Mhealth: The Medicalization of Consumer Devices



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their presence is increasingly felt in health care, whether as a means of connecting patients with practitioners or satisfying a desire for instant access to health information.

A recent Canadian study found 355 eye care apps in the iTunes store alone, ranging from education apps that provide information on eye anatomy or disease, to low vision aids like magnifiers, to eye exercises for vision enhancement, to apps for self-testing colour vision and/or the visual field.

Health-related apps, which usually take advantage of a phone's built-in capabilities, sometimes in conjunction with clip-on attachments or external wearables, have become so prevalent that a peer-reviewed journal dedicated exclusively to the study of mobile health (mhealth) was established in 2015. There is limited data on the use of mhealth in Canada, in part because apps cross both operating systems and borders. Last year, Canada Health Infoway released a study showing that one-third of Canadians used mobile apps and smart devices to track their health. Unsurprisingly, mhealth use is skewed toward the younger, educated, and healthy, while those with poor health were much more unlikely to use these resources.

Since most apps are not designed by health care providers, third parties feature prominently in their creation and use, both via the apps themselves and the devices that they run on. This complicates quality control and privacy and security issues, particularly as regulation is still applied unevenly. In the United States, while some health-related apps require FDA certification, others are exempt. In Canada, Health Canada treats all such apps as medical devices, but compliance is largely voluntary.

Mhealth apps make the patient the point-of-care in interesting ways. Many of the eye care self-testing apps currently available are explicitly intended for practitioner use via tele-eye care or pop-up clinics, and incorporate camera add-ons or VR headsets to transform smartphones into mobile ophthalmic scopes or refractors. But they also incorporate features that make them freestanding to some extent: an auto-refractor app can automatically order a prescription once the test is complete, and the scope logs its results to a patient-controlled record that allows them to choose the practitioners with whom they wish to share data.

For every app adopted by practitioners, there are ten direct-to-consumer health and "wellness" offerings. They are quickly evolving from simple biometrics and activity tracking (e.g., heart rate, steps) into more sophisticated devices for self-monitoring, self-testing or imaging analysis (for example, for skin cancer monitoring) as diagnostic technologies initially designed for practitioners begin to migrate into the consumer market. In what is still very much a regulatory grey area, at least one American app developer is engaged in a series of skirmishes with the FDA and several state governments over a refraction app that is intended for use by consumers.

Interoperability has also been an issue with mobile apps, and has acted as a brake on the full integration of these apps into health care, whether on the side of the practitioner or consumer. There is no single app that curates data from all the others, and many don't interact at all. However, there is a movement towards platform solutions in this sector; in fact, the latest wave of app development might target another traditional monopoly: custodianship

of health data. Such developments may eventually be the key to using the tremendous amount of consumer health tech-generated data for large-scale studies alongside more traditional data points, as AI tools for processing such massive inputs become available.

Mhealth, as the medicalization of a consumer device, has tremendous potential for disruptive innovation, which refers to the displacement of established, traditional players by simpler, cheaper (and possibly lowerquality) options. One possible long-term consequence of the digital health revolution is that the patient will become the point-of-care.



*Including 425,000 procedures in Quebec alone. **Prices are subject to change without prior notice and vary based on prescription strength. Standard LASIK starting at \$490/eye. Other conditions may apply.