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- Finally, the NHS goes digital. Or does it? (*BMJ* 2015;351:h3726)
- Games for doctors (*BMJ* 2014;349:g5642)

Which app should I use?

Patients and doctors are making increasing use of health apps, but there is little guidance about how well they work. **Stephen Armstrong** reports

There are well over 150 000 health apps available in Europe[1]—from those designed to improve general wellness to apps that monitor medical conditions, apps for clinicians, and apps that function as medical devices. There have been more than 102 billion downloads of health apps worldwide yet there is little regulation or guidance available for doctors or patients on quality, safety, or efficacy.

What is the problem?

Since the UK government founded the Cochrane Centre in 1992, evidence based medicine has been at the heart of healthcare.[2] With the burgeoning apps market, however, things are different.

"There's a huge and growing number of health apps out there, and with that comes a wide variation in quality, testing, and evaluation," says Sarah Williams, senior health information officer at Cancer Research UK. "As with any new technology there's a lot we still need to understand about whether they can be effective, especially in the long term, and, perhaps more importantly, whether they're helping the people who really need it."

Technically any app that makes efficacy claims needs to be able to produce some evidence to support its claims under the European Directive on Misleading Advertising. This may, however, not include the high quality evidence from randomised controlled trials that clinicians have come to expect.

"People are increasingly using apps to monitor, manage, and even treat conditions but have no information on whether or how the apps have been calibrated, and it's hard to find any information on the research used in development," explains Patricia Wilkie, chair of the National Association for Patient Participation. "It's a very murky area."

Risks of uninformed choice

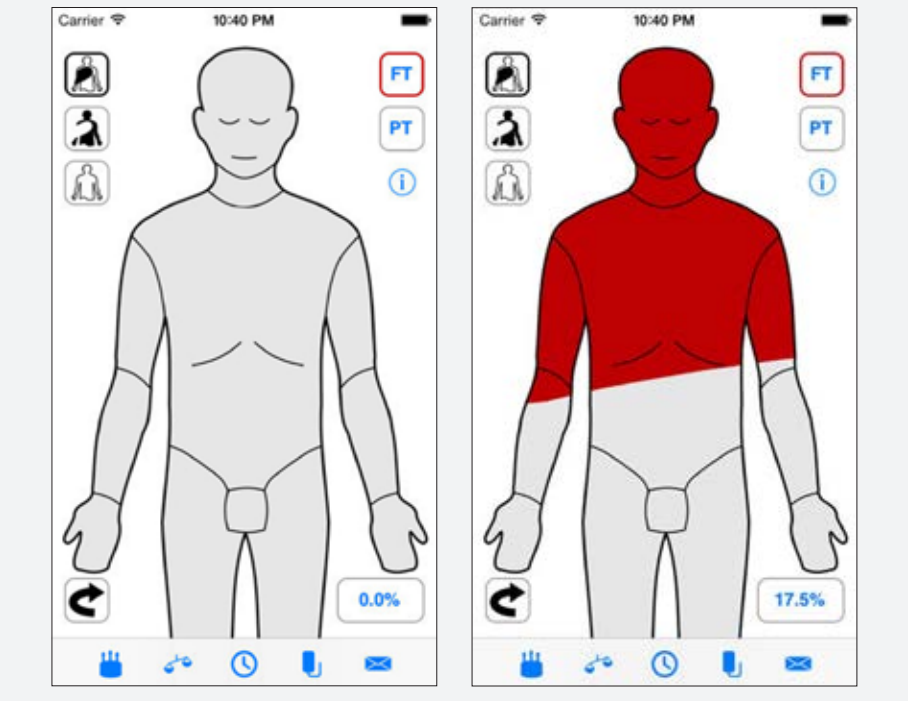
"People choose health apps the same way as they choose any apps—quality of design and how easy they are to use," explains Satish Misra, cardiology fellow at the Johns Hopkins Hospital in Baltimore and managing editor at app review site iMedicalApps. "That's why many of the top downloaded apps are not evidence based—and some don't even make sense."

Six months ago Jeremy Wyatt, chair in eHealth Research at the Leeds Institute of Health Sciences and clinical adviser on new technology to the Royal College of Physicians, tested 19 apps on the iTunes store—both free and paid for—that claimed to diagnose the user's risk of a heart attack over the next 10 years. "Given the same data, one app gave a risk of 19%, another gave a risk of 96%, and a third gave a risk of 137%," he explains. "There was bad coding and poor research in half of the apps tested, with paid for apps performing worse than free apps."

Yet patients and health professionals are increasingly using medical apps. Studies report that over 85% of health professionals use a smartphone and 30-50% use medical apps in clinical care.[3 4] A survey of 233 NHS general surgical trainees working in Scotland[5] found 82% had downloaded at least one medical app, 35% had used apps to help make clinical decisions, and 13% thought they had encountered errors. Some 58% thought that apps should be compulsorily regulated but none knew the name of any regulatory body.

What is the current system?

All apps are regulated by the Data Protection Act and the European Directive on Misleading Advertising. In addition, the European Medical Device Directive considers apps used in "diagnosis, prevention, monitoring, treatment, or alleviation of disease, injury or handicap as well as investigating, replacing or modifying the anatomy or a physiological process or controlling conception" to be medical devices.[6] These are regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) and have to undergo a conformity assessment by MHRA notified bodies to secure a CE certificate.



Mersey Burns is an app for calculating how much fluid a burns patient needs. Developed by plastic surgeons, it is the first UK app to win a CE mark

Many of the top downloaded apps are not evidence based—and some don't even make sense

The Mersey Burns App, which calculates how much fluid a burns patient needs, was the first to win a CE mark. It was accredited after clinical trials showed it was more accurate and quicker at calculating the result than doctors working out the figure by hand. It's hard to get a clear picture on how many apps have a CE mark—an MHRA spokesman said that the authority kept no register or list of CE marked apps, leaving that to the numerous notified bodies (there are 15 in the United Kingdom alone) individually.

Definition of a medical device is "a very grey area," according to Charles Lowe, president of the telemedicine and ehealth section at the Royal Society of Medicine. "I was at a meeting of the London Health Technology Forum last November with two representatives of the MHRA. They were shown examples of telehealth and asked which was a medical device but they couldn't agree."

Some apps—such as uChek, a smartphone app that sends photographs of urine test strips to clinicians—are effectively in vitro medical devices but are not currently classified as such, Julian Hitchcock, counsel at Denoon Legal, a law firm specialising in medical technology, argues.

In the United States the Food and Drug Administration regulates apps classified as medical devices with a very light touch.[7] Only 100 apps have so far been classified as a medical device and none has been banned for safety or efficacy reasons. However, the Federal Communication Commission has banned some apps that make misleading claims, including an acne cure app that could provide no evidence of its claim that the iPhone screen backlight could reduce acne.[8]

What if an app definitely isn't a medical device?

"If it isn't a medical device there is no reliable framework or standard beyond the NHS Choices library guidelines, which were created two years ago and haven't been reviewed since," warns Maureen Baker, chair of the Royal College of General Practitioners. "We're trying to apply a regulatory framework that was created in the 1960s and 1970s—it's not fit for purpose 50 years on."

NHS England has so far taken a relatively informal approach. The NHS Choices Health Apps Library—launched in March 2013—lists apps found to be clinically safe, compliant with the Data Protection Act, and relevant to people living in England.[9]

In May, the UK standards body the British Standards Institution published a voluntary best practice framework for developers with advice from a steering group including BUPA, NHS South West Academic Health Science Network, app developers, notified bodies, the Royal College of Physicians, and medical device manufacturers.[10] There are also unofficial endorsement systems such as myhealthapp.net, which focuses on user recommendations and reviews.

There is disagreement over how heavily health apps need to be regulated—and uncertainty about what is practically feasible. But in April, the Royal College of Physicians advised its members not to use any apps that didn't have a CE mark—not least, it advised, because "if it is missing, then you are leaving yourself open to . . . possible litigation." Wyatt, however, stops short of calling for National Institute of Health and Care Excellence (NICE) or MHRA regulation of every app.

Moves towards better information

Major efforts are afoot to help doctors and patients decide which apps to choose. Launched in March 2015, the Mental Health Apps Library—hosted by the NHS Choices Apps Library—lists apps that offer NICE approved evidence based treatments for mild to moderate depression and anxiety disorders. The apps are selected, according to NHS England, because there is "a strong evidence base of digital tools being effective in helping sufferers of mild to moderate depression and anxiety to manage their conditions." This is the first stage of Personalised Health and Care 2020, the government framework for digitisation of the health service,[11] which includes a library of endorsed apps and digital tools. Although inclusion will still be a recommendation, the endorsement process is intended to be much tougher than current systems.

This month the National Information Board (NIB), the body overseeing the roll-out of technology across the NHS, begins consulting clinicians and patient groups on proposals for a stronger endorsement process. The proposals suggest that assessment is made in four steps: self assessment, community endorsement through crowdsourced feedback from professionals and the public, and then robust independent assessment, possibly involving NICE, at the third and fourth stages to confirm the effectiveness of apps.[12]

The NIB foresees some 10 000 apps entering stage 1 each year, with roughly 2000 invited to move into stage 2. Of these, only around 100 are expected to move into stage 3 with roughly 10 reaching stage 4.

It is not clear whether this process will have any legal powers. "The only genuine protection consumers and patients have is via the MHRA, data protection, or mis-selling legislation," explains Hitchcock. "Mis-selling rules, however, are powerful. They can force developers to prove apps fulfil their claims, and with healthcare that could effectively mean [they have to produce] NICE standard evidence."

But Baker is concerned, "Until we have case law in this area, who knows about any of this? And there has been no case law to date."

This autumn, the European Commission will begin negotiating proposed reforms to existing directives on medical devices, in vitro diagnostic devices,[13] and use of mobile health.[14] The proposals, which include apps, point to stronger supervision of independent assessment bodies by national agencies and the EU and give those assessment bodies more powers to ensure thorough testing and regular checks, impose stricter requirements for clinical evidence, update risk classification rules for medical devices, and establish better coordination between regulators. Adoption of the new rules is expected by the end of this year or at the beginning of 2016.

Stephen Armstrong is a freelance journalist, London, UK
stephen.armstrong@me.com

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The junior doctor contract row: how did we get here?

As junior doctors prepare to vote on strike action, **Tom Moberly** explains why negotiations have broken down

Why is the contract being changed?

The current contract for doctors in training was implemented in 2000. In December 2012, the government accepted the recommendations of a report from NHS Employers that the contract needed to be renegotiated.[1] NHS Employers, which negotiates on behalf of the government, said that the current contract was "no longer fit for purpose." The current banding system is complex and makes it difficult for hospitals to predict their financial requirements. NHS Employers argued that the pay system should be updated to be more in line with that of other industries. It argued that pay for trainees should be weighted more towards basic pay than banding.

When did negotiations start?

In June 2013, the BMA and NHS Employers agreed the basis for discussion over a new contract for junior doctors.[2] They said they would discuss pay, working hours, and how much time junior doctors spent in training rather than delivering services. Formal negotiations over a new junior doctors' contract, as well as a new consultants' contract, began four months later, in October 2013.[3]

But in October 2014 the BMA announced that negotiations over both contracts had come to a standstill after the government

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"refused to agree necessary safeguards to protect doctors from working dangerously long hours."[4] Under current proposals hospitals would not be required to perform regular monitoring of junior doctors' hours. Instead, junior doctors would have to ask their human resources departments to instigate monitoring of hours when they worked too long through a process called "exceptional reporting." NHS Employers said that the BMA had "withdrawn from the discussions without notice."

What has happened since the collapse of talks?

Following the breakdown of negotiations, the government drafted in the Review Body on Doctors' and Dentists' Remuneration (DDRB) to look at the consultant contract and make recommendations for a new junior doctors' contract.[5] The DDRB published its report on how the contracts should be changed in July.[6] The BMA said that junior doctors had been left angry and frustrated by the DDRB proposals.[7] According to the BMA, the most contentious recommendation was to increase the number of hours in a week that were classed as "plain time" from 60 to 90 hours, reducing the times at which doctors are eligible for extra pay to compensate for antisocial hours. Junior doctors also raised concerns about plans to introduce "flexible pay premiums" in the new contract. The premiums are ways of adding extra incentives and monetary benefits to basic salaries.

Why didn't the DDRB report resolve the situation?

In August, the BMA's junior doctors' committee voted not to re-enter contract negotiations with NHS Employers.[8] The committee said the decision "follows the government's insistence that the BMA accepts all of the recent recommendations on a new contract made by the DDRB without question by mid-September." It added, "This would not allow junior doctors to negotiate over proposals the BMA believes are unsafe for patients, unfair to doctors and undermine the future of the NHS."

NHS Employers announced on 14 September that, as the BMA was unwilling to re-enter negotiations, it would impose a new contract on junior doctors.[9] NHS Employers pledged to "press ahead with essential reform to the junior doctors contract" and engage directly with those affected. It remained committed to an implementation deadline of August 2016. The BMA said that it would resist the imposition of a new contract for junior doctors if it is "bad for patients, bad for junior doctors, and bad for the NHS."[10] It will now ballot junior doctor members over potential strike action.

Tom Moberly editor, BMJ Careers
tmoberly@bmj.com

With extra reporting from Imran Mannan and Jessamy Bagenal

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NEWS, p 1
VIEWS, p 23

WHO ADVISES THE GOVERNMENT ON DOCTORS' PAY?

Set up in 1971, the independent Review Body on Doctors' and Dentists' Remuneration (DDRB) advises the government on the pay rates for doctors and dentists working within the NHS.[11]

In preparing its annual report, the committee weighs evidence from the government as well as organisations representing staff groups. The committee also draws on its own independent research. It is required to take careful account of the funds available to the health service and the economic evidence submitted. The government does not have to accept the DDRB's recommendations, and in recent years it has ignored advice to increase pay for general practitioners. For this year's pay settlement, the government told the body not to bother preparing a report and opted to offer staff a non-negotiable 1% pay increase instead.[12]

The body is made up of eight members. The chair, currently Paul Curran, a former NASA research scientist and adviser to the European Space Agency, is appointed by the prime minister and the other members by the health secretary. It currently includes a professor of economics, a professor of strategic management, and former NHS directors.[13]

Critics say the DDRB is no longer truly independent of government influence and has strayed too far from the organisation envisaged back in 1960, when a royal commission first recommended that it be established. It was set up to stop the government manipulating doctors' pay for political purposes. But Peter Holden, a member of the general practitioners' committee of the BMA, said last year that the DDRB was today stuffed with "public sector functionaries."

"According to their published CVs, they're all big organisations' functionaries. There are no industrials in there," he told the BMA annual representative meeting.