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Quality Assessment of Health-apps using a Public Agency Quality and Safety Seal. The Appsaludable Case

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Abstract

Standards and validation practices regarding mobile health apps need to be established to ensure their proper use and integration into medical practice. This paper proposes an innovative and integrative approach to examine and compare the quality of a certified health mobile applications set. A double classification framework (verified and perceived quality) is proposed and validated to evaluate the quality of 22 verified health mobile apps, particularly to understand whether these apps provide the service demanded by its users. Evaluation of verified quality was based on a certification public program. To analysis user satisfaction, we used content analysis to examine and extract words and expressions contained in online reviews (1,574 reviews were analyzed). The R language was used to scrape data and to perform all

statistical analyses. The results did not confirm a significant relationship between both classifications ($p > .05$). However, the requirements with the highest degree of compliance (“design and relevance” and “quality and safety”) of the app accreditation program were the best rated by the users of the apps in their comments. Reflections derived from this paper represent an important contribution to the knowledge base in the expanding research area of mobile health.

Keywords

Mobile applications

Perceived quality

Accredited quality

Online user reviews

Data mining

Web-scraping

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Introduction

Although mobile apps are poised to become a major source of health guidance, concerns about their quality and safety remain. Governments, clinicians, and health researchers are struggling to determine how to adequately evaluate the content and function of mobile health apps to guide consumers toward apps that effectively and safely support their health, provide accurate information, and are user-friendly [1, 2]. The identified main problems that a health app must address in order to be of quality are security; data protection and reuse of data; possible risks related to misuse; poor regulation; and lack of standards for validation, efficiency, and quality [3, 4, 5, 6].

Both the Food and Drug Administration (FDA) and the European Union have already put themselves to work to regulate and set minimum quality criteria for health apps. Although there is still no general consensus on this, the FDA launched a guide with the objective of regulating this area, proposing a series of recommendations that give guidelines on which apps will be on track and which ones will not. Likewise, it indicates that those mobile applications that function as medical devices and that can “put the patient at risk” will be regulated by the FDA.

For its part, the European Union has created a directory of health apps to “support patients to find useful and reliable apps.”

Along these lines, users from different countries (Estonia, Germany, Portugal, Slovenia, UK, and Spain) have the option of using accredited health apps from either private organizations or public entities [7]. Among them, the UK presents a more formalized process developed by the government (<https://www.gov.uk/government/publications/health-app-assessment-criteria/criteria-for-health-app-assessment>). In Spain, there are two certification models, Appsalut and Appsaludable, both developed by Public Health Agencies (Catalonia and Andalusia, respectively), which recognises the quality and safety of health apps. This is free and open to all public or private apps, both Spanish and from other countries. The importance of these badges justifies the selection criteria of the apps analyzed in some studies [8, 9, 10, 11].

For the user (patients, healthcare professionals, or the general public), using a certified app is synonymous with guarantee and quality. Therefore, the quality certified by a program should result in a positive evaluation of its users based on their personal experiences. However, even if the app is included in a repository or catalogue that guarantees compliance with different requirements widely recognized in the literature [12] and tested by specific accreditation programs (accessibility, usability, reliability, privacy, security, etc.), if it does not meet the user's needs, the perceived quality does not correspond to the quality accredited by an external agent. The users of the apps constitute a key piece in this process; they are "testers," evaluators of the service offered by the devices. Thus, in practice, the quality accredited or regulated by a program should result in a positive evaluation of its users based on their experiences.

Mobile application reviews are valuable repositories of ideas that come directly from the users of the application. Therefore, they constitute a valuable source of data, the analysis of which can allow detecting defects in the apps, aspects to improve, classifying the apps according to the positive or negative connotation that encloses the language, etc. Therefore, the evaluation and comparison of apps in general and health apps (h-apps) in particular based on the opinions of its users has become a research objective for different purposes. There are journals specialized in this field of study, such as JMIR mHealth and uHealth and Journal of Medical Systems, which have shown their interest in this topic by publishing different articles that examine qualitative feedback through analysis of user reviews [13, 14, 15]. Other articles study the utility for users of health applications aimed at certain diseases. They address unmet needs and determine their expectations [16, 17, 18, 19]. In general, there are quite a few research studies on the perception of users of health apps [20, 21, 22], which shows interest in this topic.

The aim of this paper is to examine and compare the quality of these h-apps under an integrative and innovative approach. For this purpose, a classification framework is proposed and validated to evaluate the quality of h-apps, especially to understand whether these certified apps provide the service demanded by its users. To achieve this purpose, our work is structured around three main research questions (RQ):

RQ1: What requirements of the certification program do the h-apps have?

RQ2: What are the comments of the online reviews reported by healthcare app users?

RQ3: Is there a significant relationship between verified quality and perceived quality?

The organization of the rest of the paper is as follows: Section 2 describes the methodology, Section 3 presents the results, and Section 4 discusses the conclusions.

Methodology

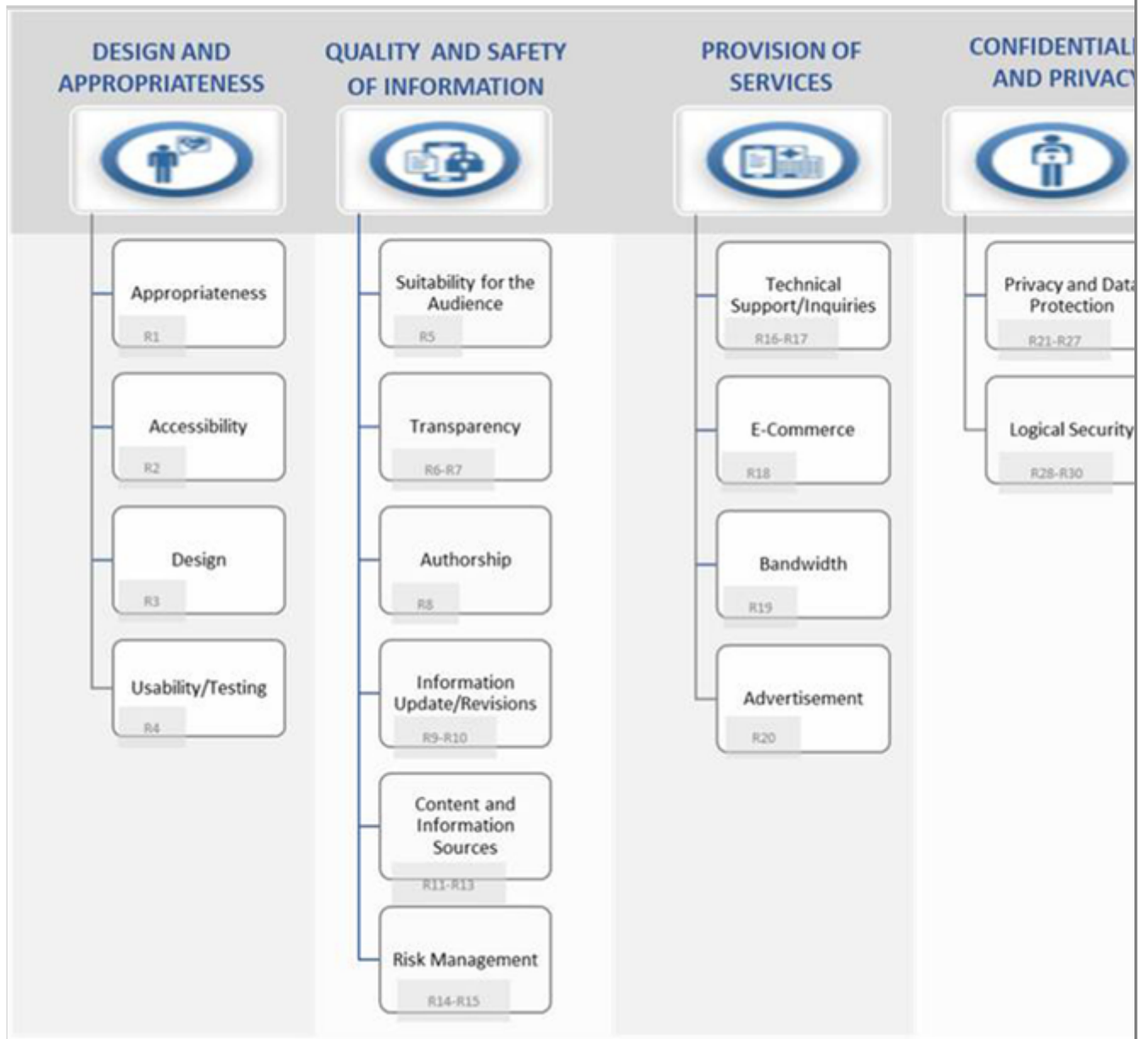
The context of the study consists of 22 healthcare Android mobile apps. The selection of this dataset is driven by two main reasons: (i) it contains all the apps included in a repository of mobile health applications that stand out for their safety and quality (AppSaludable Quality Seal) dated December 2019, and (ii) it contains Android healthcare apps, thus enabling the possibility to perform our analyses.

This certification program is based on 31 requirements grouped into four categories and published in the Guide of Recommendations on Design, Use, and Assessment of Health Apps. They assess design and relevance; quality and information security; provision of services; and confidentiality and privacy (see Fig. 1).

Fig. 1

Recommendations on design, use and assessment of health Apps.

Source: <http://www.calidadappsalud.com/en/listado-completo-recomendaciones-app-salud/>



Although all apps are accredited, the number of requirements they have with respect to the total of those contemplated in the recognition program is different. A ranking has been established based on the number of certification program requirements that h-apps achieve (Level 1 = 50%; Level 2 = 40%; and Level 3 = 30%).

For each app, we then mined the corresponding Google Play store location and extracted the list of user reviews. We were able to extract a total of 1,574 user reviews. We used content analysis to examine and extract words and expressions contained in online reviews [23, 24]. The R statistical environment was used to perform all analyses (<http://www.R-project.org/>). Figure 2 illustrates a step-by-step flow chart of our method.

Fig. 2

Process flow diagram



After that, we proposed a ranking based on the positive user comments. We established four groups formed from the quartiles ($0 \leq Q1 \leq 0.001$; $0.001 < Q2 \leq 0.232$; $0.232 < Q3 \leq 0.369$; $0.369 < Q4 \leq 0.75$; where $Q_i = \text{positive reviews}/\text{total reviews of the app "i"}$).

Finally, crosstabs were used to explore associations between perceived quality (user experiences) and verified quality (certification program requirements).

Results, analysis, and discussion

Descriptive statistics

This research found a variety of h-apps that had been classified by different users, functions, and the used platform. Table 1 summarizes the main characteristics for the 22 mobile health-apps.

Table 1

Details of h-apps (n = 22)

Characteristics adjusting the columns to the text	Frequency centre this celd and adjusting the columns to the text	
	No centre the whole column and adjusting the columns to the text	% centre the whole column and adjusting the columns to the text
Users		
Patients	7	31.82
Professionals	9	40.91
General public	6	27.27
Category		
Monofunction	14	63.64
Multifunction	8	36.36
Developer		
Health sector company	4	18.18
Technological company	8	36.36
Sanitary professional	6	27.27
Particular	1	4.55
Public administration	3	13.64
Seal date		
Before 2016	11	50.00
2016	1	4.55
2017	1	4.55
2018	7	31.82
2019	2	9.08
Interaction (bidirection)		
Yes	4	18.18
No	18	81.82

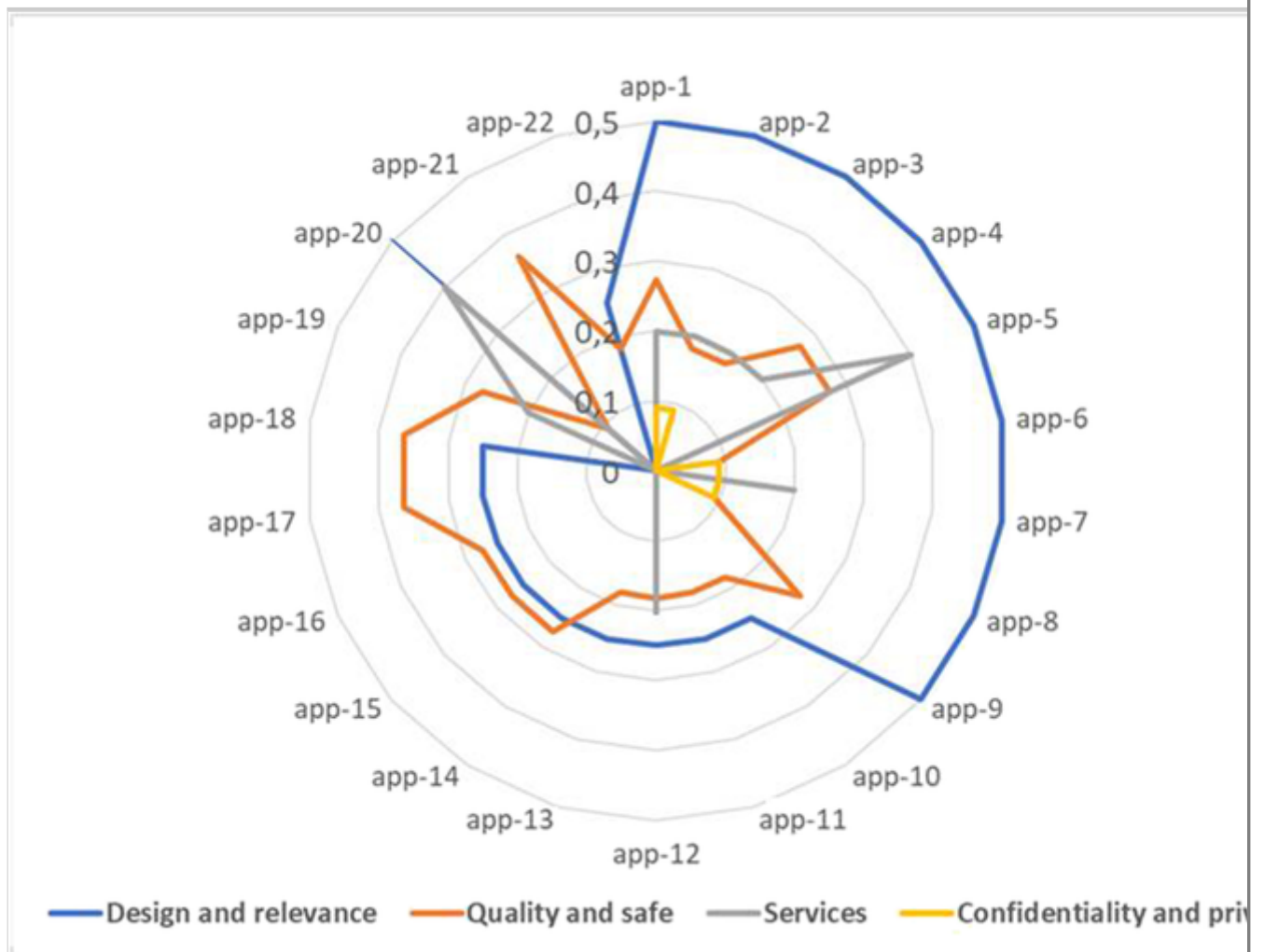
Results: Evaluation of h-apps

Accredited quality (RQ1)

Figure 3 illustrates the degree of compliance with the accreditation standard requirements (requirements achieved/total requirements) grouped into four categories: design and relevance, quality and safety, services, and confidentiality and privacy.

Fig. 3

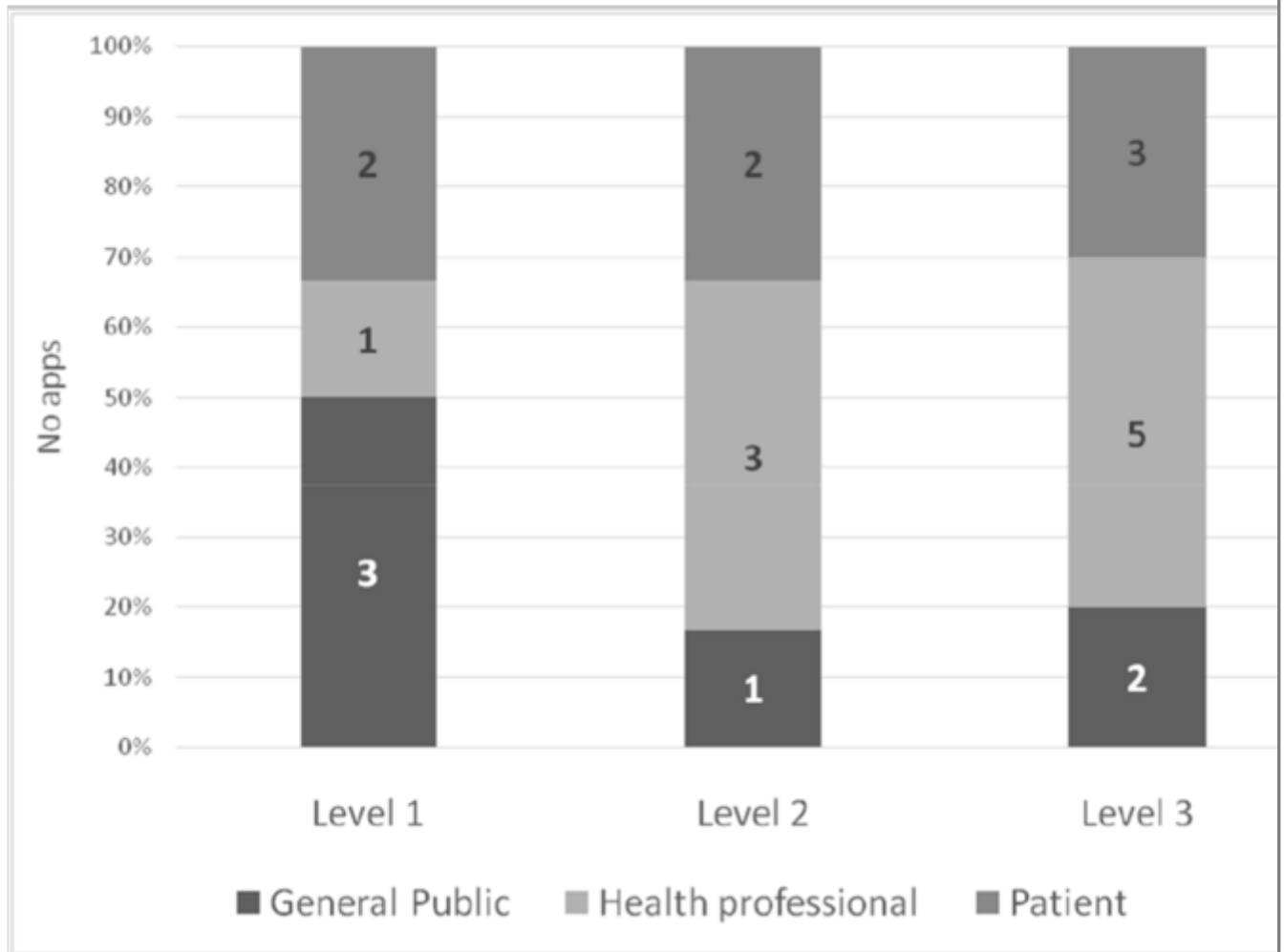
Accreditation standard requirements by apps (% compliance degree)



According to the established ranking based on the number of certification program requirements that the h-apps achieved, Fig. 4 shows the distribution of the sample by user type.

Fig. 4

Distribution of the sample according to degree compliance with program requirements and type of user of the apps (No apps)

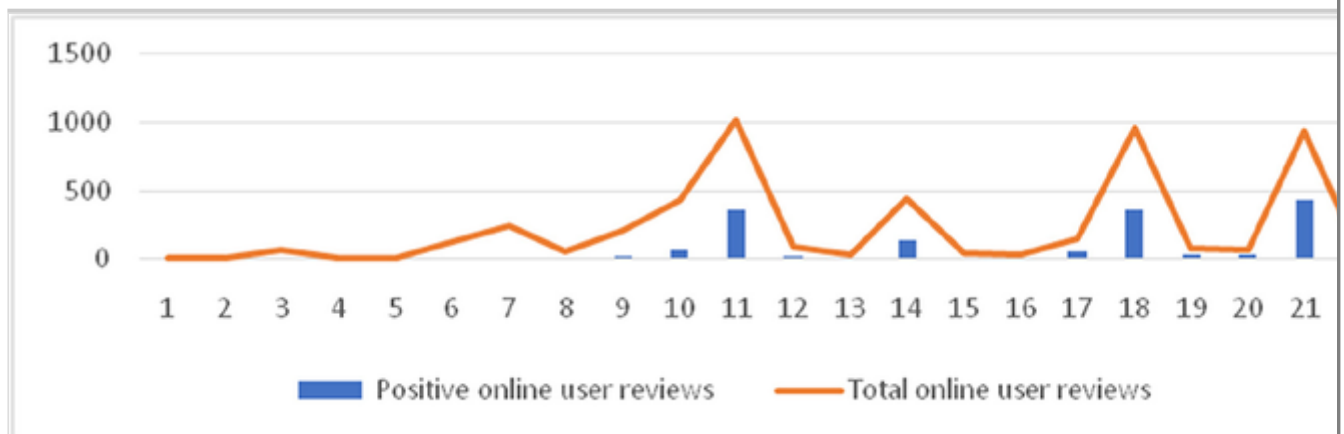


Perceived quality (RQ1)

In relation to the quality perceived by the users (user perspective), Fig. 5 shows the apps' valuation based on the analysis of their users' comments (% positive comments/total comments).

Fig. 5

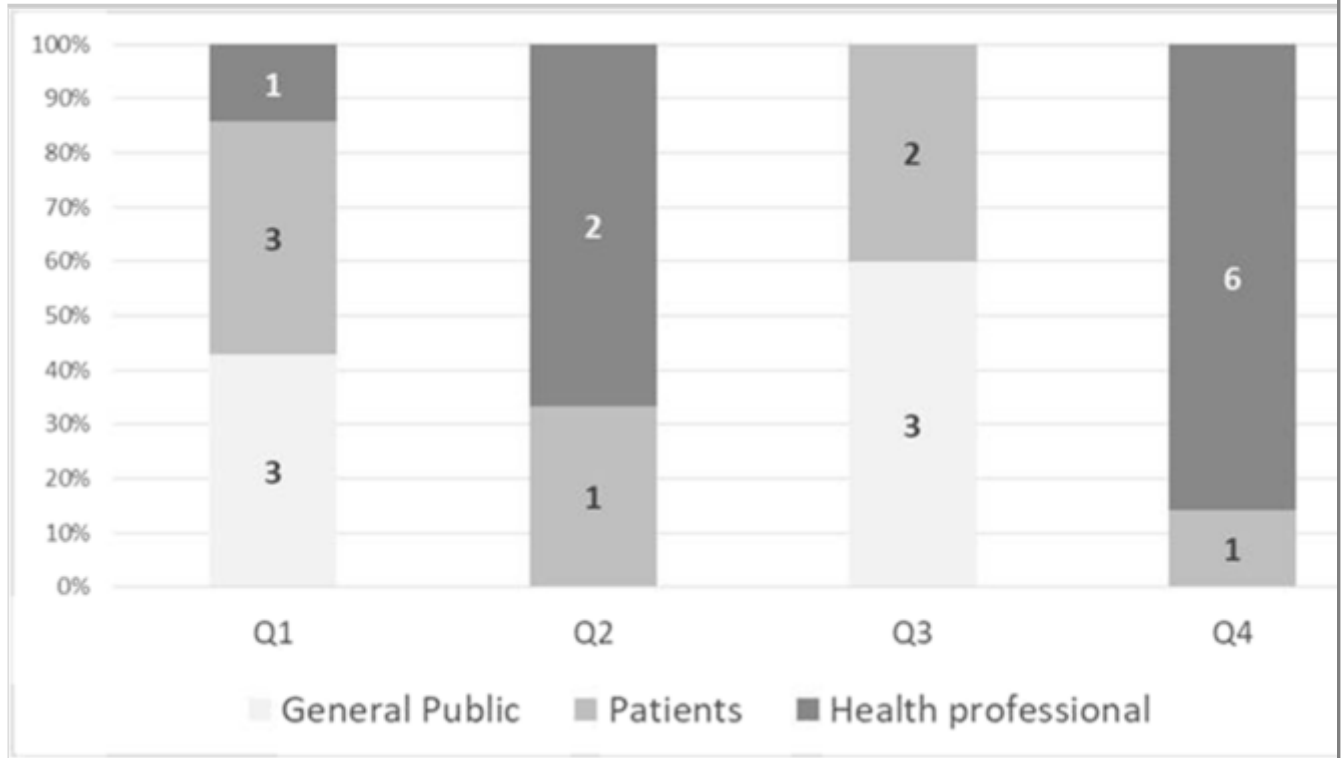
Apps' valuation (% positive comments/total comments)



In the same way as for the accredited quality, Fig. 6 shows the distribution of apps by type of users according to the ranking established about to user rating (online reviews) ($0 \leq Q1 \leq 0.001$; $0.001 < Q2 \leq 0.232$; $0.232 < Q3 \leq 0.369$; $0.369 < Q4 \leq 0.75$).

Fig. 6

Distribution of apps by type of users according to user rating (No apps)

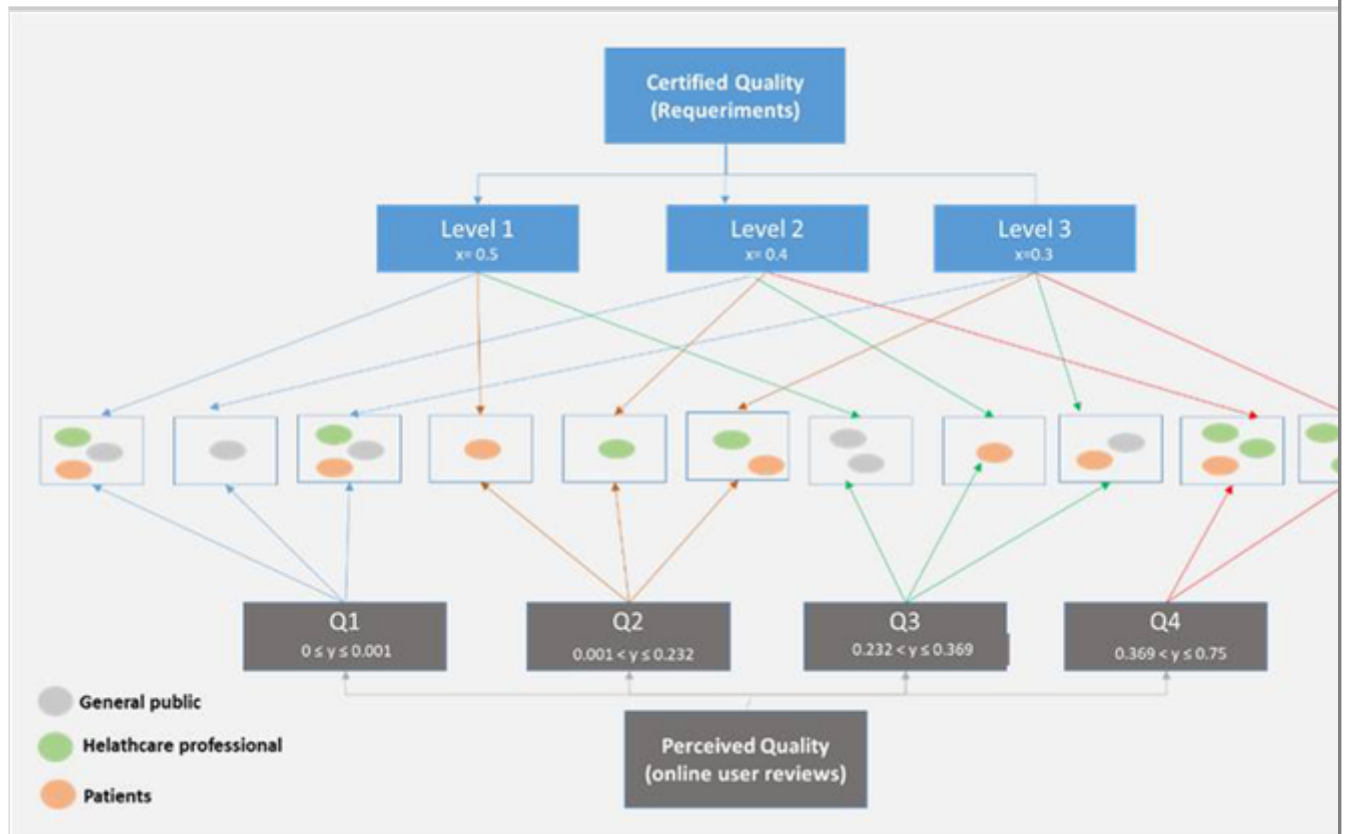


Verified vs. perceived quality (RQ3)

The results obtained from the two previous sections are shown integrated in Fig. 7 for comparative purposes.

Fig. 7

Proposal of new assessment approach for apps' quality



There is no significant relationship between the two rankings ($\chi = 32.511$; $p > 0.05$). A better position in the ranking of the accredited quality (percentage requirements get by the accreditation program) does not imply a better valuation of the users and therefore greater satisfaction of them.

The professionals are the users who value the apps best (83.33% of those included in Q4 are apps for professionals); however, they are the applications that achieve the lowest number of the accreditation program requirements (only 11.11% of those included in level 1 of the ranking of compliance with program requirements).

Considering the different requirements of the accreditation program, it was detected that the main quality attributes associated with the positive comments of the users correspond to the categories “design and relevance” and “quality and safety.” Usability, user interface, functionality, and efficacy are some examples.

However, the comments analyzed were not associated with the dimensions “services” and “confidentiality and privacy,” which are precisely those that a high percentage of apps do not comply with despite being accredited.

These mainly refer to limitations about the technology used for the design and development of apps (incompatibility with other devices, update problems,

Bluetooth connection, etc.) (e.g., “Bluetooth apparently not working properly. It takes from 5 to 10 min for the app to read the new data”).

Conclusions

In this article, we consider some issues of the quality of h-apps under an innovative and integrative approach. It is integrative because it includes a double perspective, the accredited quality and the perceived quality of the users. It is innovative due to the absence of previous works that address it and the incorporation of the technological advances of the digital age in the valuation process.

The main results obtained provide us with relevant information so that the reflections derived from them become an important contribution to the knowledge base in the expanding research area of mobile Health. We conclude the following:

- The quality of health mobile apps is a complex concept. The finding suggests that quality evaluation requirements/checklists, which are mostly based on experts' views of quality, might not effectively serve the needs of users. User experiences needs to be considered in the design of interventions that intend to promote quality evaluation.
- The quality accreditation of apps is not a goal; it is a way of conceiving, organizing, and providing an increasingly better service.
- The users of the apps play a key role in the app's quality evaluation; they cease to be merely the recipients of the services offered by the apps and become the evaluators and judges of them. The opportunity that the digital era technologies offer in this field of study is evident, allowing users to collect large amounts of data in real time and directly, also achieving savings in time and cost.
- The online comments of h-app users are a clear example of the potential offered by the integration of digital technologies in the evaluation and control of the quality of products and services. The need to adapt the quality assessment to new technologies, as in other areas of business management, is indisputable.
- Finally, note that although positive comments are the most required by the company, they are not the only ones that can be obtained or should be welcomed. Negative comments should be accepted and understood as an

opportunity for improvement. Therefore, this constitutes the continuity of this study.

The limitations of this study, derived mainly from the concept of quality and the methodology used, will mark the roadmap of the authors in future works and a valuable input for researchers who wish to accompany us in this field.

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Declarations

Conflict of Interest All authors declare that there is no conflict of interest.

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

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