Editorials
Challenges for digital services in the NHS:
drowning in a sea of innovation

INTRODUCTION

In August 2018, a paid Facebook advertisement for the Natural Cycles fertility awareness-based (FAB) contraceptive application (app) was withdrawn. This followed an investigation by the Advertising Standards Authority (ASA) which concluded that the advertisement was misleading, exaggerating the app's accuracy and reliability as a form of contraception compared to other established methods.[1] Natural Cycles is a landmark example reflecting wider issues of inadequate evidence for regulation and advertising of products being brought to market in this age of digital healthcare and social media. Through discussion of this case, which has parallels with Babylon and GP at hand, we highlight some of the challenges faced in digital healthcare innovation, and make some suggestions as to how to move forward.

NATURAL CYCLES AND FERTILITY AWARENESS-BASED CONTRACEPTIVE APPS

The Natural Cycles app uses an algorithm to calculate the fertile window of women who input data on daily basal body temperature, cycle length, and optional urine luteinising hormone (LH) testing. It is marketed as a stand-alone contraceptive method that couples can use to avoid unplanned pregnancies. Despite a Cochrane review concluding that the comparative efficacy of FAB methods remains unknown,[2] they have a growing profile as they become available on mobile apps, and paid advertisements on social media have given them significant exposure. The UK code of British advertising that vets advertising of medical devices via a clearing process does not apply to social media. This inconsistency is of concern given that prescription only medication, including pharmaceutical contraceptives, is not allowed to be advertised in the UK.[3]

When the ASA investigation[1] triggered by five complaints found a Natural Cycles Facebook advertisement to be misleading, it was withdrawn following over 500 000 downloads. However, Natural Cycles still advertises on social media, and the app is available for the public to download without the need for any contraceptive counselling. This is concerning for two reasons: first, the limited evidence for FAB apps (even Natural Cycles, which has the most evidence for its efficacy,[4] has not undergone a randomised control trial [RCT]); and second, the lack of unbiased, comprehensive information about the efficacy and usability of such apps for the general public.

According to recent research, only six out of 40 evaluated FAB contraceptive apps could correctly identify the fertile window.[5] These are all apps claiming to use evidence-based FAB methods, yet the apps themselves have no evidence-base as interfaces for such methods. It is easy to see how users could miss this key distinction, with potentially serious consequences. In a web-based survey of users and potential users of FAB contraceptive apps, a significant number of women lacked 'moderate' knowledge surrounding fertility.[6] Most women stated it was 'very important' to them that an app be based on proven scientific evidence, but the majority of apps women had used were not designed to deliver interpretation of fertility status for contraceptive purposes, rather to aid conception or simply track period dates. This highlights a need for greater clarity of the benefits and limitations of individual apps, with this information accessible to the user.

CHALLENGES FACED BY NHS DIGITAL

This turn of events is symptomatic of a wider problem with a lack of regulation leading to accessible and unreliable medical advice online. The NHS is stretched in its approach to new technologies where authentication and funding is lacking. NHS Digital's approved app library was brought up to 70 apps to celebrate the 70th birthday of the NHS: a drop in the ocean considering that more than 300 000 healthcare apps were available in 2018.

Unbiased accessible reviews of the science behind healthcare apps for the public would be of value, however there is no funding for this. Additionally, there are no financial nor reputability incentives for developers.

A recent policy paper by the Department of Health and Social Care accepts the dire need for improvements in technology in the NHS, including within digital services and innovation.[7] They propose a series of steps to aid developers: to set clear guidance on what is required, support access to finance, enhance collaboration between innovators and the NHS at both the development and implementation stages, and provide opportunities for developers to test their products in clinical settings, allowing them to build up the evidence base they need for uptake into the NHS. A systematic review on digital health app development standards is eagerly awaited.[8]

Juliet Bauer, NHS England's Chief Digital Officer acknowledged, that:

'With so much innovation, multiple NHS bodies, and a fast-paced commercial market, it can be difficult — for all of us — to understand who is doing what'.[9]

Collaboration between health professionals and app developers is crucial, but difficulties arise because these two parties may have different goals: top quality resources versus profit. We should motivate developers to not only produce the best resources, but to continue to update and refine them once they are in circulation.

How can we do this? Potential solutions would be to create lucrative contracts for which developers have to compete, and to be proactive in seeking out alternatives should the standard fall. While the government's policy paper correctly highlights the need for new products to be evidence-based, it does not explain how it will help this to occur in a timely manner. Rapid advances in technology risks products being out of date by the time researchers have collected, analysed, and published the data. In order to make the most of new technology, we must find a faster way of evaluating the efficacy of these digital products.

NICE published a more detailed guideline in March 2019, outlining minimum and best practice evidence standards for new technologies commissioned by the NHS.

> *"With so much innovation, multiple NHS bodies, and a fast-paced commercial market, it can be difficult — for all of us — to understand who is doing what."*

"While access to digital healthcare products can empower patients, we have a duty to ensure that they are not being misled, and are not coming to harm ..."

These standards begin with patient and expert healthcare professional involvement in developing the technology, building up to successful pilots in the NHS, demonstrating the ability to produce accurate, reproducible data. Standards for economic analyses on the new technologies are also described. Unfortunately, these guidelines will not apply to the majority of new healthtech products, therefore the public remains at risk. Products not seeking NHS endorsement can launch on app stores as before, freely available for download without any official commissioning or vetting.[10]

In the last two years Babylon has spread from the private sector to NHS patients via their service GP at hand. The service was commissioned before it was fully evaluated. Babylon's own research into the safety and efficacy of aspects of their service was not published until 2018.[11] The 2017 Care Quality Commission (CQC) report on Babylon found the service lacking in three aspects of safe care and treatment.[12]

NHS England is now managing the aftermath of unexpectedly high demands on GP at hand, how it fits in with our current primary care structure, and how to fund the service.[13] In addition, following complaints from eight members of the public, the ASA upheld claims that four advertisements for GP at hand, visible to the public via multiple sources including Facebook and on the app itself, were misleading in multiple ways.[14] The advertisements were banned from appearing in their current forms, but this, as with the Natural Cycles advertisement, is reactive rather than proactive regulation, and is of concern considering the vast reach of these advertisements and the potential negative impact of misleading medical information on the general public.

CONCLUSION

The NHS is struggling to keep up with new healthcare technologies. Products are being brought to market without much authentication behind them; sometimes via the NHS and sometimes, like Natural Cycles, bypassing healthcare providers and becoming immediately accessible to patients.

Advances in technology are undoubtedly exciting, and have the potential to drive significant improvements in patient engagement, satisfaction, and clinical care. We must embrace this, but also maintain high standards of care and resources. While access to digital healthcare products can empower patients, we have a duty to ensure that they are not being misled, and are not coming to harm by using products that have not undergone rigorous testing.

There is a need to review advertising rules surrounding healthcare technology, including on social media, and a need for a greater bank of NHS endorsed products which the public know they can trust. Collaboration between innovators, regulators, and the NHS, is crucial to achieve this.

ADDRESS FOR CORRESPONDENCE
Lara Shemtob
Royal Free London NHS Foundation Trust, Pond Street, Hampstead, London NW3 2QG, UK.
Email: lara.shemtob@nhs.net

Lara Shemtob,
Academic Foundation Year 2 Doctor, Royal Free Hospital London NHS Trust, London.

Rebecca Littlewood,
Foundation Year 2 Doctor, Whittington Health NHS Trust, London.

REFERENCES

1. Advertising Standards Authority. *ASA Ruling on NaturalCycles Nordic AB Sweden t/a Natural Cycles*. 2018. https://www.asa.org.uk/rulings/naturalcycles-nordic-ab-sweden-a17-393896.html (accessed 12 Jun 2019).

2. Grimes DA, Gallo MF, Grigorieva V, *et al.* Fertility awareness-based methods for contraception. *Cochrane Database Syst Rev* 2004; **4:** CD004860.

3. Hough A, Bryce M, Forrest S. Social media and advertising natural contraception to young women: the case for clarity and transparency with reference to the example of 'Natural Cycles'. *BMJ Sex Reprod Health* 2018; **44:** 307–309.

4. Berglund Scherwitzl E, Lundberg O, Kopp Kallner H, *et al.* Perfect-use and typical-use Pearl Index of a contraceptive mobile app. *Contraception* 2017; **96(6):** 420–425.

5. Duane M, Contreras A, Jensen ET, White A. The performance of fertility awareness-based method apps marketed to avoid pregnancy. *J Am Board Fam Med* 2016; **29(4):** 508–511.

6. Starling M, Kandel Z, Haile L Simmons RG. User profile and preferences in fertility apps for preventing pregnancy: an exploratory pilot study. *mHealth*. 2018; **4:** 21.

7. Department of Health and Social Care. The future of healthcare: our vision for digital, data and technology in health and care. 2018. https://www.gov.uk/government/publications/the-future-of-healthcare-our-vision-for-digital-data-and-technology-in-health-and-care/the-future-of-healthcare-our-vision-for-digital-data-and-technology-in-health-and-care (accessed 12 Jun 2019).

8. Van Velthoven M, Smith J, Wells G, Brindley D. Digital health app development standards: a systematic review protocol. *BMJ Open* 2018; **8:** e022969.

9. Bauer J. Blog. Keeping up with tomorrow's world. NHS England, 2017. https://www.england.nhs.uk/blog/keeping-up-with-tomorrows-world/ (accessed 12 Jun 2019).

10. National Institute for Health and Care Excellence. Evidence Standards Framework for Digital Health Technologies. March 2019. https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf (accessed 13 Jun 2019)

11. Razzaki S, Baker A, Perov Y, *et al.* A comparative study of artificial intelligence and human doctors for the purpose of triage and diagnosis. Cornell University, 2018. arXiv:1806.10698 (accessed 12 Jun 2019).

12. Care Quality Commission. *Babylon Healthcare Services Limited. Inspection report*. 2017. https://www.cqc.org.uk/sites/default/files/new_reports/AAAG6526.pdf (accessed 12 Jun 2019).

13. NHS England. Digital-first primary care and its implications for general practice payments. 2018. https://www.engage.england.nhs.uk/survey/digital-first-primary-care/user_uploads/digital-first-access-to-gp-care-engagement-v2.pdf (accessed 12 Jun 2019).

14. Advertising Standards Authority. *ASA Ruling on Babylon Healthcare Services Ltd t/a GP at hand*. 2018. https://www.asa.org.uk/rulings/babylon-healthcare-services-ltd-a18-439274.html (accessed 7 Jun 2019).