

行動健康應用程式： 破壞性創新、管制和信任 — 相互平衡之必須 (一)*

mHealth Apps : Disruptive Innovation,
Regulation, and Trust—A Need for Balance (I)

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摘要

行動健康，即行動裝置和無線技術在健康照護中的應用，以及行動健康應用程式（行動健康的一個子分

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關鍵詞：安全性管制 (safety and security regulation)、信任 (trust)、既存醫療結構轉型 (transformation of existing healthcare architecture)、破壞性創新 (disruptive innovation)、健康應用程式 (health apps)

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類)，預計將帶來更多聚焦於個人健康照護的成果。這些技術預計將使病人更積極地參與自己的健康照護，減少對密集醫療介入的需求。因此，行動健康應用程式技術可能會重新設計現有醫療架構，使系統更加高效、高持續性，同時更便宜。作為一種破壞式的創新，它可能會藉由病人透過遠端或線上獲得醫療服務而改變醫療專業人員的角色，從而顛覆現有的醫療系統。這與國家衛生服務政策制定者的更加廣闊的敘事不謀而合，其重點是個人化醫療中，病人自負更大的責任，以及潛在的成本降低。本文認為，雖然行動醫療應用程式作為一種破壞式技術，個人化醫療和病人自我負責的概念可能會支持醫療系統轉型和成本降低，但兩者都需要病人對新技術的安全性和保障之信任。能夠增強人民信任的方式，只能透過傳統與其他管制機制來實現，以降低科技潛在的破壞性風險。

mHealth, the use of mobile and wireless technologies in healthcare, and mHealth apps, a subgroup of mHealth, are expected to result in more person-focussed healthcare. These technologies are predicted to make patients more motivated in their own healthcare, reducing the need for intensive medical intervention. Thus, mHealth app technology might lead to a redesign of existing healthcare architecture making the system more efficient, sustainable, and less expensive. As a disruptive innovation, it might destabilize the existing healthcare organisation through a changed role for healthcare professionals with patients accessing care remotely or online. This account coincides with the broader narrative of National Health Service policy-makers, which focusses on personalized healthcare and greater patient responsibility with the potential for significant cost reductions. The article proposes that while the concept of mHealth apps as a disruptive technology and

the narrative of personalisation and responsabilisation might support a transformation of the healthcare system and a reduction of costs, both are dependent on patient trust in the safety and security of the new technology. Forcing trust in this field may only be achieved with the application of traditional and other regulatory mechanisms and with this comes the risk of reducing the effect of the technology's disruptive potential.

壹、導論

自2008年蘋果iTunes應用程式商店推出以來，行動軟體應用程式的數量急劇擴張，包含在健康照護領域中，無論是內建或下載的行動健康應用程式¹，也含括生活型態與健康生活相關的應用程式²。全球約有35萬個健康應用程式現在可在蘋果、Google和Windows / 微軟的主要應用程式商店得見³。可想而知，應用程式和健康應用程式在日常生活中扮演著越來越重要的角色⁴。行動健康應用程式可以是針對病人 / 消費者的應用程式，也可以是針對醫療專業人員的應用程式，提供他們更快獲取病人資訊和檢傷分類、病人監測和醫療資訊的可

1 The term mHealth app or health app is used in this article to refer to all health-related apps in the widest sense, including well-being and fitness apps and apps classified as medical devices. The term medical app or medical device app refers only to apps classified as medical devices.

2 S Castle-Clarke and C Imison, *The Digital Patient: Transforming Primary Care?* (Nuffield Trust 2016).

3 T Mulder, 'Health Apps, Their Privacy Policies and the GDPR' (2019) 10 EJLT 1, 2.

4 For example, M Szczepanski, *European App Economy: State of Play, Challenges and EU Policy* (European Parliament 2018) <[http://www.europarl.europa.eu/RegData/etudes/BRIE/2018/621894/EPRS_BRI\(2018\)621894_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/BRIE/2018/621894/EPRS_BRI(2018)621894_EN.pdf)> last accessed 12 December 2019.