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Report of the Working Group on the mHealth assessment guidelines: more questions than answers?

In February 2016, the European Commission appointed a Working Group to draft mHealth app assessment guidelines (the 'mHealth Guidelines') with the objective of streamlining app assessment processes across Europe and encouraging reliable, compliant uptake of mobile health apps for use in healthcare. On 9 June 2017, a Report of the Working Group on mHealth assessment guidelines¹ (the 'Report') was published, stating that it was 'impossible to achieve and endorse any guidelines.' Jackie Mulryne and Bonnie Clemence, of Arnold & Porter Kaye Scholer LLP, consider what has been learnt about the development of the mHealth Guidelines in light of the Report and the impact that the lack of mHealth Guidelines coming out of the Working Group will have on app developers and healthcare providers.

The European Union has recognised the importance - and potential - of mobile health, or mHealth, a general term for the use of mobile devices to support medical care. One area that has obtained a lot of focus is mobile apps. The uses of apps are infinite, and can range from appointment reminders, to reference materials for healthcare professionals, to monitoring and recording information about users, to diagnostic tools. However, despite the vast potential of apps and their ability to transform treatment across the EU, uptake has been relatively slow.

To help aid adoption, guidance is needed to cover areas such as app development and testing, protection of personal data, and reliability and validity of data used and collected by apps. The safety and transparency of information have been identified by stakeholders as two of the main issues with mHealth uptake; the large number of apps available combined with no clear evidence on their quality and reliability means patients and healthcare professionals find it difficult to assess their usefulness. This is particularly the

case for apps that are 'below-devices,' that is, those that do not fall within the definition of a medical device, and so are not covered by the framework set out in the Medical Devices Directive, or the new Medical Devices Regulation.

The European Commission has recognised this need, and over the last few years, there has been a flurry of activity with the hope that guidance will help patients and healthcare professionals have confidence in apps so they can be used routinely as part of diagnosis and treatment. However, developing guidance that covers such a wide range of ever-changing technologies is proving difficult. This article considers the mHealth Guidelines in light of the recent Report, which concluded that development cannot be continued in its current form, and discussed the implications of the current lack of EU-wide guidance on apps for developers and commissioners.

The mHealth Guidelines

In 2014, an mHealth Working Group, made up of stakeholders, including patients, healthcare professionals,

industry and payers, was charged with developing guidelines for assessing the validity and reliability of data that apps collect and process. The first draft of the 'EU guidelines on assessment of the reliability of mobile health applications,' published on 25 April 2016, was intended to 'establish a framework of safety, quality, reliability and effectiveness criteria to improve the use, development, recommendation and evaluation of mHealth apps.' The aim was to provide common quality criteria and assessment methodologies that could help stakeholders to assess the validity and reliability of apps, and in particular, facilitate decision-making by healthcare providers as to whether an app should be used within national healthcare systems. This is a bold aim, and it is perhaps unsurprising that the recent Report on the mHealth Guidelines concluded that "building these guidelines was a much more complex exercise than expected."

The first draft of the mHealth Guidelines divided the evaluation of an app into three phases: (i) initial validation and assessment; (ii) risk assessment to determine the level of scrutiny

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required; and (iii) scrutiny, which set out a series of questions that ought to be considered when assessing an app. These guidelines would be voluntary, but would demonstrate best practice.

The European Commission released the second draft in June 2016 following consultation with a range of stakeholders. This draft identified nine key criteria against which developers should assess their app: reliability, desirability, credibility, safety, security, transparency, usability, effectiveness, and stability. It was still up for discussion whether there would be a 'pass mark' for acceptable apps or whether, given the varied risk profiles of apps (e.g., step counters versus monitoring diabetes), there should be a range of acceptable marks.

A further draft was developed in the summer of 2016. However, the consultation due in December 2016 was cancelled because no consensus could be found among stakeholders, and so views continued to be collected.

The Report of the mHealth Working Group

In June 2017, the Working Group published its Report on the mHealth Guidelines. The Report highlights the difficulties experienced in agreeing the scope of the mHealth Guidelines and which criteria should be included, and it is noted that the discussions were plagued by "areas of apparent disagreement and different understanding of the implications, use and meaning of the criteria during app assessment." In particular, there was disagreement over whether the mHealth Guidelines should cover the assessment of apps in general, including criteria such as accessibility for users and interoperability with other technologies, or whether they should only cover

assessment of the reliability and validity of data collected and processed by an app, as was set out in the Working Group's original mandate. To the extent that any consensus could be found with respect to the assessment of apps as a whole, six criteria were considered relevant: privacy, transparency, reliability, validity, interoperability and safety. Two further criteria achieved support from some stakeholders, namely patients and payers: technical stability and effectiveness. Other stakeholders, in particular industry, focused only on the criteria for assessment of data validity and reliability.

As a result, it was concluded that the gap between those who prefer guidelines on the assessment of app data, and those in favour of assessing apps as a whole, was too wide to close. It was therefore impossible to finalise and endorse any guidelines, and the Working Group was forced to conclude that "Clearly, an important lesson from this exercise is the need to follow a step-wise approach, starting with a solid agreement on scope and terminology, especially if the [mHealth] Guidelines are to be developed by a multi-stakeholder group." As such, while the criteria and questions set out in the drafts are still useful in identifying areas to be considered when developing and assessing apps, it seems that the mHealth Guidelines will not be progressed in their current form.

Analysis

The lack of mHealth Guidelines coming out of the Working Group is disappointing for all stakeholders. The need for robust guidance to aid developers, and to assist patients and healthcare professionals to have confidence in apps, is self-evident, and the absence of mHealth Guidelines will do little to increase uptake across the EU. Coupled with this, one of the biggest issues for patients

is the protection of the data collected by apps. However, the 'Draft Code of Conduct on privacy for mobile health applications' that is being developed recently received extensive criticism from the Article 29 Working Party², meaning substantial revisions will be required. As such, app developers have little EU-wide sector specific guidance to guide them, or allow them to show that their app should be commissioned by national healthcare systems.

In reality, until there is some agreement on the minimum requirements that apps should meet, there is likely to be substantial variation across the EU on what has to be done to ensure an app is used by patients and healthcare professionals, and the extent of their use. There are various national guidelines that can help to fill the gap. For example, in the UK, the British Standards Institute has a voluntary standard for app developers identifying various aspects to consider when building an app³, the Digital Health and Care Alliance has developed guidance addressing, among other things, how app developers can meet the requirements for apps to be commissioned on the UK National Health Service⁴, and England's National Institute for Health and Care Excellence has started to publish 'Health App Briefings' - non-guidance briefings on apps setting out the evidence for an app, but without providing a recommendation on its use (which is subject to the judgment of the treating physician). There are also a number of standards⁵ covering software that are medical devices. In the absence of guidance for apps that do not meet the definitions set out in the Medical Devices Regulation, these standards offer a structured process for identifying potential areas of risk and are useful for managing the development of software intended for use in clinical practice.

1. Report of the Working Group on mHealth assessment guidelines, 9 June 2017.
2. Draft Code of Conduct on privacy for mobile health applications, 7 June 2016, and comments from Article 29 Working Party, 10 April 2017.
3. BSI PAS 277:2015 Health and wellness apps - Quality criteria across the life cycle - Code of Practice, April 2015.
4. DHACA Medical apps - processes: Guide - D019, November 2015.
5. See for example BS EN 62304:2006, Medical device software - Software life-cycle processes; BS ISO/IEC 25010, Systems and software quality models; BS ISO/IEC 25012, Software product quality requirements and evaluation - Data quality model.