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When health tech goes wrong: who pays for patient harm in the world of health apps?

Healthcare apps present unprecedented opportunities to transform the way healthcare is delivered, but these new media for delivering healthcare bring with them novel risks and challenges. The speed at which this area of healthcare is growing points to future claims for harm caused to patients and issues of risk and responsibility that are already intricate in clinical negligence litigation, and which are potentially made more complicated when traditional healthcare is shifted into the digital arena. Dan Morris, Partner at Bevan Brittan LLP, in this article discusses the evolving lines of responsibility relating to health apps when an end user suffers harm, and that whilst app developers might primarily be concerned with trying to shoehorn an app into a particular regulatory category, they should not assume that a particular designation will protect them from ultimate responsibility for fault where harm arises. Dan also shares his reaction to the US Food and Drug Administration's ('FDA') determination that Matis's My Baby's Beat app is a non-medical device.

A recent report estimates that the number of mobile health apps available on the UK market has nearly doubled in two years and now exceeds 318,000, with approximately 200 new apps being added every day[1]. Faced with oversubscribed GP surgeries, lengthy waiting times and inconvenient appointments, patients - particularly younger, tech-savvy but time-poor patients - are turning to their smartphones to stay on top of their health and wellness, whether that is by arranging a remote GP consultation which can be set up in under 10 minutes, online management of repeat prescriptions, or obtaining a referral to a specialist consultant at a tertiary care centre. Technology is radically altering the way that people are engaging with healthcare and there are clearly many positives to these developments. But the delivery of remote healthcare via such technology also raises urgent questions about risk, responsibility and cost in the event that an end user suffers harm as a result of remotely delivered care.

Regulation, responsibility and the duty of care

Whilst there is an abundance of healthcare apps that make no qualms that they are designed to assist with diagnosis, prevention and treatment of ill health or disease, others purport to focus solely on monitoring of fitness or wellness, whether that is by counting steps per day, monitoring hours of sleep per night or measuring other biometrics. With these wellness and fitness apps, it is common to see hidden amongst the terms and conditions pages a disclaimer along the lines of 'this app is not intended to be utilised for medical purposes and is not intended to diagnose, treat, cure or prevent any disease, illness or condition.' The reason for this relates to the regulatory landscape within which these apps operate. The Medicines and Healthcare products Regulatory Agency ('MHRA') distinguishes between apps which it considers to be medical devices and those which are not. Medical devices require a CE mark in order to ensure they are regulated and acceptably safe to use. But health apps that are not medical devices fall outside the scope of the MHRA.

But does this regulatory definition do anything to alter the lines of responsibility when an end user of a healthcare app suffers harm? The answer is almost certainly not. Responsibility for harm will generally be governed by traditional concepts of negligence and/or breach of implied terms about quality or fitness under contract (where a user pays a subscription fee for an app), and the courts will more likely turn to the famous 'neighbourhood principle' laid down in *Donoghue v. Stephenson* [1932] AC 562 (think snails, ginger beer, etc) to determine whether a healthcare app producer owes a duty of care to an end user, rather than look at whether a regulator has classified an app as a medical device.

Even if the MHRA (or in the US, the FDA) has decided that a healthcare app is not concerned with diagnosis treatment, cure or prevention, it is open to a court to decide entirely otherwise, looking at how end users are actually utilising and relying on these products. So whilst app developers might primarily be concerned with trying to shoehorn an app into a particular regulatory category (so as to avoid the costs associated with obtaining a CE mark), they should not assume that a particular designation will protect them from ultimate responsibility for fault where harm arises. That is a separate question, and we are already starting to see this debate play out in other jurisdictions. For

example, the Attorney General of New York last year took action against three mobile health apps - Cardiio, Runtastic and Matis (see further below) - which he felt were jeopardising end user safety in spite of the FDA holding they were not medical devices and therefore did not require regulation. His office warned that "Mobile health application developers are now on notice: we won't tolerate non-evidence-based apps that threaten the well-being of New Yorkers." The three companies agreed to provide additional information about the testing of the apps, to change their advertising and to pay $30,000 in combined penalties to the Office of the Attorney General[2].

The standard of care to be expected of a remote care provider

A patient who consults a healthcare professional remotely via, say, a GP app has a very different kind of consultation to a person who visits a GP practice and sees his/her doctor face to face. The digital doctor cannot palpate, percuss or auscultate, and relies to a much larger extent on the history of symptoms provided by the patient; objective signs will be more difficult to discern except in all but the most obvious cases, say the rash of chickenpox or measles. But what if the rash is on a two year old child and the mother raises concerns about meningitis? In the real world consulting room, the doctor would invariably apply pressure to the rash to check whether it blanches or not (the 'glass test').

But the remote doctor cannot carry out this check. Certainly they could ask the parent to apply pressure and observe, but are they really going to want to rely on this, and are you going to be able to see the reaction as well through a mobile phone screen? The safe thing would be to refer the patient to a real world GP or A&E department as a matter of urgency. But is this going to result in over-referral and further pressure on our already stretched A&E teams?

And what does the law have to say about this?

Courts currently rely on the *Bolam* test which requires claimants to establish that reasonable skill and care was not taken in diagnosis and treatment, and that the doctor's impugned conduct would not be supported by a responsible body of medical opinion in the relevant field. But is this benchmark able to stand up to these new kinds of consultations with their inherent limitations? Is the GP who consults remotely to be judged by the same standard as the GP who consults in person, when the former does not have the same arsenal of tests and investigations to explore and verify signs and symptoms? Is the *Bolam* responsible body against which the digital GP must be judged a responsible body of 'ordinary' GPs or a responsible body of GPs providing remote consultations across the ether? Only time - and future litigation - will tell. Courts can, as they always have, flex and adapt the common law to keep pace with societal and technological changes[3]. But Mr Bolam and his troubles with electro-convulsive therapy in the 1950s seem an awfully long time ago in the age of remote healthcare delivered by doctors via smartphones.

Who is the correct defendant?

In the non-digital world of clinical litigation the identification of the correct legal defendant is reasonably straightforward. Ordinarily, the defendant will be the GP or the NHS Trust (where treatment is provided in an NHS hospital), or sometimes an individual clinic where treatment is carried out privately. But if a patient is harmed as a result of remotely delivered digital care, are

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things quite as clear cut? Does liability remain with the consulting doctor, the app developer or even the telecoms provider because, say, the connection goes down half way through an online consultation? Ultimately, nobody can know who a patient will decide to sue in advance and potential defendants have no control over that. However, it is common for patients to sue the broadest possible number of defendants and let them and their insurers work out ultimately who has to pay the damages, according to contractual agreements and indemnities in place at the material time.

The potential costs of getting it wrong

One of the companies against whom the New York Attorney General took action last year was an Israel based company called Matis which sells My Baby's Beat, an app downloaded hundreds of thousands of times, which Matis previously claimed could turn any smartphone into a fetal heart monitor, despite the fact that this had never been approved by the FDA. The app was available to purchase through Apple's App store and Google Play from December 2015. The app purported to allow a pregnant user to listen to her fetus's heartbeat by simply holding a smartphone to her belly. Graph-like waves then appeared on the smartphone and peaked when any sound was made. But even if a user is not pregnant when using the app, he or she may still hear something that sounds like a heartbeat, which could be the sound of his or her own heart.

My Baby's Beat was being sold on the App store for $4.99 and on Google Play for $1.99. In 2016, it became the most popular app in the paid 'medical' category in Apple's App store. The Office of the New York Attorney General concluded that the app's name and logo depicting a fetus inside a stethoscope strongly suggested that the app was medical in nature[4].

In the UK, a significant percentage of the overall £1.7 billion cost of clinical negligence in 2016/17 related to those cases involving avoidable cerebral palsy due to negligent management of child birth[5]. Under the current -0.75% personal injury discount rate, cerebral palsy claims can frequently be valued in the tens of millions of pounds, particularly where the injured child has a long life expectancy and requires a lifetime of intensive care, case management and therapies. In these cases, the monitoring of the fetal heart rate is central to determining liability, and lawyers and obstetric experts will spend many hours poring over cardiotocographic ('CTG') traces to determine what was happening with the fetal heart and whether earlier intervention should have been taken, and whether this would have avoided the catastrophic outcome. Obstetricians and midwives are frequently criticised for misinterpreting the CTG trace and for not intervening by, for example, escalating to an emergency Caesarean section.

As a clinical risk lawyer who sees the devastating cost - both human and financial - of misinterpreted fetal heart monitoring, the idea of an unregulated, non-evidenced based app guiding expectant mothers as to what is going on with the fetal heart is extremely concerning. Clearly, some pregnant women are going to be reassured by these apps in cases where they should not be, and in other cases they will be unduly alarmed if they cannot pick up the fetal heart. I do not know why the FDA determined Matis's app to be a non-medical device, and one can only hope that the same decision would not have been reached by the MHRA. But the warning to health app developers must be clear. Get this wrong, and the liabilities can be huge whether or not you are deemed a medical device by regulators. Claimant lawyers acting for patients with devastating injuries requiring a lifetime of care will not hesitate to name you as a defendant, whatever regulatory status you may have been given, and the courts could well find that your product has caused foreseeable harm resulting in damage.

Conclusion

Healthcare apps present unprecedented opportunities to transform the way healthcare is delivered into the next decade. Pressure to reduce costs, increase efficiency and demonstrate value will continue to intensify. Coupled with this, there has been a shift away from traditional concepts of disease, illness and treatment to active, ongoing monitoring and maintenance of wellness, fitness and health. People are more interested than ever in all aspects of their wellbeing from tracking physical activity and exercise through wearable technology, to home monitoring of signs and symptoms such as blood pressure, blood sugar and pulse rate.

These are clearly exciting times for healthcare app developers and patients. But these new media for delivering healthcare bring with them novel risks and challenges. The speed at which this area of healthcare is growing inevitability points to future claims for harm caused to patients and issues of risk and responsibility, which are already intricate in clinical negligence litigation, are potentially made more complicated when traditional healthcare is shifted into the digital arena. Early appreciation of this is key and healthcare app developers should be in-building patient safety into their products from the very earliest stages of development.

1. IQVIA, The Growing Value of Digital Health: Evidence and Impact on Human Health and the Healthcare System, November 2017.
2. AG Schneiderman announces settlements with three mobile health application developers for misleading marketing and privacy practices: https://ag.ny.gov/press-release/ag-schneiderman-announces-settlements-three-mobile-health-application-developers; Assurance of Discontinuance Nos: 16-101, 16-174, 16-173; see also M. Molteni, 'Wellness apps evade the FDA, only to land in court,' https://www.wired.com/2017/04/wellness-apps-evade-fda-land-court/
3. See, e.g. FB v. Princess Alexandra Hospital NHS Trust [2017] EWCA Civ 334.
4. Assurance of Discontinuance No 16-101.
5. M. Magros, 'Five years of cerebral palsy claims: a thematic review of NHS Resolution data,' NHSR, September 2017.