

Spotlight

HEALTHCARE: A STATE OF WELLNESS?

Philip Dunne MP / Jonathan Ashworth MP / Mike Adamson



Spotlight



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A key component of the Leave campaign was the pressure it claimed that immigrants were placing on the NHS. Since the referendum, the government has continued in this vein, suggesting that hospitals might be compelled to treat only people carrying British passports. Fact-checking of these statements reveals that the NHS did pay £160m per year to treat people from other countries; this is equivalent to nearly half of what is spent in one day in the NHS, or 0.13 per cent of the total NHS budget.

That is not to say that health migrants are not a real problem. A wave of people from other countries really is about to arrive in the UK, and these people will weigh heavily on the NHS. As a result of the Brexit vote, the 1.2 million British people (nearly a five-year parliament's worth of immigration, at recent levels) who live in the EU will almost certainly lose the subsidised healthcare they were entitled to in France, Spain, Germany and elsewhere. Many of these people are retirees, about to enter the most expensive portion of their lives in healthcare terms, and they will need to return to the NHS. Should we ask, in the terms of the buoyant far right, what is to be done about this torrent of health migrants?

This is only a rhetorical question, of course. That British doctors and nurses will treat anyone, without demanding to see their identification or insurance, may be our greatest and most widely held point of national pride. It is the one aspect of British life that we can point to and say, without fear of contradiction, that all other countries should be like this. Voters of all demographics and opinions are unified in their respect and admiration for the health service; the next election will be decided, at least in part, on its future.

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Our commitment to the nursing profession

**Philip Dunne,
Minister of State
for Health, says
we must be more
innovative in our
nursing training
and supportive
of all health
service staff**

Six months may seem like a relatively short period of time to have been in a new role, but since becoming Minister of State for Health last July I've had plenty of time to experience and appreciate the vital work our frontline NHS nurses do every day of the year. Nurses really are the lifeblood of our healthcare system. They provide not only physical care for patients but emotional support at the best and worst times in their lives.

It is fantastic that there are now more nurses than ever on our wards – over 9,800 more since May 2010 and more than 51,000 training to join the profession. I have already been lucky enough to meet many nurses on visits to hospitals, so much so that meeting staff, hearing their perspectives on patient care and thanking them for what they do, are among the most rewarding parts of my role.

But I would be the first to acknowledge that there are challenges ahead. Demand for care is the highest it has ever been, our population is ageing, and complex conditions are increasing. I also acknowledge that there is more we

need to do in order to adapt to these challenges. When frontline pressures are high, we need to build the strongest possible team of frontline staff to confront them. This is the only way that nurses, and their colleagues, can continue providing the highest quality of care for their patients.

This is why investment in the future nursing workforce is one of our top priorities. Backed by our most senior nursing leaders – including the Royal College of Nursing – we are widening access to the nursing profession in a number of ways.

A few weeks ago the Health Secretary set out plans to develop new routes into nursing. Employers and our healthcare support workforce have said entry to the nursing profession through a full time university degree is too rigid and inflexible, and doesn't give them what they want or need. The new nursing degree apprenticeship, starting from September 2017, will open up more opportunities to train as a nurse for those already working in the NHS or those for whom full-time university study is not a realistic option. Dependent



The government is working with the Royal College of Nursing to reform access routes to the profession



“Nurses really are the lifeblood of our healthcare system”

SHUTTERSTOCK/CHRIS DORNEY

on previous qualifications and experience, it will take aspiring nurses from a Care Certificate to Registered Nurse.

Those successful in securing an apprenticeship will undertake part-time study to pass their nursing degree before becoming a Registered Nurse, benefiting from the practical work of a job on a ward at the same time, as well as protected clinical placement learning. By offering this level of flexibility, employers will be able to open up a career in nursing to people from all backgrounds and the NHS will have a nursing workforce equipped with the right skill mix needed for a modern day healthcare service.

We want to make sure we use every tool available to train and retain our nursing and care staff by opening work-based learning apprentice opportunities that previously would not have been possible.

The Nursing Associate role is another way to do this. The new role is designed to free up Registered Nurses to undertake the complex tasks they are trained for and take more of a lead in clinical decision-making. Nursing Associates will complement, not replace, Registered Nurses. This role will offer many existing health and care assistants, who are a vital part of our health and care system, the opportunity to develop their careers towards becoming a Registered Nurse if they wish to do so.

We want our health and care system to be the safest in the world and we know the Nursing Associate role will require a significant amount of skilled judgement. That is why we have asked the NMC to look into regulating the role and we expect a decision shortly. Regulating the role will provide assurances on patient safety and would reflect widespread views expressed during consultation with the public.

In the meantime, there has already been a huge demand from applicants for this exciting new role and those who

have been successful are starting their training at pilot sites across the country this month. I am already planning to visit one of the pilot sites in the next few weeks and look forward to hearing from new recruits and seeing how they will benefit patient care.

But to deliver the best possible care to patients, we need to do more than recruit the right staff. We must create supportive, positive and open cultures in organisations. Bullying and harassment can lead to low self-esteem, anxiety, depression and disengagement in our staff - nurses included. This in turn impacts upon their organisations, leading to low morale, reduced productivity, increased absenteeism, higher staff turnover and poorer patient care.

That is why I have made a personal pledge alongside NHS employers and trade unions to tackle bullying and harassment of NHS staff. I have challenged all NHS organisations to work in partnership with staff, publicly commit to positive action, track progress and make a difference.

When we think about innovation in relation to the NHS our minds can often jump to improved technology or a new wonder drug. But arguably, some of the most important innovation we undertake concerns our workforce – making sure they are supported and equipped to meet the constantly changing demands placed on our healthcare system.

Talented, dedicated nurses will always play a vital role in our health service. This is an important time for nursing and the government is absolutely committed to ensuring they have what they need to do their job well, in the same way that they are absolutely committed to meeting the needs of their patients.

Philip Dunne MP is Minister of State for the Department of Health

“If you take £4.5bn out of social care, it will hit the NHS”

The NHS may be the most persuasive point in Labour's new electoral agenda. Will Dunn meets the shadow health secretary, **Jonathan Ashworth**



Immediately to the left of Jonathan Ashworth's desk in Portcullis House are a large flipchart and a poster. The flipchart details the places Ashworth will visit in the coming week, when he tours different towns and cities discussing the NHS with “people who work in the NHS, patient groups, royal colleges, staff groups, people who aren't part of a group but have an interest in the future of the NHS”. The poster shows what was known, for a week or so in 2015, as the ‘Maggie Simpson map’: a Britain colour-coded by general election results, with an almost entirely Conservative-blue body and an SNP-yellow head.

In the centre of the coffee table is a copy of *The House* magazine, with Yvette Cooper on the cover.

“That's a coincidence!” laughs Ashworth, who nominated Cooper in the leadership election in 2015. He didn't declare support for either Corbyn or Owen Smith in last year's rematch. Though he would reject the comparison,

both Ashworth and Theresa May carried off a very successful 2016 by standing back while their parties fought bitterly amongst themselves. Previously a shadow minister without portfolio, Ashworth was promoted in October to one of the biggest roles on the opposition front bench, following in the steps of Andy Burnham and Diane Abbott.

It is a good week to be shadow health secretary. Three days before we meet, Jeremy Hunt was forced to redraw the four-hour waiting threshold for A&E as a target for “urgent health problems... but not all health problems”, while the British Red Cross chief executive described NHS hospital and ambulance services as a “humanitarian crisis”. The following day, Hunt was forced to admit to the Commons that the NHS had failed to provide mental health support to the 18-year-old daughter of one of its own nurses. The day we meet, the National Audit Office have reported that Hunt's plans for seven-day GP access were made “despite not having evaluated the cost-effectiveness of their proposals and without having consistently provided value for money from the existing services”. But Ashworth says he doesn't take any satisfaction from his opponent's tough week.

“I'm not one for demonising Jeremy; I rather like Jeremy. I'll probably get lots of criticism on social media for saying that. But if we get into a debate about personalities, we're missing the bigger picture – the systematic underfunding of the NHS, and deep cuts to social care.”

Does Ashworth agree with the Red Cross? Is the NHS at breaking point? “I think we have to be responsible in the language we use. It is certainly a winter crisis. A&E targets have been missed again, 20 hospitals have had to declare black alert. In the last few weeks, 50 trusts have put out messages saying they can't cope, several hospitals say they don't think they can offer comprehensive care and 140 hospitals, at least, are effectively turning people away from A&E. It is certainly a crisis this winter.

“What is outrageous is that the government were continually warned

about this. They've been consistently warned that unless they do something to solve the social care crisis in this country, it'll continue to put undue pressures on the wider NHS. And that is what we are seeing now.

"We've had six years of multi-billion pound cuts in social care. If you take £4.5 billion out of the social care sector, that is a lot of elderly and very vulnerable people not getting the support they deserve and need. It's inevitable that it's going to impact on the NHS."

Funding is the primary issue, for Ashworth. "The government insist they've given the NHS an extra £10bn. Those claims have been eviscerated this week by Simon Stevens at the Public Accounts Committee. The reality is that it's the biggest financial squeeze in its history. It's effectively flatlining, and indeed in 2018, as Simon Stevens said, head-for-head expenditure in this country will actually be cut in the NHS."

"Whenever you put this to Theresa May, she just stubbornly refuses to listen. She keeps saying we've had £10 billion, even though expert after expert after expert has knocked this down."

Ashworth says there needs to be "objectivity in the debate about the finances of the NHS", and that a new body, similar to the Office of Budget Responsibility, might offer this. By making reports to the health secretary as the OBR does to the chancellor, such a body would, says Ashworth, "allow parliament to scrutinise the judgements they are making about the allocation of resources. Government ministers have to be answerable to the people, ultimately, for the decisions they make for NHS financing."

Few would argue that NHS spending is as well-planned as it could be, but the money does have to exist for it to be allocated. Where would Labour find the funds to save the NHS?

"This government has chosen a multi-billion pound tax cut for corporations and a big capital gains tax cut for share transactions. It's chosen to give the very wealthiest estates in the country a £1bn pound inheritance tax

cut. In the most recent Autumn Statement, there was nothing for social care and yet there were millions allocated in capital expenditure for new grammar schools. And yet we have the NHS having to raid its capital budgets. So in the immediate term, I would say they do not need to make that set of decisions."

So Labour would increase taxes and reduce spending on education?

"We don't know what we would inherit in 2020. These will be the decisions for the chancellor, for his or her first budget. But if we were in government now, we would be making a different set of decisions now, to help the health service."

Previous Labour governments – for which Ashworth worked as a special advisor and Gordon Brown's deputy political secretary – found the money for

"The biggest financial squeeze in NHS history"

over 100 new hospitals in Private Finance Initiative (PFI) schemes. Many of these schemes involve repaying three to five times the build cost of the hospital – and in some cases, up to seven times the cost – over decades. The last scheme begun by Labour will not be paid off until 2049. Would Ashworth consider using PFI again? "I think the days of PFI are over," he says. "I think Jeremy Corbyn has been pretty clear on that."

Does he defend PFI? "The PFI contracts delivered huge numbers of new buildings, and we wanted new buildings. There are a handful of contracts that were not negotiated well. In fairness, a lot of those were inherited from the previous John Major government. But Jeremy Corbyn has said that he would want to have a look at these contracts, if he can,

in government. It's something that I know he and John McDonnell are looking at carefully. But we're not going to have PFI contracts in the future."

Opening the NHS up to more outsourcing is also off the table, says Ashworth. "The Health and Social care Act pushed us in the direction of greater fragmentation, of greater outsourcing to private companies. I think it is a damaging piece of legislation, and we are committed to reversing that. We don't see why these companies should be able to come in – they try to make a profit, they don't, and then they leave. And then sometimes they then rely on the public sector to pick up the pieces again."

Some recent health policy is worth keeping, however. Ashworth says the sustainability and transformation plans (STPs) introduced in 2015 "could mean more planning at a local level. They could mean a more strategic delivery of local health services. That is something we would be in favour of, and it's why we used to have strategic health authorities. The problem is, what started off as a way to get greater collaboration in the system now increasingly looks like a way of filling financial gaps. If you look at all of the STPs now, and you look at their 'do-nothing' proposals – maintaining services as they are now – it adds up to £21.8bn. That is the gap they've got to find. So they're proposing cutting beds, downgrading hospitals or maternity wings or A&E departments, while not explaining how there will be greater provision in the wider community, not explaining what social care provision will be put in place, not explaining what acute sector provision will be in place. It's a cart-before-the-horse argument."

Ashworth is at his most emotive when discussing Labour's electoral ambitions. "I sit on the opposition benches, and you see casual dismissal from the Tories of the condition of Britain. That does make me angry. I make no apologies for wanting Labour to win. It isn't a game."

"It is the ultimate betrayal of the people we're in politics to represent if we're not completely focused, laser-like, on winning elections."

Looking into the future: how will AI shape healthcare?



Within a few years, artificial intelligence could help to save the eyesight of thousands of people. **Will Dunn** meets the innovators responsible

On 15 March last year, the 18-time world champion Go player Lee Sedol conceded a fourth defeat to his opponent, a computer programme called AlphaGo. To a casual observer, a computer beating a human at a board game is not unusual – the IBM supercomputer Deep Blue beat the world chess champion, Garry Kasparov, almost 20 years ago – but to people who understood the challenge, it came as a surprise. It had not been expected that a computer would beat a human at Go for another decade, and a decade is a very, very long time in modern computing.

The reason Go presented such a challenge was that computing every possibility in a Go game is a task so complex that it is probably unimaginable. For a sense of the sheer dizzying scale of it, try this: a single grain of sand contains, very roughly, 50 million million million

atoms. A game on a 19x19 Go board contains more legal positions than there are atoms in the whole of the observable universe.

Because mastery of Go is not currently possible through brute computational power, AlphaGo won using a different approach. The developers, London-based Deepmind, wrote an algorithm that simulates human learning. The algorithm was then ‘trained’ to mimic expert human players, then ‘practised’ playing altered versions of itself until it was able to play at the highest grandmaster level.

AlphaGo’s victory demonstrated the power of a new kind of computing: artificial intelligence. The significance of AI is that the Deepmind algorithm was not written to play Go – it was trained to play Go. And it could be trained to do other things.



“We look for opportunities for AI to make a meaningful difference”

The person in charge of deciding which other things it will do is Deepmind’s Head of Applied AI, Mustafa Suleyman. “We’re inundated with opportunities,” says Suleyman. “So we prioritise which areas to focus on by finding opportunities to make a very meaningful difference. Not just something that’s incremental, but has the potential to be transformative. We look for the opportunity to have a meaningful social impact, so we want to work on product areas that can deliver sustainable business models, but in equal measure actually make the world a better place.”

This is not the first time Suleyman has spoken to the press about his altruistic aims for AI. In July 2015, Suleyman speculated in an interview with *Wired* magazine that Deepmind’s technology could have applications in healthcare. Reading that piece was Pearse Keen, an academic ophthalmologist from Moorfields Eye Hospital in London. “I’m a bit of a tech nerd,” Keen admits, saying that he had been aware of Deepmind’s research for a couple of years. Reading the interview, “when a lightbulb went on in my head, that this should be applied to ophthalmology, and in particular to the type of imaging of the eye that I specialise in, which is called OCT - Optical Coherent Tomography.”

The scanning of patients’ eyes using OCT – three-dimensional scans of the retina that are much better at revealing eye disease than traditional retina photography – is one of the biggest developments in modern ophthalmology. However, as Keen explains, it is actually a growing impediment to detecting serious eye diseases in the NHS. “Approximately 5-10 per cent of high-street opticians now have OCT scanners in the UK. It’s not like having an MRI scanner – it’s about the size of a desktop computer. They’re usually pretty easy to use and it’s very quick and safe to acquire the scans. The problem is that they’ll offer to do the scans, but in many cases they don’t have the training or the experience to interpret them. So what they do is, if there’s any deviation whatsoever from the norm on

the scan, they refer the patient urgently into Moorfields or other NHS hospitals to be seen.” The result, says Keen, is “a huge number of false positive referrals. The people who actually do have sight-threatening disease are then delayed in getting in to be seen, because the system is overflowing.”

This swamping of services could not be happening at a worse time. Ophthalmology is already the second-busiest speciality in the NHS, with more than 9 million outpatient appointments per year. What’s particularly frightening for Keen, is that among the huge numbers of referrals being produced by the rolling-out of improved scanning are people who have recently developed a disease that will blind them if they are not treated in time.

“Often, someone could potentially have developed severe eye disease, and they could not get an appointment - even if it’s an urgent referral - for weeks, or sometimes longer. If someone’s in a situation where they’ve already lost their sight in one eye, and they’ve started to develop a problem in their other eye - you can imagine, psychologically, what that would be like.”

Keen also points out that this is not happening to an unlucky few, but to a horrifying number of people. “The most important disease, to my mind, is age-related macular degeneration, or AMD, and in particular the more severe form, which is known as ‘wet’ AMD – due to the leakage of fluid at the back of the eye. Wet AMD is the most common cause of blindness in the UK, Europe and North America. It’s a massive problem. The Macular Society says that nearly 200 people develop the severe, blinding form of AMD every single day in the UK.”

These people need treating quickly. “If we intervene earlier, we have much better outcomes. If it was a family member of mine, I would want them to receive treatment within 48 hours. The national standard for age-related AMD is that they should be seen and treated within two weeks. The reality is that across the NHS, that target is not being met, and people are often waiting ▶

► much, much longer than two weeks to actually receive treatment. The reason for that is that the system is being overwhelmed, and in particular by so many false-positive referrals.”

To make matters even worse, Keen foresaw an even greater inundation of OCT scans. “The big optician chains are talking about rolling out OCT scans across their whole chains – thousands of optometry practices. If there’s no way for us to deal with that, we’re in very, very big trouble.

“It’s as if every GP in the country was given an MRI scanner, but had very limited ability to interpret the scans. Every person who went in with a headache would get an MRI scan, and then they’d have to refer every single patient into the hospital.”

Fortunately, as a follower of Deepmind’s work, Keen knew that the vast amounts of data the OCT scanners were producing were, like moves on a Go board, exactly the kind of thing that can be used to train an AI. “The techniques that Deepmind uses, these deep reinforcement techniques, are successful in the context of large data sets, and Moorfields has probably the largest data sets in the world for many ophthalmic settings. For just one of our devices, we had about 1.2 million OCT scans.” The AI pioneers were also, helpfully, just around the corner: “DeepMind is based in King’s Cross, and two of the co-founders were UCL alumni – Moorfields is affiliated with the Institute of Ophthalmology at UCL – so I thought I would be a fool not to capitalise on this. I contacted Mustafa through LinkedIn, and he, to my great delight, emailed back within an hour.”

For Suleyman, too, the problem arrived at an opportune moment. “In the last five years, we have made a lot of progress on some of the big milestones in AI. We now have very good speech recognition, very good translation, very good image labelling and image recognition. Many of the things that we try now seem to be working. We have much improved machine learning models, we’ve got access to very

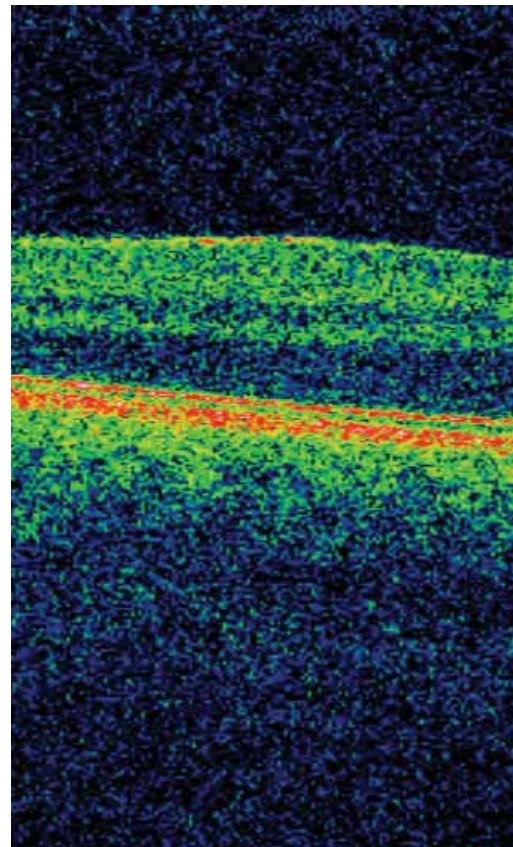
large-scale computers, and there’s increasingly enough training data to help us build effective models.”

The millions of OCT scans held by Moorfields presented the ideal dataset for Deepmind to apply its research. “If you think about the number of cases that each of the world’s very best ophthalmologists have seen during their careers,” says Suleyman, “aggregate all those cases in one place and show them to a machine, the machine learning system is going to have the benefit of a much, much wider set of experiences than any single human, or collection of the best humans, could have had during their career.”

While Suleyman says he finds the term ‘artificial intelligence’ unhelpful – “it’s imbued with a lot of anthropomorphic projection, it tends to conjure up the sense that this is a single coherent system that’s doing lots of different things, just like a human” – he is comfortable describing the AI’s interactions with its data as “experiences”.

“In some sense you can think of us replaying all of the scans to our machine learning system in the same way that an expert human might sit in front of their computer and watch scans and case studies over and over again. It’s what we call experience replay.”

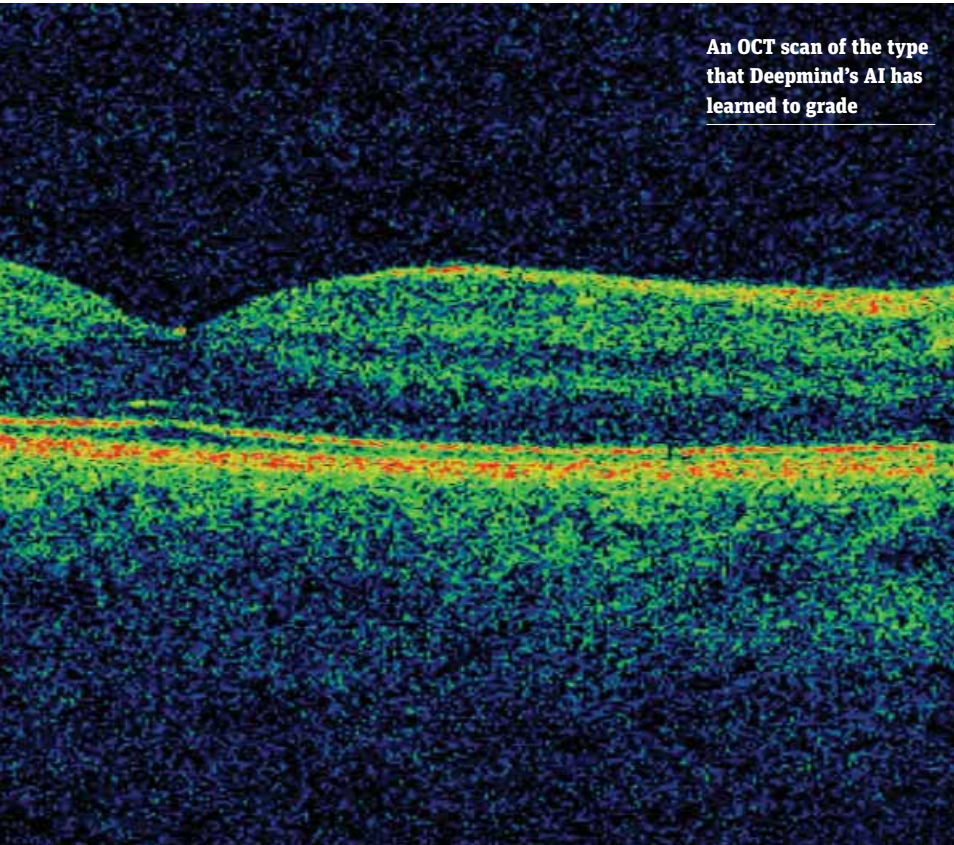
Suleyman says the AI also recalls or imagines things in a way that’s analogous to a human mind. “An ophthalmologist doesn’t recall a specific case study that she saw seven years ago. She has an abstracted, conceptual representation of, say, diabetic retinopathy or glaucoma – and that representation is built up through many, many examples of experience and teaching throughout her career. Those things combine to create a short-form conceptual representation of the idea of the particular diagnosis. We do a very similar thing with our machine learning models – we replay, many times, lots of training instances of positive examples of the pathology that we’re trying to teach the system, and then over time it builds an abstract representation of that pathology and uses that to identify new pathologies when it encounters a new case.”



Just as AlphaGo used human-like judgement to master Go, the system being used with the Moorfields data is ‘imagining’ an abstract form of the disease it looks for, seeing it in its ‘mind’s eye’. “I think seeing it in its mind’s eye is a fair description. It’s generalising from past experiences and making an inference about the new example that it’s seeing at that moment.”

Keen says this is similar to the technology used “to look at photographs on Google Photos or Image Search, or Facebook, to recognise faces in the photos or to be able to recognise that there’s a cat or a dog or a man on a skateboard in the photo.

“The way that the neural networks work is, the raw data from the photograph or the OCT scan – the pixels – are fed into the neural network, and each layer within the network extracts different features from the picture or the OCT scan. So, for example, the lower



An OCT scan of the type that Deepmind's AI has learned to grade

layers of the network will extract very simple features - they might pick out edges, or contrasts between black and white, or other very low-level features – and as you rise up through the network, more abstract features are picked out, so it might recognise that two eyes and a nose indicate a face. And then finally, the output from the network is some type of classification, so it will say that it 99 per cent certain that there's a dog in the photo, and one per cent sure there's a wolf in the photo. “

“We train the neural network using a huge amount of examples that have labels; this is called supervised learning. We're able to give it many thousands of OCTs that have diabetic retinopathy or age-related AMD or other retinal diseases, and then we tweak the parameters of the network so that it can accurately recognise those diseases again. We then test the network on a dataset of fresh scans where it doesn't know the

label, and then it will tell us if it classes a scan as having diabetic retinopathy, or AMD.”

Can the system spot eye diseases better than a human? Both Suleyman and Keen say that while it is currently very much a research project, they are optimistic that it will soon be able to 'grade' eye scans more effectively – also much more quickly, and more cheaply – than a human. Keen says he expects people will be able to walk into a high-street optician, have an OCT scan and have it graded by an AI in “two or three years. I don't think this is more than five years”, while Suleyman says mass adoption is “a reasonable thing to expect over a five-year period.”

Deepmind and Moorfields are not only breaking new ground in technological terms; the advent of AI in healthcare will require new regulation, too. If the eye diseases Keen is hunting were identified by a chemical indicator, it would be

subject to approval by the Medicines & Healthcare products Regulatory Agency in the UK, the FDA in the US and others around the world. And while the use of machine learning is physically non-invasive, the huge reserves of data that the NHS has to offer AI companies are the private property of millions of individuals. It is this data that gives machine learning its formidable power, and the NHS is in a unique position to offer huge, well-labelled datasets; how it is shared, who gets to use it and who gets to profit from it are questions that could fail to be properly answered in the rush to implement this important new technology.

There is no doubt, however, that these questions will need to be answered, because AI is coming to healthcare, soon, and in a very big way. Suleyman predicts that machine learning will become hugely valuable in diagnosing conditions earlier and planning treatment – Deepmind is also working on a separate project that could “massively speed up the process of planning for radiotherapy” – but he says doctors are not the only ones who may find themselves working alongside AI. Managers, too, could be disrupted. “The hospital environment is such an expensive and complex system. One of the reasons why I think it's reaching breaking point is that humans are simply overwhelmed by the scale and complexity of managing so many patients who are on so many different pathways, who need so many different tests and interventions. It becomes a massive co-ordination exercise. So, one of the things we're increasingly thinking about is how we efficiently and speedily prioritise the tasks that get done in different areas of the hospital.” Few would dispute that the NHS is beginning to creak under its own complexity; AI promises to parse this tangled problem with fast and tireless concentration.

For Keen, this is an opportunity to be seized. “In the next couple of years, we need to work to build on those advantages, because we might have a head start, but that might not be there indefinitely.”

What Brexit could mean for the future of UK healthcare innovation

By **Keir Woods**, Head of Oncology (UK & Ireland), Merck



The UK is at a pivot point. With Brexit approaching, the future of healthcare – like so many other areas – is destined to change. Brexit poses potential threats to some of the UK's most highly valued assets, networks and infrastructures. But it also presents opportunities to revisit, revise or even revolutionise current systems that are proving unfit for purpose – and to exploit some of our key strengths.

For life sciences companies like Merck, who are committed to operating in the UK, the possible impact of Brexit is of critical importance. Merck has as much as 20 per cent of our global venture capital invested in the UK and we employ over 1,400 people across 17 sites in the UK.¹

Moreover, Merck is more than just a pharmaceutical company. Our footprint spans Pharmaceuticals, Consumer Health, Life Sciences and Performance Materials (high-tech materials and speciality chemicals), meaning

pharmaceutical companies and academic institutions are our customers as well as our competitors and collaborators. For this reason, Merck can claim a uniquely holistic perspective on the life science sector. Here, we explore three areas where Brexit presents opportunities to improve the future of healthcare innovation within the UK: research and development (R&D), the regulatory process for new drugs and patient access to prescription medicines.

Research and development

The UK is a global power in health. It has world-class universities and centres of excellence in clinical research, publishes two of the world's top medical journals (*The Lancet* and the *British Medical Journal*) and is home to over 4,800 life sciences companies with the largest pipeline and most extensive investment in Europe. It is also a recognised leader in health policy and

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University College Hospital, London, one of the UK's state-of-the-art healthcare centres



exercises profound influence on the provision of healthcare worldwide.²

With the right changes, the UK's global contribution to R&D could be enhanced still further. As a single, fully coordinated healthcare system, the NHS has unique logistical and practical capabilities for running high quality clinical research studies across multiple sites. Such research spans not only conventional controlled, randomised trials, but also 'real-world investigations' into the performance of

licensed medicines beyond the constraints of formal trial settings to help understand their true value. Brexit presents an opportunity to elevate the NHS to the status of a truly global partner for industry, creating a collaborative environment for medical research projects of all varieties. In the oncology field, world-leading centres of excellence like the Institute for Cancer Research, the Royal Marsden, the Christie Hospital, and University College London Hospitals (UCLH) are well placed to spearhead such initiatives.

But there are caveats. To achieve its goals, the UK must remain competitive when it comes to securing the cream of international talent to power the nation's discovery engine. Freedom of movement for top scientists and highly skilled clinicians is profoundly important in this context. Competition notwithstanding, effective international collaboration is critical –

both beyond EU borders and within them. The majority of important industry-sponsored studies are multi-national and companies require consistent and aligned frameworks to facilitate collaboration between research centres worldwide.

The regulatory process for new prescription drugs

Currently, the UK's regulatory approval system for new pharmaceuticals falls within the governance of the European Medicines Agency (EMA). The EMA – currently based in London – employs a robust process for the assessment of potential new medicines, provides a framework for pan-EU research collaboration and gives a multi-national industry the convenience of a single point of contact for approval of medicines across all member states.³

However, the EMA's regulatory framework is not as expedient, efficient or flexible as it could be. Some stakeholders have argued for more rapid access to ground-breaking innovations. A UK-specific system combining the current innovative approach taken by the Early Access to Medicines Scheme⁴ (a plan established in 2015 which allows people with life-threatening or seriously debilitating conditions to access experimental medicines) with a system akin to the US Food and Drug Administration (FDA) breakthrough designation and priority review process, which fast-tracks assessment and conditional approval of promising drugs. The FDA's approach is particularly advantageous in the oncology field, where our growing understanding of how best to treat cancer has led to the development of medicines via routes which do not fit within established regulatory processes.

The danger remains that a specific regulatory process for a relatively small country, no matter how elegant, risks being deprioritised if it deviates too far from the established requirements of larger collective bodies. On balance, therefore, it seems advisable to maintain broad regulatory alignment ▶

The NHS could be a global partner for industry

► with the EMA, but Brexit undoubtedly presents an opportunity to embrace some of the more far-sighted elements of the FDA model. A bespoke regulatory framework that remains harmonised with that of EU nations but with the flexibility to adapt in areas of great unmet clinical need could make the UK's system the envy of Europe.

Access to licensed medicines

Brexit also presents an opportunity for a true step change in terms of patient access - a bold revolutionary change which can in turn democratise access to innovation. We are faced with an unprecedented wave of innovation which will change the face of modern medicine over the next decade, with UK science being one of its driving forces. The most dramatic advances are expected in the cancer field, with trailblazers including immunotherapy (mobilising the body's immune system to fight tumours), combination therapy (pairing of treatments with potentially synergistic effects) and precision medicine (identification of small, specific sub-populations of cancer patients likely to respond to tailored interventions).

However, the UK's current system is not well set up to embrace these developments. It lags behind established comparable Western European countries in terms of access to new cancer medicines in many areas while the reform of the cancer drugs fund has deprived patients of access to existing treatments which are widely used in other comparable countries.⁵

There is ongoing frustration that, while many innovative and ground-breaking medicines are being discovered and developed in the UK, the fruits of our labours are commercialised elsewhere while the majority of our own population fails to fully benefit. Some understandably ask: "What is the point of creating medical miracles if we can't pay for them?"

Despite a well-intentioned system, the UK is constantly falling behind in patient access compared to our

European neighbours. The current National Institute for Health and Care Excellence (NICE) system – now 18 years old – has remained relatively static and is widely regarded as ill-equipped to cope with the brave new world of medical innovation. Various attempts to reform the methods employed by NICE have merely resulted in superficial changes.

The recently published Accelerated Access Review (AAR)⁶ states NICE methodology may not be "fit-for-purpose" for the innovative treatments it is looking to assess. The government's planned AAR scheme³ aims to make the UK "the fastest place in the world for the design, development and widespread adoption of medical innovations and stimulate new investment, jobs and economic growth to support the NHS". The scheme will give priority status to medical innovations, including pharmaceuticals, that appear truly transformative. As things stand, though, the AAR is expected to provide access for only a small proportion of anticipated medical innovations waiting in the wings.

Still, this should not obscure a higher order challenge. For too long we have upheld the idea that healthcare in the UK has primacy, while deprioritising healthcare spending compared with our EU neighbours. Notably, the UK spends 10-20 per cent less of its national income on health and social care than France, Germany, Sweden and The Netherlands⁷. Honesty is required to openly confront this reality, then for the UK to transparently decide what kind of NHS we want.

It is in this context that fundamental reforms to NICE decision making processes and methodologies should take place, so that access bodies can move beyond a "zero-sum" game of apportioning a diminished funding pot across an ever expanding range of potentially life transforming medicines. The UK spends about 1 per cent of our GDP on pharmaceuticals, less than most of our European neighbours. We spend at least as much on fast food.⁸

In the lead-up to Brexit, the UK government is developing a new

Industrial Strategy to enhance economic growth. Life Sciences are a key part of this, with the overall aim of making the UK the world's leading life sciences 'hub'. We must ensure this laudable goal is accompanied by a rejuvenation of our national commitment to healthcare, to bridge the emerging chasm between medical innovation and its accessibility to the UK population. Brexit offers a golden opportunity for all stakeholders to embrace change, think boldly, and create the conditions for a successful future.

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Ask the experts: is healthcare innovation being hampered?



Professor Peter Johnson Chief Clinician, Cancer Research UK

“Innovation in cancer therapy, stemming from research in areas like immunology and precision medicine, is transforming our ability to treat many people. As more treatments like these emerge, it’s vital that the NHS keeps pace with the advances and adopts them quickly so that patients can benefit.

Some patients miss out on available precision medicines because their cancers aren’t analysed to see if they’re suitable for such treatments. It’s crucial that NHS England addresses this and establishes a national molecular diagnostic testing service.

We must also develop a drug approval system that’s responsive to

research advances, so UK patients get these innovative medicines promptly.”

Professor Carole Longson Director of the NICE centre for health technology evaluation

“We have regularly reviewed our approach to keep up with the latest treatment advances. Recent changes to our appraisal process for cancer drugs have meant that we will now issue draft guidance at the point of licence, this is faster than anywhere else in Europe. The changes also allow us to recommend that patients get access to promising new cancer treatments whilst more evidence is gathered on

their effectiveness, through the Cancer Drugs Fund.

NICE is committed to helping patients get fast access to the most effective treatments. We now need companies to show that they recognise the challenges as well as the opportunities their new drugs present to the NHS.”

Sir John Bell Regius Professor of Medicine at the University of Oxford and Chair of the Office for Strategic Coordination of Health Research

“The last 30 years have witnessed an unprecedented number of major innovations in healthcare that have resulted in significant extensions in life expectancy and quality of life. Most healthcare systems, including the NHS is now unable to adopt new innovation effectively and as a result continued improvement in healthcare is in jeopardy. The current model places the cost of supporting the innovation system needed to discover new healthcare interventions on healthcare systems and too often innovation is layered on top of existing practice, seldom creating any savings. The high failure rate of innovations and the regulatory burden are also creating significant challenge to innovators and industry. A solution for both parties is necessary and must come from healthcare systems and innovators working more closely together, sharing risk and cost and attempting to use innovation to take cost out of health systems wherever possible. Such collaboration is the best way to ensure both systems survive and that new interventions are available to patients.”

Professor Neena Modi, president of the Royal College of Paediatrics and Child Health, and **Clare Marx**, president of the Royal College of Surgeons consider the impact of leaving the European Union

Will Brexit help or hinder the NHS?



Professor Neena Modi

It is 2017, the realities of Brexit loom large, political certainties are in tatters and Britain's health service is in crisis. The Leave campaign has long distanced itself from its post-factual battle-cry of an extra £350m a week for the NHS. After a bruising fight with government, junior doctor morale, recruitment and staff retention are at an all-time low.

Paediatrics has a 20 per cent average senior trainee vacancy rate, while other specialities, including general medicine and psychiatry, report concerning recruitment falls of 7-18 per cent, and a surge in interest in working abroad. The UK ratio of doctors per capita is already among the lowest of western nations. The analysis is straightforward: more doctors are needed, or NHS demand must be reduced.

NHS Trusts in England, already crippled by a staggering £2.45bn deficit, either have doctors work excessive hours

to keep the system going, or appoint locums through for-profit agencies charging hefty fees. Demand could be reduced by shifting tasks away from doctors and providing more out of hospital care, but the nursing vacancy rate is 10 per cent (17 per cent in London), cuts to public health have led to falling numbers of health visitors, and a shortfall of around 10,000 general practitioners is predicted by 2020. Children form a quarter of a general practice workload but less than half of GP trainees have a paediatric placement during their three-year training.

The Royal College of General Practitioners has repeatedly called for training to be increased to four years to accommodate essential areas such as child health as children represent more than a quarter of emergency department attendances, but we have been told this is unaffordable.

Britain relies more heavily on foreign doctors than any other major European



nation with more than a third of NHS doctors and over a fifth of nurses born abroad, yet overseas doctors permitted to enter the country have been severely restricted, and nursing bursaries have been cut. And after successfully alienating a generation of junior doctors, the Health Secretary called for foreign doctor numbers to be slashed post-Brexit, heaping needless additional distress and insecurity upon the 55,000 NHS staff who are EU citizens.

The founding principles of the NHS - healthcare for all, free at the point of need, financed from central taxation - have served the UK well for over 60 years, but additionally, a uniquely stable medical workforce was created. Salaries were reliable, centrally negotiated, with nationally consistent pay and conditions across all specialties, and came with regular increments and a generous pension package.

This provided security for doctors, freedom to follow a career path without

the distractions of temptation to pursue financial gain, and a strong incentive to remain in the NHS. A reliable, high quality workforce was created that was not wealthy, but well-off, committed to delivering care wholly driven by the patient's best interests. The imposition of a new contract predicated upon the unjustified but repeatedly made claim that patients were dying as a result of poor weekend care, destroyed this stability, and provoked the junior doctor strikes of 2016. It's worth noting that this was the first strike in 40 years. The contract abolishes pay equity across specialties, introduces differences in pay and conditions between the four nations, and in England, between NHS employers; and is likely to widen the gender pay gap, though over 50 per cent of new medical recruits are women.

The Health Secretary has announced plans to increase medical school places by 1,500 a year, accompanied by the claim, implausible because it takes more than 10 years to train a doctor: "By the end of the next parliament the NHS will be self-sufficient in doctors." This slim offering was soon soured by the mean-spirited threat of a fine if new recruits don't work for the NHS for at least four years, failing to recognise or acknowledge that a defining strength of the NHS is that UK doctors have been proud to work as public servants for their entire careers, and that in a global era that the NHS benefits from a flexible workforce, with UK doctors equipped to work abroad, and overseas doctors made welcome.

The harshest financial squeeze in the history of the NHS has been imposed with exhortations to identify £22bn in efficiency savings, to do more with less. Simultaneously the costs of marketisation and service fragmentation are consuming an increasing proportion of a budget that has effectively been frozen since 2010. The resilience of a dedicated workforce is being pushed to the brink of breaking point. The end result has been a progressive contraction in NHS services.

Mismanagement on such a scale defies

belief. These actions only make sense if the purpose of constraining NHS services is ultimately to reduce demand by nudging those able to do so to seek care in the private sector. Such a fix would be shallow and short-term in its thinking; a far more suitable alternative would be for the UK to commit to sustained cross-party support for the NHS as a visionary innovation that extends the concept of healthcare beyond universal coverage to responsibility for equitable access, clinical effectiveness, and cost-efficiency as a great moral duty of state. Strengthening and modernising the NHS would benefit us all, no less the resilience and economic wellbeing of the nation. The placards carried in the streets by young doctors proclaimed "Save our NHS"; now the UK public must decide if they concur.



Clare Marx

The UK has voted to leave the European Union and the Prime Minister has been clear that her government will make sure this happens. Both sides in the EU referendum campaign pledged to strengthen the NHS and we as doctors, alongside the government, now owe it to the public to make sure that our health service comes out of Brexit negotiations better off.

First and foremost we must make certain that the many staff from the EU already working in the NHS, and on which it depends, are protected. The health service simply wouldn't be able to function without the enormous contribution that migrants make to our ►

► NHS. Surgeons are disproportionately likely, compared with other medical specialties, to have trained in the EU. Around 20 per cent of registered surgeons trained in the EU with a further 20 per cent from the rest of the world.

This compares to 9 per cent of all licensed doctors on the GMC register having trained in the EU and almost 24 per cent from the rest of the world. Add to that the thousands of technicians, porters, cleaners and other staff who have moved to the UK to work in our hospitals and you can quickly see how the NHS would buckle if tougher migration rules prevent these staff from continuing to live and work here.

Jeremy Hunt's plans to increase the number of UK doctors being trained from September 2018 are welcome, and in fact essential for the NHS's long-term sustainability, but it can take around 15 years for a surgeon to be trained and in the meantime the UK will still need to attract staff from overseas to address workforce shortages. The government absolutely has to confirm that it will protect the citizenship of all NHS professionals already residing in the UK and continue to attract foreign staff, while also training sufficient numbers of home-grown staff.

While the risks to the workforce from Brexit are high, we believe there are also some opportunities to improve patient safety legislation. As part of the EU, we've had to accept laws and regulations on issues such as language testing of non-UK staff, professional qualifications, training time and the safety of medical devices and drugs which perhaps fell short of our own standards or hindered our ability to do our jobs to the highest safety standards. Brexit offers us an opportunity to correct this and improve patient safety.

Current European legislation means devices approved in European countries with lower safety standards can make their way into the NHS. We can now toughen those laws but will need to be mindful that in removing ourselves from European legislation we could also slow

the entry of new devices to UK. We must ensure we continue to attract international healthcare innovators while maintaining high safety standards for our patients.

The Royal College of Surgeons is also concerned that EU rules have prevented the UK from applying the same English language capability tests to staff from the EU and the rest of the world. Speaking clear English is very important to patients and there have been high profile examples of doctors causing harm as a result of poor English.

The General Medical Council has been able to ask doctors from the EU to demonstrate their English language proficiency before they practice in the UK since 2014 however they cannot insist on how this is demonstrated. As a consequence, most doctors from the EU demonstrate their proficiency through the academic International English Language Test System (IELTS) test. This test asks everyday questions – such as asking a candidate to describe their hometown in English. However, it does not include questions more relevant to the NHS such as describing the side effects of a drug or understanding a patient's diagnosis.

While recent figures show the GMC has prevented thousands of doctors from practicing in the UK due to poor English language proficiency, the College is still concerned that by not testing the language skills on EU professionals in a clinical setting, patient safety is being risked.

In contrast, the medical regulators do

“Speaking clear English is very important to patients”

require professionals from the rest of the world, where EU rules don't apply, to take tests that demonstrate their language skills in a clinical setting. This two tier system is unfair and post-Brexit we want to see all healthcare professionals sit the same, more rigorous, tests.

Lastly, Brexit offers a chance to change rules which restrict surgeons' time for training. Surgical junior doctors have raised concerns that the European Working Time Directive (EWTG) has limited the amount of time they can spend in training. While it might sound intuitively strange that we want to work longer hours, surgeons learn by apprenticeship and need as much hands-on time in the theatre as possible to hone their craft. The 48-hour limit on working time that the EWTG imposes has meant doctors have less time for this important training.

We certainly do not want a return to the bad old days of excessive working hours but there is a need for greater flexibility for training hours. This is something the European Working Time Directive taskforce, which had representatives from a wide range of health organisations, including the British Medical Association trade union, also concluded. Representatives of surgical trainees have suggested a relaxing of EWTG rules so that they can work a maximum of 56 hours a week. As EWTG rules have been written into the new junior doctors' contract this change would require legislation for those specific groups of doctors seeking more flexibility.

The NHS is entering what will probably be one of its toughest years in decades and the prospect of Brexit brings a lot of uncertainty with it. That said, our health service has a strong track record of adapting to change and continually innovating. While it was unclear what sort of Brexit the public voted for, the fact that the NHS was front and centre in the debates means we must ensure any Brexit settlement will ultimately help, not hinder, the country's health service.

Connecting local health and social care economy

Healthcare professionals need to make quicker and safer decisions with real-time information, writes Hospedia's Ian Freeman

As the NHS strives to improve the efficiency and safety of the patient journey, the ability to connect the constituent parts of the local health and social care economy is imperative. So, what is required to make this a reality?

The most obvious answer is to provide the means for care providers to collaborate effectively. This requires a solution that works across organisational boundaries and focuses on the current and future actions needed to move the patient along their pathway. However, the complexities of providing an integrated information system that joins up disparate health and social care organisations have, to date, thwarted both the NHS and commercial providers.

Firstly, a system is needed that improves the quality of care, patient experience and clinical outcomes – reducing such things as risk, length of stay and re-admission. Secondly, it needs to integrate with existing systems and thirdly, it needs to deliver benefits not only for the patient but also for all of the organisations that constitute the health and social care economy. It is no good solving the waiting-time problem at the front door of the acute Trust, if bed blocking at discharge means that no beds are available. Finally, it needs to be affordable. But how can this be achieved in such a complex environment?

The answer lies in what information is collected, how it is displayed and what actions it drives. It means the real-time visibility of the patient and what actions they require at every stage of their journey by all involved in the care process. It goes without saying

that this should be across the whole hospital, but it is when this information becomes available outside the hospital walls that real benefits of the system can be realised. For example, Hospedia's Patient Flow management solution, not only manages patient in the hospital, but also:

- Allows discharge teams to know when patients are going to be fit for discharge, and provides a view of the virtual wards in the community, reducing discharge delays, and ensuring patients are quickly allocated to the most suitable care environment
- Supports GPs, who at the click of a button, can see everyone from their surgery who is in hospital and why, and can communicate directly with the patient's clinician.
- Alerts social care when one of their patients is admitted to or discharged from hospital, delivering considerable costs savings.

Capturing vital signs and nursing assessments electronically has been possible for several years, but this information needs to be accessible in real-time from anywhere in the hospital – or beyond. However, ensuring that appropriate action is taken depending on these results (as well as trending results) is equally important and should be easily configurable to the specific needs of the hospital, ward or department. The Vital Signs and Nursing Assessments solution from Hospedia does just that, with real-time reporting linked to Hospedia's Patient Flow Management solution so that all assessments follow the patient through their care pathway providing full tracking and reports.

It is this joined-up care that should be the focus for the future. The real benefits of these solutions will be realised in terms of reduced length of stay, improved discharge processing, reduced waiting times, increased patient care, improved care quality and reduced re-admission rates; and of course happier patients who recover quicker, due to more cost-effective and efficient clinical care.

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Defusing the obesity time bomb



Discipline in our diets growing up is crucial to living longer and healthier lives, according to Maggie Throup MP, Chair of the All-Party Parliamentary Group on Adult and Childhood Obesity

As the New Year gets underway there have already been numerous reports relating to obesity and the impact it is having on society and individuals. Whether it is the proportion of adults who are now classed as obese or that children's breakfasts are full of sugar, the headlines continue to come. Add to this the focus of television programmes on dieting and the numerous celebrity endorsements showing their commitment to tackling the problem.

Yet, mid-2016, when the government had the golden opportunity to grasp the issue of childhood obesity and introduce a raft of measures, it shied away. Public Health England and the Parliamentary Health Select Committee had both published strong and convincing reasons as to why it is necessary to be bold and brave when it comes to tackling childhood obesity, and had put forward various measures that would have been ready to turn into an effective and workable strategy.

The government defends its lacklustre approach to tackling childhood obesity by stating at the very end of the 13-page

Childhood Obesity: A Plan for Action that the document is just the start of the conversation. This is not the time to start a conversation when the current and future health of our nation is at stake.

So, how large is the problem and why do we need to tackle it now? The facts speak for themselves: one in five children in the UK starts school overweight or obese and, when broken down, that figure doubles for children from the most deprived parts of our country. Overall, 36 per cent of the most deprived children are predicted to be overweight or obese by 2020 compared to just 19 percent of the most affluent.

Doctors are now diagnosing and treating children with Type 2 Diabetes, a disease that until recently was only found in adults, and even then predominantly recognised as a disease of an older age. This is shocking.

Add to this that the most common reason for a child to have an operation now is for dental extraction due to tooth decay. And if we look to the future to see what lies ahead if this problem is not tackled, then undoubtedly there will be more Type 2 Diabetes cases with the



“The current and future health of our nation is at stake”

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added complications of sight loss, kidney disease and amputation, more heart disease and more cancers caused by obesity. This is not good news for the individual, the NHS or indeed the taxpayer. These are life-changing and life-limiting conditions and surely a cost too high for anyone to pay.

There is a fine balance between a nanny state, business cooperation and parental and personal responsibility, but it must be possible to find common ground. It can be argued that there has to be some level of intervention to start to reverse this worrying trend and to set the standards for the future.

The argument between voluntary action and legislation is not an easy one. Voluntary action can come about quickly and can be effective, but whoever takes the first step from a manufacturing viewpoint, for example, could be at a competitive disadvantage. Legislation does take time and there is no time to waste if this issue is to be tackled head on.

It is pleasing to note that some manufacturers and retailers are acting responsibly from both a formulation and marketing angle, with a number of supermarkets reducing sugar in own-brand cereals and fruit juices as well as repositioning high sugar foods to less tempting parts of the store.

The government’s proposed Sugary Drinks Industry Levy, with all proceeds being ring-fenced for school sports projects, is a good start and industry is already responding in a positive manner. But there are still questions as to how the levy will be allocated and will the extra activity really make a difference without other measures being implemented alongside it?

Our children spend more time in school than in any other environment. Therefore it is of paramount importance to instil the right lifestyle and form good habits at an early age, whether it is

through exercise or nutritional education. But how time out of school is utilised is also important. Activities such as Parkruns and Sky Rides which attract all ages, all abilities and are family orientated are a great way to have fun in non-competitive environments and, at the same time, allow parents to lead by example and help their children form habits that will last a lifetime.

Currently, there is a ban on junk food advertising on children’s television, but children across a wide age range are exposed to advertising on a variety of different platforms including social media and gaming that are not currently being regulated.

Consistency across all mediums was one of the Health Committee recommendations, but the lack of its inclusion perhaps indicates the lack of cross-departmental acceptance of the obesity problem. Yes, it is the responsibility of parents to ensure their children eat healthily, are physically active, and learn good habits that will last a lifetime. But this by itself has proven time and time again that it is not sufficient. Parents need more help and the current Childhood Obesity Plan cannot and will not give them what they need.

With Cancer Research UK recently revealing that teenagers drink almost a bathtub full of sugary drinks each year on average, it is evident that something needs to change. Hopefully, such a visual representation will shock some teenagers into this much needed change rather than suffer the consequences.

Childhood obesity levels will not drop tomorrow, but we do need to see some indication in the next few years that they are declining. Now is the time for the government to put its head above the parapet and be bold and brave in tackling childhood obesity, rather than wait for this ticking time bomb in public health to explode.

Early access to innovation – how much can we achieve?

Cash-strapped healthcare systems have led to innovative changes to the pathways to patient access to drugs. CASMI Programme manager **Dr Stuart Faulkner** assesses sustainability.



Such is the pace of scientific advancement, rising R&D costs, and limited budgets, that ensuring early patient access to more affordable, transformative, safe and effective products in a sustainable way is paramount. Regulatory bodies have been criticised for being slow to adapt to the pace of scientific advancement and changing patient needs. Commendably, in response to this, a suite of regulatory tools, pathways and concepts continue to emerge across North America, Europe and the UK.

Toolbox for faster access

The Food and Drug Administration (FDA) has developed several approaches to making transformative drugs available as rapidly as possible. Priority Review and Accelerated Approval facilitate faster regulatory review and approval process while Fast Track designation and Breakthrough Therapy designations speed up the early

non-clinical and clinical phases of development prior to regulatory review. Similarly, the European Medicines Agency (EMA) has a suite of early access tools such as: accelerated assessment, streamlined opinions on compassionate use, orphan drug designation, parallel scientific advice, advanced therapy medicinal product (ATMP) classification and conditional marketing authorisation. Programmes such as PRiority Medicines or PRIME (similar to FDA's Breakthrough designation) and new concepts such as Medicines Adaptive Pathways for Patients (MAPPs) support early cross-stakeholder engagement, and prospective, adaptive and iterative cycles of development.

While some such schemes already result in expedited access for some patients with the highest needs, are there now so many tools, schemes and concepts that we may get stuck in a cycle of increased scientific understanding and complexity? This

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could risk adding to the regulatory burden rather than streamlining it.

No universal manual

The eligibility criteria for all these supportive tools are complex, variable by geography and nuanced. Herein lie some of the problems. All attempt to address in some part serious conditions, unmet need, improvements in safety, efficacy, treatment or diagnosis over existing standard of care. But how does one define ‘serious condition’ or ‘unmet need’? One may argue that a list of such definitions is not practical - each drug should be assessed on a case-by-case basis. On the other hand this can lead to a narrative of misunderstandings and delay between developers and regulators.

Furthermore, for companies (for example SMEs) who may not be familiar with regulatory processes, the choice of tools could be inhibitory. There have been many calls for greater transparency of procedures from

regulatory bodies. Also, too many drug company development plans fail to generate the data the regulatory bodies require.

For all these reasons, early access tools are not yet well used. To encourage a sustainable ethos an even greater awareness of regulatory processes, greater harmonisation across geographies and promotion of early access tools is still needed. Moreover, for patient organisations-whose contribution to the life-cycle of drug development is increasingly being recognised- must have access to appropriate guidance and well-explained documentation.

Lost in translation

Accelerated development and approval does not always equate to accelerated patient access. Market access (getting the drug to the patient) poses other issues to sustainability. For example, the FDA recently approved Exondys 51 (Eteplirsen), the first drug approved to treat patients with Duchenne muscular dystrophy (DMD). Developers utilised several tools to speed up patient access- Fast Track designation, Priority Review, and orphan drug designation. Despite this, early patient access to this potentially transformative drug appears to be in some jeopardy as Anthem, one of the USA’s largest health insurers, has decided not to cover the drug after raising concerns about the data that regulators relied on to approve the medicine.

In Europe, GlaxoSmithKline (GSK) has developed a one-time gene therapy (Strimvelis) for a severe combined immunodeficiency disease (SCID). People with SCID lack almost any immune protection from bacteria, viruses, or fungi. Priced at over €500,000, it’s among the most expensive therapies in the world, but it’s also a cure. A deal struck with Italy works on a money-back approach: if the drug doesn’t work as promised, the company refunds some or all of the expense. While such deals may work on

a very small number of high-price drugs in those countries that can afford the up front costs, can such a model work in countries without the mandate, expertise or healthcare budgets to undertake risk-sharing?

The impact of Brexit

As the dust settles from the Brexit vote, what now for the relationship between the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) and the EU’s EMA? Will the pipeline to early patient access become even more complex and slower? One could argue a case for continuing close ties with the EMA to harmonise and streamline processes wherever possible.

Alternatively one could argue that now is an opportunity for the UK to strike a more independent stance, or even align more closely to the FDA. The MHRA is a respected authority that has made a substantial contribution to the development of regulatory control of medicines.

The recent Accelerated Access Review set an aspirational remit to speed up sustainable innovation in the UK. It proposes a new transformative designation for those innovations with the greatest impact, and an Accelerated Access Pathway that aligns regulatory, reimbursement, evaluation and diffusion processes to expedite patient access. Change must be radical if companies are to engage with a new ‘UK-only’ model.

With better alignment of all major stakeholders the UK may be in a good position to continue to expedite patient access to innovation in a sustainable way, as a model for others. Ultimately, what the tools are guide us to is only part of the solution. How they are used in the context of increasing complexity still needs much work. Harmonisation and transparency, where possible, can simplify the sometimes disparate nature of stakeholder opinion. We need a globally adaptive and collaborative mind-set, if new generations of treatments and cures are to reach patients rapidly yet responsibly.

The government must strike the right balance between NHS funding and reform, writes Harry Quilter-Pinner, research fellow at IPPR

How a rise in taxes could save our NHS



In June 2000, a 74-year-old lady from Wakefield named Marvis Skeet died of throat cancer. Like so many others at the time, her death was entirely needless. The NHS had the technical ability to reverse her condition, but simply did not have the capacity to get on with it, cancelling her operation no less than four times.

On the back of this, the then Labour government – which had claimed on the eve of their 1997 victory that voters had “24 hours to save the NHS” – faced a barrage of criticism in the press who saw Skeet’s story as symbolic of the wider NHS crisis.

In the now famous *Breakfast with Frost* interview a few days later, Tony Blair surprised even his own Chancellor, Gordon Brown, by announcing his

intention to increase health funding to match the EU average. In the years that followed, health spending increased by 7 per cent per annum, up from a historical average of 4 per cent.

Whilst some have claimed that much of this funding was wasted, there is little doubt that it helped cure the NHS of one of its most scandalous failings: chronically long waiting times. In 1997, nearly 300,000 people had waited six months or more for an operation; by the time Labour left office, this was down to just 199. Waiting times in A&E fell too, with 98.5 per cent of people seen within four hours of turning up, from less than 70 per cent a few years earlier.

Looking back, it seems impossible that such long waiting times were ever tolerated at all. And yet, anyone



“Across the board, targets are being missed”

monitoring the data coming out of the NHS at the moment would be forgiven for thinking that they had slipped back in time.

In the final months of 2016, around one in five patients waited longer than four hours in A&E, the worst performance since records began in 2004. Indeed, across the board, targets are being missed: ambulance response times, waiting times for operations, transfers between the NHS and social care and access to GP appointments.

In light of this, 2017 seems set to be the year when the NHS reverts to form, with over a decade's worth of work, ensuring people get timely access to life changing treatment, undone. So, where did it all go so horribly wrong?

Reform or funding?

So far, the government has argued that a lack of reform lies at the heart of the NHS's problems. In a meeting last year with Simon Stevens (chief executive of the NHS), Theresa May reportedly said that the NHS should learn from the cuts to the Home Office, whereby the police embraced reform and maintained a steady fall in crime. The Prime Minister's implication being: “Why can't the NHS do the same?”

May's reluctance to give the NHS more money stems, in part, from the deal done between Stevens and her predecessor, David Cameron. Given the increasing demands for healthcare, in 2014, Stevens came forward with new figures suggesting that between 2015 and 2020 the NHS would face a £30bn funding gap. He argued that if Cameron and then chancellor George Osborne put in £8bn in extra money, he would deliver £22bn of efficiency savings, set out in what became known as the Five Year Forward View.

Stevens' reform plans included a more closely joined up health and social care package for the elderly, moving care out of hospitals and into the community; as well as much more upstream prevention of ill health. These plans are now being put in place through a range of initiatives including the new (and much maligned) Sustainability and Transformation Plans (STPs), jointly authored by local government and local NHS leaders.

However, whilst there is little doubt that the NHS needs reform, it seems unlikely that reforms alone will deliver the scale of efficiencies promised by Stevens. To experts in the sector, this doesn't come as a surprise. Many argued at the time that Stevens' plans were over ambitious, precisely because, at its core, healthcare is an entirely different service to the police.

Unlike crime, which has been falling over the last decade, the health service faces a growing and ageing population, which suffers from an ever rising tide of complex chronic conditions, as well as rising medicine and treatment costs as exciting new scientific breakthroughs

The popularity of the NHS can cushion a rise in taxation

come on-stream.

Furthermore, whilst there is much evidence that reforms such as the integration of health and care can deliver better health outcomes (and would therefore be needed regardless of the funding settlement), there is little evidence that they deliver significant efficiencies.

Meanwhile, it is also becoming increasingly clear that any chance STPs and the Five Year Forward View had of delivering on either outcomes or efficiencies is now being undermined, as the money earmarked for supporting it is diverted towards plugging hospital deficits – which totalled £2.45bn last year – instead.

This all implies that Stevens, whilst right to put NHS reform at the heart of his plan, sold the NHS short in asking for just £8bn to back it up, something that May will have to confront, one way or the other, over the coming months.

As deficits continue to grow and waiting times spiral in 2017, she will face a choice between further entrenchment of the government's existing funding crisis or stumping up the extra cash needed to maintain a world-class health service.

Shaking the money tree

Given that the NHS remains, in the words of former Conservative politician Nigel Warner, “the closest thing the English have to a religion”, it seems inevitable that May will ultimately choose the latter – as she should. The challenge will then become, how can she fund such an increase in spending?

The most obvious solution for May would be to garner additional revenue through tax rises. This is what Brown did back in 2002, raising National Insurance (NI) contributions for employees and employers by 1 per cent, which May's government should emulate drawing on the the popularity of the NHS to ring-fence these funds for the healthcare system.

IPPR estimates that such a move could raise an additional £4bn a year, thereby providing an extra £12bn over the

remainder of the parliament, much of which should be reinvested into the government's NHS reform agenda, increasing the chances it will deliver (the much more realistic) £6bn worth of efficiency savings left to find.

However, in the longer term, it seems unlikely that tax rises alone can keep pace with the upward pressures on demand for healthcare. By 2030 the number of over-85s will have doubled. Meanwhile, those of working age, whose incomes form the tax base for these services, will have increased by just 2 per cent.

These demographic pressures could see spending on health grow from around 7 per cent of GDP at present to 16 per cent or more by 2060. This alongside other age related costs to the public sector (pensions, social care) will ensure that, even with tax rises, an ever increasing share of government spending will be spent on elderly people. At some point the working age population are going realise that they are paying more and more tax for services that they themselves will not receive when they get older.

This implies that our political leaders must also start negotiating a new social contract between the generations to fund these health and social care services. This might include a higher retirement age and an end to the triple lock on pensions, with revenues targeted on those people - both young and old - who need it most.

Together these changes would constitute a bold new funding settlement for the NHS and social care that would both help the service manage the ongoing “winter crisis”, whilst also properly funding the reform agenda to ensure we have sustainable services capable of delivering the best new treatments to its patients on time and free at the point of use in the long-term.

Harry Quilter-Pinner is a research fellow specialising in public service reform at the UK's leading progressive think tank, the Institute for Public Policy Research (IPPR).

Business intelligence as it should be

Managing a company's data effectively is crucial to its success, according to Total Intelligence owner
Chris Finch

The NHS is one of the most prolific gatherers of data in the world. It's not surprising as it employs 1.4m people, caters for a population of nearly 70m and sees about 800,000 patients every day. Every interaction with a patient whether on the phone, a home visit, at a GP surgery or a stay in hospital, results in data being generated and stored away in myriad systems.

This collection of data will only accelerate over time as new processes and methods of treatment increase. For example, one cohort of patients using technology available now, can treat themselves at home and communicate the results of any tests they may be able to undertake themselves directly to their doctor for review over the internet. All this generated data is nothing less than gold dust which has far reaching consequences not only for you and me (the individual patient) but can, and does, drive drug development, models of care and government policy in a whole set of areas.

Of course, the data can be used in more insidious ways, for example by insurance companies wanting to hike up your premiums, if they deem you to be in a high risk category. What is undeniable is the data collected by the NHS and its affiliated organisations, when used more intelligently, has the power to transform the lives of all our citizens in this country and the wider world, for the good.

So here is the rub, is all this data leveraged in a way that drives up productivity and efficiency generally within the NHS? This is critical in an era where we have an increasingly ageing

population but with more and more treatments available, this is a recipe for continuous upward pressure on costs; and this pressure is not going to go away. Is the data made available on a timely basis to the widest possible audience that can use it to good effect to the benefit of everyone? Probably not.

There is, of course, a huge elephant in this particular room called Information Governance (confidentiality to you and me), but this shouldn't be an insurmountable barrier. Data anonymisation is a well understood technique so no identifiable patient details need to be revealed if the data is circulated more widely. There will always be the possibility that the data could be used for the wrong reasons but that needs to be managed, not used as a reason for not sharing the data with appropriate parties.

So, in a perfect world is the NHS able to leverage this data? The answer, as always, is yes and no. Yes, because somewhere you will find within this huge organisation centres of excellence when it comes to use of data; however, unlike bad news, good news doesn't always travel fast so good practice is not necessarily communicated, let alone acted upon. By comparison and alarmingly you will still find data analysts within the NHS beavering away using inappropriate systems (usually spreadsheet-based), trying to make sense of all this gold dust and not succeeding. This leads to extreme inefficiency.

The retail industry has for decades 'sweated' its data assets to become more competitive and ultimately this has benefited the consumer. Shouldn't the NHS similarly sweat its data assets (i.e. become a smart NHS) to help drive transformational change, becoming more efficient which will ultimately benefit the patient with better services? When we have answered that question in the affirmative we will know we are onto a winner.

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IN ASSOCIATION WITH



Over nine million people in the UK attest to feeling lonely. Rohan Banerjee talks to British Cross chief executive **Mike Adamson** and **Ian Lucas MP** about how best to end an age of isolation

Is loneliness a disease?



Loneliness, according to the British Red Cross, represents a hidden epidemic in the United Kingdom that is negatively impacting on people's wider health and wellbeing. It has been deemed as damaging as smoking and obesity by a 2015 report by Nesta and the Cabinet Office, putting an unnecessary additional pressure on already stretched public services. The same report found that lonely people are 1.8 times more likely to visit their GP, 1.6 times more likely to visit A&E and 3.5 times more likely to enter local authority-funded residential care.

So, how do we define the problem and in an ostensibly well-connected society, what's causing it? Feeling lonely, UCLA psychologist Letitia Anne Peplau writes, is the "discrepancy between your desired levels of social contact with what you

actually achieve."

If humans are naturally social animals, then is the pace of modern life reducing the quantity and, perhaps more crucially, quality of our relationships? For Red Cross chief executive Mike Adamson herein is the crux of the issue. "Loneliness is something that someone feels as a result of their lack of connectedness, which is a natural progression of being socially isolated." The advancements in technology, though, have surely helped to bridge any such gaps? Adamson curbs his enthusiasm somewhat: "Well, yes, they have to an extent. Social media, for example, has definitely helped in some ways, but at the end of the day, people need a level of physical interaction that the virtual world can't really provide.

"There's a great line from Brian Ferry – 'loneliness is a crowded room' – and it's



Loneliness is as damaging as obesity and smoking

SHUTTERSTOCK/TANISLAW MIKULSKI

about confidence in your connections and a sense of who you are. What loneliness does is erode that sense of confidence in your identity and therefore leads to stress and anxiety. Over time, that can manifest itself in depression and other mental health issues.” Indeed, Nesta and the Cabinet Office confirmed that lonely people are 3.4 times more likely to suffer depression and 1.9 times more likely to develop dementia. On a physical side, meanwhile, they are two thirds more likely to be inactive, which may lead to a 7 per cent increased likelihood of diabetes, 8 per cent increased likelihood of a stroke and 14 per cent increased likelihood of coronary heart disease.

Adamson adds: “We’ve also got to consider that there are lifestyle triggers for loneliness. What is often the greatest

joy in someone’s life in having children, can sometimes be a period of isolation. You get stuck at home, looking after kids, and having little interaction with other adults. Life transitions can be key triggers for loneliness, from retirement to divorce or separation. There are sensory impairments too – loss of hearing, loss of sight. We have to nip these crises in the bud and if you intervene early, you can avoid situations becoming worse, entrenched and chronic.”

For Ian Lucas, MP for Wrexham and a Red Cross campaigner, the diminishment of community is at the root of the rise of loneliness. He explains: “It’s as much to do with the way that society operates now as it is to do with any medical condition. I think we really have to get people to interact better with each other. I don’t want to idealise the past but we

“For young people there is a fear of the future”

do need a world where you know who your next door neighbour is.

“I also think that family is very important. Having people who are close to you and maintaining that; fundamentally, it means keeping in touch with people. We see nowadays that families are spread out and it’s become more of an event to see your relatives, rather than something that should just happen naturally.”

Loneliness is frequently associated with old age, but Red Cross research found that over nine million people in the UK reported feeling lonely in 2016. That is almost one fifth of the UK’s total population, which of course encompasses a great many different social groups. Generation Y, or jilted millennials according to Ed Howker and Shiv Malik’s 2010 lament, have as much reason to panic as they do to bask in their privilege. Technological prowess is tempered by economic uncertainty and the lack of polio is countered by a relentless rise in rent prices. Lucas continues: “I think among young people specifically there is a fear of the future that I don’t think existed when I was in my teens. There was an optimism that isn’t around as much now.

“There’s a weight of expectation. Youngsters see examples of people who have been successful, at least in a superficial sense, and they don’t feel they can go onto achieve that themselves. There’s a lot of hard-fast living that goes on in cities, especially in London, and some of the real quality of life isn’t given a priority. So what you get is people feeling pressured, isolated and anxious. As much as they neglect the support networks they may need, the same networks aren’t there anymore.”

What is the solution to loneliness, then? Adamson insists that the Red Cross is working tirelessly towards one. “Without the right support, loneliness can go from being a temporary situation to a chronic issue and can lead to even more serious problems, both for the individual and wider society. Some of the key preventive measures we’ve been introducing, led by volunteers, have included more community social events

and in-home support. We need services to be affordable and help to instil a positive sense of identity.”

Mental health issues, many of which stem from isolation, are becoming worryingly common in the UK. What’s more worrying is the stigma that still surrounds them. Lucas admits this is challenge we are yet to overcome. “Unfortunately a lot of people still think loneliness is something that they’re responsible for as an individual. Maybe they see it as a weakness in their character or personality, so other people don’t want to interact with them. They shouldn’t feel embarrassed, but they do, and we have to work towards changing this perception.”

And what of the broader impact of loneliness? Beyond the basic appeal to someone’s humanity, how do we convince them that tackling loneliness should be treated as a priority? Adamson offers: “The first reason it’s important is because it’s the right thing to do. Of course we need to care about every person in our society. We know that kindness has not been evenly distributed in recent times and we have to change our systems to help address that. Still, in today’s world, where public funding has been cut during a period of austerity, we have to build a business case for it as well.

“Physical and mental health problem can both prove very costly for companies in terms of production or efficiency. We need to explore the correlation between how loneliness can cause cases of high blood pressure or depression. We need to make our corporate partners aware that businesses are not extraneous from this threat and draw them into the fight on our side.”

Using national averages for baseline service usage, Nesta and the Cabinet Office found that the typical ‘cost’ of being chronically lonely to the public was around £12,000 per person over the medium term (15 years). But really, what price can you put on a human life? Loneliness is a killer and must be stopped.

**For more information visit:
www.redcross.org.uk**

Educate to empower, animate to engage

Helping people to better understand and combat their conditions is crucial to reducing global healthcare costs, writes Educate4Health CEO Dr P.J. Fitzpatrick

Annual healthcare inflation across the world is outpacing national growth. Higher healthcare spend per capita means less investment in other social priorities. The World Health Organisation has identified the growing shortage of healthcare workers globally. Demand for healthcare services will continue to increase. Thus, healthcare costs will continue to rise. A growing, ageing population needs access to ever more innovative interventions to stay healthy.

At Educate4Health we work to make healthcare sustainable. Recognising that 70 per cent of annual health resources are consumed addressing preventable chronic disease, we partner with stakeholders who wish to move healthcare decision-making closer to citizens and empower populations with better health literacy. Health literacy is the capacity by which people access and process information related to health. It is essential to service improvement and behaviour change. Improving modifiable risk factors, maintaining good health, developing self-care programmes and preventing the onset of disease can all be achieved through better health literacy.

Better health literacy lowers costs. It reduces utilisation of healthcare services, improves health outcomes, reduces medication use, reduces unnecessary hospital attendances and allows one to prioritise investment.

Politicians understand the importance of national education. In healthcare, this burden falls to healthcare professionals who frequently lack the tools and time to engage in such activity. Health education

is more than a leaflet in a doctor's waiting room. Innovative complex treatments require better explanation. We work with those improving health literacy and addressing the rise of preventable chronic disease.

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Today, explanation and engagement must be customised to be effective. We know when patients are engaged with health literature digitally, they are more likely to be compliant to any medical advice. Therefore "Digital Knowledge Delivery" is core to our vision at Educate4Health - information which is relevant, informative and actionable.

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At Educate4Health, we provide our clients tailored, cost-effective digital engagement platforms. These can include multi-use videos and animations. We keep the messaging behind healthcare engaging, easy to understand and memorable. All of our output is easily distributed and multi-modal. It provides real time monitoring of impact. We also create mobile apps for iPhone and Android with secure and affordable access. Our platforms support full audit trail and convenient access for data review. We are experts in digital marketing methodologies such as search engine optimisation (SEO), social media optimisation (SMO) and online advertising. We support our clients to deliver the right knowledge to the right people at the right time.

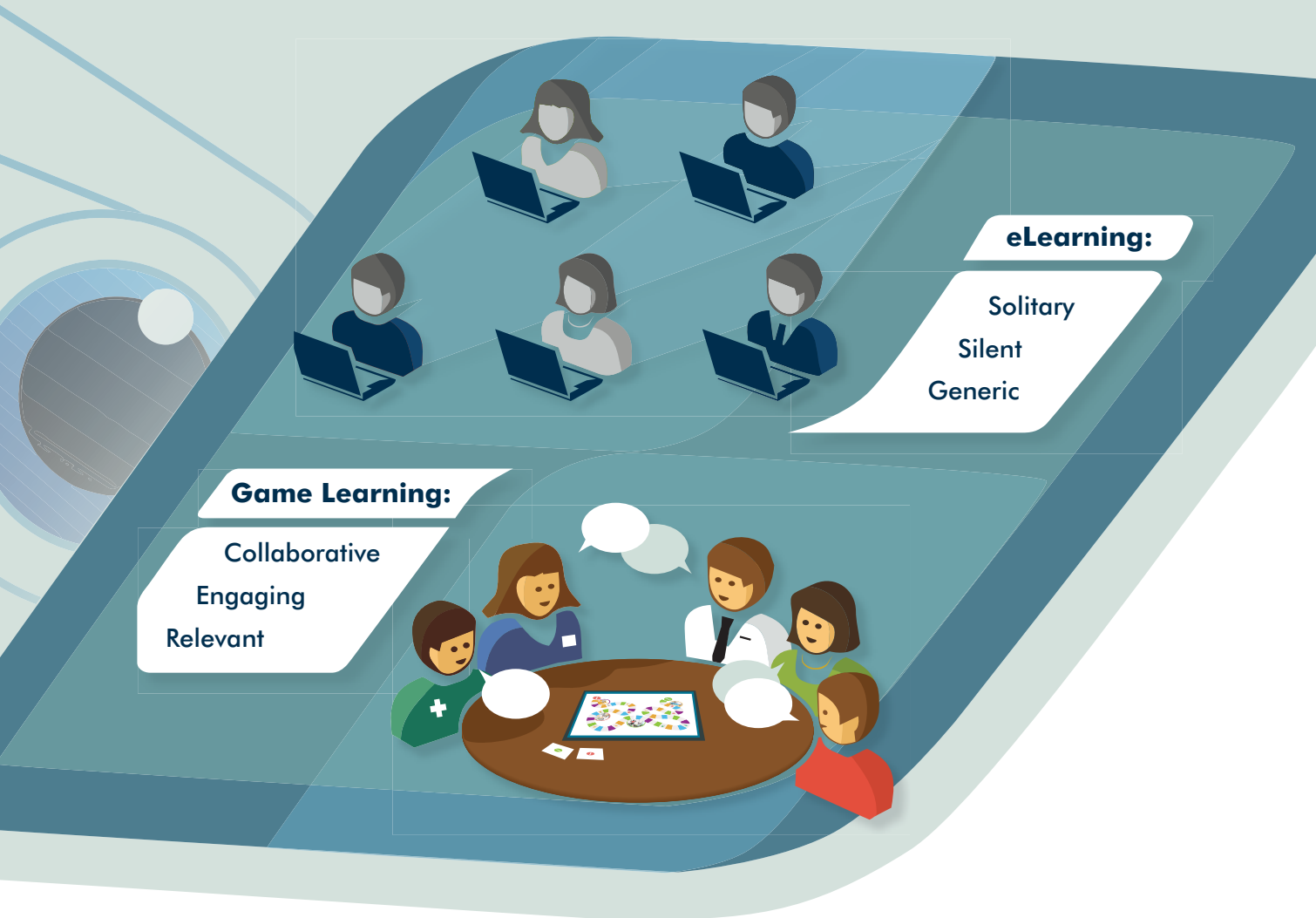
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