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Legal and Ethical Challenges in the Development of mHealth Applications

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Abstract. Researchers frequently face ethical and privacy challenges on health applications. Ethics is a branch of moral philosophy and deals with the "right" and "good" actions of humans, which often leads to dilemmas. Reasons for this are social and societal dependencies of the respective norms. Data protection is regulated by law throughout Europe. This poster provides guidance on these challenges.

Keywords. Ethics, data privacy, mHealth

1. Introduction

An ethical review of research projects involving mHealth-applications is necessary for good scientific practice. Ethical considerations arise in all projects dealing with human beings, especially vulnerable groups [1]. The development of mHealth-applications faces challenges in guaranteeing equal patient rights due to financial limitations that may determine their overall benefit. Data security also plays a central role. Many scientific journals require appropriate ethics votes before publishing articles. From the literature review, there is a need for guidelines on how developers of medical apps and mHealth devices should address ethical issues during development, and the creation of these guidelines is the subject of ongoing research by the authors. This poster provides an overview of relevant assistance for observing legal and ethical requirements for the development of mHealth applications.

2. Methods

Considering the many legal requirements and guidelines in the research of mHealth applications and standards on an EU- and national level, we created a framework for ethical and legal requirements through review procedures. Guidelines from ethics committees were reviewed in a narrative literature review and incorporated into the ELSI terms and conditions. These were derived from the results of the literature search in PubMed and Google Scholar using the keywords "ethics", "research", "dsgvo", "guidelines" and "ethics committee".

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3. Results

According to Beauchamp and Childress, the four central principles in medical ethics are respect for autonomy, justice, non-maleficence, and beneficence [1]. Fundamental principles of data protection law are: transparency of data processing; intervene ability; data economy; confidentiality; integrity; data security [2]. Next to the Federal Data Protection Act in Germany, GDPR (General Data Protection Regulation) provides a legal framework across Europe. It regulates the processing of personal data. Processing this personal data is possible with an effective consent according to Art. 6 GDPR. It must be voluntary, informed, and verifiable. It can be revoked by the data subject (owner). Privacy measures should therefore be implemented to prevent third parties from accessing sensitive data. Data security includes a number of measures, such as secure proof of origin, protection against data alteration and ensuring availability [3].

4. Discussion

Ethical considerations are imperative before the development, implementation, or release of an mHealth-application. If vulnerable groups are involved, a thorough ethical review is required. Medical principle ethics provide practical guidance and should be applied. New technical approaches (e.g., Big Data or AI) require new approaches for ethical review [4].Principle ethics will provide a solid foundation. Technology requires compliance with privacy, data security, and digital ethics. Otherwise the improvement of living conditions may come at the cost of serious disadvantages, such as the violation of personal rights or a loss of self-determination. Such implications may not only harm users, but also providers: If ethical fundamentals are not observed, product acceptance may probably decline [5].

5. Conclusions

Every research project raises different privacy and ethical issues. In healthcare, the development and implementation of new digital systems are challenging because they typically work with vulnerable populations and sensitive data. Each project must be considered and adapted individually.

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