THE CONVERSATION

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Your smart watch isn’t a medical device – but it is tracking all your health data

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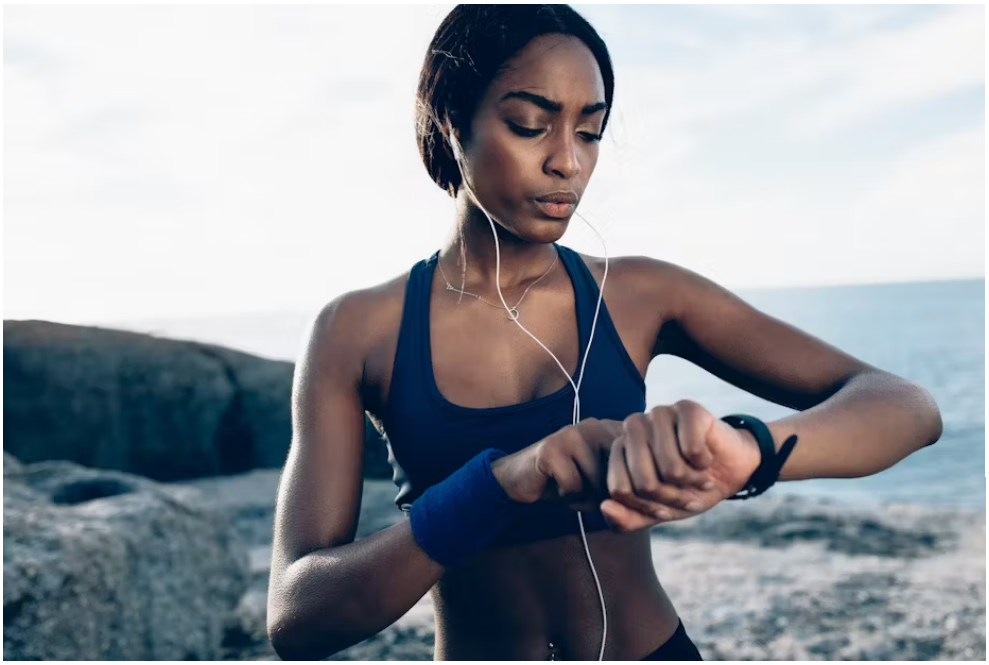

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For millions of people, smartwatches aren’t just a piece of technology. They can use them to take control of their health in ways never thought possible.

As you go on your morning run, a smartwatch can monitor the rhythmic pounding of your feet and your heart’s steady beat. The watch can record the distance covered and the intensity of your workout, guiding you towards your fitness goals.

During lunch, you can use it to log calories for a BLT sandwich. As deadlines loom, they can offer gentle reminders to take a moment for yourself. And as you doze off, they might pick up instances of apnoea or other sleep disturbances.

But some users could also conflate health tips with medical advice. Device and app developers have consistently made it clear that their products cannot replace a professional medical doctor’s advice or treatment.

A smartwatch is not a medical device as defined by law. In the UK, medical devices are strictly regulated in a way that other devices such as smartwatches are not. These regulations provide users with better legal protections and clarity as well as providing for resolution in the event of a mishap.

What qualifies

The key legal framework in the UK is the Medical Devices Regulations 2002 (UK MDR). Once a product has been identified as a medical device under UK MDR, further classification of it takes place, ranging from low risk (stethoscopes and wheelchairs) to high risk (pacemakers, heart valves, implanted cerebral simulators).

If a device is designed to go inside the body, or if it contains medicinal substances, it is more likely it is treated as high risk. Depending on the risk classification, the law then imposes stringent standards to protect users from harm. These include obligations on the manufacturers and developers to ensure their devices are safe, through conducting risk impact assessments, periodic audits and other actions.

All matters relating to medical devices in the UK fall under the responsibility of the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA conducts surveillance of medical devices available in the UK and has the authority to make decisions regarding their marketing and distribution. It is also the MHRA's duty to ensure that manufacturers and developers are complying with the regulations.

Pursuit of wellness?

An important question is how one distinguishes a device, digital tool or app as one used for a medical purpose – which is how the UK MDR defines a medical device – versus one that is used for general health and wellness. The latter would include, for example, meditation apps or step counters.

Traditionally, smart watches have been treated as smart, wearable technology. On the face of it, they offer users insight into their general health and wellness, helping them make necessary lifestyle adjustments to improve their health or fitness goals.

In recent years, however, such technologies have become increasingly advanced. Tens of thousands of digital tools and applications have flooded app stores. These include monitoring apps for mental health, symptom checkers based on information entered by patient users, or medical calculators for drug dosing.

 ECG

Electrocardiogram functions can now be incorporated into smartwatches. Pitchyfoto/Shutterstock

Smartwatches may have electrocardiogram (ECG) functions. An ECG is a test used to check a person's heart's rhythm and electrical activity. Medical professionals have traditionally used ECGs to look for signs of coronary heart disease or other cardiovascular conditions. The same functions on a watch may not have the right sensitivity to pick up on medical conditions.

The latest version of the Apple watch has embedded sensors that may be able to detect atrial fibrillation, a type of irregular heart rhythm. In the US, Apple has obtained clearance from the Food and Drug Administration (FDA) allowing it to be used for this purpose, marking a bold move into the regulated medicine and healthcare space.

Biosensors, previously thought of as devices that were administered only in clinical settings have now evolved by design into slim patches for consumer use. Take the Nix Biosensor device. When paired with Apple Watches, it is designed to measure a user’s optimal hydration level in real time by identifying molecular markers in sweat and determining the loss of fluid and electrolytes (substances that maintain a balance of fluids inside and outside cells).

Finally, emerging trends also indicate that more and more women are relying on fertility and cycle trackers in smartwatches and sophisticated apps. However, there have been concerns that users might use the information in place of actual birth control.

Hence, as smartwatches and trackers evolve, it’s possible that they may approach the threshold for what authorities could consider a medical device.

Privacy protections

There’s something else to consider too. Users of devices and digital tools regularly hand over their personal data. Businesses must ensure compliance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018 (DPA).

Personal health data is a “special category of data”. This would fall under the application of Articles 6 and 9 of the UK GDPR and Schedule 1 of the DPA. This means that more stringent standards are imposed for the collection and use of such data (in its processing), including potentially an obligation to conduct an extensive data impact assessment.

Indeed, the UK’s privacy watchdog, the Information Commissioner’s Office (ICO) issued a statement on February 8 2024 reminding all app developers to ensure they protect users’ privacy following the regulator’s review of period and fertility apps.

Other potential safeguards for users’ privacy could come from the Medicines and Medical Devices Act 2021 (MMDA), from the appointment of the Patient Safety Commissioner and from the National Health Service (NHS), which can now evaluate digital tools using the digital technology assessment criteria (DTAC).

Clear guidelines in this area are not just necessary, they’re imperative. Without them, we potentially risk both stifling innovation and compromising user care.