



Medical apps prove tricky to regulate

Carmel Sparke | 31 May, 2016 | **0 comments** [Read Later](#)

Most of us have smartphones jammed with apps that promise to improve our lives by tracking our sleep, finding the best coffee spots or, more annoyingly, reminding us it's time to go for a run.

Many are fun and entertaining, but some are for more serious medical purposes.

An estimated 165,000 medical apps are on offer that range from measuring blood pressure to helping manage conditions such as diabetes, asthma and mental health.

While some are helpful, for the most part, this field of mobile personalised healthcare is untested, unregulated, possibly ungovernable and occasionally dangerous.

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A study by the University of NSW Black Dog Institute discovered that of the 120 suicide prevention apps they looked at, none provided comprehensive evidence-based support and some even contained dangerous advice.

“Of greatest concern is the encouragement to engage in risky behaviours such as drugs and deliberate self-harm to manage a crisis,” said the researchers writing in PLOS One in April.

Two years ago, US emergency specialist Dr Ilfat Husain, an expert in digital medicine, was highlighting the problem.

A review he carried out for the iMedicalApps website on a popular \$3.99 blood pressure app, which used the iPhone's camera and microphone to secure a reading, found it simply didn't work.

With clinical trials taking years to design, run and produce results, it seems that traditional scientific evaluation methods cannot keep pace with the speed of developments in digital health apps.

“This lengthy process simply isn't viable in the current app marketplace where the focus is on rapid delivery rather than proof of effect,” noted the Black Dog Institute researchers.

“Alternative evaluation methodologies such as iterative participatory research and single case designs are better aligned with [health] needs.”

The TGA has been grappling with the challenges of regulating and approving apps that act as medical devices for the past five years.

Latest guidance on its website points out that many mobile apps are simply sources of information and so it doesn't have a role in regulating them. However, tech devices that act as medical devices do fall under its regulation.

A TGA spokeswoman told *Australian Doctor* that the number of apps listed on the Australian Register of Therapeutic Goods as a medical device was “low”.

Two examples include Cochlear's Baha app and the Widex's COM-DEX app, used by patients to control their hearing devices, she added.

More information

PLOS One 2016; online.

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