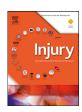
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Adapting non-medical applications for medical use: Ethical limits, coverage, and validation

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ABSTRACT

The widespread adoption of smartphones and other mobile devices amongst healthcare providers opened new possibilities arising from the use of non-medical apps, social media, meeting platforms, and non-medical devices with intended medical purposes, thus expanding the communication and imaging chat systems between these professionals and their patients, as well as amongst healthcare professionals. However, adapting non-medical applications, social media, videoconference platforms and devices for medical use present potential limitations, barriers, and risks, which should be fully recognized to reduce crossing the fine line between ethical and unethical. In the herein study, we analyse the ethical limits, coverage, and validation of non-medical applications adapted for medical use.

Level of evidence: IV (evidence from well-designed case-control or cohort studies).

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Introduction

The use of mobile technologies in general and mobile phone specifically has become an integral part of everyday life and is expanding rapidly in the healthcare sector [1]. In this scenario of rapid technological expansion, many applications (apps) have been created at high rate for specific areas of medicine, which includes the development of mobile health platforms (mHealth), visualization of radiological images, teaching medical students, and implementation of virtual clinics, which exponentially increased during the COVID-19 pandemic [2]. At present, there are over 165,000 health-related apps in the market, with approximately 1000 new apps released each month [3,4]. In parallel, smartphone usage has become popular amongst healthcare professionals, who are gradually shifting their perception of mobile apps and web-based medical resources for routine clinical use [2,3,5].

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The widespread adoption of smartphones and other mobile devices amongst healthcare providers opened new possibilities arising from the use of non-medical apps, social media, meeting platforms, and non-medical devices with intended medical purposes, thus expanding the communication and imaging chat systems between these professionals and their patients, as well as amongst healthcare professionals. Several studies have reported the emerging presence of non-medical apps and other communication tools in medicine and many other health-related fields, particularly in rural areas and low- and middle-income countries, which reflects the increased acceptance of their use [1,6-8].

However, adapting non-medical applications, social media, videoconference platforms and devices for medical use present potential limitations, barriers, and risks, which should be fully recognized to reduce crossing the fine line between ethical and unethical. It is important to consider the legal perspective relating to contact between healthcare professionals and between these professionals and their patients. In the herein study, we analyse the ethical limits, coverage, and validation of non-medical applications adapted for medical use.

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Mobile apps not developed for medical purposes

Messaging apps have been widely used in medicine for quick reference, clinical, academic, and therapeutic endorsements, as well as interpersonal communication of healthcare providers and patients [1,3,6-8]. Unlike medical devices, subject to standardized assay methods and regulatory agencies around the world, non-medical apps lack legal regulation, posing a real risk of harm and illegal exposure to patients [9,10].

Privacy and security are fundamental aspects of ethical health conduct, therefore minimizing the risks of non-medical mobile apps has been a concern of different medical entities, without however having a standard recommendation for all regions or countries. While many non-medical messaging apps are encrypted, various issues with keeping patient data confidential, such as the lack of access control with an account and the impossibility to recover the messages unless they are backed up, potentially puts healthcare professionals at risk of making mistakes in managing patient data. According to Masoni and Guelfi [11], non-medical apps are not adequate tools to share clinical information due to their non-compliance with the European General Data Protection Regulation (GDPR) and the United States Health Insurance Portability and Accountability Act (HIPAA) rules. They recommend that healthcare providers should abandon the non-compliant communication apps moving towards Secure Messagging Apps (SMA), such as Siilo (www.siilo.com) and Hospify (www.hospify.com) which are able to maintain the confidentiality and security of patient data. Outside Europe and the United States, consumer messaging services have been widely used in medical practice, following the policies of federal medical councils or associations in each country or region. In memorandum number 14/2017, the Federal Council of Medicine of Brazil regulates the use of instant messaging services for physician-physician communication and for patient care, stating that these applications should not replace face-to-face consultations, being used only as a complement to regular medical practice [3]. In Argentina and Colombia, there is no specific standard or regulation for instant messaging applications, but as a legal tool there is the Personal Data Protection Law and the Consumer Statute that guarantee the quality and integrity of information [9].

Regardless of the absence of a universally accepted recommendation, several authors have demonstrated the benefits of using these applications in medical practice. By far, WhatsApp is the most validated messaging app, allowing users to send instant text and voice messages, photos, and videos, and to make voice calls over an Internet connection. Giordano et al. [1], in a comprehensive systematic review of the literature published before January 2016, observed compelling evidence that WhatsApp is a promising system, whether used as a communication tool between health care professionals, as a means of communication between health care professionals and the public, or as a learning tool for providing health care information to professionals or to the general population. More recently, Brody et al. [6], in a systematic review of online messaging services and popular chat apps, concluded that chat-based hotlines can be effective ways to provide crisis support services in high-income environments, with potential effectiveness also in low- and middle-income countries. Despite the potential use and validation of certain non-medical apps to expand the reach of patient health and support, balancing risks and benefits is critical when using these mobile apps not developed for medical purposes.

Social media

Social media can be broadly defined as "internet-based, disentrained, and persistent channels of mass personal communication facilitating perceptions of interactions amongst users, deriving value primarily from user-generated content" [12]. They comprise

of platforms for collaboration, networking, and information sharing (eg, Facebook) and online forum for a specific community (eg, Patientslikeme) [13,14].

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The social media in the context of research can be used according to the following categories: dissemination, discussion, networking, public engagement, teaching, and data collection [15]. A recent scoping review of the literature on social media use in health research revealed that these are increasingly used to recruit patients, collect data, and establish and maintain user engagement, especially in the name of research dissemination [16]. Indeed, the rapid development of social media facilitated two-way interaction and allowed information to proliferate within an electronic community [17], which was quickly adopted within sciences, due to increasingly respect practice of science communication with public, informing specific aspects of their research and increasing engagement and science literacy [18]. The three most used social media by scientists are Twitter, Facebook and Linkedin with over 50% of 407 respondents in the study published by Collins et al. [19].

Facebook has been used by scientists for sharing their experience in the lab, finding inspiration for outreach and science communication, connecting to other researchers, and making corrections to misrepresentations of science. It is good for questionanswer interactions, but it does not facilitate discussions and presents little opportunity to develop scientific literacy [19,20]. In Twitter, it's debatable what can be considered scientific tweeting. Weller et al. [21] suggest three general requirements: 1. A tweet that includes scientific content, 2. A tweet that is published by a scientist, and 3. A tweet that includes a science-related hashtag. Scientists aim to connect to other scientists as their preferred audience well ahead of the public and other organizations [19], sharing peer-reviewed literature, having as most common subject the research within their own field, followed by science outreach and communication, personal research, and research outside own fiend [19,22].

Instagram, a free photo- and video-sharing social networking service, has rapidly become a part of daily life and increasingly intertwined with medicine, particularly for visual rich specialties [23]. The platform has the potential to facilitate exchange of clinical information to the public, as well as between healthcare providers [24]. Instagram is not very used in research, the main use in medicine is patient and health care providers education, patient support groups, health campaigns (accessibility), and online presence [25].

Dol et al. [26] published a scoping review of social media use within researchers. They found that the predominant topics included infectious diseases (7.2%), substance abuse (6.8%), cancer (6.5%), mental health (5.3%), and chronic diseases (4.6%). A quarter of the articles used social media for participant recruitment, followed by discussion on practical ways to use social media (15.5%) or for content analysis (13.3%). The most used platform was Twitter (38.2%) followed by Facebook (34.8%).

Social media appears to facilitate research on clinical populations who have traditionally been difficult to recruit or study because of stigmatization, social disadvantage, low disease prevalence, or mobility challenges that make physical participation difficult [27]. Researchers in the domain of health and medical sciences have been particularly concerned about demonstrating the impact of their work as it usually bears implications for public health. Hence, measuring the impact of health research is essential for influencing policy-making processes, improving health systems, and health-related socioeconomic impact [28]. The domain of research-related impact is generally and traditionally evaluated according to conventional and traditional bibliometric approaches, which generally include the number of citations, the impact factor (IF), or the h-index [29]. Some academic institutions in the United States, Canada, and Europe started including social media impact as an evaluation criterion in their tenure and promotion

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policies [30]. According to the systematic review by Cruz Rivera et al. [30] on the impact of health care research, researchers should consider indicators such as "the number of reads for published articles; article download rate and number of journal webpage visits; and citations rates in non-journal media such as newspapers and mass and social media (ie, Twitter and blogs)". In the beginning, the social medial impact measure was described by terms like webometrics or cybermetrics [31]. The term was changed to Altmetrics (which stands for alternative metrics) that include web-based metrics (eg, number of link shares, likes, tweets, and views) and a qualitative data that are complementary to traditional citationbased metrics [32]. The so-called Altmetrics Attention Score (AAS) includes various indices of performance of a paper, such as media (tweets, Facebook posts, and Wikipedia pages); recommendations (eg, Faculty of 1000); saved articles on popular social bookmarking such as Mendeley, and the number of citations obtained from Google Scholar, CrossRef, PubMed Central, and Scopus [33].

The widespread use of the social media by healthcare providers is accompanied by concerns about its ethical, legal, and social implications. Due to the emerging evidence of its effects on human behaviour and health, bioethicists have an important role to play in the development of standards of conduct for health professionals using social media and in the design of online systems themselves [34].

The data sharing is common in research and highlight privacy and confidentiality concerns. Many patients actively enter various data into apps and websites, but they don't know that the data may be collected, stored, and shared for research or other purposes, such as product development and marketing, which are often difficult to distinguish from research [34]. Some, but not all, offer individual privacy settings to limit the sharing of specific information privacy settings but do not necessarily affect the application's ability to collect or share information [35].

Currently there is no standardized universal consent form for the use of clinical images. There is little consensus about the use of pictures of faces and identifiable characteristics of the patient, regardless consent was obtained, because them can become "viral" and can be impossible to delete if the patient retracts consent [36]. For research purpose the principal investigator is responsible to ensure the user's privacy whenever possible, in the absence of other protections, and inform the patients that privacy cannot be guaranteed [37]. To decrease the risk of end users' privacy concerns some devices and applications support only deidentified aggregate data. However, this anonymized data is not always effective, even these deidentified data can reveal pertinent information. Patients may reasonably, although erroneously, assume that because laws protect the health information in their medical record, that same information must be similarly protected in a health-related app or website [34]. Another possible ethical issue related to the social media is the self-promotion and conflict of interest. Many professionals use social media as a marketing tool, and it's obvious that there is some conflict of interest when elements of financial incentive come into play. In cosmetic surgery over half of the posts are self-promotional nature, and the health care provider appear more trustworthy and honest. Vulnerable people may be exploited if doctors recommend specific brand or their own brand [38].

Meeting platforms

While there are videoconferencing platforms aimed at the specific telemedicine market, such as Doxy.me (www.doxy.me) and Vidyo (www.vidyohealth.com), the most widely used non-medical platforms globally for their convenience, penetration into mobile devices, and gratuity are Zoom, Microsoft Teams, Google Meet, Skype, Cisco Webex, and GoToMeeting. The ideal platform for research should be free or low-cost, easy to use (no user, use on

mobile devices, low data consumption), not requiring downloading applications, maintaining the confidentiality and security of the participant, and allowing encrypted recording of meetings and concomitant use of surveys within the same platform (Table 1).

Videoconferencing can be used from the early stages of the research process, such as recruitment and obtaining informed consent. The United States Food and Drug Administration (FDA) has provided guidance for obtaining electronic informed consents, which highlights the need to maintain the paper option for obtaining such consent. When some steps are not possible via virtual means, such as obtaining biometric measurements, these steps can be performed by certified local centres [39]. The legislations are heterogeneous, with each country having different regulatory systems for technological platforms in telehealth. Therefore, researchers must adapt their projects to these regulations, especially concerning multicentre studies. There is no doubt that in the future the global organizations and universities that regulate research processes should seek to harmonize the recommendations for the precise use of these platforms, mainly concerning privacy, confidentiality, security of data storage, and validation of these tools. One example is the McMaster University, which proposed general recommendations for the correct use of videoconferencing platforms (www.research.mcmaster.ca/ethics/mcmasterresearch-ethics-board-mreb/videoconferencing).

Qualitative research has made significant adaptations in the last year to be able to solve the inconvenience of social distancing imposed by the COVID-19 pandemic, forcing researchers to migrate to these technological tools. Mattiello et al. [40] evaluated the reliability of videoconferences for the use of functional performance scales in patients with knee osteoarthritis, observing an adequate intra-and inter-observer reliability, thus suggesting the possibility of its use in these scenarios. Victorson et al. [41], in a pilot randomized controlled trial comparing the use of videoconferencing for the delivery of mindfulness-based interventions for quality-of-life improvement in patients with advanced prostate cancer, found that participants of the videoconference intervention were highly satisfied with it. However, there are still barriers to their dissemination, especially in low- or middle-income countries, where access to the internet remains limited. According to data from the Organisation for Economic Co-operation and Development (www.oecd.org/sti/broadband/broadband-statistics) by December 2020, the average high-speed connection penetration in the countries member of this organization was 33.1 per 100 inhabitants, the highest for Switzerland (47.4/100 inhabitants) and the lowest for Colombia (15.7/100 inhabitants). Thus, the use of online videoconferencing may not be a problem for European or North American countries, but researchers in regions such as Latin America or Africa may need to consider strategies to facilitate internet access. As a limitation for accessing these technologies, researchers should consider selection bias by not involving participants who do not have access to the internet or have cognitive difficulties with its use. Carter et al. suggested a checklist for the evaluation of the correct functioning of the platforms. [42] (Table 2)

Considering the events related to the COVID-19 pandemic, research protocols to be carried out in the coming years should consider the possibility of transitioning from face-to-face follow-up visits to Internet-based visits, as well as including the training of participants in the use of videoconferencing platforms, collection of biospecimens, and sending printed copies of documents by mail through pre-addressed and post-paid direct mail [43].

Non-medical devices with intended medical purposes

The undeniable development of engineering allowed a veritable wave of disruptive innovation around the world, enabling technologies not specifically created for medical use to be used

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Table 1 Video conference platforms overview.

Video conference platforms	Free version	Lowest payment option	User requirement	Mobile Devices	Data consumption	Download requirement	HIPAA compliance	Survey an-app
Zoom	Yes Restricted to 40 min per meeting	Pro 14,99 USD / Month / License	No	Yes	9 MB / Min https://www.whistleout.com/Internet/Guides/zoom- video-call-data-use	Yes (For the host)	Yes	Yes
Teams	Yes Restricted to 60 min per meeting	Microsoft 365 Business Basic 5 USD / Month / User	No	Yes	3,75 MB / Min https://gadgetstouse.com/blog/2021/02/12/data- consumed-by-zoom-google-meet-skype- microsoft-teams-slack-and-hangouts/	Yes (For the host)	Yes	Yes
Google Meet	Yes No time restriction	Business Starter 5,4 USD / Month / User	No	Yes	15 MB/ Min https://www.makeuseof.com/reduce-amount- data-used-google-meet/	No	Yes	Yes
Skype	Yes No time restriction	The payment option is replaced by Teams Microsoft 365 Business Basic 5 USD / Month / User	No	Yes	2,25 MB / Min https://gadgetstouse.com/blog/2021/02/12/data- consumed-by-zoom-google-meet-skype- microsoft-teams-slack-and-hangouts/	No	Yes (Only for Enterprise E3 o E5 version)	Yes
Cisco WebEx	Yes Restricted to 50 min per meeting	Meet Plan 15 USD / Month / User	No (Request email)	Yes	30 MB/ Min https://help.webex.com/es- CO/article/WBX22158/%C2%BFCu%C3%A1les-son- los-requisitos-m%C3%ADnimos-de-ancho-de- banda-para-enviar-y-recibir-v%C3%ADdeo-en- Cisco-Webex-Meetings?	Yes (For the host)	Yes	Yes
GotoMeeting	No (Free trial 14 days)	Professional 12 USD / Month / User	No	Yes (Chrome)	42 MB / Min https://support.goto.com/meeting/help/how- much-bandwidth-is-used-during-a-session- g2m010029	Yes (For the host)	Yes	Yes (Until 25 questions)

Source: Adapting non-medical applications for medical use: ethical limits, coverage, and validation, 2021. Legends: USD - United States dollars; MB - megabytes; Min - minutes; HIPAA - Health Insurance Portability and Accountability Act; App - application.

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 Table 2

 Checklist for essential components of video conferencing platforms

Checklist for essential components of video conferencing platforms. Components of privacy, confidentiality and security for the participant and the research environment Password requirement for login Possibility to add or remove participants Username display control Possibility of choosing virtual background Components to facilitate effective social interaction Microphone and camera control Chat function Function of separate virtual rooms In-app surveys Ability to share screen Possibility of making annotations on screen or white board Components for data management and storage Possibility of built-in video and audio recording Possibility of subtitles and audio capture Exclusive storage outside the virtual platform

Source: Adapted from Carter et al. 2021 (reference 42).

Screenshot control

with medical purposes. A typical example is the development of smart implants in fracture care. The monitoring process of fracture healing is still evaluated by a subjective clinical and imaging analysis, devoid of precise quantitative measures. However, in the last years, several experimental smart plates applications for fracture repair monitoring have been successfully reported [44]. Generated data can be stored in the cloud and sent in real time to the orthopaedic surgeon via smartphone [44]. Lin et al. [45], using electrical impedance spectroscopy to track the healing tissue in mouse fracture models, demonstrated evidence that microscale instrumented implants provide a route for post-operative fracture monitoring.

Upcoming smart implants can play a critical role not only in monitoring fracture healing, but also using electrochemical sensors for oxygen saturation and pH measurements, thereby providing helpful information for implant infection detection [44]. In a near future, smart implants could not only collect, but analyse data and even influence the mechanical environment by changing the stiffness, therefore facilitating the fracture repair [44].

The application of reality technology in orthopaedic surgery is also a true example of disruptive innovation. Reality technology can be divided into three pillars: Virtual Reality (full visual immersion in a computed-generated artificial environment, with medical applications including patient education, medical training, and preoperative planning); Augmented Reality (currently available for smartphones and head-mounted display platforms, simulating depth perception of real-world surfaces and constituting an excellent tool for medical education); and Mixed Reality (the user views the real world while manipulating the digital content generated by the digital device). The improvement in preoperative planning using reality technology plays a relevant role for patient safety, optimizing outcomes and minimizing potential complications. Moreover, the use of reality technologies for residents training minimizes potential ethical concerns since part of the surgical skills can be acquired outside the operating theatre [46].

Another milestone in surgery is the introduction of robotics. Although the robotic-assisted surgery was a paradigm break for urologic and for some gynaecologic, bariatric, and abdominal wall surgeries, the application of robotics in orthopaedics did not follow this trend in the same speed. The hypothesis that preoperative planning and accuracy of the surgical cuts provided by robotic-assisted surgery improves the safety and accuracy of the surgical procedure, potentially minimizing complications such as limb length discrepancy and increasing the implant longevity still must

be confirmed in practice. Vermue et al. [47], in a systematic review of the literature, reported that robotics is associated with high surgical team stress levels, requires a long learning curve, and has no influence in implant positioning, preoperative planning, and postoperative complications. In the orthopaedic trauma scenario, the serial-parallel hybrid system depicts a promising device for fracture reduction. Compared with previously reported robotic systems for fracture reduction, this device presents the potential advantages of less soft-tissue damage and greater range of motion and reduction accuracy [48]. Dagnino et al. [49], using an image-guided surgical robotic system for percutaneous reduction of distal femur fractures on cadaver specimens, were able to reduce up to 77% of T- and Y-shape 33-C1 fractures with acceptable accuracy. Robotic surgeries have also been used to identify the entry point of intramedullary nailing, as well as to insert distal locking bolts [49]. The Trauma Pod, a semi-automated telerobotic surgical device experimentally developed for critically injured patients care on the battle, presents autonomous arms that can act as circulating and scrub nurses and supply delivery is performed as fast as manually performed by nurses [47]. Using this system, the surgeon could perform shunt placement in major vessels and bowel anastomosis via teleoperating supported intraoperatively by computed tomography scanning.

Conclusion

Adapting non-medical applications, social media, videoconferencing platforms and devices for medical use presents limitations, barriers, and potential risks. Privacy and security are fundamental aspects of ethical health conduct, but currently there is no standard recommendation for all regions or countries. Regardless of the absence of a universally accepted recommendation, several authors have demonstrated the benefits of using non-medical instant messaging, communication tools, and devices with intended medical purposes in medical practice. However, despite its potential use and validation to expand the reach of patient health and support, it must be assumed that no non-medical application is 100% secure, so its use must always balance risks and benefits to minimize potential ethical concerns.

Declaration of competing interest

None.

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CRediT authorship contribution statement

Vincenzo Giordano: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. Kodi Edson Kojima: Data curation, Investigation, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. Carlos Oliver Valderrama-Molina: Data curation, Investigation, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. Matheus Lemos Azi: Data curation, Investigation, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. Fernando Bidolegui: Data curation, Investigation, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. Robinson Esteves Pires: Data curation, Investigation, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing.

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Ethical approval

The study was conducted according to the guidelines of the Declaration of Helsinki and was approved by the Institutional Review Board of the Hospital Municipal Miguel Couto, Secretaria Municipal de Saúde-Rio de Janeiro.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2021.12.017.

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