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Health smart devices and applications for prevention — a cautionary note

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Many existing and emerging consumer health technologies could have various applications in health promotion and disease prevention within the general population, and in supporting chronic disease management among patients. However, as Dr Cambon points out in her viewpoint (Linda Cambon's viewpoint article) there are still many unanswered questions in relation to adopting a new model for disease prevention based on smart devices and applications (SDApps). One additional point that deserves attention is the regulatory oversight of health SDApps.

Regulation of medical and consumer SDApps

Health technologies based on SDApps can be divided into medical and consumer technologies based on their intended functionality. It is important to note that the intended functionality is defined by the manufacturer of the SDApp, not the end-user of the SDApp. If the manufacturer expresses e.g. through labelling or marketing statements that the intended use of an SDApp is for prevention of a disease, then the SDApp is likely to fall into the category of medical devices, and it will be regulated and monitored accordingly.

Manufacturers of medical devices in Europe and the US need to establish not only premarket conformity with the corresponding regulations before the device can be marketed, but also ensure post-market surveillance for harms and adverse effects throughout the lifecycle of the product.[1] The burden of proof for showing the safety, technical performance, and efficacy of a medical device is on the manufacturer. However, if the manufacturer does not explicitly indicate an intended medical use for the SDApp e.g. for preventing or managing a disease, these regulations do not apply and the device is regulated as a consumer product. Within the European Economic Community, consumer products are only regulated for their technical safety (through the CE-marking) and for misleading and false marketing statements. In other words, for consumer health SDApps there is currently no risk-based assessment regulations that would take into account the potential risks of using a given SDApp technology for its intended purpose. Furthermore, changes made to consumer technologies, such as software updates, are not monitored similarly as those for medical devices, which means that the functionality and performance of the SDApp can change considerably during its lifecycle without clear documentation.

Consumer health technology assessment

Before physicians start recommending or even prescribing consumer health technologies to patients we need to make sure that the current shortcomings of formal regulation of consumer health technologies are not going to be a threat to patient safety. Although the manufacturers of consumer health technologies are not making explicit medical claims, i.e. the intended use of a technology is not defined as medical by the manufacturer, the actual use and the motivation for using a given technology may be medical for the user of the technology. Clinicians have already used consumer technologies in making clinical decisions,[2, 3] and for many consumers the motivation for monitoring health-related parameters is self-improvement; as exemplified by the Quantified-Self and Biohacking movements.

Therefore, the scientific community should respond to these needs by developing standards for appraising consumer health technologies parallel to medical technologies. Similar to that of formal health technology assessment it needs to take into account the benefits, risks, and costs related to using a particular consumer health technology for solving a given health problem. In particular, this assessment needs to take into account the risks involved if a consumer health technology fails to function as intended, and whether there are any potential unintended consequences of using the technology.[4] Developing a European accreditation system for manufacturer quality management systems covering the lifecycle of the consumer health technology could be one option to promote the uptake of voluntary conformity to standards and recommendations.

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