

Briefing Note – summary of Briefing Paper No 6 June 2021

The future of wearable technologies

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Headlines

- The wearable device industry is rapidly expanding, especially for health and fitness monitoring devices.
- With advances in technology, the divide between medical or wellness devices is blurring.
- Wellness devices are subject to less stringent regulation than medical devices.
- No legislation exists to stop wellness device companies from improperly collecting data from users for targeted advertisements and product development.
- Clear, concise and up-to-date regulation for wearable devices is needed. This should:
 - require that commercial companies inform users about personal data use, and seek permission for commercial use.
 - be understandable by non-specialist audiences such as app developers.
 - be developed by regulators, wearable tech companies, academia and medical professionals working together to provide the safest and most effective solutions.
 - Include the potential for criminal sanctions for non-compliance with regulation.

Wearable devices

Wearable devices typically provide continuous measurements of an aspect of the user's life such as health or activity. Wearable devices come in a variety of forms. Common current examples are smartwatches (e.g. Apple Watch), bracelets (e.g. Fitbit) and rings (e.g. Oura Ring). These are driven by low-cost microelectromechanical systems and optical sensors. Wearables may monitor blood pressure, pulse variation, patterns of respiration, physical movement (e.g. step count), blood oxygen level, skin temperature or interaction with others.

Relevance to healthcare

Data from wearables can be useful for disease detection, allowing for earlier diagnosis and potentially a reduction in the severity or even occurrence of illness. Wearable technology allows monitoring of serious illnesses such as [hypertension](#), [diabetes](#), and [cardiac health](#).

Healthcare providers are starting to embrace wearable devices as tools that can remotely deliver care, e.g. [NHS using continuous glucose monitoring to manage type 1 diabetes](#). Wearable devices can aid the global shift for healthcare providers from [treatment to prevention](#), saving money and improving quality of life. Low cost wearables may be particularly attractive to healthcare settings in low- and middle-income countries.

Wearable devices adoption in healthcare remains at an early stage because:

- Wearable devices typically measure the most accessible aspects of physiology.
- Clinical study data required to validate their usefulness in a real-life patient population is expensive and slow to produce.
- Medicine is typically slow to adopt novel interventions generally.
- Public acceptability remains low.

How the capabilities of wearable tech are expected to change

The next generation of medical devices is likely to be more invasive and able to give quantitative real-time measurements of [biomarkers](#) in point of care settings. This could alert care professionals to take immediate and timely action, which would be particularly valuable in intensive care settings.

The next generation of wearable technology will have improved analytical ability from non-invasive biosensors via non-invasive sweat sensing or minimally invasive microneedle sensors. Users will have a small chemical lab on their wrist.

What are the main barriers to progress?

- Consumers may feel uncomfortable with sharing large quantities of personal data collected by wearable devices.
- The challenge of getting reliable data from non-invasive analysis of readily available analytes, such as sweat, tears or saliva.

Implications for policymakers and regulators

Stringency of regulation

Medical devices require a higher level of precision in their measurements and are subject to a significantly greater number of regulations than wellness devices. A [wellness device](#) can assist the user in generally living a healthy life, whereas a [medical device](#) is intended to deliver a medical diagnosis, monitoring or therapeutic effect. Example: [Fitbit Inspire 2](#) (wellness device) vs [QardioCore](#) (medical device). The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating medical devices in the UK. Wellness devices are usually classified as consumer electronics devices. With the anticipated blurring of what is considered a medical versus a wellness device, regulating this field, and licensing devices and software, will become more difficult.

Although there are large differences between companies regarding the value they place on privacy (e.g., Apple vs Fitbit), no current legislation exists to stop commercial companies from collecting data from each user that can be misused. Most wellness devices require users to adopt a long list of Terms & Conditions (T&C's), which often include clauses about data made available to third parties, such as external commercial companies. Using algorithms and a wide range of user data, both parent and third-party companies are able to deduce not only individuals' physical whereabouts and movements, but also their [emotional states](#), which could be used for marketing.

In the UK, this complexity has been compounded with the uncertainty surrounding the regulation of consumer devices after Brexit.

How Imperial College London, industry and entrepreneurs can work together

Imperial College London is at the forefront of designing the next generation of wearable devices. We have the interdisciplinary skills, expertise and capabilities to take ideas from concept to reality, combining medical professionals highlighting requirements, researchers able to model the interactions, chemists to synthesise compounds and engineers to develop ideas into devices.

Specialist organisations

- The [Hamlyn Centre](#) designs new wearable sensors and sensing platforms, along with addressing associated informatics challenges in collaboration with leading companies.
- The [National Institute for Health Research's \(NIHR's\) clinical research facility](#) at Hammersmith Hospital offers a streamlined approach to obtaining test data in a clinical trial context.
- [Imperial Enterprise](#) offers opportunities to access the expertise of our academics, the talent of our students, our high-tech resources and spaces on our campuses.

Examples of successful start-ups and companies

- Spyras has developed a technology that analyses breathing patterns using [sensors integrated into disposable facemasks](#).
- The flowPATCH is a [wearable, non-invasive patch](#) that captures an athlete's sweat and interprets key bio-markers in real-time to improve performance.

Educational courses

- [MRes Medical Device Design and Entrepreneurship](#): development of medical devices and biomedical engineering knowledge alongside entrepreneurship skills.
- [MRes Molecular Engineering](#): skills to work in multi-disciplinary teams at the interface of science and engineering, in both academia and industry.

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