165,000 and counting!

In 2013, the IMS Institute for Healthcare Informatics reported that there were approximately 165,000 health apps on the market. In the two years since then the number has risen and the updated report is available here.

- nearly half of all downloads came from only 36 apps
- 40% of all apps have fewer than 5,000 downloads
- over 90% are free to use
- the number of clinical trials on apps more than doubled between 2011-2013
- many are focused on seniors

Many apps are focused on treatment, there is thought to be more potential in the prevention sector.

With so many apps available, their presence really tests healthcare and the market, in terms of regulation. In other words, whose responsibility should this be and how is it possible to evaluate and regulate so many apps, especially as so many seem to present a very low usage rate?

The FDA (Food and Drug Administration) in the US, as this article in the BMJ suggests gets round the problem by defining a medical app as "a software application run on a mobile platform that is either used as an accessory to a regulated medical device or transforms a mobile platform into a regulated medical device." Most apps don't qualify under this definition. Of those that do qualify for 'medical device' only those which pose a "high risk" are regulated.

Asked whether the UK would follow this 'soft' regulatory path, Neil McGuire, Clinical Director of Devices at the Medicines and Healthcare Products Regulatory Agency (MHRA), speaking at a health technologies seminar in London, said "be under no illusion—if you have a medical device and it's software or an app and patients come to grief, we're coming looking" here.

Isn't the point of regulation, however, to be put in place, so that no one comes 'to grief'?

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