Reviewer's report

Title: A health app developer's guide to law and policy: A multi-sector policy analysis

Version: 0 Date: 28 Jul 2017

Reviewer: Jos Aarts

Reviewer's report:

The authors have written an overview of regulatory oversight of mental health apps and proposed a set of guidelines for app developers. The authors conducted a well designed literature review of both published papers and policy documents. They identified seven key regulatory domains that they found relevant for the developers. In terms of health policy they find that mental health apps do not meet the strict definitions of medical devices and therefore not subject to oversight by regulatory bodies; they propose that a new regulatory entity will be set up. Making policy recommendations for oversight is a tricky business, because foremost it must proved that health apps cause harm, or at least may potentially cause harm. Another reason may the regulation of markets. There is no documented evidence that mental health apps have caused harm or are disrupting markets. This is not to say that the app market is completely free. Data protection and patient privacy laws most likely prevent that patient data can be shared without consent. Also legislation may be in place that prevent suppliers of health apps to make false health claims. As this paper focuses on a guide how to incorporate (health) law and policy in the development of apps, it seems less appropriate to make recommendations for regulatory oversight. This belongs to the public and political domain, and is often country specific. However, the authors can address the question whether health apps can or should be considered as a medical device in the light of definitions currently used by the European Union or the United States (see e.g. Magrabi F, Aarts J, Nohr C, Baker M, Harrison S, Pelayo S, et al. A comparative review of patient safety initiatives for national health information technology. Int J Med Inform. 2013;82(5):e139-48). Note that the UK is still part of the European Union and thus bound to European Union directives that have the power of law. That may change in 2019. The paper is well written, but the authors are advised not to use the improper style of enumeration of firstly, secondly, thirdly, fourthly, etc (page 15), but just first, second, etc. or avoid it altogether (page 19).

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
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Yes
Are the conclusions drawn adequately supported by the data shown?
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Yes

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