Editorial

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From Dr. Google to CE-marked medical devices: need for ethical and legal safeguards

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In the last decades several mobile health applications (MHAs) have been developed to assist healthcare and patients in different medical and surgical fields. Nowadays more than 325,000 m-health apps were available in major app stores with more than 3.7 billion downloads and this number continues to increase daily. MHAs collect health information, provide guidelines for maintaining a healthy lifestyle or information about disease, make medical diagnosis, and assist in disease prevention and management. Despite this, there are some drawbacks that could be addressed. First, lack of adherence to the guidelines: MHAs reported low adherence to EAU (European Association of Urology) guidelines. As previously showed [1–4] MHAs were developed without healthcare support and the most important tool is their usability: they are easy to navigate, but the quality is low. Second, security and privacy remain an important debated issue yet. Suniave et al. [5] reported that MHAs developers often fail to provide app privacy policies: in fact, when reported, the privacy is not often focused on the app itself [6]. Smith et al. [7] reported that security of smartphone users is not high and sometimes many people have access to their phone. The quality rating studies conducted [8–10] show that transparency, privacy policies [11] and security documentation are still critical factors to take effort in. If on one hand MHA seem to lack of specific safeguards, on the other hand, as reported by Zhou et al. [12] there are some specific barriers and facilitators of users adopting MHA that can help developers to meet their needs [13]. EU General Data Protection Regulation is a cornerstone of privacy regulation but is not fully taken into account in all its predictions by app developers [14]. Inclusion of new health technologies is more than often something that simply "happens" and, usually the inclusion of artificial intelligence (AI) for supplementary or replacement purposes has serious social repercussions. Ethics stands as a safeguard of any indiscriminate introduction or total takeover in crucial sectors, such as Healthcare. Usually, the rush of technology is faster than the Law and not all new applications of artificial intelligence have gone through prior screening, as if apps did not require prior screening for marketing/use. According to EU Regulation 2017/745 [15], "*'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: – diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease*". Based on risk level and invasiveness, medical devices are divided into Class I, Class IIa, IIb and III. The conformity assessment procedure for class I devices should be carried out, as a rule, under the sole responsibility of manufacturers, in view of the low level of vulnerability associated with such devices. In addition to this existing regulation, in December 2023 the European Parliament reached a provisional agreement with the Council on the so-called "AI act", the first law in the matter ever. The agreed text will now have to be formally adopted by both Parliament and Council to become EU law. The purpose of this Regulation is to promote a human-centric approach ensuring a high level of protection of health, safety, fundamental rights, and democracy while supporting innovation and improving. AI tools were introduced to support diagnostic practice and brought into direct contact with the patient. Thanks to the AI act, together with previous regulations adopted at the European level (both the one on personal data protection and medical devices) the

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protection of the right to privacy as well as patient safety has been safeguarded. However, several studies are necessary to assess the impact of these new technologies in clinical practice, especially from the point of view of patients' perceptions, level of satisfaction, and any critical issue identified, just like repercussions on medical practice, possible liability profiles, and the changing physician-patient relationship that may find itself being filtered no longer by "Doctor Google" but by CE-marked medical devices.

References

1. Napolitano L, Fusco GM, Cirillo L, Abate M, Mirone C, Barone B, et al. Erectile dysfunction and mobile phone applications: quality, content and adherence to European Association guidelines on male sexual dysfunction. Arch Ital Urol Androl 2022;94:211–6.
2. Fusco GM, Cirillo L, Abate M, Morra S, Morgera V, Barone B, et al. Male infertility, what mobile health applications "know": quality analysis and adherence to European Association of Urology Guidelines. Arch Ital Urol Androl 2022;94:470–5.
3. Napolitano L, Cirillo L, Fusco GM, Abate M, Falcone A, Morgera V, et al. Premature ejaculation in the era of mobile health application: a current analysis and evaluation of adherence to EAU guidelines. Arch Ital Urol Androl 2022;94:328–33.
4. Cirillo L, Manfredi C, Barone B, Morgera V, Cacace G, Mastrangelo F, et al. Mobile health applications in kidney stone disease management: a reliable support for patients? Arch Ital Urol Androl 2023;95:11076.
5. Sunyaev A, Dehling T, Taylor PL, Mandl KD. Availability and quality of mobile health app privacy policies. J Am Med Inf Assoc 2015;22: e28–33.
6. Huckvale K, Prieto JT, Tilney M, Benghozi PJ, Car J. Unaddressed privacy risks in accredited health and wellness apps: a cross-sectional systematic assessment. BMC Med 2015;13:214.
7. Smith KA, Zhou L, Watzlaf VJ. User authentication in smartphones for telehealth. Int J Telerehabilitation 2017;9:3–12.
8. Steubl LS, Reimann J, Simon L, Terhorst Y, Stach M, Baumeister H, et al. A systematic quality rating of available mobile health apps for borderline personality disorder. Borderline Personal Disord Emot Dysregul 2022;9:17.
9. Benjumea J, Ropero J, Rivera-Romero O, Dorronzoro-Zubiete E, Carrasco A. Privacy assessment in mobile health apps: scoping review. JMIR Mhealth Uhealth 2020;8:e18868.
10. Martínez-Pérez B, de la Torre-Díez I, López-Coronado M. Privacy and security in mobile health apps: a review and recommendations. J Med Syst 2015;39:181.
11. Rosenfeld L, Torous J, Vahia IV. Data security and privacy in apps for dementia: an analysis of existing privacy policies. Am J Geriatr Psychiatr 2017;25:873–7.
12. Zhou L, Bao J, Watzlaf V, Parmanto B. Barriers to and facilitators of the use of mobile health apps from a security perspective: mixed-methods study. JMIR Mhealth Uhealth 2019;7:e11223.
13. Rezaee R, Khashayar M, Saeedinezhad S, Nasiri M, Zare S. Critical criteria and countermeasures for mobile health developers to ensure mobile health privacy and security: mixed methods study. JMIR Mhealth Uhealth 2023;11:e39055.
14. Alfawzan N, Christen M, Spitale G, Biller-Andorno N. Privacy, data sharing, and data security policies of women's mHealth apps: scoping review and content analysis. JMIR Mhealth Uhealth 2022;10: e33735.
15. REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC: 01 July 2020.