

E-health as apps – data protection and data sharing

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Summary

THE NUMBER OF digital services in society has increased considerably during the last decade. The health care area is no exception. The growth of digital solutions gives rise to great opportunities, but also has multiple legal consequences. It is against this background that the report illuminates the current legal situation for health apps. The term ‘health app’ is used in a broad sense. It can cover anything from notification apps for booked appointments to care apps that gather and share patient information with a health care provider.

In this report, the primary focus is on the legal circumstances for data protection and data sharing through digital health care solutions. The goal is to take an inventory of the problems and use current legal sources to investigate the application of law in digital environments. It is important to highlight legal aspects related to health apps specifically, not least as this has proved to be a way to highlight general legal matters regarding the digitalisation of society as a whole.

Five challenges related to the legal situation for health apps

Despite there being ambitious political goals connected to development in the e-health area, there are various legislative and legal policy challenges leading to the possibilities of digitalisation not being fully realised. There are difficulties both in finding out what rules are in force and in applying them. Below are five core issues that have been identified during the work with this report.

Firstly, the conclusion can be drawn that there is currently some opposition between the health apps on the market and the law. Health apps are used despite the legal situation being

unclear in several areas, including legal conditions regarding transfer of personal data to countries outside the EU.

Secondly, it is noted that the political governance does not provide the public agencies involved with adequate conditions for developing health apps. One clear example of this is the eHealth Agency's mission to create personal health accounts, whereby Swedish citizens were to be given the possibility to gather and access their own health data. The project continued for six years before being stopped entirely when the Data Protection Authority did not find support for the eHealth Agency's interpretation of the legislation in force. In other words, there is an obvious need for clearer governance and impact assessments in connection with the creation of instructions for public authorities and governmental missions in the e-health area.

Thirdly, it appears that there are some groundless legal obstacles inhibiting the potential of health apps, although these would likely be possible to eliminate. One example is the legislator's ambition to develop entirely technology neutral regulations. The provisions then tend to become so general that the parties that are supposed to apply them do not get adequate support in determining what is permitted and what is prohibited. The need for technology neutrality appears more clearly in regard to the development and regulation of information standards, methods for information exchange, and data disclosure.

A fourth aspect that is important to note is that the administrative fines, pursuant to the General Data Protection Regulation (GDPR), differ greatly between the public and the private sectors. Over time, this might hinder the creation of commercial health apps, as companies run the risk of much higher fines than what is the maximum level for public authorities. However, compliance with GDPR may become much riskier for some categories of health app suppliers, which may therefore be in need of legal expertise.

The fifth challenge involves there currently being a lack of clear responsibility in regard to legacy systems, i.e., older, complex IT systems that are still in use. When new technical solutions emerge and older systems start working poorly, the question of who should update and upgrade outdated legacy systems becomes increasingly urgent. This is central from a data protection perspective, as personal privacy must remain safeguarded. It is also an important aspect to take into account in register-based research, which is dependent on the storage and possibility to access and use historical data. Naturally, this applies to health apps as well, which are an important cog in the machinery of modern health care.

Recommendations

In order for continued development of health apps and their contribution to the digitalisation of health care, both existing and future regulations must be adapted to information technology. While it is important to avoid solutions that are overly technology-specific, thus quickly becoming obsolete, there is a need for a more agile – adaptable – development of the legal apparatus. This involves not only the use of traditional legal sources, such as legislation and court judgments, but also of soft law, i.e., rules that formally are non-binding. In future, it will also become more relevant to protect the rule of law in the use of AI-based algorithms and code in the context of machine learning – while not seeing technology solely as a threat.

The law also needs to play a more proactive role instead of, as is currently the case, functioning as a reactive conflict resolution mechanism when IT systems and their connected applications do not work as intended. Despite the report indicating several unclear legal situations, there are openings in the data protection regulation for data processing performed for research purposes, for example. This can, in its turn, stimulate the creation of health apps, not least given that research is a concept with a broad meaning within the EU. One method to further stimulate the development of health apps is to actively work to create legal conditions for law-oriented laboratory environments, aimed at the design of legal model solutions focused on health apps and other applications of e-health. Various solutions, such as testbeds and so-called regulatory sandboxes, can also open for law-oriented testing focused on legal IT solutions, particularly as regards processing of personal data. If the law is included from the start, this can greatly benefit many parties, such as producers, patients, and health app users.

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