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Validation of digital technologies in the health care area: integrative review

Validação de tecnologias digitais na área da saúde: revisão integrativa

Validación de tecnologías digitales en el área de la salud: revisión integrativa

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ABSTRACT

Objective: To explore, in different databases, the tools and methodologies used to validate applications implemented in health services. **Methods:** This is an integrative literature review aimed to identify articles that reveal different methods to validate digital technologies in healthcare. **Results:** Eight articles met the inclusion and exclusion criteria. Two authors chose to validate the software through a previously validated scale; others used qualitative and quantitative methodologies, with validated scale and individualized interviews; three chose qualitative methodology, from individual interviews to focus group evaluations and, finally, the last article used positive results obtained during the evaluation of the application after launch in health services to validate the software. Some authors have developed quality tools using scales, but the absence of features required by International Standardization Organization (ISO) standards limit the results. **Final Considerations:** We suggest the creation of a user-friendly and widely available scale or questionnaire based on ISO standards to validate software in health care, facilitating comparison of applications for use in health services.

Keywords: Software validation, Interprofessional relations, Patient care team.

RESUMO

Objetivo: Explorar em diferentes bancos de dados as ferramentas e metodologias usadas para validar as aplicações implementadas em serviços de saúde. **Métodos:** Trata-se de uma revisão de literatura integrativa com o objetivo de identificar artigos que revelam diferentes métodos para validar as tecnologias digitais na área de saúde. **Resultados:** Oito artigos contemplaram os critérios de inclusão e exclusão. Dois autores escolheram a validação do software partindo de uma escala previamente validada; outros, usaram metodologias qualitativas e quantitativas, com escala validada e entrevistas individualizadas; três optaram por metodologia qualitativa, desde entrevistas individuais a avaliações em grupos focais e, finalmente, o último artigo usou resultados positivos obtidos durante a avaliação da aplicação após o lançamento em serviços de saúde para validar o software. Alguns autores desenvolveram ferramentas de qualidade através de escalas, mas a ausência de características exigidas pelos padrões da *International Standardization Organization* (ISO) limita os resultados. **Considerações Finais:** Sugere-se a criação de uma escala ou questionário de fácil

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utilização e ampla divulgação, baseada nos padrões ISO para validar o software na área de saúde, facilitando a comparação de aplicações para uso em serviços de saúde.

Palavras-chave: Validação de software, Relações interprofissionais, Equipe de assistência ao paciente.

RESUMEN

Objetivo: Este estudio pretende explorar en diferentes bases de datos las herramientas y metodologías utilizadas para validar las aplicaciones implementadas en los servicios sanitarios. **Métodos:** Se trata de una revisión bibliográfica integradora cuyo objetivo es identificar artículos que revelen diferentes métodos para validar tecnologías digitales en el ámbito sanitario. **Resultados:** Ocho artículos cumplieron los criterios de inclusión y exclusión. Dos eligieron para validar el software através de una escala previamente validada; otros utilizaron metodologías cualitativas y cuantitativas, con escala validada y entrevistas individualizadas; tres eligieron metodología cualitativa, desde entrevistas individuales a evaluaciones de grupos focales y, finalmente, el último artículo utilizó resultados positivos obtenidos durante la evaluación de la aplicación tras su lanzamiento en los servicios sanitarios para validar el software. Algunos autores han desarrollado herramientas de calidad mediante escalas, pero la ausencia de las características exigidas por las normas ISO limita los resultados**. Consideraciones Finales:** Se sugiere la creación de una escala o cuestionario de fácil uso y amplia difusión basado en las normas de la *International Standardization Organization* (ISO) para validar software en la salud, facilitando la comparación de aplicaciones para su uso en servicios de salud.

Palabras clave: Validación de Programas de Computación, Relaciones interprofesionales, Grupo de atención al paciente.

INTRODUCTION

Interprofessional Teamwork (IPT) refers to the collaborative activities undertaken by a care team, extending beyond the healthcare sector, with the primary objective of addressing patients' health needs in a comprehensive and mutually reliant manner (PEDUZZI M and AGRELI HF, 2018). However, implementing IPT presents numerous challenges within the daily routines of professionals, chiefly attributable to factors including excessive workloads and responsibilities, a lack of interest or underestimation of the value of collaborative activities exhibited by certain professionals, inadequate awareness regarding the specific roles of team members, communication deficiencies, and divergent theoretical perspectives or viewpoints (GABRIELOVÁ J and VELEMINSKY MS, 2012; GUPTE G, et al., 2016).

Digital technologies employed in the healthcare domain encompass a range of tools and systems that leverage data and digital communication mechanisms for the purpose of collecting, exchanging, and analyzing information. The overarching objective is to enhance the efficiency of processes and augment the quality of services provided to patients. The utilization of digital technologies holds significant potential in fostering collaborative efforts within the healthcare sector and is progressively gaining traction in both small and large healthcare facilities. Prominent examples include remote monitoring, electronic medical records, and the utilization of software solutions such as applications and programs (KEASBERRY J, et al., 2017; SHARMA A, et al., 2017, BARNETT A, et al., 2019).

The use of digital technologies in hospital settings has been widely documented and discussed in the literature. This practice brings about notable shifts in the daily operations of healthcare teams, impacting the allocation of time across diverse activities. The integration and utilization of digital technologies, particularly electronic medical records, have significantly contributed to streamlining administrative tasks within the healthcare setting. These advancements have resulted in notable reductions in the time dedicated to bureaucratic activities, encompassing scheduling procedures and the evaluation and retrieval of test results, thereby generating a positive impact on both the healthcare team and the overall clinical outcomes of patients (CARAYON P, et al., 2015; WORMER BA, et al., 2015).

The use of digital technologies in healthcare gives rise to significant apprehensions regarding the privacy of patients. This concern stems from the potential ethical and legal dilemmas that may emerge if software systems lack adequate data protection measures, leading to the inadvertent dissemination of personal information. A pertinent example is the work of Barnett A, et al. (2019), who emphasize the importance of upholding data quality and security in the realm of digital healthcare. To this end, they advocate for the inclusion of criteria pertaining to digital technologies in the accreditation process for Australian hospitals. Consequently, hospitals that do not adhere to the established standards of security and quality in their technological services face the risk of being denied accreditation in the respective region under examination. Nonetheless, the process of assessing and gauging the quality of such digital technologies presents a complex and multifaceted challenge that necessitates careful consideration and evaluation.

Given the importance of usability-based software validation, Brooke J (1996) developed a comprehensive tool known as the Systematic Usability Scale (SUS). This scale has gained wide acceptance and is extensively utilized for software validation purposes, not only in the healthcare sector but also across various other domains. However, it is worth noting that the SUS scale does have a limitation, as it primarily focuses on assessing usability-related aspects (CORDEIRO HP, et al., 2019; KAYA A, et al., 2019; LIMA CJM, et al., 2019). The SUS scale, as devised by Brooke, encompasses an array of topics for evaluation, including the frequency of use, system complexity, ease of handling, the ability for independent use without requiring technical expertise, integration of miscellaneous functions, absence of inconsistencies in the system, adaptability to the community's routine, a lightweight and navigable system, confidence-inspiring usage experience, and self-explanatory design (BROOKE J, 1996; CORDEIRO HP, et al., 2019; KAYA A, et al., 2019; LIMA CJM, et al., 2019).

On the other hand, Sharma A, et al. (2018) concluded that evaluating the quality of digital technologies necessitates considering various criteria such as the method of data storage, interoperability, data synchronization between software systems, and data processing speed. Furthermore, Aitken M, et al. (2013) made a significant contribution by developing the IMS Institute for Healthcare Informatics Functionality Score, which focuses specifically on assessing criteria and functionality among healthcare applications through the use of a questionnaire. This score provides valuable insights into the performance and capabilities of healthcare applications, enabling a more comprehensive evaluation of their functionality.

Furthermore, it is important to note that the International Standardization Organization (ISO) has issued official documents known as standards that outline mandatory criteria for software development. These criteria, as specified by ISO/IEC 25010 (2011), encompass functional suitability, reliability, usability, efficiency and performance, compatibility, security, maintainability, and portability. Adhering to these standards ensures that software meets the necessary requirements for optimal performance and user satisfaction.

In addition, some researchers opt for qualitative methodologies when validating software, such as conducting individual interviews and organizing focus group workshops. These approaches allow for systematic and open discussions about the strengths and weaknesses of healthcare software (FARIAS AC, et al., 2019). By engaging in these qualitative evaluations, researchers gain valuable insights into the user experience and can identify areas for improvement in the software's design and functionality. This study aims to explore various databases to identify the tools and methodologies employed for validating applications used in the healthcare sector. By conducting this extensive analysis, the authors aim to develop a comprehensive understanding of how healthcare applications are assessed and evaluated, with the goal of promoting widespread availability and accessibility to society. Through this research, the authors seek to cultivate a critical mindset that will facilitate an in-depth comprehension of the evaluation processes involved in healthcare applications, thus contributing to the advancement of the field.

METHODS

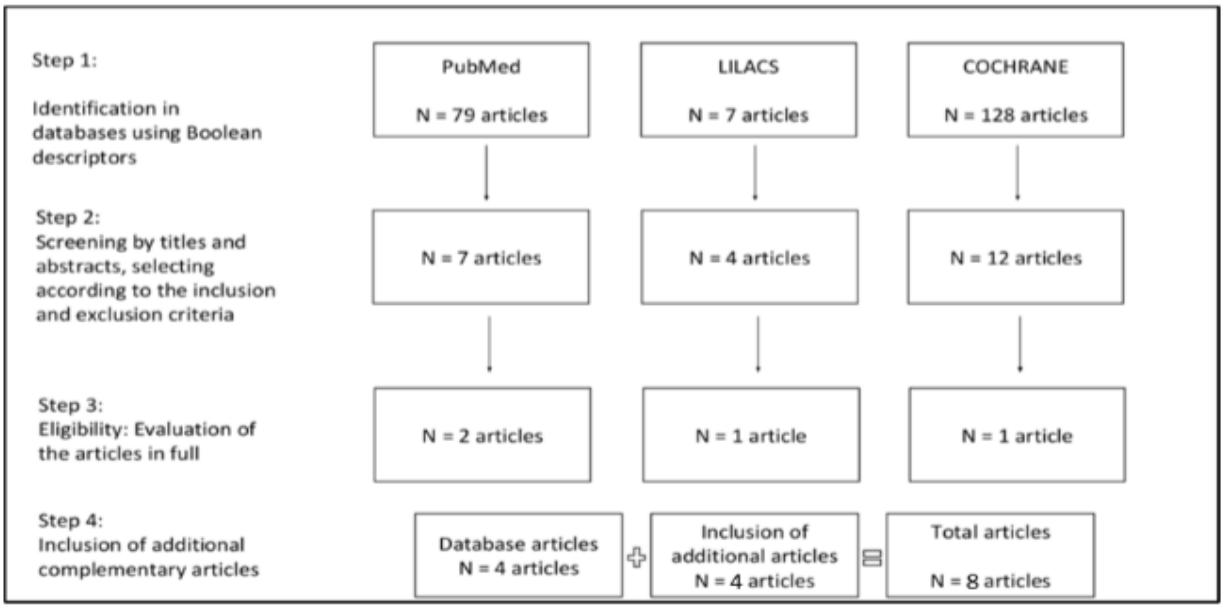
This study consists in an integrative literature review with the primary objective of identifying relevant articles that establish a correlation between the validation of digital technologies and their impact on the healthcare domain, particularly concerning Interprofessional Teamwork (IPT). The research methodology

employed a systematic approach, encompassing distinct steps in a sequential manner. These steps included initial theme identification, formulation of the research question, establishment of rigorous inclusion and exclusion criteria, determination of appropriate keywords for the search, active exploration of relevant databases, meticulous selection of articles, and evaluation and discussion of the search results in relation to the research question at hand.

The bibliographic survey encompassed a broad range of studies conducted from 2014 to 2023, sourced from reputable databases including PubMed, LILACS, Cochrane, and Google Scholar. Both original articles and review articles were considered for inclusion in the analysis. Throughout the meticulous evaluation process, works that exhibited methodological flaws, susceptibility to biases, or divergent themes were systematically excluded, ensuring the inclusion of only high-quality and rigorous research in the final review. By employing these rigorous selection criteria, the study aims to maintain a robust and reliable dataset, enhancing the overall credibility and validity of the findings.

The search strategy employed a set of targeted keywords including "software," "care team," "interprofessional work," and "validation," combined with appropriate Boolean operators (AND/OR) to refine the search results. The initial bibliographic search yielded a total of 79 articles in the PubMed database, of which two were deemed relevant and selected for further analysis based on the predefined theme and inclusion criteria. Similarly, the Cochrane database provided 128 articles, and one article aligned with the research theme and met the inclusion criteria. In the LILACS database, seven articles were retrieved, and one article was deemed suitable for inclusion. Unfortunately, no articles meeting the inclusion criteria were found in the Google Scholar database. Additionally, three additional articles were included in the review, obtained through supplementary searches conducted by the authors, ensuring comprehensive coverage of relevant literature in accordance with the predefined inclusion criteria. This meticulous search process aims to capture a wide range of literature and enhance the comprehensiveness and reliability of the study's findings.

Figure 1 - Flowchart of search steps in databases.



Source: Tenorio YCA, et al., 2023.

RESULTS

After conducting a comprehensive search across major databases, it was determined a total of eight articles satisfying the established criteria for analysis. The comprehensive details of each article, encompassing the respective authors, year of publication, study objective, software validation method employed, and corresponding results, are presented in **Chart 1**.

A segmented analysis of the collected data revealed that two authors employed a qualitative approach to validate the software, utilizing the well-established System Usability Scale (SUS) developed by Brooke J (1996) (CORDEIRO HP, et al., 2019; SILVA JE, et al., 2021). Additionally, one study opted to employ a questionnaire developed by the authors, which adhered to the stringent ISO standards (SILVA JE, et al., 2021). Another research endeavour seamlessly integrated both qualitative and quantitative methodologies, effectively amalgamating a scale assessment and individualized interviews to validate the software (GONG E, et al., 2020).

Moreover, three studies proficiently harnessed qualitative methodologies, with one employing individual interviews, another utilizing an intricately devised questionnaire formulated by the authors, and the third adopting a comprehensive approach involving focus group workshops (FARIAS AC, et al., 2019; HERMANN S, et al., 2021; WANG W, et al., 2014). Lastly, one study successfully validated the software based on a meticulous evaluation of the outcomes obtained during the application evaluation phase (VON-WANGENHEIM A e NUNES DH, 2019).

In the study by Cordeiro HP, et al. (2019), the objective was to validate an app designed for primary care physicians caring for HIV/AIDS patients and the method to validate the application was using the System Usability Scale (SUS), and the results indicated a successful validation with a SUS scale score of 77.3%. Similarly, LIMA CJM, et al. (2019) validated their work using SUS, receiving a high usability score of 85.3% in a mobile teaching application for electrocardiogram interpretation, indicating its successful validation for use in the community. On the other hand, Silva JE, et al. (2021) developed and validated a software program for risk screening in family medicine. The validation process utilized a questionnaire based on ISO standards. The software received successful validation, with over 70% positive answers in each category analysed, indicating its effectiveness in risk screening for family medicine.

Gong E, et al. (2020) conducted a comparison of various self-care applications specifically tailored for patients with diabetes. The study focused on evaluating the quality, functionality, and characteristics of these applications. To assess the quality of the applications, the researchers employed the widely recognized Mobile App Rating Scale (MARS), which is readily available in mobile application stores. The functionality of the applications was evaluated using the IMS Institute for Healthcare Informatics Functionality score, a previously validated questionnaire. Additionally, the authors developed a self-care activities checklist to assess the specific characteristics of the applications. The findings of the study revealed that the tested applications exhibited sub-optimal quality; however, they also highlighted the potential for improvement in terms of quality, functionality, and self-care characteristics.

In the study conducted by Von-Wangenheim A and Nunes DH (2019), the primary objective was to provide a comprehensive description of the experience and impact of implementing a tele-dermatology system over a period of seven years. The validation of the tele-dermatology system was carried out through an analysis of the results obtained during the implementation period. The findings indicated that the telemedicine system demonstrated effectiveness in resolving cases handled in primary care settings. Farias AC, et al. (2019) aimed to validate an electronic medical record (EMR) specifically designed for stomatology that can be accessed and utilized on smartphones and tablets. The validation process employed a qualitative methodology, utilizing focus group workshops to gather feedback and insights. The study's findings revealed that the application had the potential to enhance agility, security, and the quality of information storage and reporting within the field of stomatology, as evidenced by the valuable feedback obtained from the participants involved in the workshops.

Likewise, Herrmann S, et al. (2021) embarked on a project to develop a digital platform for assessing the self-reported quality of life among individuals living with HIV. The software validation process encompassed individualized interviews conducted with both HIV patients and assisting physicians. The outcomes indicated that the software was well-received and embraced by both groups, underscoring its efficacy in effectively assessing and gauging the self-reported quality of life within this specific patient population. Lastly, Wang W, et al. (2014) devoted their efforts to the development of an application designed to support self-care in home rehabilitation for patients diagnosed with stable angina. The validation process encompassed the utilization of a questionnaire to evaluate the overall user experience and satisfaction with the application. The study's results

concluded that the developed application exhibited promising potential in terms of its clinical utility at the community level, as evidenced by the analysis and examination of the responses garnered from the questionnaire.

Chart 1 - Articles on validation of applied software in healthcare.

Authors and year	Objective	Software Validation Method	Results
CORDEIRO HP, et al. (2019)	Validate app for primary care physicians who care for HIV/AIDS patients.	Use of the SUS[1] scale to assess the usability of the application.	The application was validated based on the survey, obtaining a *SUS* scale score of 77.3%.
FARIAS AC, et al. (2019)	Validation of an electronic medical record for stomatology that can be used on smartphones and tablets.	Use of qualitative methodology with focus group workshops for application validation.	Conclusion that the application will lead to greater agility, security, quality of information storage and reporting.
GONG E, et al. (2020)	Test the quality, functionality and characteristics of existing applications related to self-care for patients with diabetes.	Use of the Mobile App Rating Scale (MARS) to assess quality, Use of the IMS Institute for Healthcare Informatics Functionality score to assess functionality, and the use of a self-care activities checklist developed by the authors to assess application characteristics.	The quality of applications is sub-optimal, although there is potential for improvement.
HERRMANN S, et al. (2021)	Development of a digital platform to assess the self-reported quality of life of patients living with HIV.	Individualized interview using an inductive approach with the application's users, both HIV patients and assistant physicians.	The software was accepted by patients and attending physicians.
LIMA CJM, et al. (2019)	Development and validation of a mobile teaching application for electrocardiogram interpretation, based on usability.	Use of the SUS scale to assess the usability of the application.	The app scored 85.3% on the usability scale, and is therefore validated for use in the community.
SILVA JE, et al. (2021)	Development and validation os a software programing of risck screening in family medicine.	The use of questionnaire based on ISO standars.	The software was validated by reaching more than 70% in positive answers to every category analyzed (p < 0.05).
WANG W, et al. (2014)	Development of an application that provides support to patients with stable angina for self-care in home rehabilitation.	Development by the authors of a questionnaire on the overall evaluation and experience of the app.	The program has the potential to be clinically useful at the community level.
VON-WANGENHEIM A e NUNES DH (2019)	Describe the experience and impact of implementing a 7-year tele-dermatology system.	The validation of the tele-dermatology system occurred through the evaluation of the results obtained during the implementation.	The telemedicine system provides resolvability in cases assisted in primary care.

Source: Tenorio YCA, et al., 2023.

DISCUSSION

The use of scales as a form of quantitative assessment to validate applications in the health field can be considered an objective methodology, however limited. Analysing the topics present in the SUS scale (see topics in introduction), it is possible to observe limitations to topics related to usability. Therefore, other parameters end up being underestimated – such as efficiency, performance, compatibility among other

software. For example, the study developed by Cordeiro HP, et al. (2019) validated one application to use in patients with HIV-AIDS in primary care, reaching a score of 85.3% on the SUS scale. Consequently, this application was able to perform the function properly and with confidence; however, the reader may have doubts about criteria not evaluated by the SUS scale. In order to fix this issue and improve the evaluation, a questionnaire based on ISO standards was created to validate the software developed by Silva JE, et al. (2021). In the research conducted by Silva JE, et al. (2021), a novel software program specifically designed for risk screening in family medicine was developed and subsequently subjected to a validation process. In order to validate the software, a crafted questionnaire, meticulously aligned with the ISO standards, was employed as the validation instrument. The outcomes derived from the validation process were encouraging, as the analysis of the collected data revealed that more than 70% of the responses within each category unequivocally demonstrated the effectiveness of the software in executing risk screening procedures within the domain of family medicine.

On the other hand, studies that used different qualitative methodologies to validate applications were able to cover a greater number of characteristics with a broader approach; therefore, they were able to better meet ISO standards. As an example, we have the study conducted by Herrmann S, et al. (2021) who validated the application through an interview with the target audience (doctors and patients with HIV-AIDS). It was possible to analyse that percentage data, that could be used as comparison between different studies, were not possible due to the type of methodology applied, but the topics alone were evaluated according to the characteristics passed by subjective analyses and perceptions of patients and physicians who used the application while completing two questionnaires. The authors sought broader topics to validate the application, through questions related to the application's interface, data confidentiality, organization, ease, and usability.

The use of certain qualitative methodologies has the advantage of deepening with more specificity in topics related to the topic being discussed; however, as it does not always generate numbers or percentages, leading to a smaller comparative capability between other studies. Thus, an application can hardly be compared using the same criteria in two different studies. Therefore, the study directed by Gong E, et al. (2020) used both quantitative and qualitative methodologies to develop their study. As a form of quantitative assessment, the authors used the universal app evaluation score in digital stores called Mobile App Rating Scale (MARS) and the IMS Institute for Healthcare Informatics Functionality score, which was applied in the research sample. In addition, the authors chose to incorporate qualitative research data into the study through the development of a checklist created by the authors themselves.

As an alternative approach for software validation, Von Wangenheim A e Nunes DH, et al. (2019) adopted a different methodology by implementing a tele-dermatology software in a multicenter project. Over a period of seven years, the authors collected epidemiological data from the software implementation to evaluate its impact on the community. This methodology may deviate from the recommendations outlined in ISO standards; however, it allowed the authors to demonstrate the positive impact associated with the application, even though certain program characteristics may have been underestimated.

By leveraging the data obtained from the real-world implementation, the study provided valuable insights into the effectiveness of the technology and its contribution to improving healthcare outcomes in the community. These results collectively highlight the significance of diverse approaches and methods used to evaluate software quality in the healthcare domain.

They emphasize the importance of considering factors such as usability, functionality, user satisfaction, and adherence to standards when assessing the suitability and effectiveness of healthcare software applications. By incorporating these considerations into the validation process, researchers and practitioners can ensure the development and implementation of high-quality software solutions that meet the needs of healthcare professionals and patients. Based on their findings, the development of a user-friendly and accessible scale or questionnaire, aligned with ISO standards, to validate healthcare software. This tool would facilitate the comparison of different applications used in healthcare services. Evaluating software quality in the healthcare field necessitates a comprehensive approach that considers technical aspects, user viewpoints, and healthcare outcomes.

FINAL CONSIDERATIONS

The evaluation of validation of digital technologies in the healthcare domain is a crucial and complex task that requires careful consideration and implementation of appropriate methods. This paper aimed to compare various methods of evaluating the quality of software or programming in the healthcare area. Based on this analysis, the authors suggest the creation of a user-friendly and widely available scale or questionnaire based on ISO standards to validate software in health care, facilitating comparison of applications for use in health services, evaluating the quality of software in the healthcare domain requires a well-rounded approach that considers technical aspects, user perspectives, and healthcare outcomes. Furthermore, it is important to adapt and tailor these evaluation methods to the specific requirements and constraints of the healthcare domain. Collaboration among software developers, healthcare professionals, and end-users is vital for understanding the unique challenges and opportunities in healthcare software quality evaluation.

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