### **BODY POLITIC Nigel Hawkes**

## Take me to your leader

Management fads come and go, and integrated care may be just the latest fashionable policy in the NHS

For an organisation that sets a lot of store by evidence, the NHS is easily swayed by fashion. An idea takes hold, gains purchase, and becomes the accepted wisdom so swiftly you have to be on the alert to keep up. Currently, integrated care is it. The health select committee strongly endorses it, the think tank the King's Fund proselytises about it, and the Labour Party's shadow health secretary, Andy Burnham, has proposed yet another reorganisation of the NHS in England in an attempt to achieve it. I may just have a suspicious nature, but when everybody is in such warm agreement my instinct is to take to the hills.

A US psychologist, Carl Rabstejnek, has identified at least 100 management fads since the second world war, from "acceptable risk" at one end of the alphabet to "zero defects" at the other. He argues that fads reflect managers' need to appear to be "in the know" and to talk the language of change even when actual change is imperceptible. The largest financial support for fads comes, he argues, from large companies that are actually slow to change: no parallel to the NHS, clearly.

The NHS has not embraced all these fads, though it does have a weakness for those that include the word leadership. I'm sure you will be as pleased as I was to learn that the NHS is to train 25 000 new leaders, starting in September. This is the largest ever leadership programme to transform NHS culture, the NHS Leadership Academy declared. A huge cast has been assembled to carry out the task, including the consultancy firms KPMG and the Hay Group, six universities (four of them outside the United Kingdom), and various other facilitators and assorted hangers on. If the target is reached the NHS will have nearly as many leaders as the Duke of Wellington had followers at Waterloo.

In the wake of the Francis report, the NHS portrays this programme

as a means of achieving a culture of "dignity, compassion, and respect" through better leadership. It's a worthy aim that perhaps doesn't merit my scorn, but if you have to teach people who already work in healthcare these values, we're in a bad place. At the same time, we have the respected US guru Don Berwick providing guidance to the NHS on "zero harm," a management tool so newly minted that it doesn't even make it on to Rabstejnek's list.<sup>2</sup>

As for integrated care, it would be a start if everybody agreed on what it means. Maximalists argue that it involves the integration of health and social care, minimalists that it is about providing a seamless programme of healthcare without any awkward transitions across primary, secondary, and community care. Burnham has recently adopted the maximalist position, calling for local authorities to swallow the new clinical commissioning groups to become the commissioners of both health and social care.

This is an idea that would have delighted Herbert Morrison,
Labour's postwar champion of local government, who argued unavailingly that councils should be given control of the hospitals in the new NHS.
The minister of health, Nye Bevan, disagreed—and won the argument, setting up regional boards that were appointed rather than elected and had no political accountability.

He was swayed by the country's consultants, who didn't want to work for local authorities, but it's arguable that the outcome produced a system so opaque and detached from local politics that people had little idea of the costs and realities of delivering their local healthcare. Over the years this opacity has made any change in existing provision, such as integrating care, more difficult to achieve.

So Burnham's proposal has virtues, if we overlook the reorganisation involved and the





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fact that it is incompatible with his opposition to "any qualified provider" providing care. Local authorities have contracted out services through competitive tender for the past 20 years, to the point where roughly a third of their services are provided externally by private sector, third sector, or mutual based organisations. Healthcare under the local authority banner would be no different, with Conservative councils likely to contract out more services than those led by Labour or the Liberal Democrats. It would be an interesting experiment—but I'm not sure that Labour would think it a very attractive one.

More modest "care only" integration is assumed to improve care and cut costs, but a characteristic of management fashions is that everybody accepts them as true without arguing. Research findings present a more nuanced picture. The evaluation of 16 integrated care pilots launched in 2008 showed that staff were happier in their jobs and believed that the care they were providing had improved, but patients were not so sure.<sup>3</sup> There were suggestions that care became professionalised and that focus on the individual patient was lost. Emergency admissions of patients in the pilot areas were higher than in the control group, and it was hard to draw any clear conclusions about overall costs.

To my eye the existing evidence falls some way short of justifying integrated care as a panacea for the NHS's ills, attractive as it may seem. To call it a fad would be unfair; at the moment it's a fashionable policy in search of persuasive evidence that it really works.

Given the obstacles to change in the NHS, its time may pass before it has even been tried.

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2

#### MEDICINE AND THE MEDIA

## How do we know whether medical apps work?

Smartphone apps may transform management of health, says Margaret McCartney, but regulation is so far scarce

Angry Birds, Cut the Rope, and Fruit Ninja are favourite games among smartphone owners, but many apps are for function rather than fun. These include medical apps claiming to offer ways to better health. Some are aimed at healthcare professionals but are available to all. The National Institute for Health and Clinical Excellence, the Scottish Intercollegiate Guidelines Network, and the BNF have free apps allowing easy access to advice. But other apps don't just reproduce advice. In January the UK Medicines and Healthcare Products Regulatory Agency (MHRA) approved its first app: Mersey Burns is a free tool that calculates burn area percentages and fluid requirements.

Other medical apps are aimed at the public. Many advise on diet and exercise, and these vary widely in quality, <sup>1</sup> but newer apps purport to help diagnosis. The NHS Healthcare Innovation Expo this month featured an app from Skin Analytics that tracks changes in skin moles to "raise early warning signs" by comparison with previous images of the same mole. <sup>3</sup> Its website says that, for £30 a year for an individual or £50 for a family, the app can "baseline you and your family" using "patent pending technology" that can "detect small changes in both the geometrical structure and colour composition of your moles with an exceptional 95% accuracy."

A recent study in *JAMA Dermatology* showed that most previously marketed apps had a failure rate in melanoma diagnosis of about 30%. <sup>5</sup> Julian Hall, director of Skin Analytics, said that this app, which is not yet available to buy, was not a diagnostic service but was instead "trying to implement the self examination advice from public health bodies and answer the question, 'Has the lesion changed or not changed?'—prompting people to see their GP or dermatologist." Clinical trial data on the app are lacking, but Hall says a trial is planned for later this year. Yet the question of evidence is crucial. Do apps offer to gather more, or misleading, data for little useful signal?

Several apps offer to use a phone's camera light to check pulse rate. One app claims 25 million users after promotion in the United States, 6 with the ability to record serial pulse rates, but it is not clear what advantage this offers over manual pulse measurement. It is also possible to buy a small plug-in device that turns your phone into a pulse oximeter, although this is described as "not for medical use" and is marketed as useful for mountain climbers or private pilots and retails at about \$250 (£165). 5 Some free apps offer "health checks" but are just adverts for cosmetic surgery.

# Why not test these apps in a real life situation for evidence of benefit and to check that they don't have unintended harms?

Specsavers, which the *BMJ* recently reported had been advertising for contracted NHS services, <sup>8</sup> offers a free app described as a "sight check." Users cover an eye and test their visual acuity with images on the phone. (Despite having had a recent prescription, I was still "strongly recommended" to speak to my optometrist.)

Apps' interactivity distinguishes them from books or leaflets, and the handheld nature and additional recording offered are different from the reach of websites. This can widen the potential for unintended outcomes. The NHS Commissioning Board last week launched a "library of NHS-reviewed phone apps to keep people healthy"

because it is "committed to improving outcomes for patients through the use of technology." More than 70 have been approved in a review that includes a "clinical assurance team," to ensure that they "comply with trusted sources of information, such as NHS Choices," with assessment of potential to "cause harm to a person's health or condition."

However, a high standard of evidence should surely be crucial in a product approved by the NHS. The charity Beat Ovarian Cancer offers a "symptom tracker" to help women "recognise the signs and symptoms of ovarian cancer," but without real world trials to show effects and quantify harms

we do not know whether this is beneficial. The NHS Commissioning Board said that, through its review process, it is "ensuring that the apps listed in the Library are clinically safe and suitable for people who are living in the UK" and that apps "have been checked by the NHS and adhere to NHS safety standards." Yet why not test these apps in a real life situation for evidence of benefit and to check that they don't have unintended harms?

Another NHS recommended app is *iBreastcheck*, which can be set to remind women to check their breasts weekly, fortnightly, or monthly. The app includes videos of women examining themselves and a link to donate to the charity Breakthrough

Breast Cancer, which devised it. It would be possible to trial this app to find evidence of benefit and harm in the same way that other trials have investigated breast self examination, <sup>10</sup> but this has not been done. Breakthrough Breast Cancer said that the content was reviewed by a panel of experts and that it was "not a breast self examination app. It is a breast awareness app."

The US Food and Drug Administration published draft guidance for medical apps in 2011. Straightforward information or recording devices are not subject to its guidance, as long as these apps do not offer to diagnose, treat, or cure a condition. Instead, it suggested that its oversight should apply to apps that, for example, turn a smartphone into a stethoscope or that offer risk assessments of disease or diagnosis on the basis of information entered. In the UK apps that are "medical devices" must be registered

with the MHRA. It has the power to withdraw products from the market, but what constitutes a medical device is a grey area. For example, the agency said an app that charted changes in skin moles would not be a device, but one that offered diagnosis would be

But registration with the MHRA does not imply efficacy. Approval of efficacy is granted by Europewide "notified bodies," which can award the CE quality mark if their standards are met. These are "principally trade measures designed to remove technical barriers to trade," and for apps they do not insist on evidence of better outcomes, such as from randomised controlled trials.



BNF's app offers only

It would be a pity if apps with solid evidence behind them—such as several decision making aids approved by the NHS app library—become confused with ones that lack evidence. Apps are likely to be a new source of information that enable patients to interact with the NHS in a different way. We need to ensure they are safe, useful, and effective. If they work we should use them, but, as with any medical intervention, they need fair tests in the real world before we can know.

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26