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Industry Insights

Wearables and Apps - the risks of convenience

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Wearable technology and the apps that support it are an increasingly important part of the healthcare ecosystem, extending beyond the wellness and lifestyle sphere in which they largely began, to support the monitoring, diagnosis and management of a variety of health issues, particularly chronic conditions such as diabetes, asthma and arthritis.

Pre-coronavirus, the global healthcare wearables market is projected to be worth around US$27 billion by 2023 [1], with the Canadian market forecast to be US$244 million in 2020. [2] Currently, there are around 3.1 million wearable users in Canada, 30% of whom fall within the 25-34 age bracket [3]. Wearables include devices for condition management, self-care and symptom checking. Health Canada is seeking to encourage the use of such technologies and has begun to put in place the regulatory framework both to support their adoption and to manage the risks they present, notably through the establishment of the Digital Health Review Division within the Medical Devices Bureau. This forms part of a wider project to afford better access to digital health technologies, which Health Canada hopes to have in place by the Fall of 2020.

Wearable technology can produce huge swathes of data, whether across a whole range of health and wellness factors or targeted on a very specific issue. Considerable hope and expectation is already attaching itself to these technologies and the scope for data analytics and artificial intelligence (AI) to facilitate better diagnoses and outcomes. We have seen evidence for example that AI can outperform medical practitioners in the analysis of skin lesions, pathology slides, ECGs and medical imaging data. [4] The ability to access, analyse and present such data can feel empowering for consumers and patients. They may present either the raw data and/or their analysis of it to physicians or other healthcare professionals and providers, perhaps

accompanied by a self-diagnosis. It is not for nothing that wearables and their supporting apps have been described as ‘ the new “Dr Google”’! This trend is likely to intensify as there are increasing signs of convergence between wearable fitness and wearable medical devices, leading to what are often essentially consumer electronic devices being used to acquire physiological data, which in turn can be interpreted by smartphone apps and provide medical advice. However, there is a risk that allegations could arise that the data capture, storage, interpretation or transmission has been in some way compromised by a defect within the wearable device and/or any app used with it.

Healthcare professionals and providers can face a difficult balancing act between managing patients’ expectations of what use such data can be (and how easy it is to interpret in a meaningful way in a diagnostic context) and the potential insights it can provide. If a professional discusses and analyses the data with a patient, or encourages them to retain and share it with a doctor or other health provider, there may be exposure to liability if a subsequent health issue arises for the patient and there is an allegation that there was a failure by the professional to identify it, or to properly assess, explain and act upon its implications. Such issues could be more problematic if a patient has been specifically advised to use (or even prescribed) a particular wearable device and there is an allegation of harm to the user, particularly in relation to a failure to monitor or interpret data properly. Any bodily injury in such scenarios could be caused by (1) user error (2) technology failure (3) physician error and difficult causation issues could arise.

We are also beginning to see greater encouragement of wearables and apps by Canadian authorities and professional bodies. For example, it was reported last year that the Impact and Innovation Unit in the Privy Council Office was looking into providing federal workers with fitness trackers [5]. Also in 2019, the Canadian Medical Association produced a report on “The Future of Connected Healthcare” [6] in which it outlined the expectations and concerns of Canadian healthcare consumers around the deployment and adoption of various technologies (including wearables and apps) over the next decade or so, showing the level of engagement of healthcare professionals.

The benefits of wearable and app technology obviously come with the collection and use of often very large volumes of personal data, much of which will be sensitive in nature. Compliance with data privacy requirements is key. With an increased focus on the sharing of data involving medical wearables and apps, often involving third parties (including insurers and employers as well as medical professionals), there must also be a focus on data security risks. In many ways, this is an issue common to the broader Internet of Things, of which medical technology is an important subcategory.

The direction of travel is very much towards using new technologies (including wearables and apps) to empower individuals and health professionals to monitor and prevent health issues, or to manage them as effectively as possible, preferably outside hospitals, care homes etc. This coincides with a greater interest in consumer wearables and apps and their healthcare/wellness capabilities and we are likely to see greater convergence, requiring new approaches to risk management and risk transfer.

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1 Research & Markets: (https://www.zdnet.com/article/what-is-digital-health/)
2 Statista : (https://www.statista.com/outlook/319/108/wearables/canada)
3 Statista : (https://www.statista.com/outlook/319/108/wearables/canada)
4 https://www.nature.com/articles/s41746-019-0132
5 https://wt-obk.wearable-technologies.com/2019/03/canada-is-looking-to-outfit-federal-workers-with-fitness-trackers/
6 https://www.cma.ca/future-connected-health-care

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