

this week

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Patients are denied glucose devices

EXCLUSIVE Tens of thousands of patients with type 1 diabetes are being denied “flash” glucose monitoring because the devices aren’t locally recommended, a *BMJ* investigation has found.

Flash glucose monitoring, which works from a skin sensor, has been available on prescription since November 2017. Patients get readings by scanning the sensor with a portable reader or a phone app.

NHS England has said Abbott’s FreeStyle Libre, currently the only such device available in the UK, has the potential to improve patients’ quality of life, supports self management, and could save money in the long term by reducing complications and hospital admissions, although it acknowledged gaps in the evidence base. It advised clinical commissioning groups which patients should be prescribed the device. But a year after the device became available, around a quarter of English CCGs are not recommending it for patients, even those who meet NHS England’s criteria, the investigation shows.

Partha Kar, NHS England’s associate national clinical director for diabetes, estimates that only 3% to 5% of patients with type 1 diabetes in England have access to the sensor on the NHS. If CCGs were

following guidance, he believes this figure should be 20% or 25%, if not more.

He said that the variation in how the criteria were being applied had led to an unacceptable postcode lottery. “I think some of the CCGs’ resistance is financial, but also some people are just finding a reason to say no. One CCG said to me, ‘We don’t think the evidence is there.’ And I said, ‘Well, how is the evidence there for London, Manchester, Liverpool, Brighton but not for you? How does that work?’ That’s just ridiculous,” he said.

Emma Wilmot, a consultant diabetologist at University Hospitals of Derby and Burton NHS Foundation Trust, treats some patients who can get the device and others who can’t. “I’ve had to say to patients, ‘I’m really sorry, you don’t meet the criteria because your GP is not in the right area.’ I’ve had patients even consider moving to a GP a few miles down the road so that they’d be in Derbyshire and meet the criteria,” she said.

Other patients were making “huge sacrifices” to fund the device themselves, she said. “My worry is the people who aren’t in a position to self fund. The most deprived people often have the least access.”

Gareth Iacobucci, *The BMJ*

● **FULL REPORT**, pp 212 and 213

Flash monitors allow diabetes patients to check their glucose levels and can improve quality of life, but CCGs’ prescription rules vary across the country

LATEST ONLINE

- Hospital suspends chemotherapy because of nurse shortage
- Britain’s deprived areas have five times as many fast food shops as rich areas
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UK prime minister Theresa May uses Freestyle Libre

After the LMC challenge, Birmingham and Solihull CCG sent a clarification to the LMC, acknowledging it could not demand individual funding requests from GPs.

Peter Scott, chair of Solihull LMC, said he had “scrupulously” prescribed FreeStyle Libre to a small number of his patients against his CCG’s previous policy because he believed it would improve their lives. He told *The BMJ*, “I’m not contrite in any sense. I have had feedback from all of my patients [with FreeStyle Libre prescriptions], and it’s been glowing. Their quality of life is much better, their diabetic control is much better, and in all of them their HbA_{1c} has fallen.”

Elsewhere, the seven CCGs in Suffolk and Norfolk told *The BMJ* that GPs in their areas had been prescribing FreeStyle Libre against the CCGs’ advice and that they were currently reviewing their policies.

NHS England’s Partha Kar, who has been lobbying CCGs to adopt national guidance, said, “Lots of GPs are saying, ‘I’m going to prescribe it.’ I thought this was inevitable. If people are at the door of their GP, what is the GP supposed to do?”

Long term gains ignored

Cahm said some CCGs were thinking only about short term finances rather than the long term gains of patients with type 1 diabetes having better control of their condition and experiencing fewer complications.

“They are expecting the payoff now, but it’s not going to happen,” he said. “The risk of complications is unknown, and those costings don’t show themselves in the short term.

“CCGs should be trusting the experts. At the moment it comes down to the ability of specialists

in the area to drive it and show the business case.”

Consultant Emma Wilmot believes FreeStyle Libre is proving to be one of the biggest “life changing” advances in type 1 diabetes care for many years, alongside the DAFNE (dose adjustment for normal eating) educational course and insulin pump therapy. “I’ve lost count of the number of times I’ve said to people in clinic, this is the best HbA_{1c} you’ve had in a decade. That’s the level of impact it’s having on some people,” she told *The BMJ*. “By preventing people having access to the Libre you are compromising their quality of life compared with what it could be.”

Julie Wood, chief executive of NHS Clinical Commissioners, said: “Clinical commissioners have a responsibility to consider the needs of their whole populations, and it is right they should follow a due process when considering new medicines and technologies to ensure they are making the most effective use of the limited NHS pound.”

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DEMAND EXCEEDS SUPPLY

Abbott, manufacturer of the FreeStyle Libre, has been experiencing “unprecedented demand.” A spokesperson said that people who had a prescription for the device were getting it but added, “For the time being our web shop is restricted to existing customers who can purchase three sensors every 25 days, with free shipping. Potential new customers looking to purchase the system can sign up to a waiting list to be notified when they are able to order the product.”



EXPERIENCES OF PATIENTS

SUE BRIGGS, 63, FROM SOMERSET, HAS HAD TYPE 1 DIABETES SINCE 2008

“I was self funding Libre for 18 months before I got it on the NHS. Within a couple of months of using it my HbA_{1c} (in mmol/mol) fell from the lower 50s (around 7.0 in the old units) to the lower 40s (around 6.0). My consultant asked my GP to prescribe it, who said yes.



“The impact of the extra information you get with Libre is really something. When driving, for example, if I had a blood glucose reading of 5 versus a Libre reading of 5 with a downward arrow I would react in different ways.

“The flash has reduced the amount of glucose testing strips I use, from around 10 a day to maybe five. It helps me to head off the highs and the lows, and I stay in [the glucose target] range so much more.

“The eight hour graph has given me so much more information about what I eat. When I got my Libre I saw the spike after eating breakfast. Previously, I would test two hours later, when I’d be back on target. Libre helped me to change the timing of my bolus injections. The downloads that I share with my consultant help us both make decisions about my care.

“I think that funding decisions are made for the short term, and what we’re talking about is heading off long term conditions. I don’t want to lose my feet in 20 years’ time, and I’m confident that because I manage myself well now there’s a lot less chance of that happening. I’m also more likely to keep my hypo awareness, so I can save the NHS money by avoiding emergency admissions.”

VICTORIA HILL, 24, WHOSE TYPE 1 DIABETES WAS DIAGNOSED IN 2000

“I come under Bristol, South Gloucestershire and North Somerset CCG. Neighbouring CCGs have said yes to prescribing FreeStyle Libre; it’s just ours that said no.



“I was put on a trial with the Libre when I was under care in Cardiff around 18 months ago. Within two weeks my blood sugar came down at a ridiculous rate. The major difference has been knowing what my blood sugars were doing overnight. And from that data I adjusted my insulin: I split my long lasting from once a day to twice a day. After the two week trial I paid for [Libre] for about four months, and in that time my HbA_{1c} went (in old units) from 9.2 to 7.9. I wasn’t really doing anything different: it was purely reading the data and adjusting from that.

“When I was buying a house I couldn’t afford to keep paying for Libre, and over about seven months my HbA_{1c} went back up to 8.6. After we had moved I could afford it again. I’ve been using it now for six months, and two weeks ago my HbA_{1c} was 6.6. I’m absolutely chuffed—it is life changing. I’ve been on multi-syringes and then moved to pens, but this is the one thing that has made a difference to my life overall.

“It is most frustrating that in Gloucester, which is 5 miles down the road, they are getting it on prescription and I’m not. Why are they more deserving than me? I am able to afford this, but there are people out there who can’t, and they are really missing out.”



GETTY

THE BIG PICTURE

Those who also served

On 11 November 1918 the guns finally fell silent over Europe as the armistice was declared to end the first world war. As the world commemorates the sacrifices made by combatants, *The BMJ* pays tribute to the healthcare professionals who played their part on the battlefields with these three photographs.

The main image (right) shows British soldiers having their wounds treated in an underground forward dressing station by the Menin Road in France, scene of the third battle of Ypres in 1917.

Above, top: shows blinded servicemen, circa 1916, recuperating at St Dunstan's, Regent's Park, London. St Dunstan's, a volunteer organisation dedicated to troops whose eyes were damaged in battle, was founded a year earlier.

Above: nurses attend an operation on a wounded soldier in a battle hospital in France.

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Medical conflicts of interest: when a declaration isn't enough

An NHS trust is leading the way in UK medical research by strengthening its staff policy on conflicts of interest, reports **Ingrid Torjesen**

Should a doctor with a commercial interest in a new technology be allowed to lead research trials of the same product? Should researchers with extensive financial interests also be disqualified from parts of the study?

One NHS trust to confront these questions is Great Ormond Street Hospital in London. With Brexit looming and the UK looking increasingly to capitalise on research innovation in the health sector, the hospital has turned to the US for inspiration and updated its policies.

Although Great Ormond Street investigators were required to declare conflicts related to their research, the emphasis was traditionally on transparency rather than the management of those conflicts.

Now, in what is thought to be a UK first, Great Ormond Street's policy excludes people with a "significant" investment in the product from being in charge of relevant evaluation. This investment might include holding the technology's patent or having a stake in the company developing it. Any individual with a financial conflict of interest may also be excluded from certain parts of the research process.

These have been "red lines in the sand," in the US for a long time and the UK is now taking notice, says David Goldblatt, the hospital's director of clinical research and development. "There is so much emphasis now in the NHS on innovation, we need to make sure that our policies are fit for purpose in relation to protecting patients and staff," says Goldblatt.

There is a tension, he says, between academic contributions and innovation, and universities have tended to take a liberal approach, giving academics a lot of autonomy. Academic clinicians also need



"It is really important to be able to provide a safe and sustainable environment for research without stifling innovation"

David Goldblatt, Great Ormond Street Hospital

New US rules were introduced following high profile cases, such as the death of Jesse Gelsinger in 1999 after he took part in a gene therapy trial



research publications as part of their career progression, Goldblatt adds.

It is really important for Great Ormond Street to be able to provide a safe and sustainable environment for research without stifling innovation, he says. "We have a lot of cutting edge research going on here; sometimes it's the first time the product is given in humans, sometimes the first time in a child, so we need to be really careful about what we do.

"There are no treatments for many conditions that we look after, so it is really critical that our clinicians and academics linked to us are active in devising new therapies."

It is also important to be able to demonstrate no bias in trials presented to regulatory agencies for licensing devices, he says. The US Food and Drug Administration in particular is "very hot" on the conduct of the trial, and any issues with it can trigger additional oversight or scrutiny and delay licensing of the product.

"It wouldn't really be cost effective for companies to simply license in Europe for some of the rare conditions we work on here. They would want to be selling all over the world, and obviously the US would be a huge market," Goldblatt says.

US leads the way

In the US all medical schools and major research universities have policies on conflict of interest for federally funded research. Most will apply that policy, or elements of it, to all the research conducted there, says Heather Pierce of the Association of American Medical Colleges.

Under US regulations hospitals or research organisations that receive federal funds for studies must apply a conflict of interest policy to it. "This puts the onus on the institution that receives the funding, not the individual researcher, to manage those



relationships and those interests," Pierce says.

The regulations, revised in 2011, were prompted by a series of trials in which people died or experienced bad outcomes and it was later determined that trial investigators had financial interests that may or may not have been disclosed, that could have been perceived as a conflict.

"That is not to say that it was determined to be the reason those individuals died, but the ensuing discussions really brought financial interests to the forefront of the national debate," Pierce says.

Such high profile cases include a trial of a gene therapy at the University of Pennsylvania in 1999 in which 18 year old Jesse Gelsinger, who had a liver disease caused by a genetic mutation, died. One of the researchers held shares in a biotech company that stood to gain from the research's outcome.

Since 2011, investigators in the US have had to disclose any financial interest (royalties or other payments) over \$5000 (£3800) as well as any financial interests related to their institutional responsibilities, such as interest in a related company that could profit from their research.

The regulations do not specify how institutions should respond. It is still the institution's responsibility to decide whether financial interests



GETTY IMAGES

GREAT ORMOND STREET'S CONFLICTS OF INTEREST PLAN

The research planned

An anaesthetist with a PhD in plastic technology has designed an endotracheal tube, holds the patent for the device, and has set up a spin-off company to develop it.

The anaesthetist has declared a financial interest in the technology and company every year for many years and now has some venture capitalists involved. She wants to trial the device, which she argues is easier to insert and remove than existing devices, in children having complex orotracheal surgery. Children would be randomised to this new tube or to an existing device.

An acceptable conflict of interest plan

The anaesthetist would say I have invented this technology, I own the technology, and I part own the company that is developing it. I would like to do this trial, which I have designed, and this is how I intend to manage my conflicts.

The principal investigator is a colleague in the department of anaesthesiology who is non-subordinate to me and will do all the counselling of the patients. That investigator will be supported by a clinical nurse specialist who reports directly to my colleague and has nothing to do with me. They will do the randomisation, and my colleague and his team will do the surgery. If anything goes wrong with any patient I won't be contacted.

My colleague will take responsibility for writing up the study, although I will review the data and the manuscript and be a coauthor. We are setting up an independent data and safety monitoring board, which will review all the data and approve the final data analysis. I will declare my conflict of interest on the paper and at any meetings at which I present the data.

“A researcher with equity or IP rights would be considered conflicted and prohibited from being the investigator unless they bring unique expertise” Christina Doty, Johns Hopkins, Maryland

should be deemed a conflict of interest—could they directly and substantially affect the design, conduct, and reporting of research—and, if so, whether it needs to take steps to manage that conflict.

The management strategy will depend on the nature and extent of the financial conflict and the level of risk it poses to the research and patients, Pierce says.

If an investigator is enrolling people into a large multicentre trial funded by a drug company and also does a moderate amount of consulting work for that company in a different area, the research centre may decide that the influence that this one person has on the whole trial is quite small and that disclosing that relationship is sufficient, she says. However, if an investigator has created a spin-off company that is designed to commercialise a device that he or she has invented and wants to test in humans, which is common, it would be completely reasonable to say you cannot be involved with all or some aspects of the research.

When developing its policy, officials from Great Ormond Street contacted Johns Hopkins University School of Medicine in Maryland.

Johns Hopkins' faculty and some other research investigators are expected to disclose pretty much everything that they do outside of the organisation, and this is reviewed by the division of outside interests, run by Christina Doty. If it is more complex than just income that does not exceed \$25 000 received from consulting or speaking—such as equity in a startup company, intellectual property (IP) rights, licensing agreements through Hopkins or a former employer, or publicly traded stock—then the matter goes to the committee on outside interests, a group of senior faculty members.

The committee looks at: the nature of the study, particularly if it is a high risk study in humans; the potential risks to participants; and the types and level of financial interests.

A researcher with equity or IP rights would be considered conflicted and

prohibited from being the investigator unless they bring unique expertise, which means the research is not going to be able to move forward without them, Doty says. This might apply to a new device or some form of software but rarely to a new drug.

NHS catch-up

Under Great Ormond Street's policy staff are expected to declare involvement in any kind of commercial enterprise annually, and these declarations are reviewed by a trust committee convened by the research and development department.

Some of the declarations, such as “I have provided consultancy advice to x,” are quite straightforward and nothing further needs to happen, says Emma Pendleton, deputy director of research and innovation at Great Ormond Street, but where they are more complex, individuals will be asked to complete a management plan explaining how they will manage their conflict of interest (box, left). “We give them some key questions that they need to think about in terms of how they will communicate their conflict of interest to staff, students, and patients and how they will manage it,” she says.

A declaration of interest oversight group, which the trust has set up, then decides whether the action plan is sufficient.

Unlike the US, UK institutions do not currently need to have management of financial conflicts of interest policies for government funded research. However, the NHS Health Research Authority's National Research Ethics Advisors' Panel does suggest steps that a research ethics committee could take to mitigate the competing interest of a researcher. These range from public disclosure, through giving another researcher responsibility for patient recruitment, enrolment, consent, and analysis of the study, to disqualification from part or all of the research project, depending on the seriousness of the conflict.

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The next sexually transmitted superbug?

Mycoplasma genitalium's antimicrobial resistance and treatment failures are the biggest challenges

The publication of national treatment guidelines does not usually generate newspaper headlines.

However, the recent release of draft management guidelines for *Mycoplasma genitalium* infection was accompanied by high profile media coverage suggesting that it is the next sexually transmitted "superbug."¹ So how concerned should we be?

Isolated in 1981, *M genitalium* is the smallest known self replicating bacterium,² but its natural course of infection and importance for public health remain poorly understood. Most infections are probably asymptomatic and have no adverse health outcomes.^{3,4} Nonetheless, evidence is accumulating that it is associated with serious genitourinary and reproductive health morbidity.

In men, an unequivocal association exists with non-gonococcal urethritis, and it is detected in up to 40% of men with persistent and recurrent urethritis.⁵ There is some evidence of associations with balanoposthitis⁶ but no clear association with prostatitis or epididymitis.^{7,8} A study among men who have sex with men found no association with symptoms of proctitis and rectal infection.⁹ In women, a recent meta-analysis found significant associations with a range of clinical syndromes and adverse reproductive health outcomes, including cervicitis, pelvic inflammatory disease, preterm birth, and spontaneous abortion, and a weak association with infertility.¹⁰

Data on population prevalence are sparse, but a meta-analysis of six studies suggested that the prevalence of *M genitalium* infection ranged from 1.3% to 3.9% and was higher in countries with a low development index.¹¹ In Britain, a probability sample survey estimated a prevalence of around 1.3% in the sexually active population aged 16-44 years.⁴ In common with many other



About 9-12% of infections may have dual resistance mutations

sexually transmitted infections (STIs), *M genitalium* infection rates can be considerably higher in men who have sex with men, sex workers, and people attending STI clinics,¹¹ but those infected tend to be older than people with other STIs such as chlamydia; 91% of infected men and 67% of infected women are aged 25 to 44.⁴

Treatment failure

The main concern is *M genitalium*'s increasing resistance to azithromycin and moxifloxacin, the recommended first and second line treatments in Europe, North America, and Australia, especially in the Asia-Pacific region.^{12,13} For example, single nucleotide polymorphisms in region V of the 23S rRNA gene, which confer macrolide resistance, were found in more than 60% of *M genitalium* specimens from people attending Australian STI clinics in 2015.¹⁴ Furthermore, selective pressure can lead to the emergence of macrolide resistance after exposure to suboptimal drug levels.¹⁵ Mutations in the ParC gene, which confer fluoroquinolone resistance, are also becoming increasingly common.¹³

Importantly, resistance markers are highly correlated with treatment failure, especially when the organism load is high.^{12,17} A recent meta-analysis showed the pooled efficacy of a 1 g single dose of azithromycin has declined from 85% in studies conducted before 2009 to 67% in later studies.¹² About 9-12% of

infections may have dual resistance mutations and are unlikely to be effectively treated with azithromycin or moxifloxacin.^{13,16} Treatment options in those who do not respond to first and second line therapy are limited and include extended courses of doxycycline (effective in up to 30% of cases) and pristinamycin, which is not easily available in the UK.

Such high levels of resistance and treatment failure present challenges not only for managing patients but for developing a public health response. Although nucleic acid amplification tests for *M genitalium* are available, routine screening for asymptomatic infection is not recommended, even in higher risk populations.³ Detection of an infection that may not cause harm and may be difficult to cure could lead to distress, unnecessary treatment, and the selection and spread of resistance. However, diagnosis and treatment of *C trachomatis* and *N gonorrhoeae* in asymptomatic people is routine. If these people have undiagnosed co-infections with *M genitalium*, it may be exposed to suboptimal macrolide concentrations, potentially selecting macrolide resistance.

The draft *M genitalium* guideline takes a pragmatic view, recommending testing in all men with symptomatic urethritis, women with pelvic inflammatory disease, and their sexual partners (regardless of symptoms) to cut the risk of reinfection. Even such limited testing may present practical and financial challenges, but we need to improve the evidence base on the course of *M genitalium* infection and develop cost effective regimens. Diagnosis of antimicrobial resistance mutations at point of care could also better guide treatment decisions for *M genitalium* and other sexually transmitted organisms.¹⁸

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Target health, not just healthcare

A narrow focus on the NHS neglects the much wider determinants of health

Last week's budget held few surprises for the NHS because the "star bunnies"¹ had already been released from the chancellor's hat by the prime minister, whose summer announcement included a £20.5bn "70th birthday present" for the NHS.²

But, as many have noted, the extra funding by 2023 (3.4% a year) is relatively low compared with historical trends—average annual increases since 1948 have been around 3.7%³—and it follows a long period of very modest growth. When adjusted for need, NHS spending has risen by only 0.1% a year since 2009-10 in real terms,⁴ and the spending pledge is widely viewed to be only enough to get the basics back on track.⁵

Top line figures also ignore what is happening to different funding streams. Increases are directed at only one part of the system—NHS England—ignoring infrastructure such as training, IT, and buildings, all of which are under increasing pressure, as well as spending in Wales, Scotland, and Northern Ireland. Despite the efforts of local authorities to protect social care spending, it fell by 1.5% a year between 2009-10 and 2016-17,⁴ and as the deputy chief executive of NHS Providers put it, "When social care is cut, the NHS bleeds."⁶

This week's announcement of an NHS prevention plan⁷ has not reversed the real terms reduction in the public health grant to local authorities of £0.7bn between 2014-15 and 2019-20, almost 25% per person.⁸

Deep cuts elsewhere

The determinants of health are much wider than the provision of health and social care. To maximise healthy life expectancy, as espoused by the secretary of state Matt Hancock,⁷ we should establish the health effects of spending on social security, education, housing, the environment, transport, and many other areas, all



What the NHS needs is not cash but real resources, particularly staff

arguably neglected in recent spending settlements. Deep cuts in social security budgets are likely to affect adversely the wellbeing of many, particularly children and families, and are particularly concerning with regard to future health inequalities.⁹

The Institute for Fiscal Studies states that healthcare spending rose from 23% of public service spending in 2000 to 29% in 2010, and this figure is set to reach 38% by 2023-24.¹⁰ This is a remarkable increase, which reflects not only trends in NHS expenditure but also broader changes in spending across the whole public sector.

Total government spending in 2010 made up 47.6% of UK gross domestic product.¹¹ By 2016 this fell to 41.4%, and it is forecast to fall further as the government pursues a stated agenda to shrink the size of the state.¹² In the EU28, only Poland, Lithuania, Latvia, Czech Republic, Estonia, and Ireland spend less. So it is not simply that NHS spending is growing, but that public spending overall is shrinking as a proportion of the country's wealth.

Political choices

Announcements of increased NHS spending are invariably accompanied by calls for reform of the way funds are generated—advocacy of user charges, social insurance, and hypothecated taxes abounds.¹³ But in comparison, general taxation as the means of generating funds for the NHS is administratively simple, efficient, and equitable. And both the level of

spending on healthcare and the way in which funds are generated are essentially matters of political choice.

So, too, are many pledges determining how NHS budgets are spent. The previous health secretary prioritised cancer funding. The chancellor last week promised £2bn for mental health.¹ And Hancock apparently wants a greater proportion of NHS funding to support prevention and primary care.⁷

These monetary pledges can be difficult to translate into improved services, particularly in the short term. What the NHS needs is not cash but real resources—particularly staff. As NHS vacancy rates in England are increasing,¹⁴ it can be challenging to translate spending effectively into care, and this may again point to the need to consider external services.

The chancellor's view that the NHS is the top priority of the British people is supported by survey findings in 2017 that more than 60% of respondents supported tax rises to enhance NHS funding, an increase of 21 percentage points from 2014.¹⁵ But although the NHS is a valued institution, it is hard to believe that people view it as completely distinct from its overarching objective—to improve population health. If we value health above all, then increased spending on the NHS, at the expense of other services, will not be enough.

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Artificial intelligence (AI) systems simulate human intelligence by learning, reasoning, and self correction. Already this technology shows the potential to be more accurate than physicians at making diagnoses in specialties such as radiology, dermatology, and intensive care; at generating prognostic models; and at performing surgical interventions. And in 2017 a robot passed China's national medical exam, exceeding the minimum required by 96 points.

More precise, reliable, and comprehensive

Even if machines are not yet universally better than doctors, the challenge to make them better is technical rather than fundamental because of the near unlimited capacity for data processing and subsequent learning and self correction. This "deep learning" is part of "machine learning," where systems learn constantly without the potential cultural and institutional difficulties intrinsic to human learning, such as schools of thought or cultural preferences. These systems continually integrate new knowledge and perfect themselves with speed that humans cannot match. Even complex clinical reasoning can be simulated, including ethical and economic concerns.

Increasing amounts of more comprehensive health data from apps, personal monitoring devices, electronic medical records, and social media platforms are being integrated into harmonised systems such as the Swiss Personalised Health Network. The aim is to give machines as complete a picture as possible of people's health over their life and maximum knowledge about their disease.

The notion that today's physicians could approximate this knowledge by keeping abreast of current medical research while maintaining close contact with their patients is an illusion, not least because of the sheer volume of data. Here too, machines have the advantage: natural language processing enables them to "read" rapidly expanding scientific literature and further teach themselves, for example, about drug interactions.

The key challenges for today's healthcare systems are economic: costs are rising everywhere. Introducing AI driven systems could be cheaper than hiring and training new staff. AI systems are also universally available and can even monitor patients remotely. This is important because demand for doctors in much of the world is growing more quickly than supply.

Less biased, less unstable, still caring

The ability to form relationships with patients is often portrayed as the trump card in favour of human physicians, but this may also be their Achilles' heel. Trust is important for patients' perception of the quality of their care. But the object of this trust need not be a human; machines and systems can be more trustworthy if they can be regarded as unbiased and without conflicts of interest. Of course, AI systems may be subject to the biases of their designers, but this can be overcome by independent reviews and subsequent iterations.

To say that patients always require empathy from human doctors is to ignore important differences between patients: many, particularly younger, patients with minor complaints simply want an accurate diagnosis and treatment that works. In other words: they may rate correct diagnosis higher than empathy or continuity of care. In some very personal situations the services of a robot could help patients avoid feeling shame.

Even patients who crave interaction, such as those with serious or terminal diagnoses, may find that their needs are better met by machines. Recent studies show that conversational agent systems have the potential to track conditions and suggest care and can even guide humans through the end of life.

Doctors as we now know them will become obsolete eventually. In the meantime, we should expect stepwise introduction of AI technology in promising areas, such as image analysis or pattern recognition, followed by proof of concept and demonstration of added value for patients and society. This will lead to broader use of AI in more specialties and, sooner than we think, human doctors will merely assist AI systems. These systems will not be perfect, but they will be constantly perfecting themselves and will outperform human physicians in many ways.

HEAD TO HEAD

Could artificial intelligence make doctors obsolete?

Machines that can learn and correct themselves already perform better than professionals at some tasks, says **Jörg Goldhahn**, but **Vanessa Rampton** and **Giatgen A Spinaz** argue that robots will never replicate the therapeutic nature of the doctor-patient relationship



Listen to the authors discuss the issue in a podcast at bmj.com



no

The physician-patient relationship is a relationship between mortal beings vulnerable to illness and death

Vanessa Rampton, Branco Weiss fellow, McGill Institute for Health and Social Policy, Montreal, Canada vanessa.rampton@mail.mcgill.ca

Giatgen A Spinas, emeritus professor, University Hospital, Zurich, Switzerland

Machines will increasingly be able to perform tasks that were previously the prerogative of human doctors, including diagnosis, treatment, and prognosis. Although they will augment the capacities of physicians, machines will never replace them entirely. In particular, physicians will remain better at dealing with the patient as a whole person, which involves knowledge of social relationships and normativity. As the Harvard professor Francis Peabody observed in 1927, the task of the doctor is to transform “that case of mitral stenosis in the second bed on the left” into the complex problem of “Henry Jones, lying awake nights while he worries about his wife and children.”

Humans can complete this transformation because they can relate to the patient as a fellow person and can gain holistic knowledge of the patient’s illness as related to his or her life. Such knowledge involves ideals such as trust, respect, courage, and responsibility that are not easily accessible to machines.

Illness is an ill defined problem

Technical knowledge cannot entirely describe the sickness situation of any single patient. A deliberative patient-physician relationship characterised by associative and lateral thinking is important for healing, particularly for complex conditions and when there is a high risk of adverse effects, because patients’ preferences differ. There are no algorithms for such situations, which change depending on emotions, non-verbal communication, values, personal preferences, prevailing social circumstances, and so on. Those working at the cutting edge of AI in medicine acknowledge that AI approaches are not designed to replace human doctors entirely.

The use of AI in medicine, predicated on the belief that symptoms are measurable, reaches its limits when confronted with the emotional, social, and non-quantifiable factors that contribute to illness. These factors are important: symptoms with no identified physiological cause are the fifth most common reason US patients visit doctors. Questions like “Why me?” and “Why now?” matter to

patients: contributions from narrative ethics show that patients benefit when physicians can interpret the meaning they ascribe to different aspects of their lives. It can be crucial for patients to feel that they have been heard by someone who understands the seriousness of the problem and whom they can trust.

Linked to this is a more fundamental insight: as Peabody put it, healing illness requires far more than “healing specific body parts.” By definition illness has a subjective aspect that cannot be “cured” by a technological intervention independently of its human context. Curing an organism of a disease is not the same as establishing its health, as health refers to a complex state of affairs that includes individual experience: being healthy implies feeling healthy. Robots cannot understand our concern with relating illness to the task of living a life, which is related to the human context and subjective factors of disease.

Medicine is an art

Throughout history, the therapeutic effect of doctor-patient relationships has been acknowledged, irrespective of any treatment prescribed. This is because the physician-patient relationship is a relationship between mortal beings vulnerable to illness and death. Computers aren’t able to care for patients in the sense of showing devotion or concern for the other as a person, because they are not people and do not care about anything.

Sophisticated robots might show empathy as a matter of form, just as humans might behave nicely in social situations yet remain emotionally disengaged because they are only performing a social role. But concern—like caring and respect—is a behaviour exhibited by a person who shares common ground with another person. Such relationships can be illustrated by friendship: B cannot be a friend of A if A is not a friend of B’s.

A likely future scenario will be AI systems augmenting knowledge production and processing, and doctors helping patients find an equilibrium that acknowledges the limitations of the human condition, something that is inaccessible to AI. Coping with illness often does not include curing illness, and here doctors are irreplaceable.

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TAYLOR GALLERY/GETTY IMAGES

Who wants to receive a terminal diagnosis from a robot?

Hype aside, proponents of artificial intelligence in healthcare must work in partnership with patients if we are to reap the benefits, say **Michael Mittelman**, **Sarah Markham**, and **Mark Taylor**

 Listen to the authors at [bmj.com](https://www.bmj.com)



We regularly hear that artificial intelligence is going to transform the world, including healthcare, and how this disruptive innovation could spell the end for many professions as we currently know them, including lawyers and doctors.

In healthcare, however, what is crucial is that technology company executives, researchers, hospital managers, and academics are asking the right questions about AI's impact on patients.

Between the three of us, we have more than 61 years of patient history in health systems worldwide. We have different needs, conditions, and comorbidities, including multiple sclerosis, end stage renal disease, mental illness, epilepsy, and Crohn's disease. None of us can envisage our relationships with our many human doctors changing because of artificial intelligence.

Unmet promise

Patients haven't always benefited from the promises of technology. The implementation of electronic health records, which has made little difference to patients to date, is but one

example. Hospitals and health systems have spent exorbitant amounts of money only to find that records are inaccurate and inaccessible.

AI is sure to proceed further into the hospital, examination room, and primary care, but patients should not have to bear the brunt of any developments that have not been proved beneficial for their current condition.

This isn't Luddism. Technology companies have given patients few reasons to trust them with all their medical data. We continue to see systems breached and patient information exposed. What happened to "First do no harm"? It's not clear that medical ethics and responsibility for patients currently outweigh the motive of corporate profit.

Raw emotion

Imagine a mother and father being told that their 3 year old son will lose his kidneys from a rare disease. Picture the raw emotion on their faces. Now imagine yourself as a new college graduate, seeing a new doctor in a new city. That 22 year old has a brand new job, excited for her future. She waits in the examination room only to be told that she has an invisible illness, a mental health condition.

Now imagine those same scenarios with no healthcare professional in the room. The only interaction is with an artificial form of intelligence. A machine. It is unthinkable.

We can't be reduced to data

Could patients ever rely on a machine to manage their entire care pathway? Decisions about technology continue to be implemented without true partnership with patients, without knowing what patients want or need. There is much more to medicine than analysing data.

More fundamentally, AI lacks the ability to sense, process,

Decisions about technology continue to be implemented without true partnership with patients, without knowing what patients want or need

interpret, replicate, or deploy some very human forms of communication. Sensing that your doctor truly cares about what you are going through, and really does want to help, makes a profound difference to patients' experience of, and ability to manage, their health. This shared enterprise is innately human and requires a genuinely intimate and empathetic connection between two beings of the same kind.

The therapeutic power of the human-clinician encounter depends on a relationship between two humans who both can fully contextualise and appreciate the patient's values, wishes, and preferences.

Ill and vulnerable

Patients need to be cared for by people, especially when we are ill and at our most vulnerable. A machine will never be able to show us true comfort. The ability to understand fully the "human condition" will always be essential to health management.

AI may have the potential to become a useful and innovative aide in healthcare, but we hope there will always be room for humanity—human healthcare professionals. Ultimately, no one wants to be told he or she is dying by an entity that can have no understanding of what that means. We see AI as the servant rather than the director of our medical care.

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