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Conference Abstract

Improving the clinical perception of the efficacy of medical apps

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Abstract

Few doubt that there will be substantial benefits from the deployment of apps on smartphones to improve the delivery of health & social care. Evidence, particularly on the cost effectiveness of medical apps, is currently very sparse though.

This paper will report on a project carried out as part of the TSB-funded dallas programme to determine what was necessary to improve the perception of medical apps by doctors, with the expectation that they in turn will recommend them to their patients. The vision is to get to a position where doctors are able to offer patients a choice of app or drug (or both) to deal with appropriate conditions, such as depression or anxiety.

The principal finding is that the reasons for the current position are many. Doctors are indeed concerned about the effectiveness of medical apps, and about their safety. Supporting this view, there are medical apps with bogus claims, and a few with serious errors that could potentially be very dangerous. The mechanisms for doctors to prescribe apps on the NHS are not properly in place too.

Behind this are suppliers who are genuinely confused by the plethora of legal and regulatory requirements they need to meet. Few realise that the EU has established medical/in vitro device regulation, information privacy and consumer protection legislation that can all impact medical app development and sale. There is particular confusion over what evidence is acceptable both to prove safety and to prove benefit, with a particular unjustified fear of large long drawn-out randomised control trials that would both be very expensive to carry out and introduce substantial delays to market; small start-ups would not have the funding to support these.

Clearly there is a need for suppliers to understand the concept of statistical power calculations. New methods of evidence gathering are also necessary; this presentation will recommend for example that the practices used by the banking, insurance and airline industries to identify their most effective apps be investigated to see if they can be used to speed up this phase. The paper will also recommend that medical apps are treated more like drugs, with the involvement of NICE and close working with the MHRA.

The position in other EU countries will also be mentioned, as well as the engagement of the FDA, FCC and other organisations in the US in this area.

On one important aspect apps do differ from drugs though: their operation potentially is changed whenever there is an operating system enhancement or additional features added. Medical apps

therefore require to have safeguards built in and to be monitored carefully after sale to ensure they remain safe and as efficacious (if not more) as when first installed. The paper will make suggestions for achieving this.

The paper will end with a brief summary of some of the most exciting app developments underway to underline the importance of resolving outstanding challenges.

Keywords

medical apps; efficacy; doctors; benefits; safety