subjected to any provision, criterion or practice that puts them at a particular disadvantage compared with other workers; and protections against harassment.

Snow adds: "We have seen several high-profile cases of discrimination and unfair dismissal linked to Covid-19, including cases where employees have been forced back to work. Employers must ensure that they deal fairly and in accordance with their own policies to ensure that they don't become the subject of any future cases."

From an HR perspective, the focus should be on "supporting that employee, so that they can continue contributing to the organisation while maintaining their wellbeing", says Emma Parry, professor of HR management at Cranfield University.

The fact that long Covid is a relatively new illness with a broad range of possible symptoms does complicate matters, she adds. This can make it hard for an organisation to understand what adjustments someone might need and how their condition, and therefore their needs, could change over time.

Parry would encourage any employer to "undertake open honest discussions with the affected employee, alongside a formal occupational health assessment to develop an action plan for their return to work". This might include a phased return to work, a move to part-time and/or flexible employment, a reduction in workload or the freedom to pause work if need be.

Ongoing communication will be key in tracking any changes to the individual's requirements.

"Dealing with long Covid requires a flexible approach to address its unpredictability and develop an understanding of how someone's condition might progress," Parry says. "Organisations should work to develop a culture that supports this flexibility and provides the trust and psychological safety for employees to discuss their health needs on an ongoing basis."

Software company Advanced is an employer that has committed itself to recruiting more people with chronic health conditions. As part of a partnership with charity Astriid, it plans to hire 15 people who are affected by a disability or a lasting illness – including long Covid – over the coming 12 months.

"In England alone, 15 million people are living with at least one long-term health condition," observes Alex Arundale, chief people experience officer at Advanced. "The consequence is an invisible talent pool of skilled professionals who have expertise to contribute but who may need an inclusive workplace and some flexibility to do so."

According to Arundale, people's varying experiences of long Covid and the problems that many have had with obtaining a diagnosis can make it hard for an employer to determine what the most appropriate support measures might be for each person.

"Our approach is about ensuring that we provide flexibility about when and where they work. That supports the truth of how they are feeling, rather than requiring a diagnosis," she says.

Some of the adjustments that Advanced is making include assessing people's performance on output rather than attendance and broadening its employee assistance programme. "Building inclusivity and developing trust enables you to support people with long Covid," Arundale adds.

Thanks to the successful NHS vaccination programme, the worst of the crisis seems to be over in the UK. Indeed, despite the recent upsurge in infections, many commentators are using the over-optimistic phrase 'post-pandemic era' already. But long Covid is a problem that might last for years after the pandemic is officially declared over – an enduring legacy issue that employers urgently need to address. ●

BRAIN DISEASE

Critical faculty – science’s race against dementia

Dementia is one of the biggest health challenges facing the world’s ageing population. Researchers are striving to deepen our understanding of this set of diseases, but answers remain elusive

Martin Barrow

When he was a professional rugby union player, Ryan Jones was accustomed to winning tough battles on the pitch in the process of winning three grand slams with Wales. But now he is facing an unbeatable adversary, having been diagnosed with dementia at the age of 41.

“I feel like my world is falling apart,” he revealed in a recent interview with the *Sunday Times*. “I lived 15 years of my life like a superhero and I’m not. I don’t know what the future holds.”

About 900,000 people in the UK – including 42,000 under-65s with early-onset variants – have this progressive and, so far, incurable brain condition, according to the

Alzheimer’s Society, which expects the total to hit 1.6 million by 2040. As the world’s population ages, dementia is fast becoming one of its most pressing health problems.

Dementia is the umbrella term used to describe several types of disease that impair cognitive functions including memory, speech, concentration, perception and emotional control. The most common is Alzheimer’s disease, followed by vascular dementia.

The Office for National Statistics ranked dementia as the most common cause of mortality in 2020 after Covid, but the official toll is likely to be an underestimate. This is because deaths of people with dementia are often attributed to other causes.



Dementia imposes a significant burden on society. There are thought to be about 540,000 dementia carers in England, only half of whom are employed. NHS England has estimated that 66,000 of those who are still in work have had to cut their hours to provide adequate help for their stricken relatives.

In a study for the Alzheimer’s Research Trust in 2010, scientists at the University of Oxford calculated that dementia had knocked £23bn

“We need to significantly increase investment in research into the causes, which will help us to manage the progression of the disease and, hopefully, find a cure

off the UK’s economic output that year – more than the cost of cancer and heart disease combined. That figure is expected to triple by 2040.

Despite these stark figures, policymakers have devoted comparatively little attention and money to dementia care and research in recent years. David Cameron had made it a priority for the government when he was prime minister in 2010-16. But, while his initiative addressed the stigma surrounding the disease, public investment fell short of expectations. Progress in this field has been thwarted by the pandemic, during which people with dementia have suffered disproportionately.

Hopes are growing that the government will soon revitalise its dementia strategy. In May, Sajid Javid, then secretary of state for health and social care, addressed the 2022 conference of the Alzheimer’s Society and revealed that a 10-year plan would be published in the autumn.

“It means measuring ourselves against the leading countries globally and being unafraid to find new ways of working,” he told delegates. “It means being bold about finding new medicines and new treatments. It means being ambitious on new technology, like genomic sequencing and digital biomarkers.”

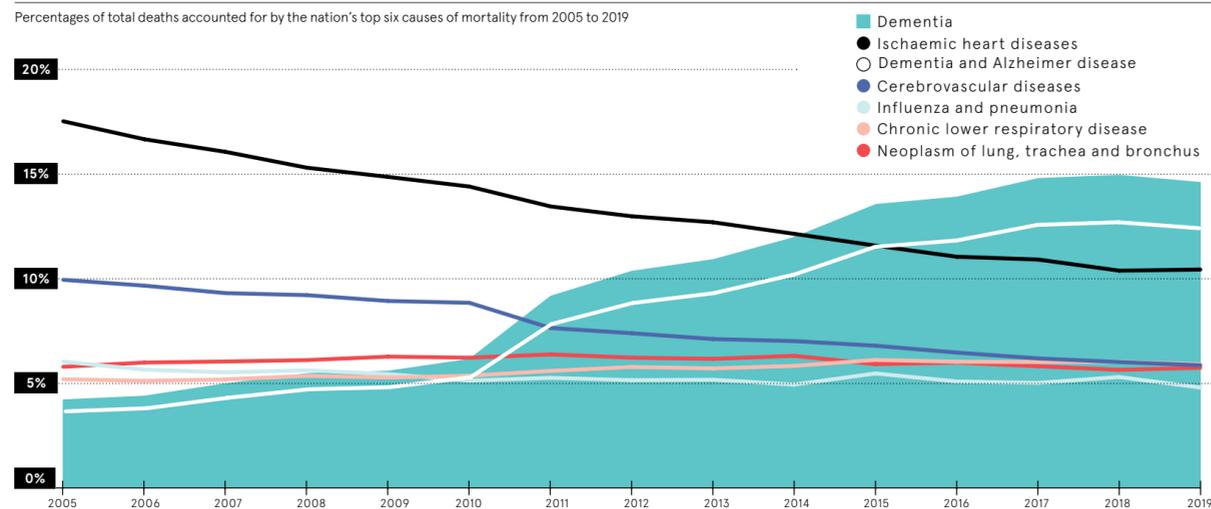
Javid’s announcement has been widely welcomed, although there is concern that too much of the plan’s budget will be allocated to longer-term studies.

“We all agree that we must significantly increase investment in

DEMENTIA BECAME THE LEADING CAUSE OF DEATH IN THE UK BEFORE COVID

Office for National Statistics, National Records of Scotland, Northern Ireland Statistics & Research Agency, 2020

Percentages of total deaths accounted for by the nation’s top six causes of mortality from 2005 to 2019



research into the causes, which will help us to manage the progression of the disease and, hopefully, find a cure,” says Paul Edwards, director of clinical services at Dementia UK. But he adds that dementia is “not like cancer, for which care mostly takes place in the health service. People with dementia and their families need reliable social care, which is not always available. Its provision may not be as exciting as the search for a cure, but it is critical to the many people who are living with dementia now and won’t get better.”

With a target of identifying treatments by 2025, the UK Dementia Research Institute is leading the nation’s scientific efforts. For instance, it played a key role in a project that has identified 75 genes associated with an increased risk of Alzheimer’s disease, including 42 that weren’t previously connected to the disorder. This was hailed as a landmark study when it was published in April.

Gene-based treatments are also being used to try to control the production of proteins such as tau, which become misshapen and tangled in the neurons of people with Alzheimer’s disease.

Other projects have been capitalising on advances in stem-cell engineering to deepen their understanding of dementia. They have been able to take skin cells donated by Alzheimer’s patients and reprogramme these in the lab to become stem cells and, thereafter, neurons. From studying these cells, researchers have gained important insights into how brain damage starts to occur and how that process might be halted. Engineered neurons can also be used to test potential treatments at an early stage.

Having proved effective in treating some cancers, immunotherapy is another promising field. Some studies are using vaccinations to counter abnormal accumulations of beta-amyloid peptides in the brain. Others are using lab-manufactured antibodies to target these molecules. Scientists are also seeking to repurpose drugs that are already used to treat other conditions – a popular ploy in the pharmaceutical industry, as it’s relatively cost-effective. Existing medicines being explored as possible treatments for Alzheimer’s and vascular dementia include those for hypertension and rheumatoid arthritis.

A breakthrough won’t come soon enough for hundreds of thousands of British families that are already dealing with dementia. They include Rachel, who gave up her job at a care home to become a full-time carer for her mother, Brenda, after she was diagnosed at 59.

“I loved that job and the freedom that came with it,” Rachel recalls. “I’m now on carer’s allowance, back in the home I grew up in. It’s just the two of us, so it’s a huge responsibility for me. It can be overwhelming. This isn’t what I thought my life would look like in my late 20s.”

Soon after Brenda was diagnosed, a specialist admiral nurse, trained by Dementia UK, started visiting the pair every month.

“We clicked straight away and I immediately felt a huge sense of relief. It was amazing to talk to someone who understood what I was going through. She has also helped me to prioritise my own well-being,” Rachel says. “I’d like to follow in her footsteps and be an admiral nurse one day.”

“People with dementia and their families need reliable social care, which is not always available. Its provision may not be as exciting as the search for a cure, but it is critical

15.9%

of female deaths in 2019 were attributed to Alzheimer’s disease and other dementias, making them the leading cause of death for UK women

8.8%

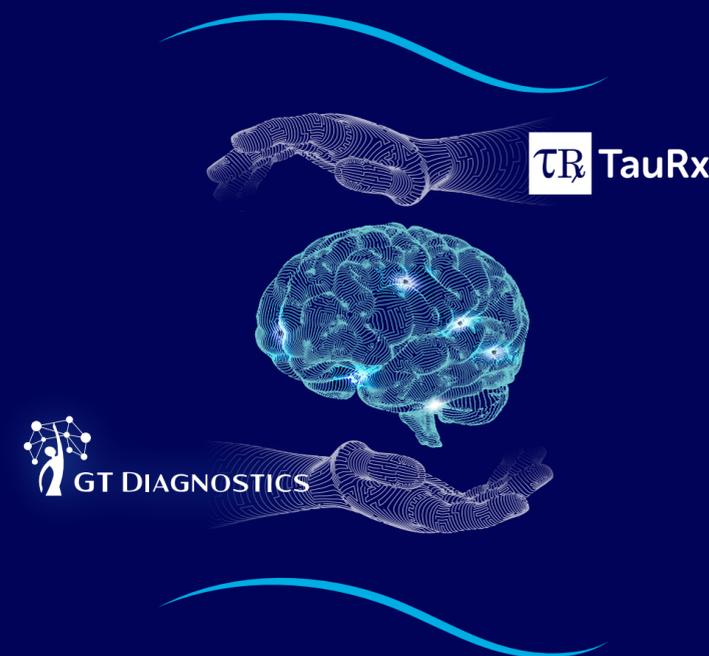
of male deaths in 2019 were attributed to Alzheimer’s disease and other dementias, making them the leading cause of death for UK men

2x

The annual dementia death toll among over-75s in England doubled from 2007 to 2017

Public Health England, National Records of Scotland, Northern Ireland Statistics & Research Agency, 2020

Working together to diagnose and treat one of the world’s greatest unmet medical needs



Every three seconds someone in the world develops dementia and Alzheimer’s disease is the most common cause.

At TauRx, it’s our mission to discover and develop products to treat, diagnose and cure the neurodegenerative diseases, such as Alzheimer’s, caused through protein aggregation.

Globally, it’s estimated that 75% of people with dementia are not diagnosed.

At GT Diagnostics, our vision is to change the dementia diagnostic landscape by developing much-needed tools to support early diagnosis and continued monitoring of progression.

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TREATMENT

Gene genius

It's the cutting-edge treatment that is revolutionising healthcare, but how exactly does gene therapy work?

Joy Persaud

Gene therapy, whereby correctly functioning genes are introduced to cells to replace or repair missing or defective ones, solves medical problems at source. Often, the therapy will need to be administered only once, liberating patients from having to undergo repeat treatments.

Gene therapy might sound like the stuff of science fiction, but work on it got under way in the 1950s, when the chemical structure of DNA (the molecule that stores an organism's genetic information) was discovered. Scientists have been trying to cure diseases by manipulating genes ever since – with increasingly effective results. A dozen gene therapies are available on prescription in the UK.

The Human Genome Project, which was completed in 2003, identified and sequenced the full set of human genes, noting where certain genetic sequences could cause disease when mutated. For instance, some disorders, such as haemophilia, result from the lack of a particular protein, whereas others, including certain cancers, are linked to an excess of a particular protein.

The latest gene therapies typically work using an adeno-associated virus vector (AAV), a harmless virus that can carry DNA or RNA (a molecule that acts as a messenger carrying DNA instructions) to a target area in a cell or tissue to stimulate or inhibit the production of a protein. AAVs do not cause disease, but they are monitored closely to assess any effect they might have on immunity.

Professor Alan Boyd has worked in the field for 25 years, focusing on rare diseases. He points to the

fact that a cutting-edge technique known as Crispr (clustered, regularly interspaced short palindromic repeats) – which allows genetic material to be added, removed or altered at particular locations in the genome – has been used to study the Sars-CoV-2 virus. In fact, Crispr has been key to the development of the rapid diagnostic tests used by health services to stay on top of the pandemic.

Here, we look at three diseases that historically spelt infirmity or even death for affected patients but have since been rendered more manageable by gene therapy.

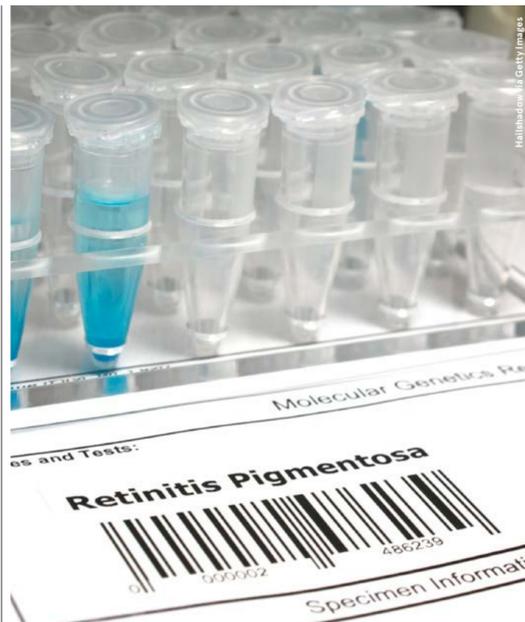
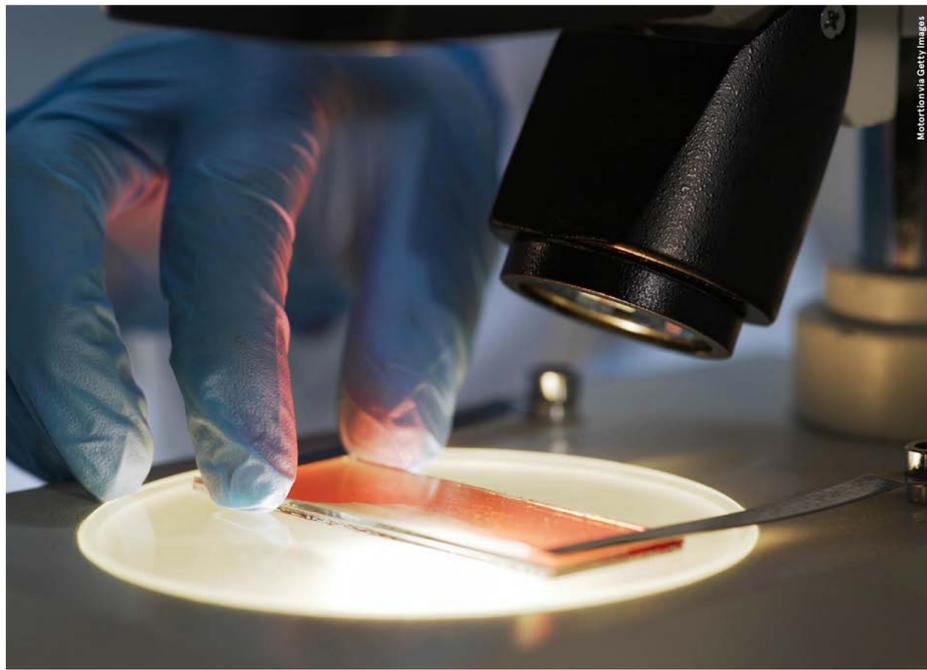
Haemophilia

Haemophilia is a genetic disorder whereby people lack factor VII, the clotting protein that stops bleeding, typically in joints and muscles. Potentially fatal haemorrhages can strike spontaneously. The condition is thought to affect about 6,000 people in the UK, mostly men.

Before gene therapy became available, patients were treated with injections of various drugs to treat or prevent bleeding.

Dr Gavin Ling is a consultant haematologist with a PhD in haemophilia gene therapy from University College London. He reports that gene therapy for the disorder is proving effective, but adds that it's likely to take a decade to achieve a consistent response, last a lifetime and provide a "cure".

He says: "For those who have enrolled in haemophilia trials, a one-off gene therapy treatment has meant that the standard treatment of clotting-factor injections – often a painful process that may have to be undergone every other day – is no longer required."



Indeed, Luke Pembroke, a haemophiliac, spent his childhood trying to avoid causing himself dangerous internal joint and muscle bleeds, which meant missing out on activities such as football and having to inject a vein three times a week. So, when the opportunity came along to enrol in a gene therapy trial, he took it.

He describes the first year as tough, as his body was "out of balance". But, in time, he realised how much he could do as a result of the treatment – including living at a research station in the Peruvian Amazon and hiking the Inca Trail.

“Gene therapy has changed my life for the better. It wasn't an easy journey but I have no regrets

“Having the opportunity to not worry about my haemophilia afforded me the chance to truly enjoy the experience,” Pembroke says. “Instead of it being something I had to factor into my everyday plans, I could just get out there and focus on catching snakes and frogs along jungle trails, or navigating my way up a snowy track and avoiding bears, with haemophilia being the furthest thing from my mind. Gene therapy has changed my life for the better. It wasn't an easy journey but I have no regrets.”

Retinitis pigmentosa

Known as RP, retinitis pigmentosa is a group of chronic hereditary diseases that affect the layer of light-sensitive tissue in the retina at the back of the eye. It affects

about 23,000 people in the UK and is typically diagnosed in young adulthood. The retinas deteriorate gradually, rendering many RP patients legally blind by their 40s.

The only treatment available is Luxturna, a gene therapy developed by biotech company Spark Therapeutics, in partnership with pharma giant Roche. It involves a copy of a normal human retinoid isomerohydrolase gene (RPE65) being injected into the retina via an AAV after part of the eye is removed. Common side effects include redness in the eye caused by the increased supply of blood, cataracts and pressure inside the eye.

“Retinal disorders are good candidates for gene therapy,” says Paul Stroemer, cell and gene therapy expert at PA Consulting. “Loss of

“Retinal disorders are good candidates for gene therapy. Loss of tissue in the eye is gradual, giving a wide treatment window

tissue in the eye is gradual, giving a wide treatment window. Nerve cells in the eye don't divide, meaning that there is no requirement for administering further treatments. The therapy is permanent – one and done.”

Stroemer adds that only one eye is treated at a time, so the untouched eye will not be affected if there is an adverse reaction.

Spinal muscular atrophy

SMA exists in different forms. Type 1 is a life-threatening variant that becomes evident in a baby's early months. Its typical symptoms include weakness in the arms and legs; movement problems, such as difficulties sitting up; breathing problems; and shaking.

Infants with type 1 SMA rarely survived beyond their first few years until gene therapy made early diagnosis and treatment possible.

“Patients with this disease lack the survival motor neuron protein, which is essential for the normal functioning of motor neurons. Without it, these nerve cells deteriorate and eventually die,” Stroemer explains. “Diagnosis can be made via gene screening, which can be done at birth.”

In June, a trial conducted by pharma giant Novartis showed that the gene therapy Zolgensma was effective for, and well tolerated by, pre-symptomatic infants at risk of severe SMA, highlighting the urgency for newborn screening and intervention. Zolgensma, an AAV, works by replacing the function of the missing or faulty survival motor gene.

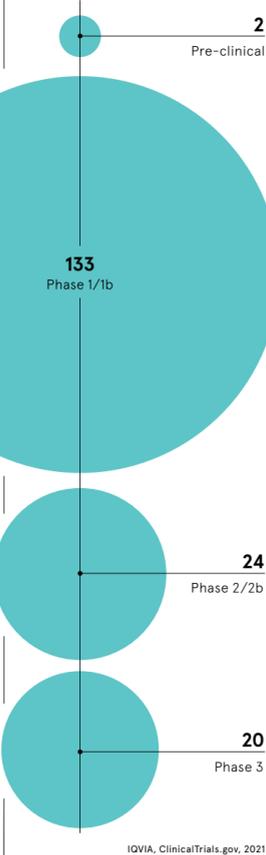
“When injected, it passes into the nerves and provides the correct gene to make enough of the protein and thereby restore nerve function,” Stroemer says. “Given that there were practically no other viable permanent treatment options available before, the significance of Zolgensma's introduction as a treatment for SMA should not be underestimated.”

Despite the promising results for the diseases mentioned, the price tag is eye-watering. The processes involved cost millions of pounds, and the NHS and other healthcare providers are grappling with ways to manage the outlay for groundbreaking gene therapies. But the fact that many therapies need only one dose could be weighed up against the ongoing costs of traditional treatment in the long term.

Ling believes that costs will fall as the manufacturing of these treatments increases, but they will

THE NUMBER OF TRIALS FOR GENE THERAPIES IN THE PIPELINE WORLDWIDE

Broken down by trial phases, where phase 1 is the earliest



still be expensive. Progress needs to be slow and cautious, he says, because, “finding the right approach has been much like threading a needle. In the past, when some different viruses or the wrong dosages were used, there were harmful effects ranging from bad allergic reactions to cancer.”

When it comes to tinkering with the DNA in human reproductive cells, Boyd stresses that there is an international convention forbidding research and gene therapies.

“That is because these changed eggs and sperm might then be used to create a human. That sounds like science fiction, but there are many reasons why we should never do that,” he says. “The important ethical safeguard is that any clinical study that involves gene therapy does need to be reviewed and approved by an independent research ethics committee.”

Q&A

Let's shift the narrative on health to focus on the root cause: workplace stress

Reeva Misra, founder and CEO of workplace stress resilience platform, Walking on Earth, reveals how technology can create a targeted approach to ending the workplace stress epidemic



Q How large of an issue is work-related stress?

A Work-related stress is at an all-time high. It is reported that stress regularly affects around 80% of UK adults, and the World Health Organisation officially classified burnout as a syndrome caused by chronic workplace stress. These results are staggering when you consider that we spend roughly a third of our lives at work. When employee health is not met, the health of the business suffers. It's estimated that 57% of annual lost working days are due to stress, anxiety and depression, and this costs businesses around £42bn a year. I believe we should use this as a catalyst for change. The pandemic and current market conditions have also thrown a much needed spotlight on workplace stress. We have an opportunity to redefine the narrative that stress is necessary for success, and instead create workplaces that succeed by placing the health of their employees first.

Q What is the impact of stress on our health?

A A certain degree of workplace stress is acceptable and unavoidable. But when stress builds up over time, it causes physiological changes in the body that compromise our immune system and increase our risk of developing chronic diseases. We are increasingly moving towards a world where the majority of diseases, currently over 70%, are chronic and have no medical cure. The only way to address them is through prevention, by changing our lifestyle to build healthy habits; sleep, diet, exercise, and building in periods of recovery from stress. Our current workplaces and healthcare systems just aren't built to address our health in a preventative way.

My background in artificial intelligence and healthcare, combined with witnessing the benefits of preventative health solutions, led me to develop Walking on Earth (WONE), to end the global stress epidemic. Our platform quantifies an individual's stress state and develops tailor-made intervention programmes based on a user's specific profile.

Q How can WONE help to alleviate stress in the workplace?

A Understanding your individual stressors is crucial to develop early warning systems to address your stress before it reaches a point of crisis. Providing solutions for breaking the cycle of chronic stress and making them accessible in a workplace is surprisingly simple. Neuroscience has shown that as little as a 60-second breathing exercise is enough to move from a heightened bodily stress state, to a calmer one, the parasympathetic state. It's as simple as creating workplaces where employees can switch off for short periods in the day to destress, re-focus and improve cognitive performance.

WONE is built to address this need. Our platform centres around the proprietary WONE Index, designed with leading scientists to quantify an individual's stress state. Our recommendation engine develops a tailored health plan consisting of live classes and content. All sessions are hosted by carefully curated experts that include neuroscientists, New York Times best-selling authors, TEDx speakers and world-leading practitioners. We monitor fluctuations in index scores over time and provide feedback on changes in stress measures through engagement in the platform.

80%
of UK adults are regularly affected by stress

57%
of annual lost working days are due to stress

Q Why should businesses invest in a preventative health solution for their employees?

A Rather than the 'tick box' wellbeing benefits that serve as a plaster for unhealthy cultures, WONE is creating a category of its own: a health-tech company that benefits employees just as much as their employers. Because, when employees are engaged, healthy and happy at work, they bring their best selves to work, go above and beyond what's required, and are committed to helping the business reach its goals. Investing in a preventative health solution can provide a significant ROI, or cash savings against the cost of days lost to absenteeism or high staff turnover caused by chronic stress.

For more information, please visit walkingonearth.com





Lewis Till, Quanta Dialysis patient

Time to revolutionise kidney care

Advances in kidney care in the UK and around the world have remained almost static for two decades, but transformative innovations in home dialysis are bringing about much needed change

Lewis Till was a normal 19-year-old who spent his time working out in the gym, going to the pub with his friends and training for his dream career as a fireman, until his life turned upside down. Returning home from a mountain expedition with his course mates, Till's legs were unusually swollen for a man of his age and fitness. His doctor initially said it was nothing to worry about, but two weeks later the swelling had moved to his chest. A blood test and subsequent biopsy found he had focal segmental glomerulosclerosis - or FSGS - a rare autoimmune kidney disease. "Since then, my life hasn't been the same," he says. Lewis is one of the more than 3 million people in the UK whose kidneys don't work as they should - more than the number of people living with all cancer types combined. In Till's case, his kidneys have failed him, meaning he passes minimal amounts of urine.

"Anything I eat or drink pretty much stays inside me, which is a life-threatening condition," he says. To stay alive, Till requires a dialysis machine to perform the functions his kidneys can't. Initially, this meant travelling to hospital three days a week to hook up to a dialysis machine for four hours each time. "A normal kidney works 24/7, so I just felt awful all the time," he recalls. "When you have a condition with no cure, more or less no research into it, and you spend your life in and out of hospital, you just feel left in the dark." This is the stark reality for millions of people suffering with kidney disease globally each year. A year after his diagnosis, Till was one of the few, lucky patients to be offered a home dialysis machine. Despite the NHS's Getting it Right First Time (GIRFT) programme, which recommends that at least one in five patients should be on home dialysis,

more than half of dialysis centres in England are yet to meet this target. But while his home set-up was better than travelling to the hospital, the device the NHS gave him - the most used home-dialysis machine in the UK - had major flaws. "My blood tests were never great and I never really felt good after coming off of it," says Till. "There were lots of issues with maintenance and needing to constantly replace parts. The machine just isn't up to scratch. It's very inaccurate at measuring how much fluid is removed, so I would come off dialysis feeling dehydrated, lethargic and dizzy. At one point my potassium levels were at 9.7, which can be lethal." Fortunately, Till was offered a lifeline when the NHS invited him to use an innovative new home dialysis machine from Quanta Dialysis Technologies, a medtech firm based in the Midlands. The company's SC+

haemodialysis system packs the performance of a large, in-centre dialysis machine into a simple cartridge-based device that's a fraction of the size. Rather than alternative home dialysis machines, which are often as big as a large fridge freezer and require substantial space, preparation and, often, significant home renovations, Quanta's plug-in device causes minimal disruption to patients. With a revolutionary design and bright, easy-to-read touchscreen, the SC+ system is seamless and intuitive for patients to use at home. "Traditional dialysis care models are insufficient and a huge burden on patients," says Dr Paul Komenda, a nephrologist and chief medical officer at Quanta. "Add that to the significant expense, transportation, infrastructure and skilled labour required to keep these units running, and the result has been unacceptably poor health outcomes for kidney care patients." This includes a mortality rate comparable to most metastatic cancers and class four heart failure. "When you can do dialysis more frequently and at a slower pace, it unlocks huge autonomy that dialysis patients typically haven't had, tailored to their lifestyle," says Komenda. "There hasn't been a large impetus for startup companies to develop this type of technology in the UK because of a lack of buy-in from the NHS and the incredibly complex, resource-intensive development process. However, realisations around the unacceptable health outcomes associated with in-centre

“Very few things in life are cheaper and better for patients, but this is one. It's a no brainer.**”**

dialysis are slowly changing that and Quanta is committed to revolutionising kidney care around the world." Quanta has undertaken extensive clinical studies within the UK and patients are on active treatments in multiple NHS trusts. The momentum is building, but there is still a long way to go to secure the buy-in required to truly transform kidney care in the UK. This will not only benefit the patients themselves through improved health outcomes and a substantially better life-style, but also the NHS, which currently spends an estimated £1.4bn every year treating chronic kidney disease. "Very few things in life are cheaper and better for patients, but this is one. It's a no brainer," says Komenda. "If we can get patients on the optimal therapy early, which is home dialysis, and smooth out their transition on to treatment, those people are going to have a much better experience after receiving the gut-wrenching news that they will need life-sustaining therapy and dialysis. They are going to feel a lot better at a much lower expense to the overall healthcare system."

The last person who needs convincing that it is a no brainer is Till, whose own life has been transformed since using Quanta's SC+ haemodialysis system. Having felt the impact physically and mentally, he now believes more awareness about kidney disease at the general population level will bring about the necessary changes to help everyone who relies on dialysis to live better. "The first time I tried using Quanta's SC+ system, my blood was cleaned within one dialysis session," he says. "It's highly accurate and has given me a major energy and wellbeing boost. It's given me back control over my life. It's incredibly scary when you have to use a dialysis machine for the first time, both for patients and their families but if there was more awareness of the disease, the treatment and the different options available, it would be less scary. Millions of people have chronic kidney disease but don't seem to find out until it's progressed too far. It's an epidemic that isn't being dealt with and there's so much to do."

For more information, visit quantadt.com



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Olshana Ryazanova via iStock

ALLERGIES

Not up to scratch

Recent studies have indicated that several allergies are being significantly over-diagnosed. This finding, along with a lack of reliable public information and effective training for GPs, is causing consternation among allergists

Josh Sims

If you were to read some recent online articles about allergies, you might well conclude that children are developing them at record rates. In October 2020, for instance, Graham Rook, emeritus professor of medical microbiology at University College London, told the BBC: "That food allergies have risen is unquestionably the case, to an absolutely crazy extent." But the true picture for allergies - hypersensitivities of the immune system, most typically to foodstuffs such as nuts, eggs, wheat, milk, soya and shellfish - is anything but clear. Consider the results of a consensus study published late last year suggesting that infants are being wildly over-diagnosed with milk allergies. One of the study's co-authors is Dr Hilary Allen, a GP and milk allergy

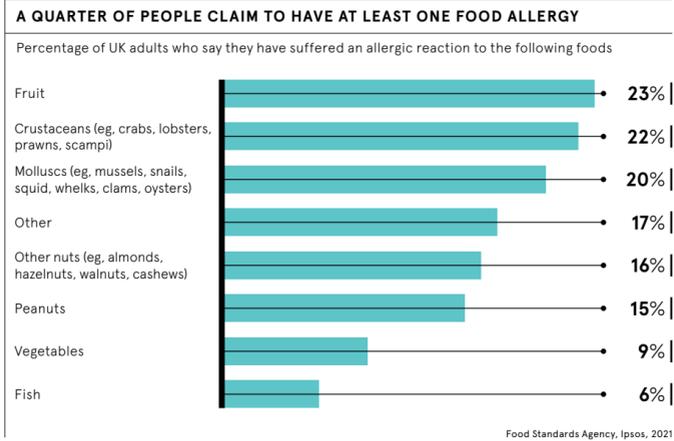
specialist. She says that "only about 1% of infants have a milk allergy, yet the amount of formula prescribed is 10 times what you would expect. That gives you an idea of the scale of the problem." Noting that NHS England is spending about £60m a year on special formula, Allen adds that the over-diagnosis of milk allergies has several other ramifications, including the "undermining of confidence in breastfeeding". Evidence suggests that food and other allergies are also being over-diagnosed. About 10% of US citizens have been labelled as allergic to penicillin, for instance, whereas the latest data indicates that the true percentage is closer to 1%. Dr Robert Boyle, clinical reader in paediatric allergy at Imperial

College London (ICL), is another co-author of the milk allergy study. He says that food allergies are "very much a younger person's issue". This is because misdiagnosis can lead to "the excessive medicalisation of large parts of their childhoods and inappropriate restrictions to their diets and activities, causing them undue anxieties and emotional burdens. The impacts of allergy over-diagnosis are very real." The main cause of the problem has been "a perfect storm of misinformation and poor provision". So says Professor Adam Fox, consultant paediatric allergist at Guy's and St Thomas' Hospital, London, and chair of the National Allergy Strategy Group, which campaigns for improved allergy services. Fox believes that the prevalence of food allergies has been overstated, which is confusing the public, particularly when it comes to distinguishing these from intolerances. He observes that 30% of parents will say that their child has a food allergy, even though only about 5% of children have one. Moreover, deaths from food allergies are extremely rare and, according to research published by ICL last year, the mortality rate is falling. While he acknowledges that allergies are "unequivocally" more common than they were half a century ago, Fox argues that the evidence that an epidemic has been occurring over a shorter period is not robust. Indeed, some studies have concluded that the prevalence of food allergies has not changed significantly in recent decades. Allen agrees. "We do need more understanding of allergies, but the media, patient charities, healthcare professionals and the formula industry have pushed the pendulum too far in terms of public awareness, because the evidence doesn't show

a dramatic increase in milk allergy," she argues. "We need more balance." Small wonder, then, that Allen is calling for better and, crucially, independent guidelines on milk allergies to be published. She and her co-authors claim that their guidance is only the second to be produced anywhere in the world without any financial conflicts of interest involving formula manufacturers. And, while there is evidence indicating the benefits of gradually introducing allergenic foods to infants, more work needs to be done to help parents overcome their natural reluctance to do so. That's the view of David Stukus, professor of clinical paediatrics and a spokesman for the American College of Allergy, Asthma and Immunology. He says: "It is extremely challenging to undo old dogma, especially when new evidence contradicts long-held beliefs." A more immediate problem, in the UK at least, is a lack of allergists, according to Fox. GPs typically have limited knowledge of the subject, as it isn't a core aspect of their training, which drives more people online for information "of very questionable quality and, typically, with vested interests", he says. "The science may be complex but, in all but the most extreme cases, managing food allergies isn't. We simply need space on the curriculum." Over-diagnosis is further driven by unreliable testing methods and diagnostic uncertainty. Boyle notes that the skin-prick test, whereby the patient's arm is scratched by needles coated with proteins from suspect foods and examined for wheals, is "100 years old". There is great variation in immune responses and someone's threshold for reaction can vary from day to day. He cites a 2017 study which demonstrated that, even when someone tests positive for an allergy, that person is not actually allergic half of the time. Equally, some allergies may go undetected. Stukus notes that the "accurate identification of a true food allergy requires observation of objective symptoms during an oral food challenge". This is a placebo-controlled test under which the patient ingests a tiny dose of a suspected allergenic and their reaction is observed. "Unfortunately, these tests are time-consuming and difficult to use for large population studies,"

“About 1% of infants have a milk allergy, yet the amount of formula prescribed is 10 times what you would expect.**”**

he says. "As such, most studies evaluating the prevalence of food allergies have relied on proxies such as self-reported diagnosis or detection through skin-prick or blood tests. These are more convenient, but it is well established that they over-estimate cases of food allergy." Fortunately, there are new tests in development that are giving allergists reason for optimism. Pilot studies of one that measures the reaction of white blood cells known as basophils to potential allergens suggest that it could prove as accurate as an oral food challenge, for instance. Another notable advance has come in the shape of allergen component testing - in which a patient is challenged with a specific protein rather than a mixture. This has been approved by authorities in the US. Boyle expects that more accurate and user-friendly tests will become available within the next 10 years. But he adds that, "with commercial and professional interests still pushing towards more diagnosis of allergy", there is still much work to be done on several fronts. It's a view shared by Clare Bristow, whose daughter, Sadie, died of an extreme allergic reaction to food in 2018 at nine years of age. She and her husband Stewart have since set up the Sadie Bristow Foundation to improve public knowledge about allergies. One of its long-term goals is to open a clinic and advice centre. "Parents need help, because there is a lot of misunderstanding about allergies. Understandably, some are very fearful and need practical and psychological support. We also need to see improvements in GPs' understanding and the training of more specialists," she says. "But that just doesn't seem to be happening." ●



VR and haptics: how technology is transforming surgery training

Haptic technology, when combined with virtual reality, is aligning the neglected sense of touch with sight and situational awareness in surgical training; add in AI and it's a game changer

Press a scalpel into human flesh and, as the blade moves, the sensation subtly changes. Skin has a specific feeling: arteries offer a level of resistance, veins less so, while bone and muscle can be tougher. The complex catalogue of sensations that travels from blade to hand to brain is known as haptic feedback. If a surgeon is less than a millimetre out, it can mean life or death. Now technology can recreate this accurately and cost effectively.

Haptics is the science of simulating pressure, texture, resistance and other feelings related to touch. Married with virtual reality (VR), it can be vital in reducing medical errors. One in 10 patients are harmed accidentally while receiving healthcare, while one in 300 die, according to the World Health Organisation. More than 250,000 NHS patients in England suffer disability or death resulting from healthcare interventions every year. Any effort to reduce these numbers is welcome.

"Healthcare professionals do an amazing job in often difficult conditions. The fact is critical errors do still occur. Now, we don't have to accept error as inevitable. It's not just a human and societal tragedy, the cost is also huge, with the NHS paying more than £2bn yearly for medical-error settlements. A change in safety culture is crucial and it starts with innovation. This is where more accurate surgical simulations can make a real difference," explains Richard Vincent, CEO of FundamentalVR, a global leader in virtual reality and haptic healthcare software.

The healthcare system across the globe, and surgery in particular, faces a perfect storm. There's a shortage of trained surgeons worldwide and a lack of cadavers to practise on in

some settings. The pandemic also stalled physical training for surgical techniques and operating room observations. Concurrently, face-to-face operating room teaching is increasingly expensive and time-consuming to deliver.

"By combining immersive VR with cutting-edge haptics and AI at scale, we can now create an incredibly life-like training experience with accurate physical sensations. This is a gamechanger. We are laser focused on pre-human competence, which is about training surgeons in the most realistic way possible before they enter any operating theatre," says Vincent, who also co-founded FundamentalVR, which counts The Mayo Clinic, one of America's leading centres of medical excellence, and Sana Kliniken, one of Europe's leading medical organisations, among its investors.

"It's all about lowering the risk to real-life patients. Digital twins of surgical realities can help with this. Virtual surgeries are repeatable and safe environments to operate in. We also deploy machine learning and deep data insights to inform our models and assessments so that training via our software continually improves."

When you run your virtual instrument up and down a spine, as you view the backbone through a VR headset, the resistance created by the handheld device or haptic gloves in real time means that you can actually feel the tip of the instrument ricocheting off each vertebra. Muscle memory and sub-millimetre precision is a key aim of this immersive experience since many surgical techniques require an incredibly high degree of accuracy.

A near-infinite array of surgery scenarios can now be performed in VR without harming actual patients,



ensuring that learning from medical errors is risk-free. Software and 3D recordings also allow surgeons to review their work visually, with real-time feedback, so they can learn from their mistakes.

Hundreds of data points can now be tracked to provide a level of analysis not previously available. Specific metrics include economy of movement, 3D spatial awareness, surgical gaze, respect for tissue and human factors, such as dealing with adverse events and complications.

"The focus is now on value-based care: we want to speed up the adoption of new procedures and products. Innovations and greater complexity to do with surgical devices, robotics and new drugs is also driving the need for a new approach to surgery. We need to shorten the learning curve and accelerate the speed of medical knowledge and skills acquisition. This is where VR and haptics is invaluable," says Vincent,

whose scaling operation employs more than 100 people globally.

"Our Fundamental Surgery platform is the first in the world to combine VR, haptics, deep data, AI and multi-modal learning. We are also helping Life Science companies accelerate the safe and compliant introduction of medical innovations," says Vincent. The simulations created by FundamentalVR have so far received accreditations from the prestigious Royal College of Surgeons and American Academy of Orthopedic Surgeons.

"Focusing on software and cloud solutions means we are hardware agnostic. This allows surgeons and teachers to adopt new headsets and devices when they are released. We have future proofed our solution. At the same time medical professionals around the world can use equipment that is readily available to them locally."

The aim is to scale surgical simulations so they are easily accessible, particularly in developing countries that use off-the-shelf, low-cost equipment. That way surgical students even in the remotest areas of the world can train. Haptic devices are also small enough to fit inside a flight case - portability matters if surgical knowledge is to be delivered to isolated regions.

The future looks bright. VR and haptics are already supporting ophthalmology and regenerative therapies, as well as robotic and orthopaedic medical disciplines. Future simulations will support general surgery, as well as emerging procedures.

“Combining immersive VR with cutting-edge haptics and AI at scale

The development of 5G infrastructure should increase the power, quality and reach of immersive solutions in this field. New types of virtual reality training will also be needed as robotic surgical interfaces, patient specific modelling and new procedures around genomic and regenerative gene therapy are developed.

"As the use of immersive solutions continues to grow, the industry will need to develop new content delivery channels to meet capacity. Rather than multiple systems, a single interface and access points for users will emerge - a Netflix of medical education. We want to be there delivering at the forefront of this. It will not only train the surgeons of tomorrow, it will also help to save many more lives," says Vincent.

For more go to fundamentalsurgery.com

FUNDAMENTAL SURGERY

DRUG RECLASSIFICATION

Special dispensation

As the UK medicines regulator permits another prescription drug for women to be sold over the counter by pharmacists, female healthcare products are moving to the forefront of a self-care revolution

Ailsa Colquhoun

Women for whom sexual intercourse is painful or simply too 'dry' may soon be heading straight to their local pharmacists for a solution. Gina, a 10 microgram vaginal tablet delivering the hormone replacement therapy drug estradiol, has just been approved for sale at UK pharmacies without prescription. It's set to be available from September.

Manufactured by Danish-based multinational Novo Nordisk, Gina will join a number of other drugs that have been reclassified from prescription-only medicines (POMs) to pharmacy (P) medicines. Regulators worldwide see the latter as a useful middle ground between POMs and general sales list medicines, which other retail outlets can stock.

Since the mid-1990s, the UK has had a reputation as a leader in reclassifying medicines from POM to P. The aim has been to give the public easier access to effective drugs, lighten GPs' workloads, reduce pressure on NHS drug budgets and make better use of community pharmacists' skills.

P medicine shelves, which used to be the preserve of painkillers and treatments for common ailments such as hay fever, have come to include contraceptive pills, a weight-loss aid, anti-malarial tablets and a treatment for erectile dysfunction.

The UK Medicines and Healthcare Products Regulatory Agency supports this trend. The watchdog's stance is that a medicine should be classed as P unless it meets the criteria for prescription control, most of which concern the level of health risk associated with its incorrect and/or unsupervised use.

Extensive public consultations and expert safety reviews accompany each reclassification procedure to ensure the product's suitability for non-prescription sale. For the contraceptive desogestrel, for instance, there were an unprecedented 493 responses, 80% of which supported the proposal to make it a P medicine.

Two key arguments in favour of the reclassification was that it would make contraception more accessible

and give women more choice in how to obtain it - both of which are backed by the government's political agenda. Factors cited against it included the pharmacies' lack of access to buyers' medical records and the inequality of access caused by the drug's relatively high price to those wishing to buy it over the counter.

The Faculty of Sexual and Reproductive Healthcare (FSRH) - an organisation representing more than 15,000 professionals working in the field - welcomed the reclassification of desogestrel and other similar progestogen-only drugs in July 2021.

Its president, Dr Asha Kasliwal, said that the FSRH had been recommending the move "for many years. Availability over the counter in pharmacies will make it easier for women to access essential contraception. Reclassification may also reduce unnecessary pressures on GPs, who will not need to see patients for repeat prescriptions. We are calling for these pills to be made available to everyone for free in community pharmacies, as well as the reclassification of other contraceptives."

Anna Maxwell is the founder and CEO of Maxwellia, a pharma startup based in Alderley Edge, Cheshire. She recently led a successful POM-to-P reclassification application for its desogestrel product, Lovima.

"About 34% of women say that they can't access the contraceptive services they need," she says. "It's a huge step forward to give women access to the pill without the administration and anxiety of having to see a doctor."

Despite all the scrutiny, P medicines can - and do - have their status

“It's a huge step forward to give women access to the pill without the administration and anxiety of having to see a doctor



revoked. An example is the painkiller sold in 2015 under brand names including Voltarol Pain-Eze tablets. This was reclassified to a POM when a small increased risk of serious cardiac effects associated with its use came to light. Another post-switch clampdown was the restriction placed on sales of pseudoephedrine, an over-the-counter nasal decongestant, because of its links with the illicit manufacture of crystal meth.

Licensing conditions can restrict a drug's commercial viability as a P medicine. These are necessary for safety but can make its sales more time-limited for the pharmacy, potentially affecting profitability. Take Aquiette, a treatment for overactive bladders, for instance. It can be sold for a maximum of only 12 weeks by a pharmacist and only then after the user has attempted at least six weeks of bladder training with no medicinal assistance first.

Adding to the complexity is that, when a medicine is classed as P, variants can remain available on the NHS and free to those who don't pay prescription charges. Such is the clear disincentive for these patients to then buy the product 'privately' that GPs in England have been given guidance to reduce their prescribing of items that are routinely available from pharmacies.

Restricting the inappropriate use of GPs' time on ailments such as colds is the NHS's public health message of the moment - and for good reason. The Proprietary Association of Great Britain (PAGB), the trade body for suppliers of non-prescription drugs, estimates that there were approximately 18 million GP appointments and 3.7 million A&E visits in the UK annually for self-treatable conditions before the Covid crisis.

The association believes that people have learnt better self-care practices since the pandemic started, partly because it has limited their access to surgeries and hospitals. Its

October 2021 white paper, *Realising the Potential: developing a blueprint for a self-care strategy for England*, cited a survey of 2,000 adults which found that 70% of those who would not have considered self-care as their first option before Covid had since changed their minds.

The pandemic has "made people understand the value of a pharmacy," says the PAGB's CEO, Michelle Riddalls. "It has made them realise that they can deal with self-treatable conditions at home."

People's problems accessing primary care continue to make headlines, as doctors struggle to handle the perfect storm of an ageing population with more time-consuming medical conditions, staff shortages

and the Covid backlog. But tech solutions that support effective diagnosis and care without requiring a physical GP appointment are becoming available to consumers at home.

Those with an interest in the reclassification business believe that such developments create a conducive environment for further POM-to-P switches.

"When you have a chronic condition, most of the time you'll manage it yourself at home with whatever you've been prescribed," says Dr Stephen Mann, a pharmaceutical consultant. "If you know what you have, is there any great reason to keep returning to the doctor when you could have the convenience of being able to look after yourself?"



How medicines are classified

How a medicine is classified determines how its supply is controlled. This classification depends to a certain extent on how much input is needed from a health professional to diagnose and treat the illness or condition that might require that medication.

In the UK there are three medicine classifications. These are as follows:

- Prescription-only medicine (POM) - must be prescribed

by an authorised healthcare professional and dispensed from a pharmacy.

- Pharmacy medicine (P) - may be purchased from a pharmacy under the supervision of a pharmacist.

- General sales list medicine (GSL) - may be bought from any retail outlet, such as a newsagent or supermarket, without supervision.

When classifying medicines, the aim is to maximise timely access to effective medicines while minimising the risk of harm from inappropriate use.



DIGITAL TRANSFORMATION

Why the NHS's paper-ectomy is way more than a cosmetic procedure

The minority of health trusts that haven't already implemented electronic patient record systems are set to do so within three years. The implications, especially for hospital care, are profound

Nick Easen

Your electronic patient record (EPR) is the digital thread that guides your journey along an NHS care pathway, ensuring that each clinician you encounter is fully informed about your condition as you proceed through hospital from admission to discharge. At least that would be the case if you happened to be in the care of one of the 80% of trusts that have put an effective EPR system in place.

Sajid Javid acknowledged that the other 20% had yet to achieve that capability when the then health secretary addressed a conference hosted by the *Health Service Journal* in February. But he added that the

government was set on remedying this situation as soon as possible. "EPRs are the essential prerequisite for a modern digital NHS," he told delegates. "Without them, we cannot achieve the full potential for reform." Indeed, the Department of Health and Social Care has just committed £2bn to the task. It is aiming for 90% of trusts to have EPR systems in place by the end of next year and 100% by March 2025.

Ditching paper records, rationalising several systems, installing new software and training everyone in how to use it is a serious undertaking for any hospital. Yet an EPR implementation is well worth all the time, effort and money, according

to Dr Afzal Chaudhry, consultant nephrologist and chief clinical information officer at Cambridge University Hospitals NHS Foundation Trust (CUH), an early adopter of the technology.

He reports that the trust's nurses have started using handheld devices "integrated with our EPR to enter their observations and document the medication they administer at the bedside. This makes care more timely. Automated early-warning scores generated using this same data can prompt them to contact the outreach team to support the care of a deteriorating patient."

Chaudhry continues: "We are also integrating multiple devices, such

as cardiac monitors and ventilators, so that they feed data into the EPR. We're introducing voice-recognition tech too. This speeds up documentation by converting speech to text, bringing greater levels of efficiency. And, from a sustainability perspective, we are saving money and releasing information to patients more quickly by sending them letters electronically."

The transformative potential of digitalisation is so great that it's even prompted some hospitals to prioritise EPR systems over built infrastructure. Torbay and South Devon NHS Foundation Trust had

been allocated funds as part of the government's plan to construct 40 hospitals by 2030, for instance, but it's planning to spend a significant proportion of this money on an EPR implementation first, pushing back projects such as rebuilding work at Torbay Hospital.

CUH estimates that its system has enabled annual cost savings of £460,000 on staff time, simply by freeing clinicians from having to handle paper records, and £1m on cutting the number of inpatient admissions resulting from allergic drug reactions. That said, the typical cost of installing, running and maintaining the software over a decade has been estimated at close to £100m. CUH's budget at the time of its EPR implementation in 2014 was double that figure.

Trusts have been finding that the move to a unified, data-led system of joined-up healthcare involves far more than merely procuring the most appropriate tech. A successful project also necessitates a razor-sharp focus on processes and people, requiring a whole new level of workforce engagement and training.

That's the view of Alyssa Scriver, an implementation project manager at Epic, a US provider of EPR software that has worked with numerous NHS trusts, including CUH. She stresses that implementations are "significant undertakings that touch on almost every aspect of a care provider's operations. At the same time, change management is a typical challenge."

Electronic medical records, and the improvements in data quantity and quality they promise, will be vital if the NHS is ever to unlock the full potential of data-driven analytics technology – after all, what gets measured gets improved.

“While EPRs can reduce paperwork, we must realise that data entry can still be a significant burden on staff

HOW THE UK RANKS AGAINST ITS EUROPEAN NEIGHBOURS ON THE ADOPTION OF ELECTRONIC HEALTH RECORDS

Share of clinicians using electronic health records in selected European countries in 2020



Deloitte, 2020

EPR systems also have the potential to release new data sets to inform innovation work. This includes "tackling pressing challenges such as improving the delivery of outpatient services and reducing times for diagnoses", says Charles Tallack, interim director of data analytics at the Health Foundation. "Data can also help trusts to assess the impact of service innovations such as virtual wards."

But he adds: "While EPRs can reduce paperwork, we must realise that data entry can still be a significant burden on staff. Ensuring that such systems are easy to use and fit well within people's workflows is crucial if these are to reduce their work rather than add to it."

EPR systems must therefore improve care standards, not serve simply as electronic filing cabinets. They need to provide truly useful data for clinicians who are often busy and stressed yet must always give the highest standards of care.

Lynette Ousby is UK managing director at Alcidion, an Australian company that provides modular EPR systems. She says that most medical professionals have been working under tremendous pressure over the past couple of years, adding that many have typically had to "perform 1,000 different procedures manually. But many of these tasks can be automated through natural-language processing and clinical decision support. EPR systems should now be able to suggest appropriate actions that clinicians need to take. This is becoming recognised as a requirement for them."

A more data-led way to provide care is also an attractive proposition for a new generation of IT-literate doctors and nurses who want to be part of the health service's digital transformation. Gary Hotine, director of the health informatics service at Torbay and South Devon NHS

“Ensuring that such such systems are easy to use and fit well within people's workflows is crucial

Foundation Trust, reports that "we have already experienced clinicians voting with their feet and choosing to work at neighbouring trusts that already have EPRs, citing this as the deciding factor in their move."

EPRs are just a starting point, adds Chaudhry at CUH. For him, the next logical step involves re-engineering care pathways. This is hard to do unless you have the right digital infrastructure in place.

Each trust has the freedom to select any EPR provider it wishes to. This piecemeal approach is less of a risk to the whole service if a supplier were to go bust, say. But it's not so effective if a patient needs to be transferred between two hospitals operating different systems.

"There is a conversation around convergence," he reports. "This is not only about the EPR; it is also about bringing workflows together across regions."

That conversation will surely be informed by some of the lessons learnt from the ill-fated national programme for IT (NPFIT). Implementing a unified EPR system for all English hospitals had been core to that project, which was scrapped after nine years of trying when the coalition government accepted in 2011 that imposing a one-size-fits-all solution was unworkable. By that point, the NPFIT had burnt through nearly £10bn of public money. ●



There's an NHS app for that

As well as scheduling the EPR system roll-out, the government's plan for digital health and social care talks of expanding the functionality of the NHS App, which was downloaded by millions of people during the depths of the Covid crisis.

The plan is for the app to act as a digital front door that grants access to several more healthcare services. For instance, users could soon

be able to manage their hospital appointments and see new details in their GP records. Hospital patient portals that are integrated with EPR systems could also be accessible via the app.

One of the main objectives is to empower patients, according to Dr Pritesh Mistry, a fellow in the King's Fund's policy team who specialises in digital tech.

"This is all about improving communication between the healthcare system and the public. This will be a significant and very beneficial evolution," he predicts. "It's all about granting easier access to data on what's being prescribed and advised."

But Mistry is quick to point out that "not everyone has health literacy skills, so this isn't just about making data available. It's also a question of how we support people to make the best use of that information for themselves."



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