UCL INSIGHTS: RESEARCH BRIEFING

Getting safe and effective digital medical devices to patients

Introduction

What are digital medical devices?

Medical devices are a wide range of technologies that have a specific medical purpose such as diagnosis, prevention or treatment of an illnesses or injury, and which achieve this purpose primarily without the use of a drug. Examples include scalpel blades, patient monitoring equipment, joint implants and MRI scanners. Recent developments in digital technologies are leading to the development of a new generation of digital medical devices, which can be highly innovative, are often mainly or entirely software, and are sometimes powered by artificial intelligence, allowing them to continually improve by learning from the data they process.

How are they regulated?

Medical device regulations have traditionally focused on hardware (or largely hardware) devices. The speed of advancement in digital technologies, and their ability to improve with the data they collect is pushing boundaries of the traditional regulatory framework. *Regulators are aware of these challenges, and significant activity is going on in order to update the regulations.* Some key examples are:
- The EU Medical Device Regulations 2017 is replacing the Medical Device Directive and contains more specific information about software.
- The International Medical Devices Regulators Forum (IMRDF) is leading harmonisation activity on clinical evaluation of "Software as a Medical Device".
- The US Food and Drugs Administration (FDA)'s pre-cert program is trying to reimagine the way medical devices are developed.

AT A GLANCE

KEY CHALLENGES

- The regulatory path for the marketing of digital health technologies lacks clarity.
- It is not clear how digital technologies fit into the existing regulatory framework.
- There needs to be a balance between ensuring patient safety and trust and fostering innovation.
- Regulatory capacity is highly constrained

SUGGESTED ACTIONS

- Provide guidance to clarify how the current regulatory framework applies to digital technologies
- Share good practice and develop common standards.
- Increase funding to respond to the capacity constraints of the regulators.
- Develop new "regulatory technology" embedded in the device to streamline the regulatory process and surveillance.
- Prepare and anticipate the needs for the future generation of devices.
- Create a new forum for regulatory discussions between stakeholders.

UCL Public Policy and the European Institute convened a policy roundtable in December 2018 to focus on the challenges of "getting safe and effective digital medical devices to patients". Experts from academia, industry, policy and regulators discussed the current challenges for British policy-makers in Government and Parliament and if Brexit provides an opportunity for the UK to think about developing an independent vision. As regulations in this field are increasingly set outside national frameworks, the UK needs to assess how it can continue to shape international harmonisation activities and explore ways in its own national regulatory framework to foster innovation.

Key challenges

- **The regulatory path for the marketing of digital technologies lacks clarity.**

Large and small medical device companies struggle to understand the path they need to follow, and the data they need to collect, to demonstrate that a digital health device is safe and effective and meets the regulatory requirements to be marketed to healthcare providers and/or patients. This is due to an insufficient definition of what is required and contrasts with the development of traditional medical devices, where there is a well understood route to market. This uncertainty can be a significant barrier to innovation, and potentially prevent patients from getting the benefits that new digital technologies can bring.

- **It is not clear how digital technologies fit into the existing regulatory framework.**

It isn't always clear how current medical device regulations (in Europe, US and beyond) are interpreted when applied to new digital technologies that challenge current definitions and frameworks**.** This includes the question of how much data is required prior to marketing a product compared to once it is on the market.

- **There needs to be a balance between ensuring patient safety and trust and fostering innovation.**

Digital technologies are often based on novel uses of patient data and algorithms such as artificial intelligence that may not be very transparent. This raises important issues around safety and trust for health care professionals and patients.

- **Regulatory capacity is highly constrained.**

The large volume of digital health technology marketing applications is significantly increasing the burden on the regulatory system, including notified bodies (organisation designated by an EU country to assess the conformity of products before being placed on the market), MHRA (Medicines and Healthcare products Regulatory Agency) etc. This is causing bottlenecks.

Suggested actions

The challenges listed above are time-critical, both because they can act as a barrier to innovation preventing patients benefiting from new technology, and because the safety of these new technologies needs to be appropriately ensured. We therefore propose that policy professionals encourage the following actions to take place within the UK:

- **Provide guidance to clarify the regulatory framework for digital technologies;**

Within the currently applicable regulatory framework (EU Medical Device Regulation), **provide clarity eg: through guidance documents to**:

- Improve the transparency and clarity of the landscape for digital health products, including how machine learning can be used in product development and in marketed products.

- Increase emphasis for digital health technologies on continuous monitoring of performance once a product is marketed thereby reducing the pre-market burden without comprising patient safety.

- Refine the way notified bodies and regulators operate, reducing the pre-market burden and moving to a "continuous inspection" mode.

- Review regularly the boundary between medical and non-medical devices to account for evolving technology.

- **Share good practices and develop common standards;**

Examples: use of Quality Management Systems in development of technologies; data collection in post-market for continuous monitoring of safety and efficacy and reporting to regulators.

Embed the regulatory engagement within the ecosystem, through alignment with international standards, to reach other markets in Europe and beyond.

Engage suitably with relevant international organisations including the IMDRF, EU and FDA to ensure UK guidance is consistent with EU regulations and to encourage these approaches to get adopted internationally.

- **Increase capacity to review and monitor digital medical devices;**

Identify ways to increase funding for regulators (eg: from industry fees, government funding), and review the incentives for notified bodies to increase their capability and capacity.

Invest in technology to partially automate the regulation of digital medical devices.

Increase the resources to **support high quality clinical evaluation** of digital health technologies to support medical device approval eg: through building on the National Institute of Health Research (NIHR) could potentially build on what it already does for drug development to make the NHS suitable for this evaluation.

- **Improve stakeholder engagement.**

Improve early-stage communication between device manufacturers and regulators, to help them navigate the regulatory landscape.

Reduce the regulatory burden pre-launch and therefore the lag between improvements in digital technologies and these technologies becoming available to patients. This would also aid in reducing the strain on regulator capacity. This will aid in ensuring appropriate flexibility of the way notified bodies operate across the pre-market and post-market landscape.

Create a new forum for regulatory discussions between stakeholders. This forum could aim to 1) share good practices and develop common standards 2) agree on the balance to strike between pre-market and post-market data collection. An appropriate separation between the regulator and the companies that are regulated would have to be ensured. This forum might usefully learn from the approach used by the FDA in their pre cert pilot program. *UKRI, particularly Innovate UK, might be an appropriate organisation to take a leadership role in this forum.*

Longer term goals

Catalyse the development of novel "regulatory technology" for medical devices that can provide improved post-market surveillance and rapid reporting of safety issues, and also streamline regulatory processes.

Horizon scanning and consider how next generation Medical Device Regulations might support new types of AI product, for example those that learn on the fly while on the market, and how existing clinical evaluation and validation approaches might need to encompass these technologies.

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