ABSTRACT
The past few years have witnessed unprecedented acceleration in the development of digital technologies with a health application (digital health technologies DHT). While these applications have been associated with significant promise, there is a paucity of robust evidence of the actual benefits and costs – for healthcare systems and patients – associated with the use of DHT.

Regulation of healthcare technologies has been a pivotal cornerstone to ensure that manufacturers generate an appropriate scientific evidence base in support of any claims associated with their products. In contrast, historically, software engineers had not been formally required to generate scientific evidence in support of any claims regarding digital technologies.

Identification of a subset of DHT as medical devices has provided software engineers and other stakeholders in the DHT ecosystem, with a strong incentive to fully immerse into defining a minimum set of scientific evidence standards in support of their products. In this lecture, we will reflect on the recently published Evidence Standards for DHTs produced by the National Institute for Health and Care Excellence (NICE) in the United Kingdom.

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