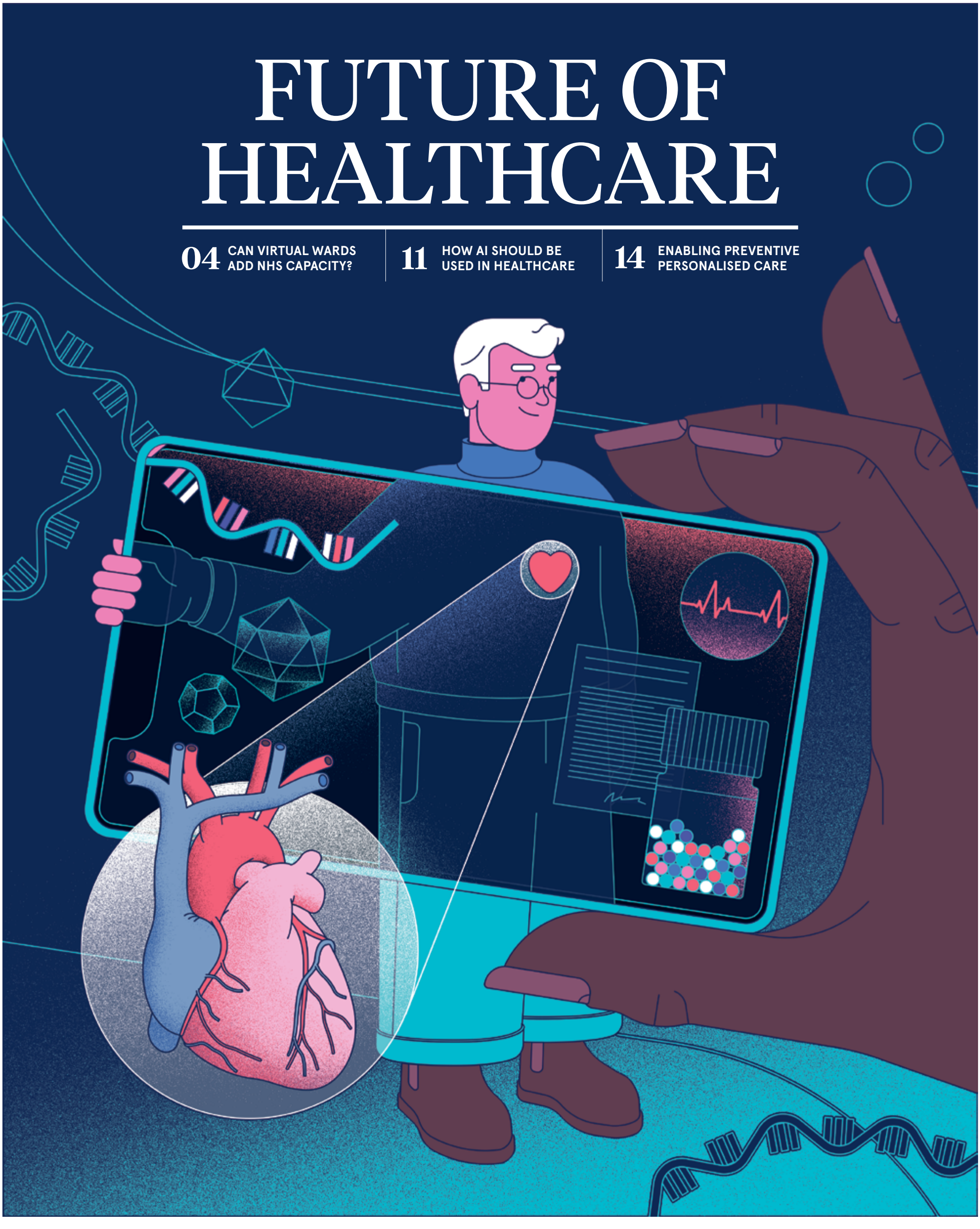
FUTURE OF HEALTHCARE



FUTURE OF HEALTHCARE

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HEALTH POLICY

Yet another NHS review, but can Labour fix healthcare?

Sir Keir Starmer's government has big ambitions in everything from energy to employment. However, the party will likely be judged on how it reforms the NHS

James Gordon

In September, Labour published Lord Darzi's Independent Investigation of the NHS in England. Its findings were stark: the service is in a "critical condition", its decline driven by factors such as funding shortfalls and the Covid-19 pandemic.

Lord Darzi's diagnosis of the country's healthcare ails has been widely accepted by industry commentators. But was another root-and-branch investigation really necessary?

Darzi's review was the third such exercise in the past decade. In October 2014 the NHS published the Five Year Forward View, which was followed in January 2019 by the NHS Long Term Plan from the Department of Health and Social Care (DHSC), in which some goals – particularly those around cancer survival – stretch to 2028.

"Lord Darzi's diagnosis contained little that was wholly new," says Tim Gardner, assistant director of policy at the Health Foundation, an independent research charity. "However, the review strengthens the case for sustained investment in the health service by highlighting the consequences of a decade of under-investment and policy failures prior to Covid-19, which weakened the NHS and worsened the impact of the pandemic."

Starmer's government intends to introduce its own 10-year plan early next year.

Mark Dayan is a senior policy analyst at the Nuffield Trust who has worked in healthcare policy for more than a decade.

"Timescales as to when national health strategies start and end aren't always perfect," he says. "They are not legal documents. They should be viewed through the same lens as spending reviews, which also contain future commitments, but operate on the understanding that the next spending review may override them."

Darzi's review found many of the same faults as previous examinations, and some of its recommendations will likely overlap with current initiatives. It is therefore important to understand why previous plans to fix the NHS have been unsuccessful.

According to Dayan, "continued short-termism in funding settlements, and a necessary focus on addressing immediate pressures and crises, has left the NHS unable to translate these ideas into reality."

Getty Images/iStock

Labour's 10-year plan will be unveiled in the spring. Dr Layla McCay, director of policy at the NHS Confederation, the membership body for NHS organisations, hopes it will deliver for NHS workers and their communities by "listening to the reality of their experiences and incorporating the many examples of best practice and innovation that are taking place across the country".

But what will this large-scale reform look like in reality? How much will it cost? And, crucially, how can the NHS ensure outstanding patient-centred outcomes?

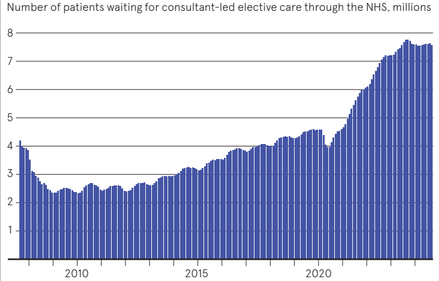
The Darzi review has laid the groundwork for a strategy that Gardner says will introduce three key shifts: moving more care from hospitals to community care, making better use of technology and ensuring a greater focus on preventing ill health.

While Dayan broadly agrees with Lord Darzi's reforms, he says that shifting services from hospitals to the community "is not necessarily the silver bullet that will free up cash". The social care sector will also need an increase in funding to meet demand.

Before any wholesale changes are introduced, Dayan says the NHS must first lay the appropriate cultural foundations. "The NHS needs to set objectives that are actually achievable rather than aspirational. Staff must understand the goals and be involved in decision-making."

MORE THAN 7 MILLION NHS PATIENTS ARE AWAITING TREATMENT

Number of patients waiting for consultant-led elective care through the NHS, millions



BMA, 2024

Second, Dayan says services must be driven by data, which he believes will enable the NHS to adopt an evidence-based approach to gauge whether its initiatives are working.

Next, to really effect change, leaders at the health service must be prepared to think outside of the box. "That could mean financial incentives, allocating grants for innovative pilot projects, or training managers to teach staff to do things differently," he says.

As for spending, Dayan says the NHS requires a funding increase of roughly 3% to 4% every year. But implementing all of Labour's ambitions – which include cutting NHS waiting times, doubling the number of cancer scanners, creating a new dentistry rescue plan, hiring 8,000 more mental-health staff and restoring GP continuity of care – would cost considerably more, he adds.

How much more? The previous Labour government increased funding by 8% each year. Dayan believes the Starmer administration "would need to do something similar to achieve a similar outcome".

For many, including Wes Streeting, the health minister, a hike in capital investment can only be justified if the NHS adopts a clear and carefully considered strategy that delivers outstanding patient-centred care without waste. In January, he told the Institute of Government that the NHS squanders £10bn each year.

Is he right? Gardner says that compared to health systems in other high-income countries, the NHS spends relatively little on administering the system.

"Many of the examples Labour has pointed to as waste are problems caused by past under-investment, where realising any savings will need further investment," he says.

As to whether Labour's reforms will enable the NHS to flourish once again, a spokesperson for the DHSC claims that the upcoming 10-Year Health Plan will "deliver fundamental reform that will get the NHS back on its feet and build a health service fit for the future".

Gardner is less bullish. He believes the service "is weakened but not broken" and says staff "can recover services" if they are given the resources to make it happen.

"Reform needs to be accompanied by sustained investment and that investment needs to be sustained for the long term to transform the NHS, so all eyes now turn to next year's Spending Review." ●

Commercial feature

How digital healthcare can help win the global battle against obesity

More than half of adults across the world are overweight or suffering from obesity, according to the World Health Organisation. But genomic sequencing and a proactive, personalised and preventative approach to treatment, delivered using digital technology, could help to solve the global obesity crisis

The world is facing an obesity crisis. In February, research by Imperial College London's School of Public Health revealed that the total number of children, adolescents and adults living with obesity worldwide has surpassed 1 billion. That's one in eight people globally.

Researchers, who gathered data from more than 190 countries, estimated that among children and adolescents, the rate of obesity in 2022 was four times higher than in 1990. In adults, rates of obesity have more than doubled in women and nearly tripled in men.

Once considered a high-income-country problem, obesity is now on the rise across low- and middle-income countries too. In Africa, the number of overweight children under 5 years old has increased nearly 23% since 2000. And, almost half of the children aged under 5 who were overweight or obese in 2022 lived in Asia.

These statistics are having a devastating financial impact on global healthcare systems too. At its current rate the cost of obesity is expected to reach $3tn (£2.3tn) per year by 2030 and more than $18tn (£13.7tn) by 2060.

But, more worryingly, the disease is also increasing the risk of millions of people developing a host of other serious health problems. These include heart disease, Type 2 diabetes, high cholesterol, high blood pressure and even some cancers, which could put the healthcare system under more strain.

The role of genetics

People suffering with obesity are often accused of simply eating too much and not exercising enough. But groundbreaking research by biotech firm Genomics PLC has revealed a critical underlying factor. At Bupa's Healthcare Symposium: Unboxing Digital Health, Genomics PLC's CEO, Sir Peter Donnelly, unveiled the results of a study that showed how a person's genetic profile has a direct influence on their BMI and subsequent risk of developing obesity.

During his talk, a series of graphs illustrated how a child's BMI is already associated with their genetics by their fourth birthday. As they grow into adults, this problem worsens. Over the next 20 years of their lives, adults in their twenties with a relatively high genetic-risk score for BMI will typically experience an increase in BMI that's three times higher than those with low risk. People with a higher genetic-risk BMI and an unhealthy lifestyle will suffer an even greater increase. Donnelly says the research must spark a change in the conversations around obesity and underpin future treatments that target long-term lifestyle changes.

"We need to change the discourse around being overweight, from a culture of blame and guilt to focusing on how best to help people overcome these challenges," said Donnelly. "We know our research, and others', shows that a healthy lifestyle can prevent obesity and comorbidities even in individuals with a high genetic risk. However our research shows that those at high risk of obesity will need more support to help them stay at, or return to, a healthy weight. It also shows that the effort required for those with a high genetic risk is much greater."

Above: Bupa's Healthcare Sympsosium 2024, which explored the latest trends and innovations in the healthcare industry

> **We need to change the discourse around being overweight, from a culture of blame and guilt to focusing on how best to help people overcome these challenges**

For example, a person with a polygenic-risk score (PRS) at the 95th percentile has to walk 10,000 steps a day more than someone at the 20th percentile to balance the impact of their PRS, notes Donnelly.

He added: "It's clear that healthcare initiatives that take into account genetic profiles would be significantly more effective in helping people stay healthier for longer. This information means we have a golden opportunity to develop much more sophisticated, personalised and successful obesity-prevention programmes."

Personalised treatments

The starting point for creating a personalised treatment programme is genetic testing. Bupa has become the first major private healthcare provider in the UK and Spain to offer its customers whole genomic sequencing under its two-year pilot programme, My Genomic Health. The pilot will give more than 14,000 healthy customers the opportunity to undergo an analysis of over 300 genes and nine polygenic-risk scores to identify their risk of developing obesity and 36 other health conditions that are often associated with the disease. These include heart disease, diabetes and 10 types of cancer.

Bupa's chief medical officer, Anne Lepetit, says the pilot could have a transformative impact on the treatment of obesity. "Early detection enables us to deliver a risk-factor action plan," she says. "People can be really preventative in this area by understanding the lifestyle habits they need to maintain a healthy BMI. The tests will also give people insights into how their bodies are likely to respond to different types of medications if they're already suffering with more serious health complications from obesity."

Digital technology

In recent years, the potential of weight-loss wonder drugs such as semaglutide have generated headlines and optimism for those suffering with obesity. But pharmaceutical solutions are expensive and questionable if taken over the long term. For Bupa, personalised lifestyle-focused interventions delivered by digital technology are exciting.

For example, Bupa's clinicians can use genetic testing to create personalised health and exercise programmes that may eventually be delivered through the company's digital health solution, Blua. In Spain, an AI-powered physio function in Blua also enables users to use their smartphone camera to track physio sessions and provide real-time feedback on their efforts. Alerts can keep people on track by informing them about their daily step count or reminding them of upcoming sessions.

For patients suffering from complications from obesity, other digital services can aid their treatment. Virtual or in-person physio appointments can be booked via Blua to address musculoskeletal issues and mental health problems. "People with obesity are more likely to suffer from anxiety and depression," says Lepetit. "In Spain, we can use Blua to monitor their activity levels and their physical and mental health on an ongoing basis and recommend lifestyle interventions or a therapist before a serious problem occurs."

Find out more about how Bupa's Blua is transforming digital healthcare at bupa.com/impact/digital-healthcare/blua

Bupa

DIGITAL TRANSFORMATION

The real health benefits of virtual wards

Virtual wards enable healthcare staff to remotely monitor patients. Although their present use is limited, they may be the long-term answer to the NHS's acute capacity problem

Jon Axworthy

"I just recover better with a cup of tea and being in my own home."

For Tara Donnelly, these words confirmed the benefits of virtual wards. "She was a 90-year-old lady called Edna, living with heart failure and being cared for in a virtual ward," says Donnelly, a former chief digital officer for NHS England who now leads a consultancy called Digital Care. "Her experience really brought home to me the benefits that the concept can deliver."

Introduced in NHS England's delivery plan for recovering urgent and emergency care services in 2023, virtual wards seek to save on inpatient bed days with clinical staff communicating with patients in their own homes through remote-monitoring technology, including apps and wearables.

The strategy set out a fully funded two-year action plan. It was updated this year with a commitment to scale up the concept, after a review of the first year found that virtual wards had created the equivalent of 20 hospitals' worth of bed space.

The issue is acutely relevant at this time of year, as the annual winter pressure begins to take its toll on NHS services.

Who wouldn't prefer to be treated somewhere entirely familiar, unencumbered by visiting hours and NHS toast? Nearly eight in 10 patients (78%) would rather monitor their own health at home using technology, according to a report by The Health Foundation. This rises to 85% for those aged 65 and up.

NHS England established its commitment to the scheme in the UEC update. But what will this involve?

In the UK, virtual wards are populated only by patients presenting with respiratory infections, frailty or heart failure, along with those who have diabetes or Covid. But the health service intends to expand their use, with a focus on children and young people. Pathways are already being set up for paediatrics and as part of the elective process for people recovering after surgery.

For Donnelly, the next logical step is broadening the use of virtual wards to those with long-term conditions. She points to chronic obstructive pulmonary disease, a group of common and progressive lung conditions – such as emphysema – that worsen over time and result in multiple admissions, particularly in winter. NHS England data suggests COPD is responsible for more than 1 million bed days, which could be saved with virtual wards at scale.

With virtual wards, it is possible for healthcare staff to comfortably treat far more people.

"A nurse on a ward may have eight patients to supervise," explains Donnelly. "On a virtual ward, if people are acutely unwell, it may be five times that many; if they have a long-term condition, it could be 10 to 12 times as many."

This is because economies of scale would come into play. Consider one nurse supervising eight patients, Donnelly says. "On a virtual ward, where the monitoring information is fed into a dashboard that flags any alerts, that nurse could safely look after many times that number."

> **A nurse may have eight patients to supervise. On a virtual ward, it may be five times that many**

Donnelly is also excited about the potential of AI to enable a step change in the delivery and scale of digital home care in the form of clinical co-pilots.

"There are innovators working on bots and clinical avatars that can interact with patients. We can imagine clinical co-pilots helping in the future so that a clinician could perhaps supervise thousands of patients safely at home," she says.

Doccla is one of the largest British tech companies working with the NHS. It is already investigating how to integrate large-language models (LLMs) into the clinical workflow of its technology so that data from wearable devices, patient records and call transcripts can be leveraged in virtual ward co-pilots.

Recruitment and staffing could be significant barriers to deployment. Data from a freedom-of-information request reveals that out of 107 health trusts surveyed, 40% need to recruit additional staff to support the delivery of virtual wards.

Although a virtual ward populated with patients with long-term conditions would be manageable with the existing workforce, extending their use to patients with more complex conditions would be a stretch. And the burden would likely fall on district nurses and primary care, according to Professor Alison Leary, chair of healthcare and workforce modelling at London South Bank University.

"This is a recurring issue. We know remote care works well in a lot of specialisms, such as heart failure, but patients with multiple needs are often more reliant on nursing care," she explains. "If virtual wards are to be scaled up, the caseloads of the existing services and types of patients need to be considered carefully."

Most of the new initiatives in the NHS have little workforce planning, adds Leary. Resourcing decisions are often based on what is available and affordable, not what is needed in terms of skilled labour.

The challenge of attracting staff was well known to the UEC architects; they allocated £450m of investment over two years, with 90% of that money ringfenced for workforce salaries.

It's possible that as staff become more familiar with virtual ward operations, the capacity could grow. Encouragingly, The Health Innovation Network noted in its evaluation of virtual-ward models that in terms of recruitment, "positive word of mouth has helped to generate interest, especially among internal candidates."

Concerns remain over operational costs, with a Lancaster University study of virtual wards in Wrightington, Wigan and Leigh concluding that a virtual-ward bed costs twice as much as an inpatient bed.

In contrast, a report by the National Institute for Health and Care Excellence found that virtual-ward models are usually more cost-effective, thanks to the reduction of inpatient bed days and the lower per diem cost.

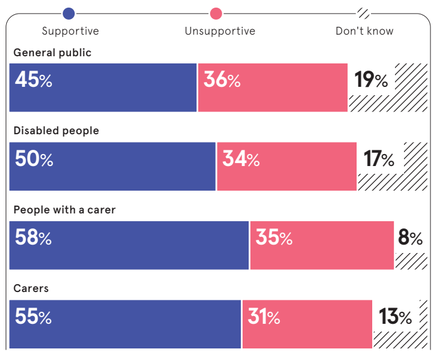
But even if virtual wards proved costlier, better patient outcomes may still justify the additional outlay. Donnelly believes it all comes back to Edna and her homemade cup of tea.

"I think the key to scaling up is all about people being ready to try new models of care that put the patient squarely at the centre," she says. "The leaders of the NHS and government must have the courage to bring about a step change in the use of this model, so it isn't just 8,000 people like Edna who benefit: it's 50,000 people every day, supported by the NHS and spending much more time at home and far less in hospital." ●

Maria Symchych-Nanrotskaia/iStock

PUBLIC SUPPORT FOR VIRTUAL WARDS

Support for virtual wards among UK public, by population group



The Health Foundation, 2023

Commercial feature

Cross-sector collaboration can transform the future of patient care in the UK

Partnership-based care models can unlock the bold thinking and collaboration required to help the NHS tackle healthcare challenges, deliver innovation and ensure equitable access to care

We are living in a time of unprecedented healthcare innovation, where breakthrough science has the potential to transform treatment options for some of the toughest health conditions faced by patients worldwide. But in the UK, many question whether our healthcare system is set up to adapt quickly enough, so that patients can reap the full benefit of this clinical progress.

"I am continually inspired by the possibilities that science provides to shape the future trajectory of healthcare in the UK, but truly transformational progress will only be achieved through stronger collaboration to ensure our access environment and patient pathways keep pace with scientific advancements." says Roz Bekker, managing director UK and Ireland, Johnson & Johnson Innovative Medicine.

The new government recognises the success that arises from partnership between government, the pharmaceutical industry and academia. Earlier this year, a £400m investment programme, backed by the life sciences sector, was launched with an aim to stimulate clinical trial activity and fast-track new treatments to NHS patients. Whilst this is a positive step, to deliver on their pledge to build an NHS 'fit for the future', Labour's public-private model must be applied to day-to-day healthcare outside of health research.

The positive news is that the new government has had the good fortune to inherit the 2022 Health and Care Act, a foundation for partnership-based care. As NHS England put it: "When local partners - the NHS, councils, the voluntary sector and others - work together, they can create better services based on local need." The act granted Integrated Care Services (ICSs) - partnerships between organisations who have responsibility for health and care services in a geographical area – legal powers to serve populations in England of between 500,000 to three million people. The NHS Confederation, which speaks for the whole healthcare system in England, Wales and Northern Ireland, has said that cross-sector partnerships are 'essential' to help the NHS overcome its many challenges.

These include record waiting lists, financial constraints, limited access to new medicines, workforce pressures and an ageing population. In combination with the ever-increasing number of patients expected to develop multiple conditions requiring integrated care, a critical need for change is upon us.

"As we all know, age increases the risk of long term and major illness. From cardiovascular and metabolic diseases like heart failure and type 2 diabetes, to mental health and neurological conditions like anxiety, depression and dementia. All are set to increase in prevalence by 2040,"[1] says Bekker. "The incidence of cancer is also estimated to rise from three million people living with the condition today to 5.3 million by 2040."[2]

And worryingly, right now, innovative medicines that UK patients will increasingly rely on are simply not available at the same rate as other European countries. Of all recently approved new medicines by the European Medicines Agency (EMA), just 56% are available in England and 54% in Scotland, compared to 88% in Germany and 77% in Italy.[3]

"This gap in availability of medicines highlights the urgent need for regulatory reform and enhanced partnerships between government and industry to ensure UK patients are not left behind. While there is no single reason for access limitations in the complicated sphere of healthcare, with a new government in place, we have an unparalleled opportunity to drive holistic improvements and ensure the NHS is fit to lead the future of healthcare" says Bekker.

Partnering for patients

Johnson & Johnson (J&J), which celebrated its UK centenary this year, already has a strong tradition of working in partnership with patients, charities, clinical researchers and the NHS.

Its UK Services and Solutions Centre of Excellence was created to establish dedicated, local partnerships with the NHS and healthcare professionals, to support fragmented services and help meet the varying health needs of patients across the country.

"This can involve working hand in hand with NHS trusts and supporting them to look at the bigger picture concerning a model of care," explains Bekker. "Sometimes having that additional, external perspective can identify where current service challenges exist."

One of these projects is currently being progressed for patients receiving oncology and haematology treatment within the catchment of Hull University Teaching Hospital's NHS Trust. Present challenges mean that service delivery is spread across the region, with some patients travelling long distances for treatment.

> **We have an unparalleled opportunity to ensure the NHS is fit to lead the future of healthcare**

"The knock-on effect can be delayed or missed appointments, which leads to reduced efficiency and capacity across the system," notes Bekker. "Based on extensive local insight, our teams are working to deliver an interactive mapping tool which will support healthcare providers to bring services in closer alignment with local patient needs and priorities. Through such initiatives, our aim is to reduce missed appointments and improve patient outcomes, supporting more efficient care pathways."

J&J has also designed services which expand care outside of traditional settings, seeking to create individualised treatment experiences for patients.

"We know all too well the challenges facing patients with a cancer diagnosis who may have limited options regarding where and how they receive their treatment. Focusing on prostate cancer, after initiating treatment with their doctor, patients can opt for home delivery of their medication. They can also receive additional support from a telephone nursing service for the first six months of treatment. This enhances regular contact with patients, which can ultimately improve their outcomes."

These examples of patient-focused, 360 degree healthcare remind Bekker of her time as a young doctor in rural South Africa, where resources were limited, and patients sometimes travelled for hours to see a healthcare professional.

"When working within these communities in South Africa, I truly learned the importance of patient-centric care - appreciating a person's presentation and illness within the context of other challenges they faced. This is an approach we champion in the UK through ICSs and pharmaceutical partnerships."

Bekker is confident that ICSs have the potential to reinforce deeper levels of strategic partnership with the pharmaceutical industry. She remarks: "With the knowledge of what our future health needs will be, we must employ forward-thinking strategies to ensure healthcare professionals have every tool available to support patients with the best possible treatment and care."

Bekker adds, "We call on healthcare leaders and policymakers to embed these long-term partnerships and reforms, so we can build a healthcare system that meets the needs of every patient. Only through working together can we champion equitable improvements in population health, best in class healthcare provision and prosperity for the whole of the UK."

Follow Johnson & Johnson Innovative Medicine UK on LinkedIn for updates on our business, our people and our community

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[1] The Health Foundation (2024). Available at: https://www.health.org.uk/sites/default/files/upload/publications/2024/Health%20inequalities%20in%202040.pdf. Accessed November 2024.

[2] Macmillan Cancer Support (2024). Available at: https://www.macmillan.org.uk/about-us/what-we-do/research/cancer-statistics-fact-sheet#references. Accessed November 2024.

[3] EFPIA WAIT Indicator (2024). Available at: https://www.efpia.eu/media/vtapbere/efpia-patient-wait-indicator-2024.pdf. Accessed November 2024.

CP-488199 | November 2024

Commercial feature

Hidden costs, broken systems: fixing the UK's social-care crisis

As hospital waitlists grow, the need for social care reform is urgent. Calls are growing for fairer funding, reduced means testing and sustainable solutions to secure late-life care

Wes Streeting, the new health and social care secretary, has one of the toughest jobs in government. With hospital waiting lists of about 7.5 million patients, the NHS must be his first priority.

But this should not be at the expense of care and nursing homes. Despite endless commissions and reviews over the past 40 years, successive governments have left social care underfunded, under-staffed and locked into an inequitable system. While the NHS is free at the time of use, care-home admissions are means tested.

As The King's Fund healthcare charity put it so succinctly: "The difference is huge. No one is asked about their house value if they need medical treatment for cancer, yet, if they need social care because of dementia, that is exactly what happens. This level of means testing sets England apart from many other progressive, developed countries such as Germany, Japan and Denmark."

This is why Hartford Care Group, which runs 19 care homes, is campaigning for better public education around paying for social care, and the appointment of a visionary minister for care and nursing homes to eliminate means testing and the financial insecurity riddling social care. More than 370 care homes in England closed in 2023.

The Department of Health and Social Care estimates that one in seven residents pays more than £100,000 for care. Means testing results in thousands of families selling their homes.

People with assets of more than £23,500, including property, savings and investments may be liable for all care-home charges. The Office for National Statistics reported that of the 372,000 people living in care and nursing homes in 2022-23, more than a third were 'self-funders'. The rest were supported wholly or partly by local authorities or by the NHS if they had complex, long-term health problems.

Kevin Shaw, chief executive of Hartford Care, says: "There are strategic, far-reaching national campaigns to help people understand the importance of pension savings, but nothing exists to provide clarity on care-home placements and provision. All too often, information simply comes too late."

In a national survey of 2,000 UK adults commissioned by Hartford Care, 49% of respondents said that they had no savings for later life care. Those aged 30 to 59 were the least likely to save.

Hartford Care has a simple solution for care and nursing homes. Shaw explains that all workers could begin making additional national insurance (NI) contributions early in their lives – in their 20s, perhaps. Whereas existing NI payments are used to fund the NHS and state pensions, the extra contributions could be used for late-life care.

He adds: "If I took out a mortgage now, I could get insurance for, say, £140,000 for £5 per month over 30 years. A state-run, care-home insurance scheme could work in exactly the same way.

"Tax free, it would have the government seal of protection. I'm sure most people would contribute willingly if they were properly informed about the cost of and the challenges facing social care."

Bureaucratic red tape is another multi-million pound bill. English care homes must register with the Care Quality Commission, the independent regulator of health and social care services. Registered care homes can accept self-funding residents as well as those funded by local authorities and the NHS.

But some local authorities refuse to pay care homes unless they have had a CQC inspection — even, remarkably, if they are CQC registered. Hartford has been waiting for more than 12 months for the CQC to inspect its two new £20m homes.

Shaw says: "These two homes are running at only 50% occupancy for want of CQC inspections — local authorities are a big chunk of our business.

"This has left us with 132 empty beds even though we pay the CQC about a quarter of a million pounds in registration fees. In my three years at Hartford Care we've had only two CQC inspections. This is at a time when local authorities are screaming for places."

The 1.2% rise in employers' NI contributions will add millions to care homes' NI bills. The NHS is exempt from the new charge, but GPs, care homes and hospices are liable.

Setbacks for future residents include the scrapping this year of the government cap restricting the amount a person could pay for their personal care to £86,000.

So where do we go from here? The government has promised to "grip" the social care crisis, which means closing the widening gap between the population's need for support and the availability of publicly funded care.

It could do so by adopting Hartford Care's vision for care home charges to be met through additional NI contributions. Home-care provision could then keep up with the needs of a population that is both ageing and increasingly susceptible to multiple long-term conditions. The life expectancy of older people with learning disabilities is increasing, adding to the pressure — as is the number of people with Alzheimer's, including those under 65.

In April 2024, the Nuffield Trust, the independent healthcare think-tank, reported a decline in the total number of beds in care homes per 100 people aged 75 and over, from 11.3 in 2012 to 9.6 in 2020 — a 15% fall.

The shortfall is projected to reach 64,000 by the end of 2024. Thousands of patients who should be in care homes are blocking beds in NHS hospitals, resulting in longer wait times for other NHS patients.

The government has allocated an additional £600m to social care, but Shaw says, "This isn't enough." No one will blame him and others in social care for looking on with envy at the additional £22bn NHS funding.

But the King's Fund argues that social-care reforms should look beyond funding. It says: "The fundamental need is to make the system fairer, with more people able to access care that is, at least in part, funded by the state. This would be the mark of a more decent society."

Shaw concludes: "We believe that there is a huge opportunity to transform social care for the better. Not least, because of the dedication and compassion we see from our staff every day to create a home away from home for every single resident of the Hartford Care family."

> **We believe that there is a huge opportunity to transform social care for the better. Not least, because of the dedication and compassion we see from our staff every day to create a home away from home**

To read Hartford Care's *Social Care in Crisis* report in full, visit hartfordcare.co.uk

hartfordcare

INTERVIEW

'You really have to invest time in educating investors'

Flo Health is Europe's first femtech unicorn. The company's CFO, **Tamara Orlova**, outlines the challenges femtech startups face in getting investors onside

Sam Birchall

Femtech has faced an uphill battle ever since women began using diaphragms for contraception in the 1800s, with age-old taboos around women's health causing under-investment and a lack of research. But is the rise of Flo Health a sign of change?

In July, Flo Health became Europe's first femtech unicorn. The period- and pregnancy-tracking app raised $200m (£156m) from General Atlantic, a growth investor, becoming one of the handful of femtech companies to be valued at more than $1bn.

Founded in 2015, Flo's platform enables users to track their ovulation cycle and monitor symptoms, and offers relevant educational insights. Apps such as Flo have changed how women engage with their health. The platform's 70 million monthly users are evidence of the demand for such services.

Tamara Orlova is Flo's chief financial officer. Since joining the company in 2019, she's focused on cutting losses and helping to drive the firm from a startup to a rapidly growing scale-up. Flo's revenue in 2023 was $112m (£86m), up from $35m (£27m) in 2022, according to the latest annual accounts.

Despite the growing demand for female health solutions, firms must contend with deep-rooted prejudices that make accessing capital much harder, Orlova says.

Although women make up more than half of the population, products and services focused on their health have long been viewed by investors as a niche market. Part of the problem, Orlova explains, is a male-dominated investment community that "often fails to grasp the value proposition" for women's health products.

She recalls walking into pitch meetings and having to explain to a room full of men the intricacies of the female fertility experience. "Like most niche markets without a track record, investors struggle to validate the business model and scalability. You really have to invest time in educating investors."

Orlova faced considerable pressure to map out and communicate a clear equity story that investors would buy into. "It's easier the more milestones you hit and the more funding rounds you go through," she says. "But it's a long process and it can be hard to stay enthusiastic."

For Flo, securing game-changing investment was about building and managing the relationships with investors. This began long before the firm went to market.

There are no shortcuts, Orlova says. "A lot of it came down to research and preparation. We identified investors that we knew could help with our specific challenge and made sure we knew exactly what their profile was," she says. "Not every investor is going to have the same questions or way of thinking, so come prepared – I've found that the more information you are able to give them up front, the more comfortable they are to move faster."

Orlova says Flo's leaders spent considerable time crafting the story of the company, and cautions business leaders against waiting until their 'runway' is too low.

"You'll be in a harder position to get the best deal," she warns. "Start communicating with your investors as early as possible. We were in discussions with General Atlantic for years prior to their investment."

What role should the CFO play in investor discussions? "It's probably the one function in the company that is actively involved through the entire process," says Orlova. "And the fact that investors have become more data-driven means they are looking more closely at us to provide those crucial pieces of information."

> **Not every investor will have the same questions – the more information you give them up front, the more comfortable they are to move faster**

Women's health is still a controversial topic in some parts of the world. Orlova says there are additional complications that come from operating in the female fertility market that Flo has had to navigate as a result, including reproductive laws and data privacy concerns.

In 2022, the US Supreme Court overturned women's constitutional right to abortion, triggering fears among users of menstrual-tracking apps that their data could be used against them in states where abortion has lost legal protection. Thanks to growing concerns over political policies, some women have deleted their period-tracker app. Global usage decreased 7% in 2023, according to analysis by Sensor Tower, an app intelligence firm.

In response, Flo established an "anonymous mode" that allows people to use the app without linking any personal data to their name. It has since open-sourced the technology behind this anonymous feature with the rest of the femtech sector.

Concerns about data privacy are not unfounded. Prior to the recent update, Flo's average daily users had been on the decline for several months following its 2021 settlement with the US Federal Trade Commission over allegations it had shared data on users' menstrual cycles and pregnancies with third-party companies, including Google and Facebook.

A recent poll by the Information Commissioner's Office of women using fertility apps found that transparency over how their data is used and how secure it is were bigger concerns than cost and ease of use when it comes to choosing an app.

"Protecting our users' data has become a huge focus for the business," says Orlova. "It is important that we have a direct line of communication with our users and are continually striving to improve the experience we offer."

Despite its female-focused service, Flo was founded by two brothers, Dmitry and Yuri Gurski. The fact that a male-founded firm has become Europe's first unicorn femtech to achieve unicorn status has sparked online backlash.

In a viral LinkedIn post earlier this year, Anna-Sophie Hartvigsen, co-founder of Female Invest, an investment learning app, wrote: "A company founded by men, led by men and funded by men became the first women's health app to achieve unicorn status. If this doesn't show you everything that's wrong with the ecosystem, I don't know what will. No other company in the industry founded by women has been able to scale equivalently because they can't raise money."

It's no secret that female business leaders find it more difficult to raise money than their male counterparts. Female-founded startups accounted for just 2% of VC investment in 2023, according to data by PitchBook, an investment-insights platform. On average, female-led femtech startups raise $4.6m (£3.9m), whereas those with all-male teams raise $9.2m (£7.4m), according to data published in the *European Femtech Report 2023-2024*.

Such findings raise concerns that female founders may feel pressure to add a male to their executive team to improve their chances of funding.

Although Orlova acknowledges these challenges, she believes that a successful femtech business, regardless of who is at the helm, is a win for the entire sector.

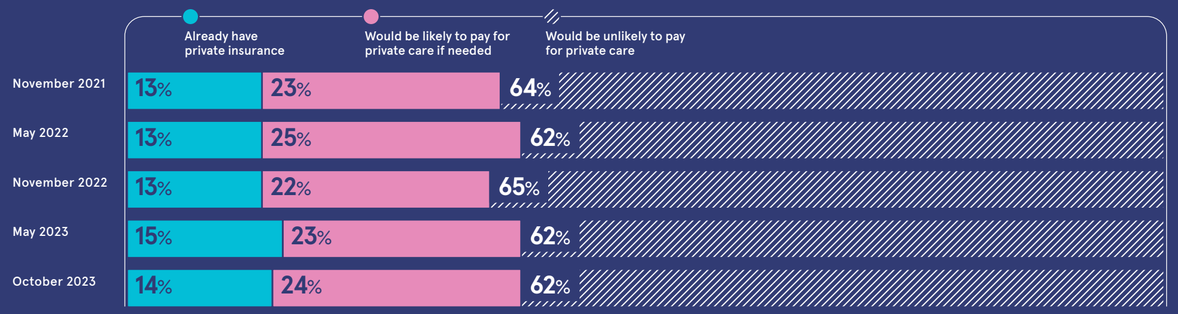
With its newfound unicorn status, Orlova hopes Flo will open the door for other femtech businesses and drive further innovation in the space. The startup already has plans to expand into new areas in women's health, including perimenopause and menopause. Whether Flo's own success is a sign of things to come for the sector remains to be seen.

PRIVATE CARE IN THE UK

The NHS is facing historic pressure on its services and public satisfaction with the health service is at an all-time low. There are concerns therefore that those seeking care will increasingly turn to private insurance or self-pay options, which could lead to a two-tiered health system and further deterioration of the NHS. But such fears are yet to be realised. Rates of privately funded inpatient admissions, as well as the UK public's willingness to pay for healthcare, remain stable and relatively low.

ONE-QUARTER OF UK ADULTS DO NOT HAVE PRIVATE COVERAGE BUT WOULD BE WILLING TO PAY FOR PRIVATE CARE

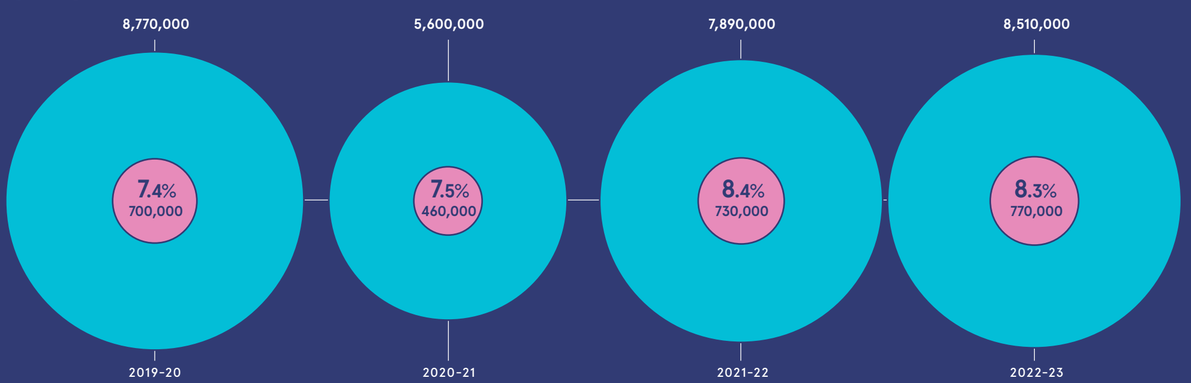
Share of UK adults who have private health insurance or would be likely to pay for private care if they needed it



The Health Foundation, 2024

FEWER THAN 1 MILLION ELECTIVE INPATIENT ADMISSIONS ARE HANDLED PRIVATELY

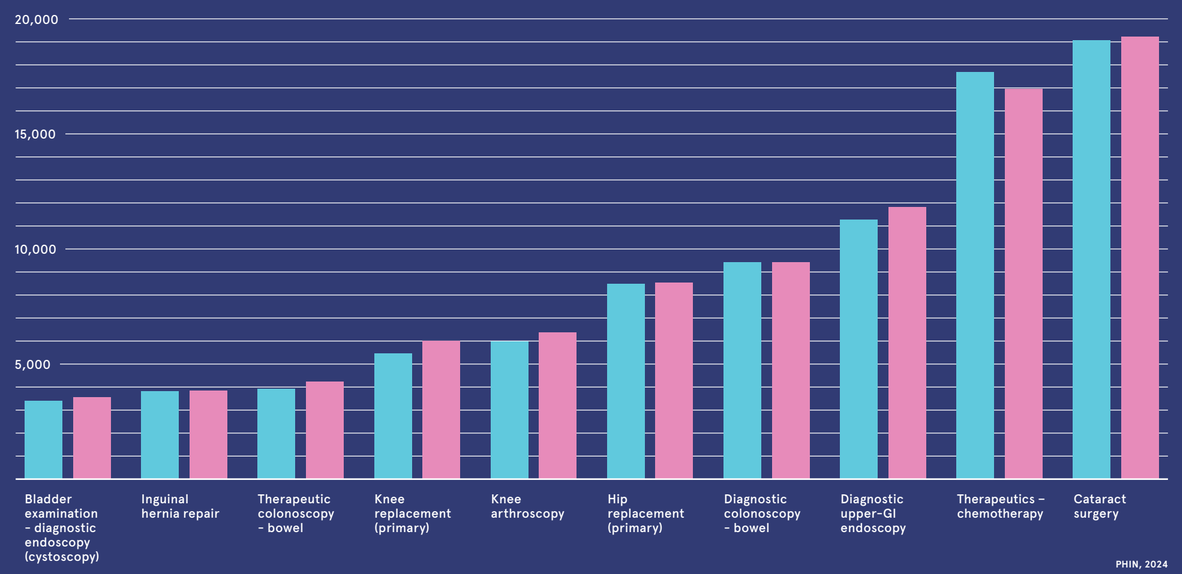
Number of elective inpatient admissions handled by the NHS and private sector; plus private sector share of total



The Health Foundation, 2024

CATARACT SURGERY IS BY FAR THE MOST COMMON PRIVATE-CARE PROCEDURE

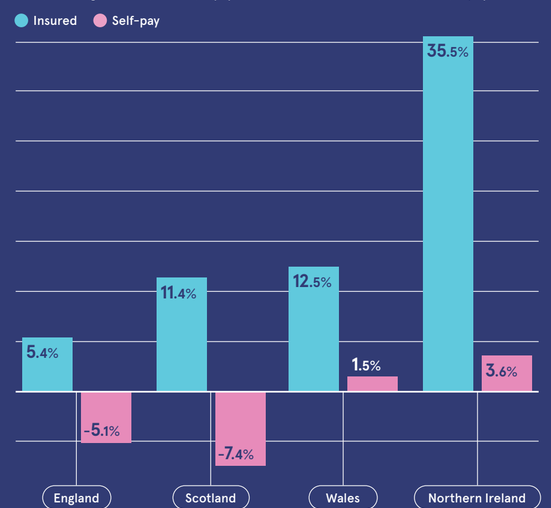
Number of insured and self-pay admissions for particular procedures in the UK



PHIN, 2024

RATES OF PRIVATELY FUNDED CARE ARE GROWING FASTER IN THE DEVOLVED NATIONS

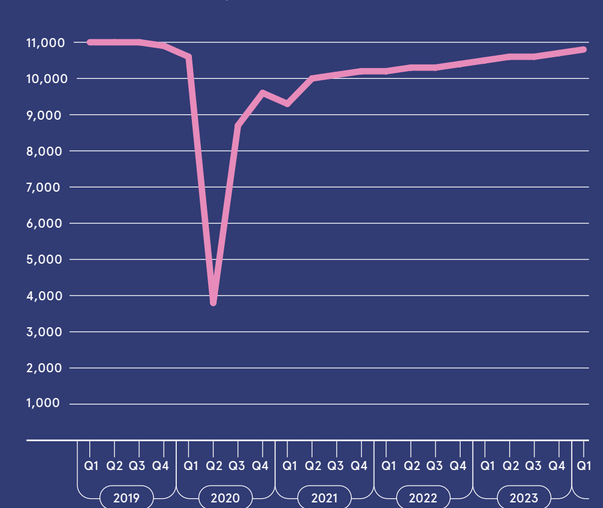
Percent change in insured and self-pay admissions between Q1 2023 and Q1 2024, by nation



PHIN, 2024

THE NUMBER OF CONSULTANTS WORKING IN PRIVATE CARE HAS REMAINED BROADLY STABLE

Number of active consultants in UK private healthcare



PHIN, 2024

Commercial feature

Patient-first serial innovation: a new era in biotech discoveries

Vertex Pharmaceuticals is committed to reshaping the landscape for people living with serious diseases

Vertex Pharmaceuticals is a global biotechnology company that invests in scientific innovation to create transformative medicines for people living with serious diseases. It is best known for its innovative treatments for cystic fibrosis (CF), a life-threatening condition that causes sticky, tar-like mucus to build up in the lungs and other organs. But the model it developed for research in CF has led to the development of other innovative treatments.

Its success stems from an unwavering commitment to research and development (R&D) and understanding of causal human biology to course correct a disease. The company believes that the true value in the industry lies in scientific innovation, which is why three out of every five Vertex employees work in R&D.[1]

David Altshuler, Vertex's chief scientific officer for ten years, says: "Every dollar we don't invest in sales and marketing is another dollar we can invest in R&D. At Vertex, everything started with our corporate strategy, we made sure it was designed to enable serial innovation." This is not hyperbole. Innovative medicines are defined as those with an active substance or combination of active substances that have not been authorised before. Vertex has launched five since 2012. The total will be seven if the US Food and Drugs Administration (FDA) approves its two newest potential treatments.

Transformative advances in the treatment of cystic fibrosis

Vertex's pioneering CF programme followed the 1989 discovery of the cystic fibrosis transmembrane conductance regulator (CFTR) gene, which controls salt and water flowing in and out of cells. Affecting tens of thousands of people worldwide, CF is caused by a defective or missing CFTR protein.

The CFTR discovery generated global excitement as the first disease-causing gene to be identified in any condition. But, as Altshuler points out, the following decades highlighted the wide gulf between identifying a genetic problem and knowing how to fix it.

Pre-existing medicines such as antibiotics and steroids treated the symptoms of CF such as infections and inflammation, but the R&D vision was to address the genetic defect by addressing the underlying cause of CF by restoring the function of the CFTR protein. Developing its CF therapies, Vertex screened more than one million molecules, designed and synthesised more than 30,000 molecules and ran more than 150 clinical trials in over 10,000 patients.[2]

In 2012, the European Medicines Agency (EMA) approved Vertex's first medicine targeted at the underlying cause of CF; it treated 4% of the patient population.[3] But R&D laid the foundations for a string of three more transformational therapies. By 2019 the company had developed four medicines that were capable of treating approximately 90% of CF patients. Given this progress, they are also looking to develop an mRNA therapy, to support the less than 10% of patients with CF who do not benefit from small molecule CFTR modulator therapies.

There are few comparable recent advancements - the development of powerful HIV drugs in the 1990s is one. HIV/AIDS had been a death sentence. Like the CFTR medicines, the new HIV therapies did not cure, but they turned a terminal illness into a chronic, manageable one.[4] Between the 1970s and 1990 life expectancy rose to about 30 due to nucleoside reverse transcriptase inhibitors.

Altshuler says: "Innovative treatments for cystic fibrosis have changed patient outcomes over time. Estimates have shown that the median age of survival, for patients with CF relying on supportive care alone, would be 38 years.[5] With early adoption of new standard of care therapies before the age of 12, some patients could live up to their 80s."[6]

Vertex has applied its unique R&D strategy to discover potential treatments for other serious diseases:

- **Sickle cell disease & transfusion-dependent beta thalassemia:** Both diseases are serious and lifelong inherited blood diseases, which can cause damage to, or failure of, multiple organs in the body. They are caused by mutations in the HBB gene and require lifelong treatment, ultimately leading to a decreased quality of life and reduced life expectancy.[7]
- **Pain:** There hasn't been a new class of acute pain medicine in more than 20 years and Vertex believes it can redefine the treatment of pain with a new mechanism of action. Vertex is investigating small molecules that aim to inhibit selected sensory nerves and prevent pain signals from travelling to the brain to potentially alleviate both acute and chronic pain.
- **APOL1-mediated kidney disease:** A genetic condition linked to two variants of the APOL1 gene. It can cause rapid progression to kidney failure, characterised by fatigue, lower limb swelling and weight gain.[8]
- **Type 1 diabetes:** Linked to genetic, immune and environmental factors, type 1 diabetes results in an absence of insulin producing cells. Vertex is investigating multiple treatment approaches.[9]

> We are relentlessly working to bring more medicines to patients. We are already working on programmes that are not just for 2025, but 2030 and 2040

Vertex strives to take on the impossible, it is developing the first non-opioid acute pain treatment in more than two decades, and has set a goal to change the paradigm of pain management. "We're incredibly focused on serial innovation. If something has never been done before, many companies will say it cannot be done, but at Vertex, we see it as an opportunity," says Altshuler.

"Vertex is in a very interesting and exciting position. Each step forward requires more energy and even more hard work from our world-class team. Over the last 10 years, we have shown that we're not only able to discover and develop medicines for CF. We have shown that our R&D strategy can work. But of course, we are relentlessly working to bring more medicines to patients. We are already working on programmes that are not just for 2025, but 2030 and 2040. We plan to keep helping patients decades from now."

For more information please visit vrtx.com/en-gb

VERTEX

[1] 2023-Vertex-Corporate-Responsibility-Report.

[2] Vertex Pharmaceuticals: Humanizing drug discovery.

[3] Vertex Receives European Approval for KALYDECO™ (ivacaftor), the First Medicine to Treat the Underlying Cause of Cystic Fibrosis in People With a Specific Genetic Mutation (G551D).

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[6] Lopez A et al. Elexacaftor/tezacaftor/ivacaftor projected survival and long-term health outcomes in people with cystic fibrosis homozygous for F508del. J Cyst Fibros. 2023 Jul;22(4):607-614.

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ARTIFICIAL INTELLIGENCE

Machine medicine: how AI could transform the NHS

AI holds great promise for the healthcare industry, from improving diagnostics to accelerating treatments. But is the technology really a panacea for the NHS?

Portrait via iStock

Chris Stokel-Walker

The NHS is suffering from years of lacklustre performance and an overwhelming patient backlog. Could AI put it on track for a full recovery?

The technology holds enormous promise across the economy, but one of its greatest potentials is in supercharging the sluggish health service. In fact, three-quarters of NHS staff believe that AI should be used for patient care, while 81% believe it will be a boon for the administration of the NHS, according to a July 2024 survey by The Health Foundation.

The public are slightly more reticent, but there are still signs of support for the technology: 54% want to see AI in treatment, while 61% believe it will benefit operations behind the scenes.

So where and how should AI be deployed – and in which areas should it be avoided?

"The real value of AI in healthcare is in applying it where it's genuinely needed and can make the greatest impact – not just because it's possible," says Alan O'Reilly, chief innovation officer at Purple Transform, which develops AI for the health system. "With the NHS under tremendous strain, AI-driven solutions can provide critical support to understaffed teams and help make community-based virtual care a reality."

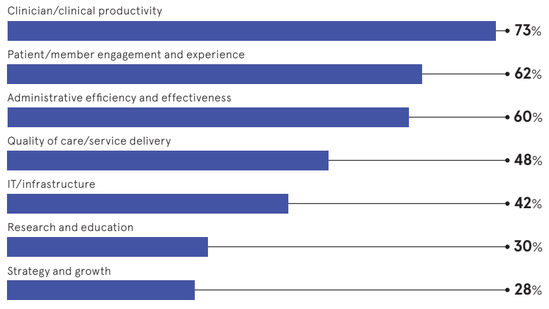
For instance, remote and virtual healthcare can help to free up beds in hospitals while ensuring that patients are still given comprehensive care and attention. "AI-powered remote patient monitoring – using sensors that measure vital signs – could enable individuals to recover at home more safely, reducing hospital strain and enhancing patient comfort," says O'Reilly.

Systems that alert staff when a vulnerable patient leaves a room or a dementia patient opens and closes refrigerator doors and cutlery drawers can help health professionals to understand when and how to intervene to support their recovery or treatment. The technology could also assist patients in need, such as issuing a dementia patient a reminder to eat.

> The real value of AI in healthcare is in applying it where it's genuinely needed and can make the greatest difference – not just because it's possible

HOW MIGHT THE HEALTHCARE INDUSTRY BENEFIT FROM USING AI?

Share of healthcare leaders ranking the following as key benefits of using AI in the sector



McKinsey, 2024

"These AI-driven insights can enhance healthcare delivery and ensure that resources are focused where they matter most – on better patient outcomes and quality of life," O'Reilly adds.

AI could also be used in mental health support, says Aynsley Bernard, principal data scientist at Kooth, a digital mental health provider. For instance, the technology can be used in interactive tools and chatbots, which can help to address skills shortages and build workforce resilience, ensuring more efficient patient care.

"Beyond triage and referral, AI has the potential to provide highly personalised care, especially when it comes to mental health support," Bernard says. "This includes offering coping strategies tailored to an individual's specific needs, enabling continuous self-management."

AI can also be used to rifle through large volumes of data to pick out patterns, which can help to predict mental health trends in individuals and populations. "This would enable healthcare providers to respond proactively to risks by identifying early signs of mental health deterioration and intervening before symptoms escalate," says Bernard.

Marta Zanchi is the founder and managing partner of Nina Capital and the former director of biodesign for digital health at Stanford University. She believes AI has the potential to unlock efficiencies that could spread across the healthcare industry. "There are some novel use cases that haven't yet been explored to their full potential," she adds.

Zanchi says AI tools could be used to automate workflows involved in running pharmacies. For instance, the technology can be used to track and check inventories to identify when new drugs need to be ordered and analyse patient-use patterns to better predict and head off shortages. She also thinks AI could be used to triage patients: "In the context of the overstretched NHS, AI tools can help overwhelmed clinicians prioritise patients based on risk and direct them to the right care settings," she explains.

What's more, research by the National Institute of Health and Care Excellence shows that AI can reduce the number of broken bones missed when analysing X-rays. The technology can also provide high-quality responses to many medical questions, according to research by Harvard University.

Yet Zanchi and others worry about the knock-on effects of going all-in on AI. Some predict a world where AI supplants the human doctor.

Experts tend to agree that health providers should avoid wholesale AI implementation on the front lines of treatment. "Autonomous 'AI doctors' would face resistance due to a lack of trust and concerns around accuracy and regulatory compliance," Zanchi explains. "Instead, we should be looking at AI co-pilots that can take the burden of manual tasks – such as utilisation management and writing documentation – away from clinicians."

Bernard is equally concerned about an over-reliance on AI, which she believes could lead to "skill regression among clinicians". Some healthcare professionals even worry that AI integration will result in a two-track health system, where those who can afford to pay are given human-based treatment and those who cannot are left to consult with virtual assistants. For these reasons, Bernard stresses that AI tools must be used to augment humans, rather than replace them.

What's needed is a change in perception, says Zanchi. While she acknowledges the excitement surrounding AI is understandable, the industry must think about patient outcomes first and AI second. There's no doubt the technology will be transformative, but it is unlikely to be a panacea.

INTERVIEW

‘This is for the benefit of individuals, their families and the population’

The UK’s largest medical research project has big ambitions for the prevention, detection and treatment of diseases in the NHS, from cancer to diabetes, says **Raghib Ali**

Sarah Dawood

When Dr Raghib Ali was a child, his father developed glaucoma. The eye condition eventually led to the loss of his sight and forced him to stop working in his 40s.

This personal experience sparked Ali’s interest in preventative medicine. The level of deterioration endured by his late father can be avoided; early diagnosis of glaucoma and treatment can be life-changing for glaucoma patients.

“If you catch it early enough, you can prevent most of the blindness from glaucoma,” Ali says. “It’s an example of the kind of disease that we would hope to tackle through Our Future Health and what we’d hope would be possible for many, many more conditions. It was too late for my father, but that’s why it’s very relevant for me personally.”

Ali is chief medical officer and CEO of Our Future Health, the UK’s largest-ever medical research programme and the biggest study of its kind in the world. The programme hopes to lay the groundwork for earlier prevention, detection and treatment of diseases in the NHS.

Our Future Health aims to enlist 5 million UK-based volunteers from a diverse range of backgrounds to donate blood samples for testing to assess how genetics contribute to the development of disease. These people will then be asked to return for further testing so they can be tracked over a long period of time.

The huge data project mainly focuses on tackling the diseases that impact most people and cause most deaths, such as dementia, cancer, diabetes, heart disease and strokes. However, it also aims to investigate the genetic causes of rarer diseases such as motor neurone disease, multiple sclerosis and heart failure. “These conditions are not as common but have a major burden both in terms of death and disability,” Ali says.

Our Future Health was set up as a charity in 2020 and is being delivered in partnership with the NHS, health charities and the pharmaceutical industry, with funding from UK Research and Innovation. Recruitment to the project officially started in 2022; it has just reached its milestone of 1 million participants providing blood samples.

Ali is a clinical epidemiologist and consultant in acute medicine at Oxford University Hospitals NHS Trust, where he still works shifts in A&E. He qualified as a doctor 25 years ago. His experience has shown him that serious health emergencies – such as heart attacks, strokes or kidney failure – are often the repercussions of uncontrolled long-term conditions.

“Essentially, we are operating more as a national sickness service, treating people who are already sick, than a national health service that tries to keep people healthy,” he says.

> **We are operating more as a national sickness service than a national health service**

The current model of healthcare is unsustainable and rates of disease are only expected to escalate. The Health Foundation predicts that nearly 25% more adults will have major illnesses in 2040 than now, accounting for an additional 700,000 people. Our Future Health aims to help the NHS move to a model based on earlier detection and intervention instead.

Currently, most disease screening programmes, such as those for certain cancers, don’t start until middle age or older. The project will identify people at the highest risk of developing certain diseases in their 20s, 30s or 40s instead, through analysing a combination of their DNA, environment and lifestyle. Those with the highest risk would be offered targeted screening programmes that are not simply based on age, which is “very important, but not the only factor”, says Ali.

Take glaucoma, for example. Ali himself could be tested to see if he is genetically susceptible to the disease, which is more reliable than relying on family history alone. If he is, he could receive routine eye pressure and visual field tests, as well as retina scan checks. “It’s a big change in our approach to how we manage health and disease, but it’s trying to keep people in good health for as long as possible,” he says.

Our Future Health is already one-fifth of the way towards its participant goal. But a major challenge is encouraging people to part with their personal health data for the greater good of the programme. The public is understandably wary, given several high-profile NHS data breaches in recent years. Earlier in 2024, for example, a Russian ransomware attack brought South London blood tests to a standstill for months and resulted in people’s medical records being published on the dark web.

Ali says that building public trust is vitally important to the programme’s success. Invitation letters have been branded with the NHS logo and come from him directly as CEO; this approach has helped, he says, because trust in doctors and the health service is still high. There are public-perception issues surrounding the involvement of pharmaceutical companies, he admits, but they play a crucial role in developing new diagnostic tests or treatments and in providing funding.

Communicating the overall purpose of the study has been paramount. “People understand what we’re trying to achieve – that this is for the benefit of individuals and their families and the population. This is why [so many] people have already joined the project.”

Building public trust relies on transparency around the data being collected, how it is used and the steps being taken to maintain its confidentiality and security, which is laid out through a data protection section on the charity’s website. This explains how all health data is encrypted, anonymised and placed in a “trusted research environment” – a secure space protected from unauthorised access.

> **It's a big change in our approach to how we manage health and disease, but it's trying to keep people in good health for as long as possible**

Anyone who wants to use the resource – such as a researcher at a pharmaceutical company – must go through a separate independent access board and prove their research is for public health benefit. “This is the primary mechanism to ensure that data is being used in the right way,” Ali says.

But no system can ever be foolproof. “We can’t guarantee 100% that no one will ever get access to the data,” he says. “That’s not possible. But we will do whatever is humanly possible to minimise that risk.”

For Ali, moving from A&E doctor to CEO is quite the career change. But this is not his first time in a senior administrative role, having previously worked as the director of the Public Health Research Centre at New York University in the United Arab Emirates (UAE), where he also set up a much smaller version of Our Future Health.

Being both CEO and chief medical officer is challenging, but the huge scale of the project has made his job easier. “The project is so unique. People have joined from all different backgrounds – from the private sector, the NHS, academia,” he says. “It’s a once-in-a-generation opportunity for the UK and the world to understand how to better prevent common chronic diseases. So we have attracted very good people.”

The Labour government has vowed to transform the NHS from a “sickness service” to a “health service”, a sentiment that’s long overdue. With 3.7 million people expected to be living with serious diseases such as cancer, diabetes and dementia by 2040, there will be even more pressure on an already-stretched service.

Ali believes medical research will play a vital role in transforming the model of care, enabling the NHS to get on top of its backlog and creating the capacity it so desperately needs.

“Those of us in the field recognise just how much pressure the system is under. The current model is unsustainable,” says Ali. “The principle of being able to access health free at the point of need is something I’m personally very passionate about and I genuinely believe that Our Future Health is an important part of that solution.”

Commercial feature

Advancing global healthcare through medical-device innovation

The Voluntary Improvement Program boosts medical-device quality, improves patient outcomes and promotes industry collaboration

The world’s estimated two million different types of medical devices range from artificial hips to heart pacemakers and from blood pressure monitors to nifty gadgets that split pills in two.

Regulating quality and safety in this $515bn (£385bn) global market is a huge challenge for authorities like the US Food and Drugs Administration and the UK Medicines and Healthcare Regulatory Agency.

Medical devices do not have to be of the highest quality to meet the ‘compliance standards’ required to bring them to market. Some manufacturers have expressed concerns that increasing regulatory requirements for quality and safety standards would result in increasing costs and wait times for patients.

But a novel FDA initiative, the Voluntary Improvement Program (VIP), has shown that ‘going above and beyond compliance’ towards excellence has the opposite effect. VIP appraisals within companies have been shown to increase manufacturing efficiency and product availability by helping device-makers better understand, measure and improve everything they do.

Manufacturers can decide whether or not to apply for the VIP – more are expected to do so in the light of the programme’s early, astounding successes. ISACA reports that one VIP company has increased production capacity by 11%, resulting in an additional $15m (£11m) in sales. Another participating company has generated $286,000 (£224,000) in annual savings.

From a patient perspective, the appraisals have enabled a VIP company to provide 882 more patients with faster life-saving treatment. Production at yet another VIP company has been increased by 62%, staff turnover has decreased by 70% and customer complaints have reduced by 95%.

> **Results from the VIP demonstrate that prioritising quality and collaboration benefits both patients and manufacturers**

Kim Kaplan, senior product manager at the Information Systems Audit and Control Association (ISACA), explained that the programme followed an FDA study in 2011 into how to improve device quality and safety.

This prompted the launch of the Medical Device Innovation Consortium (MDIC), the only US public-private partnership to work with government and industry to promote innovation in medical devices. “The MDIC provides a safe space where the industry and the FDA can collaborate on solutions together,” says Kaplan. The MDIC launched VIP in 2021 following a pilot version in 2018.

The New Zealand company Fisher and Paykel Healthcare (FPH), was among the first 120 manufacturers – including UK companies – in the ‘Case for Quality’ VIP programme. FPH makes devices for respiratory care and treating obstructive sleep apnea, a condition which restricts breathing.

Brian Schultz, FPH VP of quality, safety and regulatory affairs, said that the VIP had enabled the company to achieve improvements in its quality system processes by ensuring staff understood the rationale for them.

“We really worked to communicate the purpose and efficiencies of each process. The appraisals have changed mindsets and helped us get better at what we do,” says Schultz.

Other benefits included better resource planning and project management, improved data use and better control of performance objectives and targets.

A major plus for VIP enrollees is that they receive select regulatory relief from FDA to modify an existing product or launch a new one. This decreases the usual ‘review and inspection time’ and reduces the costly regulatory burden.

Asked what was the VIP’s major benefit, Kaplan replied: “This may sound strange, but I think it’s the relationships the industry develops, both with the FDA and with each other. The VIP facilitates cross-industry conversations. We have working groups and industry representatives on the programme’s governing committee.”

Fostering these kinds of relationships is especially beneficial when there is significant regulatory flux. “Look at the UK’s MHRA, it is in the process of developing a new MedTech regulatory framework. This is a perfect example of when companies need to be working hand in hand with regulators,” says Kaplan.

“VIP is a wonderful opportunity for them to get connected with their peers and identify solutions to challenges they’re all facing. To learn from each other, as well as to be more collaborative with the agency. It’s a win-win for everyone.”

Results from the VIP demonstrate that prioritising quality and collaboration benefits both patients and manufacturers. With increased efficiency, reduced costs and improved patient outcomes, the initiative paves the way for a stronger, safer medical device industry. As more companies join, VIP has the potential to redefine global healthcare standards.

For more information please visit isaca.org/vip

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PREVENTION

Healthcare providers weigh the benefits and pitfalls of personalised preventive care

Personal health data could support a range of medical applications, boosting interventions and lessening the load on the NHS. But significant obstacles must be overcome

Tom Ritchie

UK healthcare providers have long aspired to deliver personalised preventive care. The benefits are clear: an individual's health data can be used to establish their risk of future disease and prescribe more effective medical interventions. However, success will demand an attitude change from clinicians and the public.

Preventive care has generated excitement in both the private and public sectors. For instance, an analysis by The Health Foundation found that the term "personalised prevention" was mentioned 30 times in policy documents published by The Department of Health and Social Care since 2013.

Andy Wilkins is programme director for healthcare innovations at Imperial College Business School and founder of Future of Health, a think-tank. He is optimistic about personalised preventive healthcare. "Imagine knowing in advance that a chronic condition could be prevented or mitigated because those involved in your healthcare understand how the interplay of your unique genetic, behavioural and environmental factors are shaping your health."

According to Wilkins, harnessing health data will enable professionals to move from treating symptoms to addressing root causes. "It's a move towards a more humanised, anticipatory approach," he says.

The potential of such solutions is clear to health professionals and legislators alike, with the Conservatives and Labour both pledging to expand personalised care in their 2024 manifestos. But the technology and systems necessary to deliver tailored healthcare have yet to be implemented widely.

Stephen Critchlow is founder and chairman of Evergreen Life – an app that enables users to track and manage their health data – and a former NHS pharmacist. He thinks part of the problem is a mindset barrier. "It's not the way traditional medicine thinks," Critchlow explains. "We're asking simple questions. How's the health of your skin? How's your sleep? From there we can steer people to have a lifestyle that means they're less likely to get disease in the future."

If GPs had access to large pools of such data, they could identify trends associated with common health ailments in certain areas and potentially provide a better service. Wearables and app-based solutions also enable individual patients to take charge of their health metrics, which could motivate healthier lifestyle choices.

Such democratised tech also helps to redress historical biases in the health industry, which negatively impact certain demographics.

> **Imagine knowing in advance that a chronic condition could be prevented or mitigated**

The technology has already been trialled. For instance, in 2021 residents of Wolverhampton were given fitness trackers and access to an app that prompted them to make healthier choices. Incentives such as vouchers or theme park passes were given to those who ate well and exercised regularly.

Widespread adoption in the health service of any such scheme is at least three years away, according to the NHS's technology roadmap.

"Structurally there are real barriers to adoption," Wilkins explains. These include resource constraints, outdated IT systems, fragmented silos and the challenge of upskilling a healthcare workforce to use new technologies. But the most significant hurdle may be cultural, he says.

Wilkins adds: "Transforming and broadening national service-oriented systems, such as the NHS, to include a wider set of community actors and emphasise prevention demands a fundamental change in collective attitudes."

Critchlow agrees. Thanks to constrained budgets and a reticence to take risk, he explains, the health service is far more likely to buy the data and insights of third-party apps than build its own capability.

A personalised preventive model would also require a change in patients' habits. So far, attempts to change behaviour through information alone have been unsuccessful. A 2019 study published in the British Medical Journal shows that while interventions in smoking have been successful, childhood obesity is still rising. Moreover, healthy life expectancies have fallen in the UK over the past decade.

"We need to create environments where individuals feel supported, not burdened, in taking ownership of their health," Wilkins says. "Patients have to be more involved, but systems must also become more empathetic to make this engagement meaningful and manageable."

Trust is key to any engagement involving personal health data. In 2022, a paper published by the Department of Health and Social Care acknowledged that to reach future aims, the public must trust the NHS to handle patient data in a way that is safe and secure. Although seven in 10 NHS patients (69%) trust the public health service to protect their information, only four in 10 (42%) trust third-party service providers, according to a 2023 survey by the Health Foundation. As the NHS will likely rely on private sector partners to deliver personalised preventive care, could an unwillingness to adopt app-based solutions hamper the rollout of this strategy?

This will depend on how the health service conducts private sector partnerships. Wilkins believes third-party service providers that can provide the technology to track, collate and analyse data will be integral to a functioning health service of the future.

But he stresses: "Partnerships between tech firms and the NHS must prioritise meaningful outcomes over market-driven interests, ensuring that the benefits of innovation are felt by all, not just a tech-savvy few."

Can wearable tech reduce bias in medical trials?

The development of effective medical interventions relies on data recorded in medical trials. Ideally, treatments would be tested across demographics, accounting for population differences in gender, age, weight and ethnicity.

However, "traditionally medical trials have lacked diversity among participants, with white males making up the majority of research cohorts", says Professor Esther Rodriguez-Villegas, director of the Wearable Technologies Lab at Imperial College London.

For example, a 2019 analysis of global Phase 1 oncology trials found that 62% of participants were Caucasian.

"This leads to tools and treatments validated in these studies that may not be as effective for individuals outside the largest demographic," says Rodriguez-Villegas.

She points to the use of pulse oximeters during the Covid-19 pandemic as an example of bias in action. The tools used to read blood-oxygen levels were less effective on patients with dark skin tones, leading to some patients recording incorrect "safe" readings and receiving delayed or insufficient care.

Well-designed wearable tech offers a solution to these problems. Rodriguez-Villegas recently conducted research where patients wore technology that tracks sleep over several nights to collect data for treatments in sleep apnoea.

"It enables us to collect data over extended periods in natural environments, providing a more authentic view of the patient's real-world experiences. Additionally, it yields patient-specific insights that were previously unattainable, as conventional methods only provide snapshots of physiological data in controlled settings."

Sleep-disorder trials have historically skewed towards white men. Continuous Positive Airway Pressure (CPAP machines) – used to treat sleep apnoea – and even treatments such as cognitive behavioural therapy for insomnia are therefore biased towards males. For instance, Rodriguez-Villegas explains that insomnia is often caused by an imbalance of hormones in women, which is often overlooked in treatments.

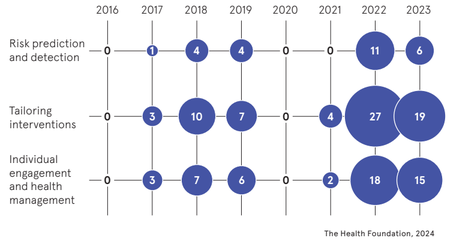
"Ensuring that diagnostic tools and clinical trials include a broad range of demographics could help to reduce disparities, fostering more equitable healthcare outcomes," she adds. "When universal design isn't feasible, developing devices with tailored calibrations for specific populations offers a safer and more effective approach."

But wearable technology is by no means a silver bullet. Relying on commercial products to glean medical data could lead to inaccurate readings owing to design or misuse.

"The UK government's proposal to deploy smart watches at large scale is an ambitious idea," says Rodriguez-Villegas. "There are notable risks in relying on devices that were not conceived with medical use as their primary purpose and hence do not yet deliver consistent high-quality data for clinical use."

THE FOCUS ON PERSONALISED PREVENTION IS GROWING

Number of references to personalised prevention in UK health policy documents, by ambition



The Health Foundation, 2024

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