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Electronic patient-reported outcomes for patient care improvement

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Electronic patient-reported outcomes for patient care improvement

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Effect of electronic health records on doctor-patient relationship in Arabian gulf countries: a systematic review

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Background: The electronic health record (EHR) has been widely implemented internationally as a tool to improve health and healthcare delivery. However, EHR implementation has been comparatively slow amongst hospitals in the Arabian Gulf countries. This gradual uptake may be linked to prevailing opinions amongst medical practitioners. Until now, no systematic review has been conducted to identify the impact of EHRs on doctor-patient relationships and attitudes in the Arabian Gulf countries.
Objective: To understand the impact of EHR use on patient-doctor relationships and communication in the Arabian Gulf countries.
Design: A systematic review of English language publications was performed using PRISMA chart guidelines between 1990 and 2023.
Methods: Electronic database search (Ovid MEDLINE, Global Health, HMIC, EMRIM, and PsycINFO) and reference searching restricted to the six Arabian Gulf countries only. MeSH terms and keywords related to electronic health records, doctor-patient communication, and relationship were used. Newcastle-Ottawa Scale (NOS) quality assessment was performed.
Results: 18 studies fulfilled the criteria to be included in the systematic review. They were published between 1992 and 2023. Overall, a positive impact of EHR uptake was reported within the Gulf countries studied. This included improvement in the quality and performance of physicians, as well as improved accuracy in monitoring patient health. On the other hand, a notable negative impact was a general perception of physician attention shifted away from the patients themselves and towards data entry tasks (e.g., details of the patients and their education at the time of the consultation).
Conclusion: The implementation of EHR systems is beneficial for effective care delivery by doctors in Gulf countries despite some patients' perception of decreased attention. The use of EHR assists doctors with recording patient details, including medication and treatment procedures, as well as their outcomes. Based on this study, the authors conclude that widespread EHR implementation is highly recommended, yet specific training should be provided, and the subsequent effect on adoption rates by all users must be evaluated (particularly physicians). The COVID-19 Pandemic showed the great value of EHR in accessing information and consulting patients remotely.

KEYWORDS

electronic health records, electronic medical records, information systems, computer records, EHR systems, GCC

Background

Continuity of patient care and overall healthcare safety are strongly associated with reliable medical records. Traditionally, medical records have used paper-based systems to record relevant details such as treatment and outcomes. However, in recent years, medical organisations are increasingly turning to computerisation for managing the plethora of data surrounding each patient entering the health system. The electronic health record (EHR) is a promising tool for enhancing national and international healthcare, particularly primary care delivery (1). An EHR can be defined as an application environment that captures the individual clinical data of patients, is linked to a clinical decision support system, and allows computerised order entry and clinical documentation applications (2). Electronic health records were initially developed and used at academic medical facilities, but many leading providers in the health industry are implementing computerised clinical record systems to manage the huge volume of clinical, administrative, and regulatory information that occurs in contemporary health care (3). The COVID-19 Pandemic and the need for virtual care demonstrated how essential EHRs are in delivering effective care remotely in both primary and hospital care settings.

Introducing any new information technology system into an organisation leads to changes in processes and workflows, which can lead to user dissatisfaction as they encounter teething problems in the system, bugs, or even simple annoyance at the requirement to learn a new way of doing things (4). Although EHRs are gradually entering widespread use within the Arabian Gulf, their impact on physician attitudes and the patient-doctor relationship remains to be determined. A previous systematic review has examined the impact of EHRs on patient-physician communication, finding no significant change in patient satisfaction or patient-doctor communication (5). However, this work focused on Western (Europe, United States, Australia) medical facilities; thus, the relevance to the culturally differing healthcare systems of the Gulf countries is still to be seen.

To shed light on this field, this systematic literature review seeks to understand the impact of EHR use on patient-doctor relationships and communication in the Gulf Cooperation Council (GCC) countries.

Methods

Search strategy

A systematic review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) standards.

It was performed based on the methods of Alkureishi et al. (5). This study conducted a systematic electronic search of the English literature in Ovid MEDLINE, HMIC (Health Management Information Consortium), Eastern Mediterranean Index Medicus (IMEMR), Global Health, and APA PsycINFO between December 2021 and Sep 2023, with no date limit. Moreover, cited references searching of prior reviews and a manual search were performed with Scopus, Google Scholar, PubMed and The Cochrane Library.

The search on all databases was ((“electronic w/1 record”) OR (“EMR system”) OR (“computer w/1 record”) OR (“Medical Records Systems, Computerized”)) AND ((“middle AND east”) OR (“gulf AND cooperation AND council”) OR (“GCC”) OR (“KSA”) OR (“UAE”) OR (“saudi AND arabia”) OR (“Oman”) OR (“Bahrain”) OR (“Qatar”) OR (“Kuwait”) OR (“united AND arab AND emirates”) OR (“arab AND states”)).

The systematic search included all relevant studies by exploring Medical Subject Heading (MeSH) terms and keywords related to electronic health records and doctor-patient communication and relationship. The selection of search terms was performed in consultation with a biomedical librarian.

To explore publication bias and mirror Alkureishi et al. (5), unpublished studies were searched for in past meeting abstracts of the Society of General Internal Medicine, the American Academy of Family Physicians, the International Conference on Communication in Healthcare and the European Association of Communication in Healthcare.

Only studies related to EHR use, and face-to-face patient-doctor communication or relationship were included; editorials and commentaries were excluded. All study designs, and all patient populations were included, but the search was restricted to studies on the six Gulf countries (Bahrain, Kuwait, Oman, Saudi Arabia, United Arab Emirates). Studies exclusively reported physician attitudes, perceptions, and other interactions, but face-to-face patient-doctor relations (i.e., remote online access) were discarded.

Study selection

After duplicate removal, title and abstract screening were performed by the author and an independent reviewer. When titles or abstracts were unclear, they were included in full-text screening, followed by a second independent review. Quality assessment of the final selection was performed using the Newcastle-Ottawa Scale (NOS).

Data synthesis and analysis

Studies were compared by the study population, design and outcomes and sorted according to the data collection method. They were then organised in a data extraction table. Initial codes relating to the research question were generated to capture the ideas from the studies. Themes were defined from recurring patterns that provided insights into the effects of EHR implementation on patient-doctor interactions.

The data collected did not allow for a meta-analysis due to the heterogeneity in interventions, methodology, and outcomes of the studies included. Thus, a narrative synthesis was conducted.

The initial search provided a total of 94 studies. From these, 93 studies remained for screening following the removal of duplicates.

Manual search and backward reference screening produced a further 7 items. Seventy studies were excluded in an initial assessment (e.g., references lacking an abstract or unrelated to health). A detailed analysis of the remaining 30 studies was performed. As part of this detailed analysis, 15 studies were excluded as irrelevant to electronic health records or not presenting a doctor-patient relationship outcome. The 18 remaining studies were then included. An overview of this process is shown in **Figure 1**.

Data availability

The data supporting this systematic review are from previously reported studies and datasets. Details of the publications used in this systematic review are included in **Table 1**.

Results

Figure 1 shows the number of studies identified, excluded (duplication, not EHR-focused), and selected with the criteria for the systematic review. This process generated 18 eligible articles.

Study characteristics

A summary of the results found for each of the 18 articles is provided in **Table 1** (6–24). The articles that met the inclusion criteria were assessed to determine the characteristics and effect of EHR implementation in GCC countries, including a summary of the study features such as information on doctor communication, quality of care, medication error, data retrieval and waiting time. The Newcastle-Ottawa Scale (NOS) was applied for quality assessment, as shown in **Table 2**. Publication dates ranged from 1992 to 2021. The number of participants in each study varied from 23 to 700, including male and female healthcare workers.

Effect of EMR on quality of care

Almost two-thirds of the studies (72%) found that EHR improves the quality of care for patients, noting that retrieval and entry of patient information is more straightforward and more accurate, access to the system is efficient, and the presence of an EHR reduces medical errors and enhances work productivity (6, 7, 10, 14, 16, 18–24) and comfort while entering the data through typing instead of writing (14). This general finding supports the previously shown positive impact of advanced technology in the healthcare sector and supports the desire of GCC healthcare providers to adopt paperless systems (10, 17). Nevertheless, lack of reliability or completeness of data (13, 15) and gaps in users' computer skills (15, 17) are also reported.

Effect of EHR on doctor-patient relations

The disadvantages of EHRs listed in the assessed publications included concerns about confidentiality (6, 11), general underutilisation of the system (6, 7), and a need for applicable or flexible disease coding (6). In Kuwait (7, 9), the participants disliked the requirement for physicians to work with the

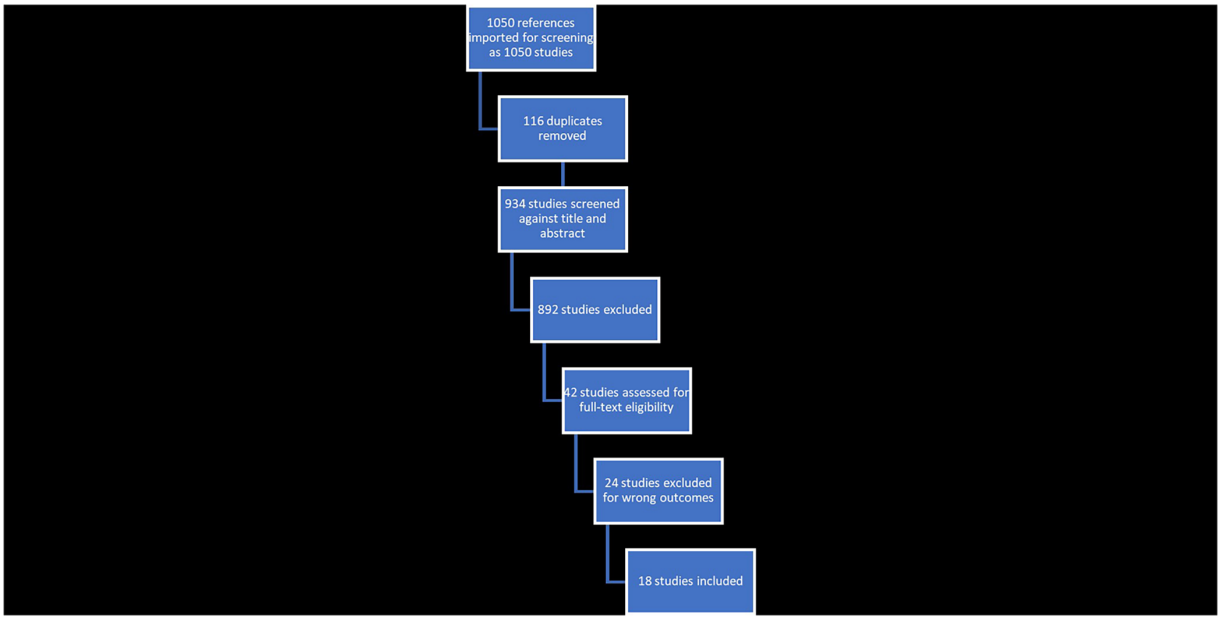

FIGURE 1
Exported PRISMA data from covidence.

TABLE 1 Summary of the studies extracted that show the relationship between doctors and patients when using the EMRs.

Date/ Author	Title	Methodology	Primary outcomes	Secondary outcome
1-Al Farsi (6)	Use of Electronic Medical Records in Oman and Physician Satisfaction	Nonexperimental "survey" research, Included 70 physicians Age of physician is from 30 to 65 years. Included both female and Male physicians.	EMR improves the communication between department in 95% Improves the quality care of patient (85%); Retrieval and entry of patient information is accurate and easy way (80%) Access to the system is easy and available (70%) Reduces medical errors (67%) Enhances the productivity (59%).	80% agreed the EMR system required increased confidentiality. The EMR system is underutilized (75% of physicians agree); hospital is still using a paper system in some departments (74%); Disease coding represents a major problem (70%); The EMR system is time consuming (67% agree); Speed of the system is too slow (60%). Participants' feedback: Each doctor receives a specific access password that changes periodically. // Train and advise staff on the requirements of patient // Information privacy and encourage their input on how protection should be developed.
2-Al-Azmi et al. (7)	Patients' Satisfaction with Primary Heath Care in Kuwait After Electronic Medical Record Implementation	Descriptive cross-sectional A random sample of 200 people (at age of 18 years and above) Structured questionnaire Exit interview (47.5%) were males and 52.5% were females	81.5% of them agreed that EMRS improved the physician performance. System helped to improve not only arrangement of patient's turn (93.0%), but dispense medication from pharmacy (92.0%) Improved accuracy and easiness of follow up for health status was 89.5% System improved time spent to retrieve medical record (78.5%) and that for receiving medication (82.0%).	Physician selection or waiting time. The system did not achieve much improvement in physician selection (29.5%) or waiting time (25.5%). 13.2% of the participants did not like physician's handling of computers in the examination room as this decreases his attention and communication.
3-Al-Mujaini et al. (8)	Satisfaction And Perceived Quality of An EMR System in A Tertiary Hospital in Oman	A cross-sectional survey including 200 physicians in Oman over 6 months. Response rate was 70.5% (141/200) Of the 141 respondents; 55 (39%) were consultants, 28 (19.9%) were registrars and 21 (14.9%) were senior house officers (SHO). Eighty-one (57.4%) participants were males. The majority of the participants were in the third to fourth decade of age.	(15.4%) Respondents rated the EMR to be a success in improving their work in terms of quality, performance, and timelines Factors affecting poor ratings: (OR = 1.3 95% 0.2 7.3) not working with patients (15.6%) rated the current EMR system as an effective tool.	29.4% of respondents considered EMR not worth the time and effort required to use it. In our study, the low satisfaction associated with junior designations and respondents with low familiarity with computers may be related to this fact (67.4%) Reported increasing difficulty with the performance of work after applying the EMR system. The overall quality of work was perceived not to have changed (41.2% of the respondents) or declined (27.4% of the respondents). 60% of users still resorted to paper records for some tasks not supported by EMR, such tasks included statistics, codification, and patient transfers between institutions. difficulty in transferring older paper-based records to the EMR system, issues based on long-term preservation and storage of data, as well as how to ensure the physical and virtual security of the archives, software problems of codification (standards that help to ensure that clinical information input and retrieval are not arbitrary), and customization (system adapted for the users and tailored to workflows specific to a user site) (68.1%) had prior training on the use of the EMR system
4-Al-Jafar (9)	Exploring Patient Satisfaction Before and After Electronic Health Record (EHR) Implementation: The Kuwait Experience	A random sampling 700 subjects The majority of participants (67 percent) were 19 to 34 years of age.	EHRs increase trust in doctors 27% Doctor pays more attention to typing, and EHRs increase trust in physicians) varied from 36 to 50 percent EHRs affect relationship with doctors 27%	At visit, doctor pays more attention to typing 17%
5-Al-Rowibah et al. (10)	The Impact of Computerized Physician Order Entry on Medication Errors and Adverse Drug Events.	Cross-sectional research design at the King Fahad Medical City Hospital (KFMCH) of the Kingdom of Saudi Arabia (KSA). 93 physicians	88% of the physicians agreed that the use of CPOE improved their performance 76% reported that the use of CPOE increased their productivity 56% of the participants agreed that CPOE was a simple system 64% reported that it was easy to use.	44 percent of the physicians agreed that CPOE lacked a user guide during medication ordering

(*Continued*)

TABLE 1 Continued

Date/ Author	Title	Methodology	Primary outcomes	Secondary outcome
6-Al Alawi et al. (11)	Physician User Satisfaction with an Electronic Medical Records System in Primary Healthcare Centres in Al Ain: A Qualitative Study	A total of 23 physicians—focus groups A descriptive qualitative study conducted in primary healthcare centres (PHC) in Al Ain, United Arab Emirates (UAE).	Physicians expressed satisfaction with the orders and results of laboratory and radiology functions Physicians satisfied with the electronic prescription function, stating that it reduced errors and saved time. Physicians' perceptions about patient reaction were mixed. unhappy because of the disturbed patient–doctors' relationship waiting time increased due to data entry causing more frustration to the patients. Difficulty in use at the beginning ▶ Training was sufficient and good Past computer skills ▶ Different users' generations with different, computer skills The impression about the pre-completed notes ▶ Precompleted notes definitely saves time Doctor–patient relationship • No eye contact • Waiting time is more • Patients are accepting the system because it is reflecting an advance modern of technology. Many physicians were concerned about their patients' perception about the new technology. They felt that many patients were unhappy but indicated that few patients approved and made positive remarks to their physicians.	The impression about the pre-completed notes and no eye contact Many physicians were pleased about the orders and results of laboratory and radiology as they emphasised that this is the strongest point in the EMR system. Participants identified the messaging system within the EMR software as a practical, useful, and important tool for enhancing efficiency within the team. Major barriers to implementation and adoption included computer literacy, training, and time. Participants mentioned the loss of confidentiality in the patient's files, because anybody who has access could open any file.
7-Alasmary et al. (12)	The Training on Clinical Productivity and User Satisfaction In Using The Electronic Medical Record In Saudi Arabia	123 physicians and nurses A cross-sectional study design	Self-reported system productivity and satisfaction was statistically correlated at $p < 0.01$ ($R = 0.509$)	?
8-Alharthi et al. (13)	Physician Satisfaction with Electronic Medical Records in a Major Saudi Government Hospital	220 physicians—115 included 71% were male, 64% were Saudi, Cross-sectional analytical observational study Average age was 39.8 years. Government hospital in the Eastern Province, Kingdom of Saudi Arabia The tool used to collect the data was a self-administered survey based on the DeLone and McLean model	Only 40% were satisfied with the system; furthermore, 61% were willing to totally abandon the system and go back to paper records. Of the physicians surveyed, 90%wanted to change the system, and 70% of those who did not want to go back to a paper system wanted to change this system. 60%of the physicians agreed with Information is accurate", "relevant" About 50% agreed with the statements "features allow me to perform my work well" and "the performance of the system is reliable" "system easy to use" and "security is acceptable", were satisfactory to about 65% Fewer than half of the respondents agreed "the system is fast" and "the system is integrated with my workflow".	Only 48% of the system was integrated well with their workflow The physicians in our study might also have been experienced computer users but expected more sophisticated training. Additionally, only half found that the system support was acceptable. The screen layout was acceptable to 62% of the physicians, who considered that information was presented in a suitable format. The physicians were not satisfied with the completeness or accuracy of the information: only 45% reported that the information was complete and 64% that it was accurate. The system was considered easy to use by 64% of the physicians, a finding similar to those of other studies. 58% of the physicians were dissatisfied with the speed of the system, reporting that it took a long time to move between screens and that the system was slow to start up.
9-Shaker et al. (14)	Physicians' Perception About EMR System in Makkah Region, Saudi Arabia	Cross-sectional survey 317 completed questionnaires, Age group 36–45 years Subjects were from King Fahd Hospital	Improved quality of practice was appreciated by majority, that is, 77.7% "EMRS improve quality of practice (work life)" 71.2%,	"It does not disrupt the workflow" (35.1%) "EMRS is comfortable while entering the data instead of writing" (34.8%)
10-Bani-Issa et al. (15)	Satisfaction Of Health-Care Providers with EMR And Perceived Barriers To Its Implementation In The United Arab Emirates	A cross-sectional survey of 680 health-care providers	Of the 680 participants, a total of 317 (46.6%) expressed high levels of satisfaction with the EHR system	A lack of trust in the system's reliability Inadequate computer skills and inadequate training

(*Continued*)

TABLE 1 Continued

Date/ Author	Title	Methodology	Primary outcomes	Secondary outcome
11-Alsohime et al. (16)	Satisfaction And Perceived Usefulness with Newly Implemented Electronic Health Records System Among Paediatricians At A University Hospital	A cross-sectional survey [112 physicians who completed the survey, 97 (86.6%) attended training courses before the implementation of new HER] distributed to all physicians working in the paediatric department of King Saud University Medical City (KSUMC)	The participants rated the perceived usefulness of the new system at 6.4/10 for patient care and physicians' satisfaction levels were 5.2/10. The top indicator of HER usefulness was the system's ability to reduce errors and improve the quality of care [mean 3.31, SD 0.9, RII 82.8%]; The top indicator of satisfaction with the HER system was enhanced "individual performance" [mean 3.04, SD 1, RII 60.9%];	This study revealed that higher level of satisfaction was associated with the perceived positive effect of HER on individual performance and patient care. The results of this study are provided a "pediatricformatics" insight to establish specialized children hospital and similar forms of integrated paediatric health care services. Academic centres might face other difficulties in implementing HER, due to the involvement of medical students, interns, and residents in the clinic care
12-Al-Hashimi et al. (17)	The Potential For Medical Informatics In The Eastern Mediterranean Region	A feasibility study questionnaire done in December 1989 at Salmaniya Medical Centre (SMC) in the state of Bahrain.	Opinions about the current information system. Twelve of the physicians (22.2%) indicated that 30% of their time is spent on daily charting and paperwork. Knowledge about computer usage. Only 17 physicians (32.1%) had worked with computers before. Most of the physicians either "strongly agree" or "agree" (46/86.8%) that computerization will make some of the physician's duties easier Ranking of the priority of certain tasks to be computerized. The majority of the physicians ranked generating clinical reports not less than an 80% priority (38/74.5%).	Based on this study, the HIS experience in Bahrain will be different from the experience in the United States due to some factors: (a) the health care system in Bahrain is centrally organized under the Ministry of Health, b) the majority of physicians in Bahrain support the idea of HIS, based on the idea that the system will help them to optimize patient care and save time c) the majority of physicians feel that they are under pressure from increased patient flow and limited bed capacity, d) the majority of physicians believe that there is a need for more specialized physicians. One final contrast between this evidence from Bahrain and the United States is that the acceptance and diffusion of HIS among physicians in the United States was slow from the start.
13-Khalifa (18)	Perceived Benefits of Implementing And Using Hospital Information Systems And Electronic Medical Records	The study used quantitative survey methods through a questionnaire to collect data and information directly from different categories of healthcare professionals of four Saudi hospitals. Data was collected with 153 valid responses out of 300 selected participants	Participants overall agree that there is a lot of benefit from using Hospital Information system and Electronic medical records (the mean was 4.18) Participants strongly agree that the HIS and EMR improve the information access (mean was 4.49) Participants strongly agree that the HIS and EMR Increased healthcare professional Productivity (mean was 4.31) Participants strongly agree that the HIS and EMR improved efficiency and accuracy of coding and billing (mean was 4.30) Participants strongly agree that the HIS and EMR improved quality of healthcare (mean was 4.27) Participants strongly agree that the HIS and EMR Improved clinical management (mean was 4.22)	HIS and EMR can also decrease costs of some services such as medical transcription and reporting, making the work of healthcare professionals more productive.
14-Saddik and Al-Fridan (19)	Physicians' Satisfaction with Computerised Physician Order Entry (CPOE) At the National Guard Health Affairs: A Preliminary Study	A survey was developed measuring physician satisfactions with CPOE on Likert scale.	85% of the physician perceived that the CPOE reduced patient care errors and that the order system easy to use. 50% of physician reported a positive and negative perception that Laboratory data retrieval is fast. 60% of the physician stated that they were satisfied with order entry system.	The study shoes that COPE characteristics were strongly correlated to physician satisfaction efficiency and quality of care.
15-Wali (20)	Patient Satisfaction with The Implementation of Electronic Medical Records In The Western Region, Saudi Arabia, 2018	A cross-sectional survey was conducted to explore patient satisfaction with the EMR compared to the previous PMR in 2018 in PHCs in Jeddah, KSA. The setting was the waiting areas in the PHCs, all are satellite clinics of King Abdulaziz	physician's attention to the patient during the consultation improved from 77% ($n = 291$) to 82.3% ($n = 314$) with the implementation of EMR and the physician's explanation of the reasons for ordering tests and medication improved from 80.7% ($n = 302$) to 85.8% ($n = 325$). The time spent with the patient during the consultation also improved from 73.8% ($n = 279$) to 80.4% ($n = 303$) and active listening improved from 73.5% ($n = 278$) to 77.3% ($n = 289$). Patients feeling that the physician is more	This study showed positive participant's perception about primary health care services after implementation of the EMR in all of the aspects; it improved information access, health care professional productivity, quality of provided health care, and overall patient satisfaction, overall physician-patient relationship improved with the implementation of EMR, as well as the total waiting time and the overall quality of

(*Continued*)

TABLE 1 Continued

Date/ Author	Title	Methodology	Primary outcomes	Secondary outcome
		Medical City in the Western Region, including Jeddah, Makkah, and Taif. The study was conducted over 6 months, from July 10 to December 31, 2018. The centers are Bahra, the Specialized Polyclinic, King Faisal Residential City Clinic in Jeddah, Sharia Primary Healthcare Clinic in Makkah, and King Khalid Residential City Clinic in Taif. 377 participants	interested in the medical records improved from 44.1% ($n = 166$) to 57.5% ($n = 218$) majority agreed that the implementation of the EMR improved the physician-patient relationship in general and reduced the waiting time (63.9%, $n = 242$). The majority (81.6%) also agreed that the services provided by the PHC improved with the implementation of EMR; specifically, more efficient prescription dispensing (80%, $n = 304$), improved appointment booking (80.6%, $n = 304$) and an improved referral system (76.1%, $n = 287$)	services, the appointment booking time, and referral system.
16-Karim Jabali (21)	Predictors Of Anaesthesiologists' Attitude Toward Ehrs in Saudi Arabia For Clinical Practice	Cross-sectional study, carried out in Saudi Arabia during March–June 2020 comprehensive questionnaire about the adoption and perception of EHRs. 67 anaesthesiologists/ physician responses	About 88% of respondents strongly agree or agree that EHRs positively changed their working clinical experience. EHRs are positively affecting healthcare cost, quality of care, communication, patient satisfaction, efficiency of practice and occurrence of medical errors. However, the respondents are about evenly divided regarding the burnout because of the use of EHRs. More than 75%– 100% agree that the given features are either very easy or at least easy to use. The small deviation from the 'near consensus' is seen in the answers about the continuity of care (67%) and analysis of care results (69%) which is not a bad result in general at least 67% agreement regarding the consistency of monitored and recorded clinical details and suitability of documentation features, while the screens and layouts of pages and other web-based tools found an agreement of 69%.	The above results show that the young generations of specialists (86%) are more adaptable to change and accept the EHRs even if the experience they have is less than three years. the need for integrating some EHRs related training in the curriculum of medical schools is of paramount importance
17-AlSadrah, Sana (22)	Electronic Medical Records and Health Care Promotion in Saudi Arabia	In this literature review, the author focused on the benefits of widespread adoption of EMRs in Saudi Arabia, the perceptions of health care professionals, and the challenges and barriers toward improved implementation of this technology.	The ease of communication is another major advantage when health care professionals can communicate with patients through email, fax, and phone.18 important for clinical investigations, but for evaluating health care policies and informing stakeholders about approaches to improve access to high-quality health care.25 Other advantages related to accessibility and management include management and records of patient referrals, allowing health care professionals, even when out of the hospital, to access patient health records, allowing patients to access parts of their health records and providing data backup and disaster recovery.2	Recommendations are related to improving the communication between different health care personnel as well as between physicians and their patients. Ensuring the possibility of short message service (SMS) or email communication is a must. This can be achieved by providing quality Internet connection to hospitals and other healthcare delivery facilities, improving patients' awareness about the value of online communication with their health care provider, and increasing physicians' computer literacy.39 Physicians should also be able to customize their preferred, easy-to-use EMR interface and should be able to select the optimal tools to achieve effective communications with their patients.40 A literature review summarized the barriers of EHRs by physicians and classified them into 8 main categories. These categories included technical, financial, psychological, social, legal, time, organizational, and change processes. In short, the main highlighted barriers across the eight categories were probable security breaches, loss of access to data upon computer crashes or power failures, the time needed to enter data and check their quality, the complexity of the technology (especially among personnel with poor English language and computer skills), the potential to disturb physician-patient communication, and the lack of system customization for all hospital needs. Other barriers were concerned about the lack of continuous support from IT staff in hospitals

(*Continued*)

TABLE 1 Continued

Date/ Author	Title	Methodology	Primary outcomes	Secondary outcome
				and poor training of health care personnel in the use of EMR.
18-Koutzam-pasopoulou Xanthidou (23)	Electronic Medical Records in Greece and Oman: A Professional's Evaluation Of Structure And Value	The study took place in the natural setting of the medical units' environments. A purposive sample of 40 professionals in Greece and Oman, was interviewed.	Some believe that religion should be included in the patient's record to help understand the patient's habits and, possibly, culture that affect an individual's health condition while others find such an idea highly disputable, to say the least, pointing to the discrimination practices that it might lead to. Likewise, with the cases of a person's nationality, language, and religion; some find the idea of their inclusion to the EMR useful or even essential while others find it unacceptable. Category of 'eating habits' or 'life style'—MD could provide better health care to the patients and avoid mistakes that are related to the elimination of the effects of a medicine because of these behaviors. The race, education level and the language are important because they may assist in communicating with the patient."	The study suggests that: (1) The demographics of the EMR should be divided in categories, not all of them accessible and/or visible by all; (2) The EMR system should follow an open architecture so that more categories and subcategories can be added as needed and following a possible business plan (ERD is suggested); (3) The EMR should be implemented gradually bearing in mind both medical and financial concerns; (4) Sharing should be a patient's decision as the owner of the record. Reaching a certain level of maturity of its implementation and utilization, it is useful to seek the professionals' assessment on the structure and value of such a system.

computer in the examination room. In Al Alawi's study in the United Arab Emirates (UAE), this behaviour was perceived as reduced attention and communication, lack of eye contact and added overall waiting time (11). Increasing difficulty with work performance after applying the EHR system has also been reported (8). For example, it has been mentioned that the system was inadequate (24), slow (6, 19) or lacked a user guide during medication ordering (10).

Discussion

This review investigates the impact of EHR systems on the relationship between doctors and patients in the Gulf countries. Our results showed that the EHR facilitates the development of an environment in which all relevant patient clinical data is captured, which in turn helps doctors to make decisions that directly influence patient outcomes. Furthermore, in agreement with other literature, it has been observed that EHR facilitates communication between patients and doctors (5, 25). The enhanced communication between patients and doctors improves the overall quality of care delivery in healthcare settings, especially in the physician-focused healthcare systems in Gulf countries.

However, it has been observed that some patients would like more satisfaction with respect to the implementation of EHR in the healthcare setting. There is a sense that doctors shift attention away from their patients and towards the recording of their entries. Therefore, patients feel dissatisfied, feeling doctors require more time for "data entry" than they do to assess the presenting patient.

Implementation of EHR was described as improving the transmission of accurate and reliable patient information, reducing chances of medication errors and "lost files". Furthermore, it was observed that the use of EHR improves the ability of physicians to note relevant information at the time of consultation rapidly. This, in turn, allows them to invest more time in decisions relating to medication and treatment, thereby improving the quality of care delivered to the patients. Despite this, it should also be noted that the implementation of EHR leads to large changes in physician workflow and processes, which may lead to increased errors during this transition period and thus adversely affect patient outcomes. As revealed in this study, the introduction of EHR systems brings about significant changes in the daily routines of healthcare professionals. These transitional challenges may contribute to a temporary increase in errors during the initial stages of implementation, necessitating the need for comprehensive change management strategies. It is imperative that healthcare organisations pay close attention to mitigating these disruptions to maintain the quality of patient care.

Furthermore, it is noteworthy that while EHRs are demonstrated to enhance healthcare delivery in the Gulf countries overall, there exists a divergence in perspectives between healthcare providers and patients. Physicians often perceive the benefits of EHRs, such as improved data accuracy and efficiency. However, patients may feel that these systems lead to reduced attention from their doctors, lack of eye contact, and extended waiting times. Addressing this disparity in perceptions through comprehensive education and transparent communication is pivotal to ensuring that the full potential of EHR systems is realised while simultaneously upholding patient satisfaction and trust in the healthcare system.

These behavioural outcomes are generally consistent with those previously observed in systematic Western healthcare facility reviews (5, 25–29). Similarities to this study include that effective communication of the benefits of EHRs to patients needed to be improved, leading to a general impression that physicians were spending more time on their computers than with the patients themselves. But that, nonetheless, led to enhanced surveillance and monitoring and decreased medication errors. Hence, it may

TABLE 2 The New-Ottawa scale (NOS).

NOS criteria	Studies (year)																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
	Al-Farsi (6)	Al-Azmi et al. (7)	Al-Mujaini et al. (8)	Al-Jafar (9)	Al-Rowibah et al. (10)	Al Alawi et al. (11)	Alasmary et al. (12)	Alharthi et al. (13)	Shaker et al. (14)	Bani-Issa et al. (15)	Alsohime et al. (16)	Al-Hashimi et al. (17)	Khalifa (18)	Saddik and Al-Fridan (19)	Wali, R. M. 2020	Jabali, A Karim 2021	AlSadrah, Sana A et al, 2020	Xanthidou, Ourania 2018
A. Selection (maximum of four points)																		
1. Representativeness of the exposed cohort	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2. Selection of the non-exposed cohort	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1
3. Ascertainment of exposure	1	1	0	0	0	0	0	1	1	1	1	0	0	1	0	1	1	0
4. Demonstration that outcome of interest was not present at start of study (no bone disease at start of study)	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	1
B. Comparability (maximum of two points)																		
1. Confounding factors	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
C. Outcome (maximum of three points)																		
1. Assessment of outcome	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2. Statistical	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Total (maximum of nine points)	7	7	6	5	6	5	6	7	7	7	7	6	5	6	6	7	7	6

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be generally agreed that the benefits of EHRs are not sufficiently communicated to all stakeholders. Even though all the studies were of good quality according to the NOS, limitations of this study included a lack of data and publications from all Gulf countries on this topic. Future studies should tackle the EHR and patient-healthcare provider relationship to further explore the impact of digital transformation in health systems.

Recommendations

Through this review, it has been noted that there needs to be more computer skills and trust in the EHR system, which leads to problems in effective implementation. This, in turn, hampers the potential relationship between doctors and patients in Gulf countries. The authors provide the following suggestions to ensure the effective implementation of EHR in healthcare settings of Gulf countries:

- Physicians should be provided with specific training on the EHR system being implemented, preferably paired with general computer training in medical school and during the early years of the residency programmes. This is essential considering the huge surge of artificial intelligence and efforts to digitalise health systems.
- Trust in the system itself should be built by openly communicating the objectives and advantages of an EHR system to physicians. In addition, the system implementation outcomes should also be communicated by doctors to patients. This will help to improve patient perspectives of the change and reduce overall dissatisfaction.

Conclusion

Implementing EHR systems is beneficial for effective care delivery by doctors in the Gulf countries. EHR assists doctors with recording patient details, including medication and treatment procedures, as well as their outcomes. Despite the patient's perception of decreased attention, EHR promotes and enhances healthcare delivery in the GCC. The EMR has the potential to be a key tool for improving continuity of care in the GCC by flagging up follow-up dates and tests, medications, and overall surveillance. Based on this study, the authors conclude that widespread EHR implementation is highly recommended. However, specific training should be provided, and all users' subsequent effects on adoption rates must be evaluated (particularly physicians). The COVID-19 pandemic showed the great value of EHR in accessing information and consulting patients remotely.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Author contributions

CT and MR collected data, performed the analysis, and wrote the paper. AA: wrote initial draft idea. SR reviewed the paper. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Electronic medical record systems data use in decision-making and associated factors among health managers at public primary health facilities, Dodoma region: a cross-sectional analytical study

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Background: Tanzania has shown some improvements in the adoption of electronic medical record (EMR) systems in public health facilities; however, the rate of utilization of data generated from EMRs among health managers is not well documented. This study aims to assess the use of electronic medical record systems data in decision-making among health managers at public primary health facilities in Dodoma Region, Central Tanzania.

Methods: A facility-based quantitative cross-sectional analytical study was conducted among 308 randomly selected health managers. A self-administered questionnaire supplemented with documentary review was used. Descriptive summary statistics and bivariable and multivariable logistic regression analyses (crude and adjusted odds ratios) were used. A *P*-value of <0.05 was used to declare statistically significant associations.

Results: Overall, more than a third (40.6%) of the health managers, that is 174 of the 308 included in the study, reported using data generated by EMR systems in decision-making. One-third (33.4%) of the health managers were adequately using data generated by EMR systems, of which 39.3% used data to support continuous quality improvement initiatives. Among the facilities visited, only nine (30%) had good documented EMR systems data use. Access to computers [adjusted odds ratio (AOR) = 4.72, 95% confidence interval (CI): 1.65, 13.48, *p*-value (*p*) = 0.004] and discussions on EMRs during meetings (AOR = 2.77, 95% CI: 1.01, 7.58, $p = 0.047$) were independent predictors of EMR system data use. Those who reported having EMR systems in all working areas were seven times more likely to use EMR system data (AOR = 7.23, 95% CI: 3.15, 16.59, $p = 0.001$). The respondents with good perceived EMR system information quality were more likely to use EMR system data (AOR = 2.84, 95% CI: 1.50, 5.39, $p = 0.001$) than those with poor perception. Furthermore, health managers who had excellent knowledge of computers and data use had higher odds of using EMR system data (AOR = 1.84, 95% CI: 3.38, 10.13, $p = 0.001$) compared with their counterparts.

Conclusions: The findings of this study indicate that utilization of EMR system data in decision-making among health managers was optimal. It was found that training in itself is insufficient to improve use of EMR, which points to more organizational

aspects of work routine as a challenge. Hence, a comprehensive approach that addresses these factors is essential for maximizing EMR system data use in decision-making.

KEYWORDS

electronic medical records, data use, decision-making, health managers, public primary health facilities, cross-sectional analytical study

1. Introduction

Electronic medical record (EMR) system, which is an integral part of the larger health management information system (HMIS), is a software that records health-related information of patients on computers. It is a program that collects, manages, and generates data that are used by authorized workers within health facilities. EMR systems provide substantial benefits to health facilities and organizations in patient management and are quickly replacing paper-based systems. They solve many of the limitations of paper-based systems and have proved to be cost-effective in improving the quality of health services (1). They improve the accessibility of health records as well as the quality and accuracy of patient information. Given these benefits, institutions have widely adopted EMR systems in healthcare globally (2).

Previously, all tasks related to the administration and management of patients, such as human resources, procurement, and clinical management, were managed using paper-based record-keeping systems, which proved to be inefficient in terms of information retrieval, security, and data quality and did not allow concurrent data access. However, paper-based systems are still used by health facilities largely because many facilities have not installed EMR systems and the health workers are more familiar with paper-based records due to the long-term use and the fact that they do not require a high level of technical knowledge and skills compared with the electronic systems (1).

An EMR system is a powerful tool for improving clinical and administrative/managerial decision-making by providing access to accurate and relevant information (3). It provides a comprehensive way to manage patients and streamline administrative tasks, and is one of the best healthcare analytics solutions as it collects and analyzes patient data to identify trends and patterns and develop predictive models (4). The increasing integration of highly diversified technologies in the healthcare field has resulted in the need for such an organized gathering of accurate data for informed decision-making in the health sector (5).

Globally there is an increasing volume of health-related data being generated, accelerating the trend towarddigitalization in health. However, there are persistent data gaps and fragmented approaches to the governance of health data in different contexts, which has contributed to inadequate data use (6). EMR systems have begun to be widely used in healthcare facilities worldwide as a data collection and aggregation tool (7). A systematic review of publications from 15 Sub-Saharan African countries revealed that about 91% reported the use of open-source healthcare software. However, the use of EMR systems in low-income countries remains in its initial stages (8, 9).

In developed countries like the USA, 94% of the hospitals use electronic health records (EHR) data in decision-making, such as for quality improvement (82%), monitoring patient safety (81%), and measuring organizational performance (77%). EHR data were least commonly used to develop approaches to query for patient data (51%), assess adherence to clinical practice guidelines (59%), and identify care gaps for specific patient populations (60%). While EHRs are used by multiple care providers and health organizations, hospital characteristics (public, private, rural, and urban) significantly impact the use of EMR data. However, there was substantial variation in the use of EHR data (10).

In Sub-Saharan Africa, a study conducted in a Malawian hospital revealed that utilization of EMR functionalities varied among departments as well as among users. Health facility workers used half of the system functions, and the most commonly used were capturing demographics (82.9%) and capturing and assessing clinical data (68.8%). These functions were frequently used because they applied to almost all the patients who visited the hospital. Gender, age, and previous computer use did not influence EMR systems usage. However, education and employment levels were predictors of EMR systems use (1).

In Tanzania, public health facilities use different EMR systems; some of the EMR systems used include the government of Tanzania hospital management information system (GoTHOMIS), Jeeva, Afya Care, and CTC2 database (11, 12). An EMR system is intended to improve and strengthen electronic data capture at the point of care to improve patient clinical care and facility management. The use of electronic data systems has led to improvements in the quality of health services delivery, including improvement in revenue collection, human resource management, supply chain management, health information management, and improved planning and decision-making at different levels of the health system (13, 14).

A study conducted in Tanzania on paper-based HMIS data use in decision-making revealed that about 56.9% of the facilities had functional HMIS, 18% of the facilities had used their data for planning and services improvement, 26.3% had disseminated data, and about 9.1% of the facilities had proper medical records. The level of the facility was associated with the use of data, with hospitals and health centers showing higher use (15). Another study (16) on paper-based data use in decision-making revealed that 60% of the respondents reported using HMIS data in decision-making, of which data was most used to compare service coverage (53%).

The government of Tanzania, through its fifth Health Sector Strategic Plan (HSSP V), has set the priority to improve the application of digital health technologies. The aim is to facilitate

the attainment of high-quality health services to all citizens. Despite this, very few health facilities have installed and made use of EMR systems as data gathering and aggregation tools. Expansion of the system to all government-owned facilities is a priority (14). Owing to the limited resources, most electronic systems are still being used side by side with paper documentation, which is creating a burden on the healthcare workers (2, 17).

HSSP V prioritizes the application of digital health technologies, including the use of EMR systems in public health facilities (14). The government, through support from implementing partners, started the development and implementation of comprehensive electronic medical record systems in 2015 (18). As of now, the AfyA Care and GoT-HoMIS have been approved for scale-up country wide (19). Currently, the GoT-HoMIS system has been deployed in 1,424 healthcare facilities (20). Despite EMR systems supporting data synthesis and visualizations, the use of EMR systems in decision-making in Tanzania is still inadequate (13, 21).

The increasing adoption of the EMR system in Tanzania as a data collection and aggregation tool should be implemented together with improvements in the capacity of health managers to harness its potential. The weakness in general managerial capacity of the health system has been cited as one of the contributory factors in failing to scale up effective health interventions. Hence, understanding how health facilities are currently using data generated by EMR systems in decision-making is important as one of the policy initiatives (14). A study (16) on paper-based systems revealed that 60% of health facility workers and 38.5% of district officials use routine health information for decision-making, with the majority using it in comparing service coverage and monitoring disease trends over time and health promotion activities.

In 2023, the government introduced a data use toolkit for the health sector that insists that the availability of timely, retrievable, and accessible quality data is a cornerstone of all health systems. The health facilities are advised to conduct regular data review meetings (weekly or monthly) to understand their data, identify challenges, and set action items to improve health services. The health facility management team (HMT) has a role in conducting data use review meetings, monitoring the use of data, ensuring evidence-based planning and documentation of data use activities, and increasing the capacity of health workers in data use skills. One of the data sources insisted on in this guideline is EMR systems such as GoT-HoMIS (22).

Despite large investments to support the adoption of EMR systems in Tanzania, so far limited studies have been conducted to give an insight into the acceptance and use of data generated by EMR systems in decision-making in the study area. Therefore, this study aims to fill the knowledge gap related to EMR data utilization in decision-making and its associated factors among health facility managers in the public primary health facilities in Dodoma Region, Central Tanzania.

1.1. Conceptual framework

In this study, the Performance of Routine Information System Management Series (PRISM) framework was conceptualized and adapted in establishing the association between the individual, organizational, behavioral, and technical factors related with EMR systems and the utilization of the systems data in decision-making. The PRISM framework was modified to include individual factors that can influence data use in decision-making, such as age, sex, work experience, level of education, and managerial experience.

Other determinants of data use in decision-making such as organizational (governance, planning, training, supervision, quality, promotion of culture of information, availability of resources), technical [complexity of reporting forms, health information system (HIS) design, computer software], and behavioral (level of knowledge of contents of EMRs, data quality checking skills, problem solving for HIS tasks, competence in HIS tasks, confidence) factors were adopted as per the original PRISM model (Figure 1).

The PRISM framework was adapted because it has been used by other scholars to study EMR system data use in Ethiopia (2) and Malawi (1).

2. Methods

2.1. Study design and setting

This is a facility-based cross-sectional analytical study design that uses a quantitative approach. This study was supplemented by document review to ascertain the existing EMR system data use practices in decision-making at the facility level. It was conducted in Dodoma Region, which is among the regions with an increasing trend in coverage of facilities utilizing EMR systems (18). Dodoma Region is one of the 31 administrative regions of Tanzania and it is located in Central Tanzania. It has a total of eight district councils. The region also has a total of 497 health facilities, including 26 hospitals, 69 health centers, and 402 dispensaries (23). Among the health facilities, 35 public primary health facilities have installed and use EMR systems, of which seven are district hospitals, 24 are health centers, and four are dispensaries (24).

2.2. Study participants

The study participants of this study were health facility managers randomly selected across 30 public primary health facilities with functional EMR systems. A sample size of 315 was estimated with an assumption of a 95% confidence interval, a 5% significance level, and a standard normal deviation of 1.96. The proportion of EMR utilization was set at 26.6% (2). A total of 308 health managers were eventually included in the data collection process. The eligibility criteria for participation were as follows: (1) position: health managers working in public primary health facilities with functional EMR systems, and (2) age: 18 years or older. The exclusion criteria included (1) not consenting to participate in the study, (2) using program-specific EMR systems such as CTC2 database, and (3) being on leave during the period of data collection.

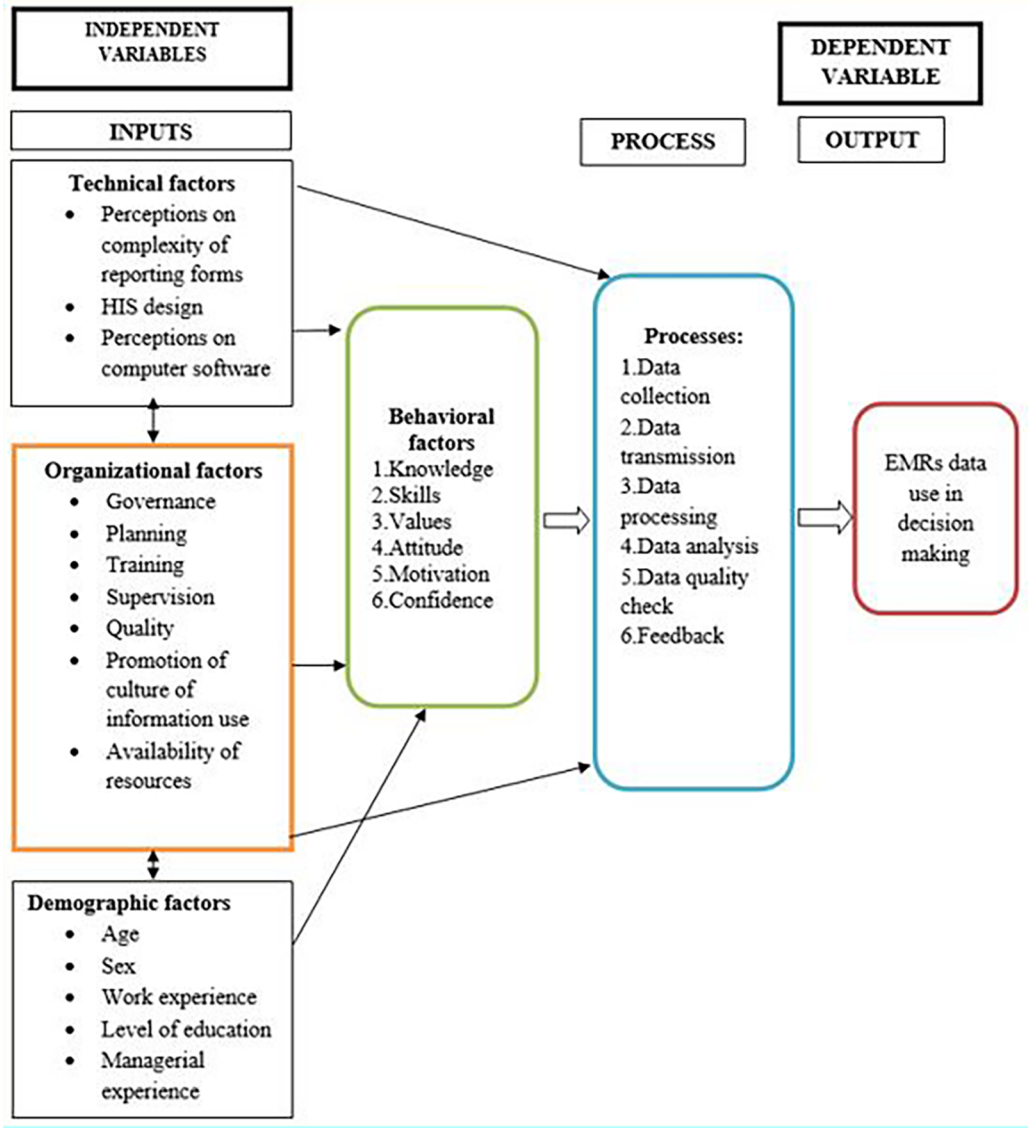

FIGURE 1
Conceptual framework. Source: Adapted and adjusted from literature review (2023).

A stratified sampling technique with proportionate allocation to each facility was employed. To recruit 315 participants from the selected facilities, Neyman's allocation formula as cited by Mathew (25) was used:

$$n_h = (N_h/N) \times n$$

where n_h is the sample size for stratum h, n is the total sample size, N_h is the population size per facility, and N is the total population.

Samples were distributed according to their respective strata (hospital, health centre, or dispensary). The sample size per facility, N_h, was determined by using the recommended number of HMT members, which for the hospital and health center is 14 members each and for the dispensary is nine members (26). Hence, the population of participants was sampled as shown (Figure 2).

2.3. Data collection methods

A structured self-administered questionnaire supplemented with documentary review was used to collect data on sociodemographic, organizational, behavioral, and technical factors as well as knowledge and attitudes regarding the use of EMRs. The tool was adapted from and constructed using PRISM (27) and was based on previous studies (2). The questionnaire was administered in English. Before administration, the questionnaire was designed using Kobo toolbox software, and diploma holder nurses were involved in administering the tool after 2 days of training.

A document review checklist was used to assess the existing EMR use in decision-making at the facility level over the past 6 months. The documents reviewed included HMT meeting minutes, commodity audit reports, commodity procurement

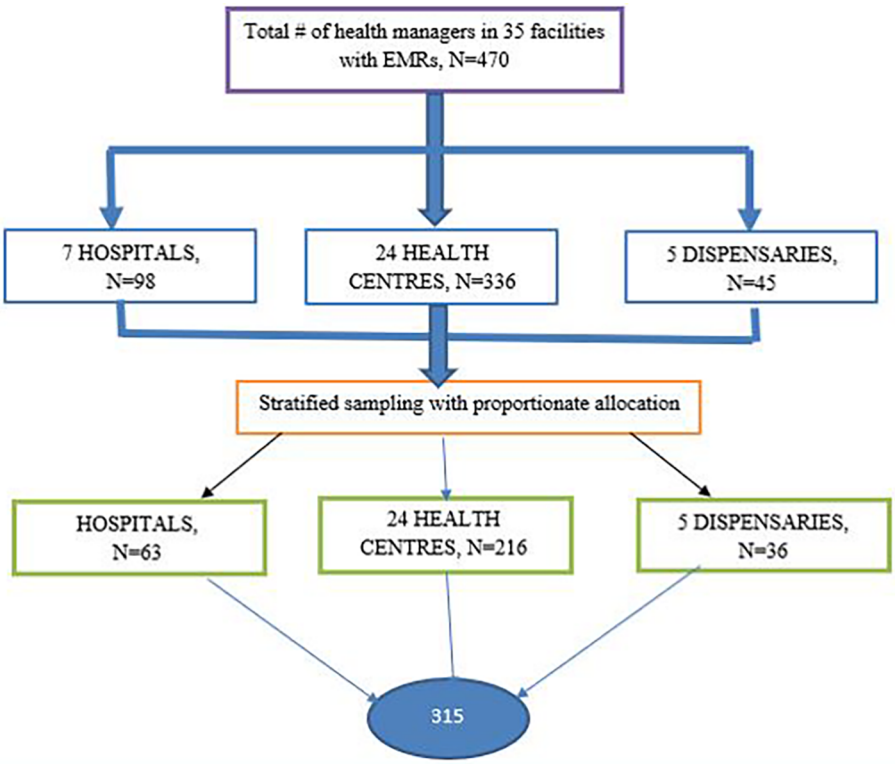

FIGURE 2
Schematic presentation of the sampling procedure for EMR system data use, Dodoma Region.

reports, and annual facility planning reports. To ensure good data quality and avoid problems of missing data, the recruitment team were trained for 2 days. The respondents who were absent during data collection were repeatedly visited to minimize the rate of high non-responses.

2.4. Variable measurements

2.4.1. Knowledge of computer and data use

This was assessed by using a 10 question score as follows: internet browsing, making calculations, sending email communication, managing the EMR database, checking accuracy of data, plotting data by months or years, computing trends from bar charts, explaining findings and their implications, using data for identifying gaps and setting targets, using data for making various decisions, and providing feedback. A mean score above or equal to 90 denoted excellent, 80–<90, very good, 60–<80, good, 50–<60, fair, and less than or equal to 50, poor (2).

2.4.2. Attitude

This was assessed by using eight questions that could be answered on a scale (strongly disagree, disagree, neutral, agree, strongly agree). Those who scored an aggregate of above 32 indicated a positive attitude (good), and those who scored below 32 were considered as having a negative attitude (bad) (2).

2.4.3. Perceived EMR system quality

This was assessed by using five questions that could be answered on a scale (strongly disagree, disagree, neutral, agree, strongly agree). Those who scored an aggregate score of above or equal to 20 indicated a positively perceived EMR system quality (good), and those who scored below 20 were considered as perceiving a negative EMR system quality (poor) (2).

2.4.4. Perceived EMR service quality

This was assessed by using nine questions that could be answered on a scale (strongly disagree, disagree, neutral, agree, strongly agree). Those who scored an aggregate score of above or equal to 36 indicated a positively perceived EMR service quality (good) and those who scored below 36 were considered as perceiving a negative EMR system service quality (poor) (2).

2.4.5. Perceived EMR information quality

This was assessed by using seven questions that could be answered on a scale (strongly disagree, disagree, neutral, agree, strongly agree). Those who scored an aggregate score of above or equal to 28 indicated a positively perceived EMR information quality (good) and those who scored below 28 were considered as perceiving a negative EMR system information quality (bad) (2).

2.4.6. EMR use in decision-making (health manager)

This was defined as having ever used EMR system data in decision-making, and the extent of use was assessed by a question with 10 items on the participants use of the EMR to perform one or more of the following clinical and administrative/managerial functions: (1) support quality improvement (QIT), (2) assess adherence to clinical practice guidelines, (3) create a dashboard with measures of organizational performance (e.g., revenue collection), (4) identify high risk patients, (5) create individual provider performance profiles, (6) create dashboards with unit performance (e.g., trend in revenue collection), (7) generate reports to inform strategic planning, (8) identify care gaps for patients, (9) assess adherence to guidelines, (10) create an approach for clinicians to query for data (10). A mean score above 5 denoted adequate data use, and a mean score below 5denoted inadequate data use.

2.5. Data analysis

Data analysis was conducted by using the statistical software SPSS version 25. All filled out questionnaires were carefully reviewed by the data collectors for clarity and completeness. Data were coded, and data cleaning was performed before entry into the SPSS software. For this study, we conducted two main analyses corresponding to our objectives. The first was a descriptive analysis, to describe the proportion of study participants and the proportion of facilities using EMR data in decision-making. The aim of the second analysis was to determine the associations between technical, behavioral, organizational, technical, and demographic factors and EMR data use in decision-making by using bivariable and multivariable logistic regression analyses. All variables were subjected to chi-square test and then predictor variables with outcome at a p-value below 0.2 were considered for the logistic regression analyses. All statistics with a P-value < 0.05 were regarded as significant.

3. Results

3.1. Sociodemographic characteristics of study participants

A total of 308 health managers from different categories and educational levels out of 315 sampled participants with a mean age of 33 years were interviewed. The majority (53.9%) of the respondents were men. Among the study participants, 118 (38.3%) were aged less than 30 years, 141 (45.8%) were aged 30–40 years, and 49 (15.9%) were aged 40 years and above. In addition, 75 (24%) had attended undergraduate degrees. Approximately 39.9% of the study participants had work experience of more than 6 years. In addition, most of the respondents (42.9%) were nurses compared with other professions (Table 1). However, the majority 204 (66.2%) of the facility health managers were from health centers, and only 33 (11%) were from dispensaries (Figure 3).

TABLE 1 Distribution of social demographic characteristics of study respondents ($n = 308$).

Variable	Category	Frequency	Percentages (%)
Study site	Dodoma CC	39	12.7
	Kongwa DC	55	17.9
	Chamwino DC	84	27.3
	Kondoa TC	44	14.3
	Kondoa DC	28	9.1
	Bahi DC	12	3.9
	Chemba DC	46	14.9
Residence	Urban	146	47.4
	Rural	162	52.6
Sex	Male	166	53.9
	Female	142	46.1
Age (years)	≤29	118	38.3
	30–40	141	45.8
	≥40	49	15.9
Education	Certificate	64	20.8
	Diploma	169	54.9
	Degree and above	75	24.4
Profession	General practitioners	70	22.7
	Nurse/midwives	132	42.9
	Medical laboratory	26	8.4
	Pharmacists	28	9.1
	Others*	52	16.9
Managerial position	Facility incharge	31	10.1
	Matron/patron	31	10.1
	Pharmacy incharge	31	10.1
	Laboratory incharge	30	9.7
	Facility accountant	19	6.2
	Health secretary	5	1.6
	OPD incharge	31	10.1
	HMIS focal person	17	5.5
	Others*	113	36.6
Work experience	≤6 years	185	60.1
	>6 years	123	39.9
Administrative experience	≤1 year	92	29.9
	>I year	216	70.1

*Other cadres (laboratory staff, radiology staff, accountants, health secretary).

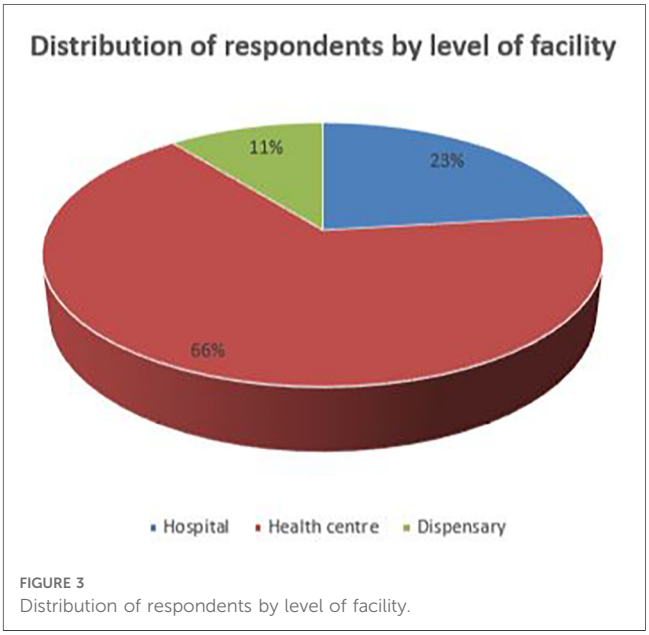

FIGURE 3
Distribution of respondents by level of facility.

3.2. EMR system data use practices in decision-making among health managers

EMR use in decision-making among health managers was measured if a participant reported use of the EMR data in decision-making and clarified the purpose of EMR data use. The majority of the participants, 174 (56.5%), reported that they currently used EMR in their facility, and 128 (73.6%) used it on a daily basis. Approximately 142 (46.1%) of the participants had used the EMR system before. Among the respondents, approximately 125 (40.6%) reported the use of EMR system data in decision-making, and among them, approximately 103 (33.4%) had adequate EMR data use practices (Table 2).

The EMR data were most commonly used for continuous quality improvement (121,39.29%) and were least commonly used for identifying high-risk patients (78, 25.32%) (Figure 4).

Furthermore, approximately 168 (54%) of the managers did not use EMR in decision-making frequently, and the main reported reason for not using the system frequently in decision-making was the unavailability of the EMR system in some units/departments (150, 89.3%) (Figure 5).

3.2.1. EMR system data use and related organizational characteristics

Overall, 184 (59.7%) of the participants had access to at least one computer, and among them, 19 (10.4%) shared the computer with more than four people. Furthermore, 120 (39%) of the participants had been trained on HMIS, while 152 (49.4%) had been trained on EMR use. However, 174 (56.5%) of the health managers are currently using the EMR system.

Most of the participants, 263 (85.4%), held regular discussions on EMR during facility meetings, and 180 (60.0%) reported that there was facility management support in the use of EMR system data. Approximately 109 (35.4%) of the participants mentioned that there was a person assigned to the facility to facilitate EMR use within the institution as an EMR champion (Table 3).

TABLE 2 EMR system data use practices among health managers in public primary health facilities, Dodoma Region ($n = 308$).

Variable		Frequency	Percent
Past EMR use	No	166	53.90
	Yes	142	46.10
Current EMR use	No	134	43.51
	Yes	174	56.49
Frequency of EMR use	Daily/all the time	128	73.56
	Three times a week	35	20.11
	Once a week	3	1.72
	I do not remember exactly	8	4.60
EMR data use	No	183	59.42
EMR data use	Yes	125	40.58
Extent of data use	Inadequate data use	205	66.56
	Adequate data use	103	33.44

3.2.2. EMR system data use in decision-making and related behavioral characteristics

Preference of the EMR system compared with the paper-based system, attitude, and knowledge of computer and data use were assessed. Among the participants, 288 (93.51%) reported that they prefer the EMR system over the paper-based system. Knowledge of computer and data use ranged from 67.53% to 93.83% in all 10 areas assessed. Furthermore, 267 (86.69%) of the health managers had a good attitude toward the EMR system (Table 4).

3.2.3. EMR system data use and related technical characteristics

Almost all the participants (289, 93.8%) reported that they were able to use a computer. A total of 134 (43.35%) had positively perceived EMR system quality but only 22 (7.14%) had positively perceived EMR system service quality (Table 5).

3.3. Factors associated with EMR system data use in decision-making

Binary logistic regression analysis was used to determine how the independent variables influenced the dependent variable collectively. The analysis was also meant to establish the extent to which each independent variable affected the dependent variable and which factors were more significant.

The following factors were found to independently influence EMR data use: age of respondent, education level, access to a computer, motivation to use data, functionality of the computer, perceived EMR system information quality, and computer and data use skills as provided in Table 6.

3.3.1. Sociodemographic factors

Health managers with a diploma and a degree or above were three and five times more likely to use the EMR system than certificate holders, respectively [AOR = 3.24 with 95% CI of (1.29, 8.15), $p = 0.012$ and AOR = 5.26 with 95% CI of (1.84, 7.15), $p = 0.002$]. In addition, specialists/general practitioners were 2.64-fold more likely to use EMR system data than other cadres [AOR = 2.64 with 95% CI of (1.17, 5.94), $p = 0.019$]. Those who were working in rural areas were less likely to use EMR data than those working in urban areas [AOR = 0.46 with 95% CI of (0.26, 0.81), $p = 0.008$]. Those having managerial experience of ≤1 year were less likely to be associated with EMR system data use [AOR = 0.38 with 95% CI of (0.19, 0.74), $p = 0.004$]. However, other factors, such as age, sex, and type of facility did not have significant findings.

3.3.2. Organizational factors

Those who reported having access to computers and discussions on EMR during meetings were 4.72 and 2.77 more likely to use EMR system data adequately compared with others,

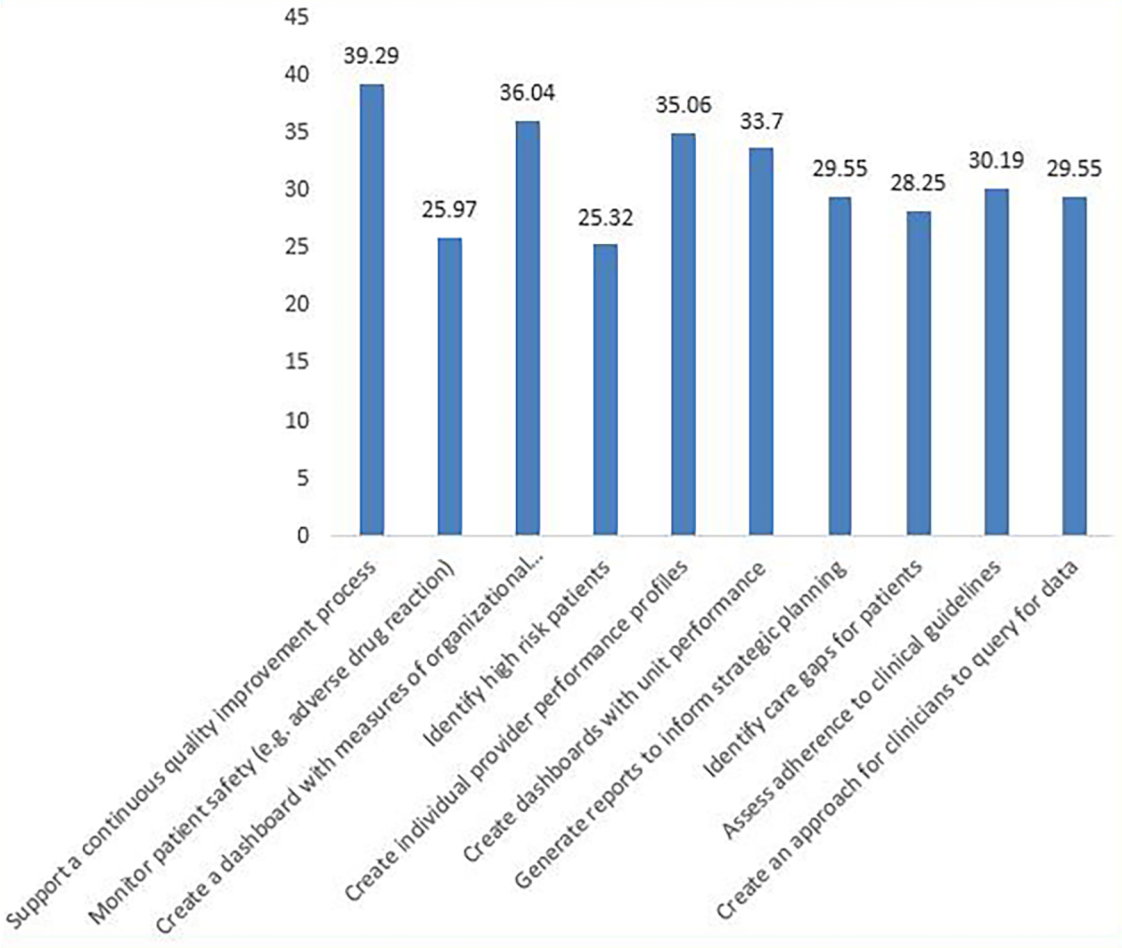

FIGURE 4
Purpose of EMR use by health facility managers.

respectively [AOR = 4.72 with 95% CI of (1.65, 13.48), $p = 0.004$ and AOR = 2.77, 95% CI: 1.01, 7.58, $p = 0.047$]. Those who reported having EMR systems in all working areas were seven times more likely to use EMR system data in decision-making than those who reported having EMR systems in some units [AOR = 7.23 with 95% CI of (3.15, 16.59), $p = 0.001$]. Other factors did not have significant findings.

3.3.3. Behavioral factors

Respondents with good perceived EMR system information quality were three times more likely to use EMR systems than those with poor perception of system quality [AOR = 2.84 with 95% CI of (1.50, 5.39), $p = 0.001$]. However, preference for the EMR system and attitude toward EMR did not have significant findings.

3.3.4. Technical factors

Health managers who had excellent knowledge of computer and data use were two times more likely to use EMR system data than those with poor knowledge of computer and data use [AOR = 1.84 with 95% CI of (3.38, 10.13), $p = 0.001$]. Interestingly, those who reported being able to use computers were less likely to use EMR system data adequately [AOR = 0.12 with 95% CI of (0.019, 0.79), $p = 0.028$].

4. Discussion

This study set out to assess the EMR system data use in decision-making and its associated factors in public primary health facilities. We assessed variables related to (1) sociodemographic, (2) organizational, (3) technical, and (4) behavioral factors.

The findings of this study revealed that approximately half (56.5%) of health managers were current users of the EMR system, of whom 73.6% used the system on a daily basis. Among them, approximately 125 (40.6%) used EMR data in decision-making. This rate was higher than that in a study conducted in Ethiopia, which revealed that EMR system data were used by 26.6% of the healthcare workers (2). Most of the facilities were partially electronic and partially paper-based. This finding is the same as those revealed in studies conducted in Ethiopia and Malawi (1, 2, 28).

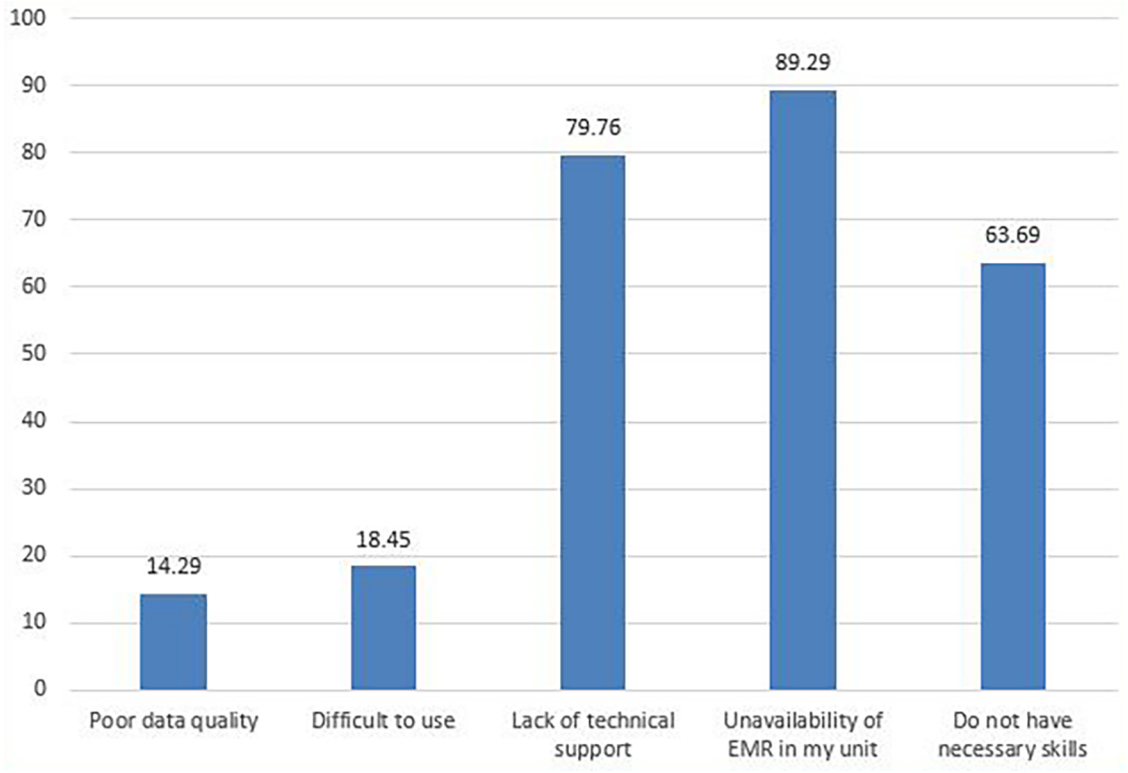

FIGURE 5
Reasons for not using EMR data in decision-making frequently (%).

TABLE 3 Organizational factors and EMR system data use, Dodoma Region ($n = 308$).

Variable	Response	Frequency	Percentages (%)
Availability of computer	Yes	184	59.7
	No	124	40.3
Number of accessible computers	1	132	71.7
	2	25	13.6
	3	8	4.3
	4 and above	19	10.4
Functionality of computer	Yes	165	89.7
	No	19	10.3
Sharing computers	Yes	124	67.4
	No	60	32.6
Training on EMR	Yes	152	49.4
	No	156	50.6
Discussion on EMR	Yes	263	85.4
	No	45	14.6
Motivation on EMR use	Yes	180	60.0
	No	120	40.0
Trained on HMIS	Yes	120	39.0
	No	188	61.0
Current use of EMR system	Yes	174	56.5
	No	134	43.5
Availability of EMR champion	Yes	109	35.4
	No	199	64.6

TABLE 4 Behavioral factors and EMR system data use, Dodoma Region ($n = 308$).

Variables	Response	Frequency	Percentages (%)
Prefer EMR than paper-based system	Yes	288	93.51
	No	20	6.49
Attitude level	Poor	41	13.31
	Good	267	86.69
Knowledge of computer and data use			
1. Internet browsing	Yes	289	93.83
	No	19	6.17
2. Calculations	Yes	275	89.29
	No	33	10.71
3. Email	Yes	285	92.23
	No	23	7.47
4. EMR database management	Yes	157	50.97
	No	151	49.03
5. I can check data accuracy	Yes	223	72.4
	No	85	27.6
6. I can plot data by months or years	Yes	239	77.6
	No	69	22.4
7. I can compute trends from bar charts	Yes	272	88.31
	No	36	11.69
8. I can explain findings and their implications	Yes	219	71.1
	No	89	28.9
9. I can use data for identifying gaps and setting targets	Yes	209	67.86
	No	99	32.14
10. I can use data for making various types of decisions and providing feedback	Yes	208	67.53
	No	100	32.47

The relatively high use of EMR system data may be attributed to the fact that most of the users preferred EMRs over paper-based systems (93.5%). In addition, respondents also had good computer

TABLE 5 Patterns of technical factors and EMR use among health managers, Dodoma Region ($n = 308$).

Variables	Response	Frequency	Percentages (%)
Ability to use computer	Yes	289	93.83
	No	19	6.17
Perceived EMR system quality	Poor	174	56.49
	Good	134	43.51
Perceived EMR service quality	Poor	286	92.86
	Good	22	7.14
Perceived EMR information quality	Poor	123	39.94
	Good	185	60.06

and data use skills ranging from 50.93% to 93.83%, which might have contributed to this level of implementation. This is supported by a study conducted in Dire Dawa (2) and Eastern Ethiopia (28).

Health professionals with excellent knowledge of computers and data use skills were more likely to use EMR systems than others. This finding is similar to that from a study conducted in Tanzania, which shows that the knowledge gap and skills among healthcare workers significantly influence EMR system use and the data management process (16, 29). In a study conducted in Ethiopia, it was revealed that staff with good data analysis skills were more likely to use health information system data than others (30). Moreover, a study conducted at Muhimbili National Hospital revealed that one of the challenges in the implementation of EMRs was inadequate skills of healthcare workers in the use of computers, which was because most of the old staff were aging and had inadequate basic skills in the use of computers, and the new staff turnover at the facility was high. All this resulted in poor quality of clinical note documentation. Refresher trainings and interfacility forums to share real practical experience were recommended (31).

In this study, the age of the health managers did not significantly impact their likelihood of using EMR data. This was different from a study conducted in Ethiopia that revealed that health professionals in the age group of 26–30 years were 1.61 times more likely to use the EMR system than those whose age was more than 40 years (32). However, another study in Ethiopia revealed that health professionals with a higher age, above 35 years, were more likely to use EMR systems than others (28). The different outcomes might be influenced by contextual factors such as the availability of training programs, the complexity of the EMR system, and the overall technological environment in the healthcare setting.

In this study, it was further revealed that motivation (managerial support) for the use of EMR system data was less likely to be associated with improved use of EMR data. This is different from a study conducted in Bahir Dar City, Ethiopia, which revealed that healthcare workers with managerial support were more willing to use EMR systems than others (33). However, another study (34) revealed that good governance (leadership, participatory monitoring, regular review of data) was associated with improved data use practices. In addition, performance-based financing was also found to have a role in promoting data use. In another study too, conducted at Mount Meru Hospital, EMR use was limited by low knowledge and skills of healthcare workers on information and communication technology (ICT) and inadequate management support (35). Therefore, the differences in findings could be due to variations in the healthcare

TABLE 6 Factors associated with EMR data use among health managers, Dodoma Region ($n = 308$).

Variable	Response	EMR data use		COR (95% CI)	AOR (95% CI)	*P*-value
		Adequate data use, *n* (%)	Inadequate data use, *n* (%)			
Level of education	Certificate	8 (7.77)	56 (27.32)	1	1	
	Diploma	58 (56.31)	111 (54.15)	3.66 (1.63, 8.18)	3.24 (1.29, 8.15)	0.012
	Degree or above	37 (35.92)	38 (18.54)	6.82 (2.86, 16.23)	5.26 (1.84, 7.15)	0.002
Cadre	Nurses	29 (28.16)	103 (50.24)	1	1	
	Specialists/general practitioners	35 (17.07)	35 (33.98)	3.55 (1.90, 6.63)	2.64 (1.17, 5.94)	0.019
	Other cadres*	39 (37.86)	67 (32.68)	2.07 (1.17, 3.66)	1.53 (0.76, 3.08)	0.236
Managerial experience	>1	83 (80.58)	133 (64.88)	1	1	
	≤1	20 (19.42)	72 (35.12)	0.45 (0.25, 0.78)	0.38 (0.19, 0.74)	0.004
Have access to computer	No	12 (111.65)	112 (54.63)	1	1	
	Yes	91 (88.35)	93 (45.37)	9.13 (4.71, 17.07)	4.72 (1.65, 13.48)	0.004
Discussion on EMR in meetings	No	7 (6.80)	38 (18.54)	1	1	
	Yes	96 (93.20)	167 (81.46)	3.12 (1.34, 7.26)	2.77 (1.01, 7.58)	0.047
Degree of EMR implementation	Partial	75 (72.82)	193 (94.15)	1	1	
	Fully	28 (27.18)	12 (5.85)	6.00 (2.90, 12.42)	7.23 (3.15, 16.59)	0.001
Perceived EMR information quality	Poor	26 (25.24)	97 (47.32)	1	1	
	Good	77 (74.76)	108 (52.68)	2.66 (1.56, 4.48)	2.84 (1.50, 5.39)	0.001
Ability to use computer	No	6 (5.83)	13 (6.34)	1	1	
	Yes	97 (94.17)	192 (93.66)	1.09 (0.40, 2.97)	0.12 (0.019, 0.79)	0.028
Knowledge of computer and data use	Poor	6 (5.83)	36 (17.56)	1	1	
	Fair	1 (0.97)	15 (7.32)	0.40 (0.044, 3.61)	1.017 (0.085, 1.21)	0.989
	Good	6 (5.83)	52 (25.37)	0.69 (0.21, 2.31)	2.35 (0.36, 1.54)	0.372
	Very good	8 (7.77)	12 (5.85)	4.1 (1.15, 1.38)	1.3 (2.02, 9.14)	0.007
	Excellent	82 (79.61)	90 (43.9)	5.46 (2.19, 3.45)	1.84 (3.38, 10.13)	0.001

*Other cadres (laboratory staff, radiology staff, accountants, health secretary).

settings, organizational cultures, levels of managerial support, and overall readiness of healthcare workers to adopt and utilize EMRs.

Those who were working in rural areas were less likely to use EMR data compared with those working in urban areas. This is congruent with a study conducted in the USA (10) in which hospital characteristics influenced use of EHR data, with the small, rural, state/local government run, and non-teaching hospitals having the lowest rates of EHR data use. This might be because EMR adoption rates in rural areas are significantly lower than in urban areas. This could be attributed to factors such as technology access, limited resources, and lower EMR adoption rates in rural settings.

Furthermore, respondents with good perceived EMR information quality were three times more likely to use EMR system data than those with poor perceived information quality. However, in this study, perceived system quality and service quality did not have a significant influence on EMR use. This is different from a study conducted in Ethiopia in which EMR system service quality and system quality were independent predictors of EMR use (2). Another study conducted in Gabon revealed that perceived EMR system quality and information quality were 1.7 times more likely to impact use of the system (36). This may be because data use is influenced by how users perceive the quality of the data produced.

The degree of EMR implementation was also a predictor of EMR use. Those who had EMR systems in all departments/units were more likely to use EMR systems than others. This is congruent with a study conducted in Ayder Hospital in Ethiopia in which 95% of the units were using the EMR system; hence, EMR use was higher (37). Another study conducted in Kenya revealed that EMR use was not adequate due to infrastructure challenges (38). In addition, another study revealed that the availability of health information system resources, such as EMR systems, organizational structure, and training, potentially influences data use (34). This may be because the availability of the EMR system in all departments increases the chance that in hospital discussions, all staff will be discussing data generated from the EMR system rather than a mixture of sources of data.

Training on EMR use had no influence on EMR system data use in this study. This was in line with a study conducted in Dire Dawa, Ethiopia (2). However, this finding is in contrast with findings from other studies conducted in different regions of Ethiopia (28), Malawi (1), and Kenya (38). It is well known that training has great potential to improve EMR use, as it can improve the attitude, knowledge, and skills of health managers. While training is a crucial component, its effectiveness in promoting EMR data use is intertwined with other factors, such as managerial support, cultural considerations, and resource availability. Hence, a comprehensive approach that addresses these factors is essential for maximizing the benefits of EMRs implementation.

A higher education level was also associated with EMR system data use, in which those with a diploma and a degree or above were 3 and 5 times, respectively, more likely to use EMR system data than those with a certificate. This is congruent with a study conducted in Ethiopia in which health professionals with an educational level of first degree and above were 1.92 times more likely to use the EMR system than diploma holders (32). This finding suggests that providing higher education and training opportunities to healthcare professionals could enhance their ability to engage with EMR systems and leverage the data they provide. This could lead to improved decision-making processes and patient care.

Overall, the study identified several factors that influenced the use of EMR system data among health managers. These factors included education level, professional role, managerial experience, access to computers, discussions about EMR, system implementation status, perceived system quality, and computer and data use skills.

5. Conclusions

The electronic medical records system has a proven advantage of enabling easy retrieval of data, including data analysis and use. This can potentially lead to more informed decision-making in the health sector. However, in this study, almost half of the respondents were current users of the EMR system, and 40.6% of the health managers were using EMR data in decision-making. This indicates that although many health managers are using EMR systems, a notable portion of decision makers have not fully integrated EMR data into their decision-making practices. Thus, for improvement in EMR system data use, future investments in issues such as training, installation of the system in all units/departments, education, and integration of EMR data into established decision-making workflows should be advocated. Since it was found that training in itself is insufficient to improve use of EMR, other organizational aspects of work routine that may serve as a challenge must be considered. Many health projects focus on training and technical aspects rather than improving organizational culture. Therefore, a comprehensive approach that addresses these factors is essential for maximizing EMR use in decision-making.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by The University of Dodoma Institutional Review Ethics Committee (IRREC). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

EK: Conceptualization, Data curation, Formal analysis, Funding acquisition, Methodology, Writing – original draft. JN: Supervision, Writing – review and editing. SK: Supervision, Writing – review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Assessing the clinical benefit, safety, and patient-reported outcomes with the use of the PAHcare™ digital platform in pulmonary arterial hypertension: a pilot study

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Introduction: Digital health interventions, particularly mobile health platforms, have shown promise in supporting patients with respiratory conditions, but their application in pulmonary arterial hypertension (PAH) remains limited. We aimed to assess the feasibility, acceptability, and potential clinical benefit of the novel PAHcare™ digital platform as a patient-centred intervention for PAH management through a prospective, single-arm, multicenter pilot study conducted on 53 patients diagnosed with PAH who used the platform for 6 months.

Methods: The primary objective was to assess the impact on Health-Related Quality of Life (HRQoL) through questionnaires. Secondary objectives included evaluating clinical outcomes, including disease progression, PAH signs and symptoms, the 6-min walking test, and the patient's symptom perception. Additionally, we assessed patient satisfaction and engagement with the PAHcare™ platform, interaction with health coaches, retention, costs and healthcare resource utilisation (HCRU), and safety through monitoring device incidents.

Results: Minimal changes in HRQoL and clinical outcomes were observed over 6 months. A noteworthy 92.4% of patients actively used the platform in the first

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month, maintaining high usage throughout the study. Patient satisfaction was substantial, with more than half of the patients expressing excellence in service quality, willingness to reuse the platform, and fulfilment of their needs. Health coach interaction was high, with 76% of patients initiating contact within the first week. User retention rates were 70%, with prevalent ongoing usage and interaction with healthcare professionals even after the study. In terms of HCRU and costs, the study showed no significant changes in PAH-related hospital admissions, clinical visits, or tests. Finally, the low number of device-related incidents indicated platform safety.

Conclusion: This pilot study provides compelling evidence supporting the feasibility and acceptability of the PAHcare™ digital platform to empower patients to manage their disease and significantly enhance their overall experience with PAH.

KEYWORDS

pulmonary arterial hypertension, digital intervention platform, mobile health (mHealth), electronic patient-reported outcome, health services research, patient support program

1 Introduction

Pulmonary arterial hypertension (PAH) is a debilitating and progressive, rare microvascular disease characterised by elevated pulmonary artery pressure, eventually leading to right heart failure (HF) and death, with reported 1 year survival ranging from 67 to 99% worldwide (1, 2). Besides, this condition imposes a substantial burden on individuals and healthcare systems. On the one hand, PAH significantly reduces the patients' health-related quality of life (HRQoL), limiting their physical activity and affecting daily functioning (3). On the other hand, the disease often requires complex and costly medical management, frequent hospitalisations, and ongoing monitoring (4). Moreover, the burden extends beyond physical health and seriously impacts emotional well-being, requiring significant adjustments in daily life (3).

Effective management of PAH requires a comprehensive approach where close interaction between patients and healthcare professionals plays a pivotal role in ensuring regular monitoring, adherence to treatment regimens, and implementing necessary lifestyle modifications (5). Moreover, the active engagement of patients in shaping decisions regarding their health conditions is progressively gaining significance (6, 7). An illustrative example is the active participation of patients in the development of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS) clinical guidelines (5, 8). In order to attain this objective, two indispensable elements are health education and the patient's unique perspective.

Digital health interventions, including mobile health (mHealth) platforms, have emerged as promising tools to support patients and their care teams in the routine management of chronic respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD) (9–12). Furthermore, a plethora of digital health applications have emerged to enhance HF care throughout the entire spectrum of the HF disease process, encompassing primary prevention, early detection, disease management, and the reduction of related morbidity (13, 14). Digital tools and platforms have the potential to significantly impact patient outcomes by providing continuous support, personalised education, and real-time monitoring (15, 16). Additionally, they can enhance treatment adherence and empower patients by offering access to resources, fostering self-management, and facilitating regular communication with healthcare providers (15–17). Despite their proven efficacy in various healthcare contexts, limited attention has been given to the utilisation of such interventions in the context of PAH. Moreover, existing studies in PAH have predominantly employed electronic health devices, such as wireless or portable tools, mainly focusing on clinical outcomes or their accuracy and reliability, while often neglecting the assessment of health-related QoL (HRQoL) (18, 19).

The PAHcare™ digital platform is a novel mHealth intervention designed to adopt a patient-centred approach to PAH care (20). This innovative platform offers a variety of features, including symptom tracking, educational materials, medication reminders, and effective communication channels with healthcare professionals (20). By granting convenient access to educational resources, facilitating seamless communication with healthcare professionals, and promoting self-care behaviours, the platform possesses the potential to empower patients and augment their active involvement in their own care.

In this manuscript, we present the findings of the pilot study conducted to evaluate the clinical benefit and safe use of the PAHcare™ digital platform in patients with PAH. The study quantitatively assessed health-related quality of life (HRQoL), disease severity, disease-related signs and symptoms, cost and healthcare resource utilisation, as well as patient engagement and satisfaction with the PAHcare™ platform.

2 Methods and analyses

2.1 Study design

This prospective, single-arm, multicenter pilot study was designed to evaluate the safety, feasibility and potential clinical

benefits of the innovative PAHcare™ digital platform in patients with PAH and their care team over 6 months (20). The study was conducted at five specialised PAH units of reference hospitals within the Spanish public healthcare system (Supplementary Table S1).

2.2 Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki, the international standard ISO 14155 "Good Clinical Practice" guidelines, and the European and Spanish Regulations on Medical Devices (21, 22). All patients gave written informed consent to participate in the study. The competing Ethics Committee of Hospital 12 de Octubre, Madrid, Spain, approved the study protocol V4.0 on March 22, 2022 (FPAH-CI-2101).

2.3 PAHcare™ digital health platform overview

The CBS-PAH study's protocol, previously published, provides details of the PAHcare™ digital platform (20), which consists of a patient-oriented mobile app and dedicated dashboards for physicians and health coaches (HCs). Briefly, it enables users to log patient-reported outcomes (PROs) data, including symptoms, medication-related adverse events, hospitalisations, clinical information, and lifestyle details. Besides, the app provides evidence-backed content through magazine articles, frequently asked questions (FAQs), lessons, and quizzes. Additionally, users receive medication reminders and personalised support through chats and calls with specifically trained HCs offering assistance tailored to individual treatments. For those on the prostacyclin analogue treprostinil, HCs can assist with treatment, medical device support, adverse event reporting, and provide advice on platform use, self-monitoring, lifestyle changes, behavioural modifications, and symptom management. Patients on other treatments receive HC support focused on platform usage and overall health management. Lastly, an external portal offers additional psychological support for treprostinil patients as needed.

2.4 Population

All enrolled patients were adults aged 18 years or older with a confirmed diagnosis of PAH, regardless of disease severity (World Health Organization [WHO] functional class I to IV), who were considered suitable for participation in the self-care/caregiver-driven support program for PAH based on the investigator's judgement. Additionally, participants were required to provide signed informed consent and be able to read, speak, or understand Spanish.

Exclusion criteria included any psychological and/or physical conditions that could negatively affect the proper adherence to study procedures (e.g., uncorrected hearing and/or visual impairments) or the absence of a smartphone for accessing the program. Additionally, patients who had undergone a major surgical intervention within the 30 days prior to enrollment or those experiencing complications that could hinder the complete utilisation of the patient support program were excluded. Lastly, pregnant women, lactating or planning to become pregnant within the subsequent 6 months, were not eligible for study participation (20).

2.5 Study procedures and outcome measures

Enrolled patients underwent a baseline visit and two follow-up visits 3 and 6 months after the initial visit. As part of the onboarding process, patients were instructed to download the mobile app [a complete description of the app's features can be found in the previous publication of the CBS-PAH study protocol (20)]. With the assistance of their assigned health coach (HC), patients configured the app and provided their basic personal information, medical history, and lifestyle details.

The primary objective of the CBS-PAH study was to assess the impact of PAHcare™ intervention on patient's HRQoL. To evaluate this, participants completed two different questionnaires at each visit. The first questionnaire used was the Spanish-validated version of the emPHasis-10, which explicitly measures HRQoL in PAH (23, 24). It focuses on breathlessness, fatigue and lack of energy, social restrictions, and concerns regarding effects on patients' significant others, including family and friends. Each item is scored on a semantic differential six-point scale (0–5) using contrasting adjectives at each end. The total emPHasis-10 score ranges from 0 to 50, with higher scores indicating a worse quality of life. The second questionnaire employed was the Spanish-validated version of the Euroqol 5-dimension questionnaire (EQ-5D-5L) (25, 26). The EQ-5D-5L consists of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), each with five levels of severity (ranging from no problems, slight problems, moderate problems, severe problems and unable to/extreme problems) scored from 1 to 5, respectively. Lastly, the EQ-5D-5L also includes a visual analogue scale (VAS), where responders mark with an X on a 20 cm scale with endpoints labelled "Best imaginable health state" (100) and "Worst imaginable health state" (0) their health that day.

As a secondary objective, we determined the impact of the PAHcare™ intervention on the clinical progression of the disease. This was assessed by analysing clinical parameters recorded at each visit. These parameters included the severity of the disease on the WHO functional classification, as well as the presence, frequency (times/day and/or week), and intensity (mild, moderate, or severe) of PAH signs and symptoms (such as dyspnoea, orthopnoea, fatigue, syncope, chest pain, and oedema), 6-min walking test (6MWT) and patient's PAH symptoms perception graded on a visual analogue scale (VAS). Furthermore, the study had secondary objectives that focused on evaluating the usage and engagement of the PAHcare™ platform. This was done by analysing the interactions between patients and the platform, including the number and duration of logs for PROs, the consumption of educational content such as magazines, lessons, and quizzes, and the number and duration of calls and completed chats with the health coach (HC). Moreover, the patient's satisfaction with the use of the PAHcare™ platform was assessed using the 8-item Client Satisfaction Questionnaire (CSQ-8), with each item rated on a 1 to 4 scale (25), completed by the patients after 6 months of using the platform. In addition, the description of the reason, duration and procedures for PAH-associated hospitalisation/visit/emergency room admissions and formal and informal costs related to the disease through an *ad-hoc* questionnaire were also

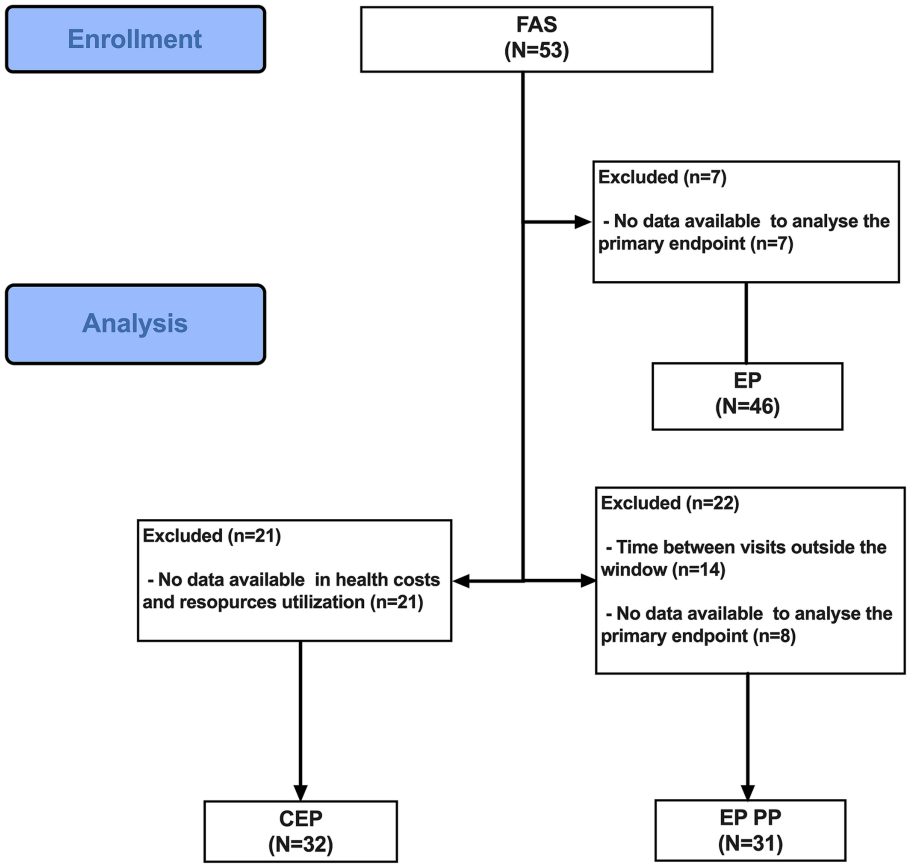

FIGURE 1
Flow diagram of the CBS-PAH study. CEP, cost evaluable population; EP, evaluable population; EP PP, evaluable population per protocol; FAS, full analysis set.

assessed. Lastly, safety was evaluated by monitoring reported device incidents, which referred to any inadequacy of the medical device concerning its identity, quality, durability, reliability, usability, safety, or performance.

2.6 Sample size and statistical analyses

Since this pilot study was exploratory, we did not conduct a power analysis to determine a specific difference in the outcomes. Instead, our primary objective was to ensure a minimum sample size of 50 individuals actively utilising the PAHcare™ platform.

The primary and secondary objectives were evaluated in two populations: the full analysis set (FAS), which included all selected patients, and the evaluable population (EP), which included selected patients with available data (baseline and at least one post-baseline assessment in one of the two HRQoL questionnaires) for analysing the primary endpoints. Additionally, the evaluable population per protocol (EP-PP) consisted of patients in the EP who had assessments at baseline and at least one post-baseline evaluation in both HRQoL questionnaires within the specified window of ±15 days as defined in the protocol. The cost evaluable population (CEP) included all patients with data available in baseline and 6 months who answered at least 10 questions of the 20 performed related to health costs and resources.

All variables were analysed descriptively at each visit, with categorical variables summarised using absolute and relative frequencies and continuous variables through mean, standard deviation (SD), median, and minimum and maximum values. To compare continuous variables between baseline and different clinical investigation visits, *t*-tests or Wilcoxon test were used, while Mc Nemar's test was employed for categorical variables. For the primary endpoint (change in the EmPHasis-10 and EQ-5D-5L scores), missing data from post-baseline visits were imputed using the last observation carried forward (LOCF) method. In contrast, no imputation of missing data was performed for secondary variables. The significance threshold was set at a two-sided $\alpha = 0.05$. All data processing, summarisation and analyses were performed using the Statistical Analysis System (SAS) statistical software package, version 9.4. SAS Institute Inc., Cary, NC, United States.

3 Results

The study enrolled a total of 53 patients who had a confirmed diagnosis of pulmonary PAH and actively utilised the PAHcare™ platform (Figure 1). Among them, 46 patients constituted the evaluable population (EP) with available data for analysing the primary endpoint. Seven patients discontinued the study prematurely,

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TABLE 1 Participant's characteristics.

Characteristic	Patients (*N* = 46)
Age (years) (mean, SD)	48.8 (12.6)
Gender (*n*, %)	
Female	38 (82.6)
Male	8 (17.4)
Body weight (kg) (mean, SD)	66.1 (15.1)
WHO Functional class (*n*, %)	
Class I	17 (37.0)
Class II	27 (58.7)
Class III	2 (4.3)
Class IV	0 (0.0)
6MWD (meters), mean (SD)	486.2 (85.2)
Signs and symptoms, *n* (%)	
Dyspnoea, *n* (%)	20 (43.5)
Frequency, mean (SD)/day	2.6 (1.8)
Mild	10 (50%)
Moderate	9 (45.0)
Severe	1 (5.0)
Orthopnoea, *n* (%)	3 (6.5)
Mild	2 (66.7)
Moderate	1 (33.3)
Fatigue, *n* (%)	12 (26.1)
Mild	6 (50)
Moderate	6 (50)
Chest pain, *n* (%)	8 (17.4)
Frequency, mean (SD)/day	1.5 (0.7)
Frequency, mean (SD)/week	1.6 (0.9)
Mild	6 (75.0)
Moderate	2 (25.0)
Oedema, *n* (%)	5 (10.9)
Intensity	
Mild	3 (60.0)
Moderate	2 (40.0)
Syncopes	0 (0.0)
Hemodynamics as per RHC (*n* = 45), median (Q1, Q3)	
PAP (mmHg)	49.0 (37.0, 60.0)
PCWP (mmHg)	9.0 (7.0, 12.0)
PVR (Wood units)	9.6 (6.3, 15.6)
Right Atrial Pressure (mmHg)	7.0 (5.0, 9.0)
Mixed Venous Oxygen Saturation (%)	67.4 (64.0, 74.9)
Cardiac Index (mL/min/m^2)	2.5 (2.1, 3.1)

6MWT, 6-min walking test; PAP, pulmonary arterial pressure; PCWP, pulmonary capillary wedge pressure; PVP, pulmonary vascular resistance; RAP, right atrial pressure; RHC, right heart catheterization; WHO, World Health Organization functional class.

two withdrew consent, three were lost to follow-up, and two withdrew for other reasons.

At baseline, the mean age of the patients was 48.8 years (SD = 12.6). The majority of participants were female (82.6%), with more than half being classified as WHO functional class II (58.7%), while none were classified as class IV (Table 1). The most commonly reported symptom was dyspnea, reported by 43.5% of patients, with approximately 50% of them experiencing mild intensity.

3.1 Changes in EmPHasis-10 and EQ-5D-5L scores

At baseline, the mean EmPHasis-10 QoL questionnaire score was 19 (ranging from 9 to 26), which corresponds to an intermediate risk level associated with a 10% likelihood of 1 year mortality (27). Throughout the follow-up period (6 months after the baseline visit), there was a minimal decrease of less than 1 point (−0.6; SD = 8.1), which did not reach statistical significance (Figure 2). As for the EQ-5D-5L, the initial mean scores for all dimensions were between 1 and 2, thus ranging between "no problems" and slight problems," and the mean EQ-5D-5L VAS at baseline was 72.1 (SD = 20.4). No statistically significant differences were observed between the baseline and final visit for any of the five dimensions of the EQ-5D-5L or the VAS score (Figure 2). The findings were consistent across both the FAS and the EP-PP populations, which did not deviate from the results obtained in the EP.

3.2 Change in severity and signs and symptoms of PAH

Most patients (72.7%) remained in the same WHO functional class throughout the study duration. Among those who experienced a change (27.3%), there were five cases (41.7%) showing improvement and seven patients (58.3%) showing deterioration. When considering the 6MWT, the mean distance covered slightly decreased from baseline to the end of the study, but this difference was not statistically significant (difference = −0.2 meters; SD = 45.7; $p = 0.889$). These results were consistent with those observed in both the FAS and the EP-PP populations.

Furthermore, no significant changes were observed in the mean VAS self-rated perception of PAH symptoms, nor in the percentage of patients experiencing different signs and symptoms of PAH (Figure 3). These figures were comparable to those reported in the FAS and EP-PP populations.

3.3 Patient-reported satisfaction with the use of the PAHcare™ platform

The responses to the CSQ-8 questionnaire revealed a notable level of satisfaction with the platform, as more than half of the patients assigned the highest score to nearly all the questions (Figure 4). Specifically, 68.4% of patients regarded the quality of the service as excellent, 73.7% expressed their willingness to use the platform again, and 84.2% believed that their needs had been met (with 47.4% specifying that all their needs were met, and 36.8% stating that most of their needs were met).

3.4 Consumption of educational content

The proportion of patients engaging with disease-specific knowledge and management magazines is presented in Supplementary Figure S1. Among the articles, the highest readership was observed for the one centred around pulmonary rehabilitation, with 57% of patients accessing it. This was followed by the articles

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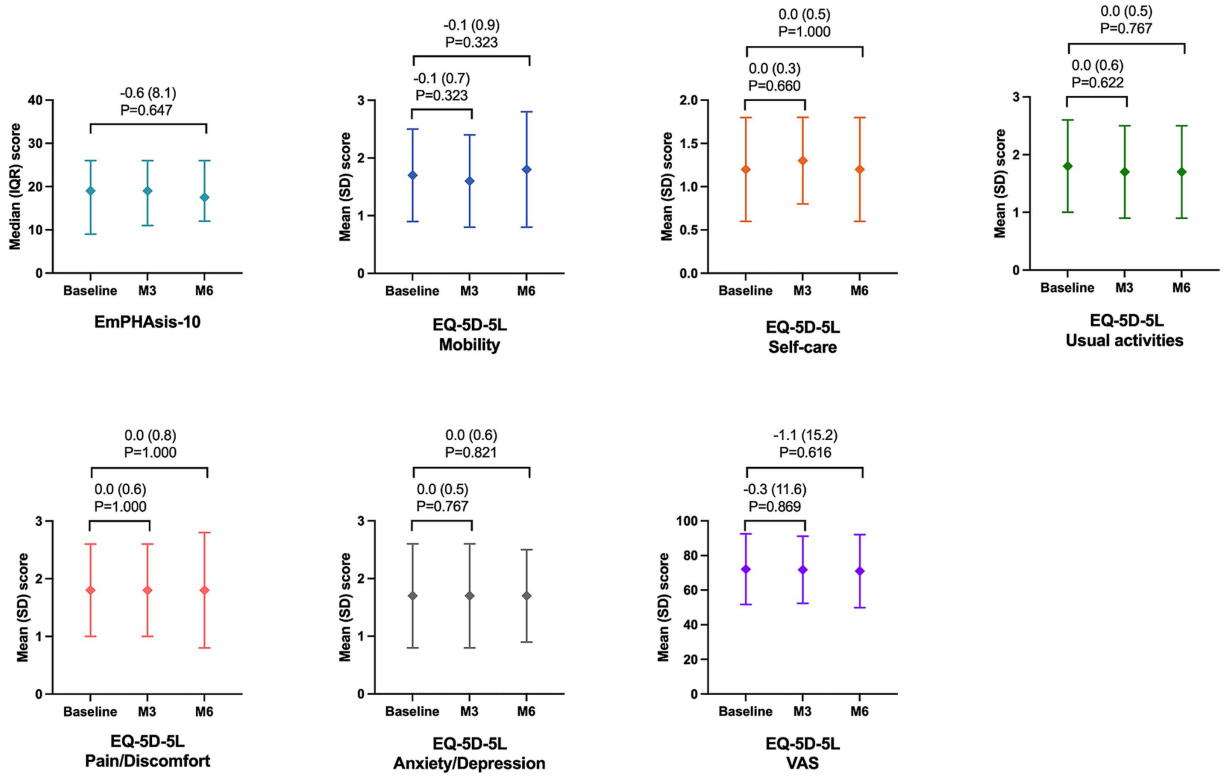

FIGURE 2
Change in the EmPHAsis-10 and EQ-5D-5L scores during the study follow-up.

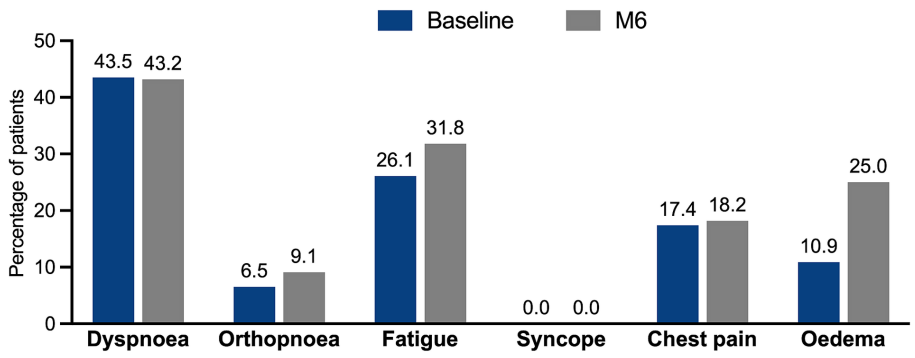

FIGURE 3
Change in the percentage of signs and symptoms of PAH experienced by the patients throughout the study.

titled "All about PAH" and "Living with a pump," both accessed by 40% of patients. Additionally, the articles "Coping with cognitive impairment" and "How to accomplish more in 1 day" were accessed by 38% of patients each. The remaining articles had a readership of less than 36% among patients.

Regarding the utilisation of the platform's structured educational pathway, 45.3% of patients successfully completed Level 1 (Supplementary Figure S2). Afterwards, the proportion of patients progressing to subsequent levels decreased gradually, with 36% of patients completing at least two levels of education and 26.4% successfully completing all four levels.

3.5 Adherence, engagement, and retention

During the first month of the study, an overwhelming majority of patients ($n = 48$; 92.4%) actively engaged with the PAHcare™ platform (Figure 5A), resulting in a total of 2,912 recorded visits. On average, each patient launched the platform 215 times, indicating a daily usage rate of at least one launch per patient. Although the proportion of patients accessing the platform gradually decreased over time, it remained notably high at the end of the study ($n = 37$; 69.8% at 6 months). Additionally, nearly half of the patients continued utilising the app even after the study concluded, with 43.4% still accessing it

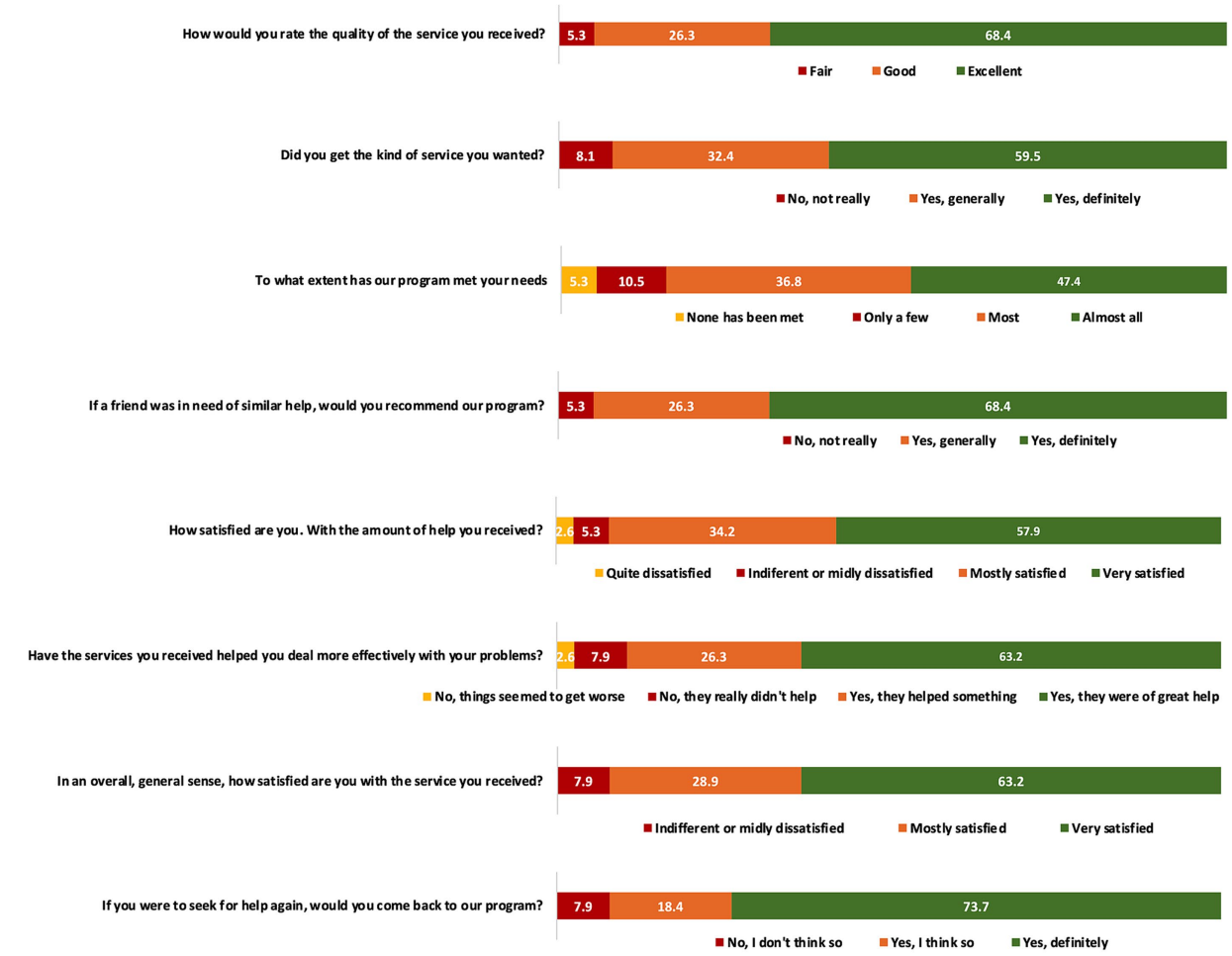

FIGURE 4
Results of the CSQ-8 questionnaire on the patient's satisfaction with the use of the PAHcare™ platform.

after 6 months of use. Moreover, the logging of activities within the app was extensive, with nearly all patients ($n = 49$; 92.4%) actively using the app's activity logs (Figure 5B). The most frequently logged activities were meals (mean = 210; SD = 393.6), followed by weight (mean = 46.5; SD = 85.3), water intake (mean = 18.6; SD = 39.1), and blood pressure readings (mean = 18.3; SD: 38.2). A total of 21 patients (39.6%) actively recorded their symptoms assessments within the app, averaging 2.26 days per month (SD = 2.56).

During the initial week of platform usage, 76% of patients opted to contact or chat with their assigned HC (Figure 6A). Although the proportion slightly declined over time, it remained above 50% even after 19 weeks. At the conclusion of the study (24 weeks), 28% of patients still sought HC contact, and following the study's end, between 38 and 32% continued utilising this feature. On average, patients made 7.6 contacts or chats with HCs (SD = 5.7), maintaining a consistent level throughout the study (Figure 6B). On the other hand, health professionals made an average of 2.9 phone calls to each patient per month (SD = 1.3).

Remarkably, the PAHcare™ platform exhibited outstanding user retention rates, with 79.2% of patients continuing to use it after 3 months. Furthermore, patient retention remained substantial, with rates of 69.8 and 43.4% at 6 months and after 6 months, respectively.

3.6 Costs and healthcare resource utilisation

The CEP population consisted of 26 patients at baseline and 32 at the end of the study. No significant changes were observed in the number of PAH-associated hospital admissions (including visits to the emergency room), clinical visits/consultations to health professionals, or the number of tests performed during the 6 months before inclusion and the 6 months lapsed between study initiation and final visits (Supplementary Tables S2, S3).

Noteworthy, 41.9% of patients ($n = 13$) were working at baseline, a number that increased to 46.9% ($n = 15$) at the final visit. On the other hand, only five patients reported a decrease in their regular incomes (16.7% of the baseline sample and 17.9% of the final visit sample).

Three patients (9.4%) at baseline and one patient (3.1%) at the final visit had to buy a medical equipment or device to carry out works to adapt their home to their needs. One patient had to pay himself a wheelchair (2.237 €) and one a dehumidifier (49 €). Three patients at baseline and one at the final visit reported to benefit from help in domestic cleaning (private in all cases; median = 2.0 days). Help from family and friends was available for

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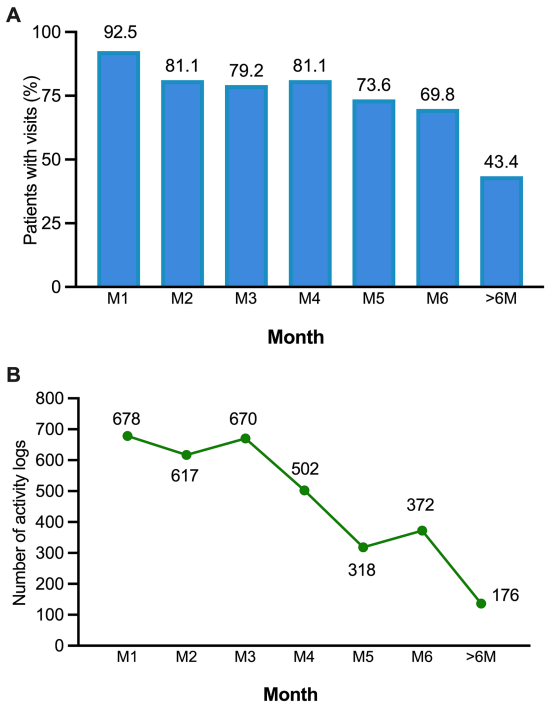

FIGURE 5
(A) Proportion of patients accessing the PAHcare™ platform by month of use. **(B)** Number of activity logs to the platform by month.

seven patients at baseline with a median dedication time 25.8 h (IQR:12.9, 51.6) and for six patients at the final visit with a median time of 10.8 h (IQR:8.6, 28.0).

Data available data on formal and informal care costs was not sufficient to conduct a proper economic analysis to assess the impact of the platform on disease-associated costs.

3.7 Safety of the PAHcare™ platform

Only 5 (11.1%) patients experienced incidents with the device in the EP population. Those were reported as one case of "frozen app," two as "it does not work," and the last one as "no information of all food." Three of them occurred at the initial use of the medical device. None of them was reported as serious. Safety analysis was comparable in both EP and FAS populations.

4 Discussion

We conducted a pilot study to evaluate the clinical benefit and safe use of the PAHcare™ digital platform as a novel, patient-centred mHealth intervention for the routine care of patients with PAH and their care team. To the best of our knowledge, this study is the first one of its kind to be implemented in patients with PAH, making it unique and without any existing benchmarks. After 6 months of utilisation, there were no significant differences compared to baseline in HRQoL

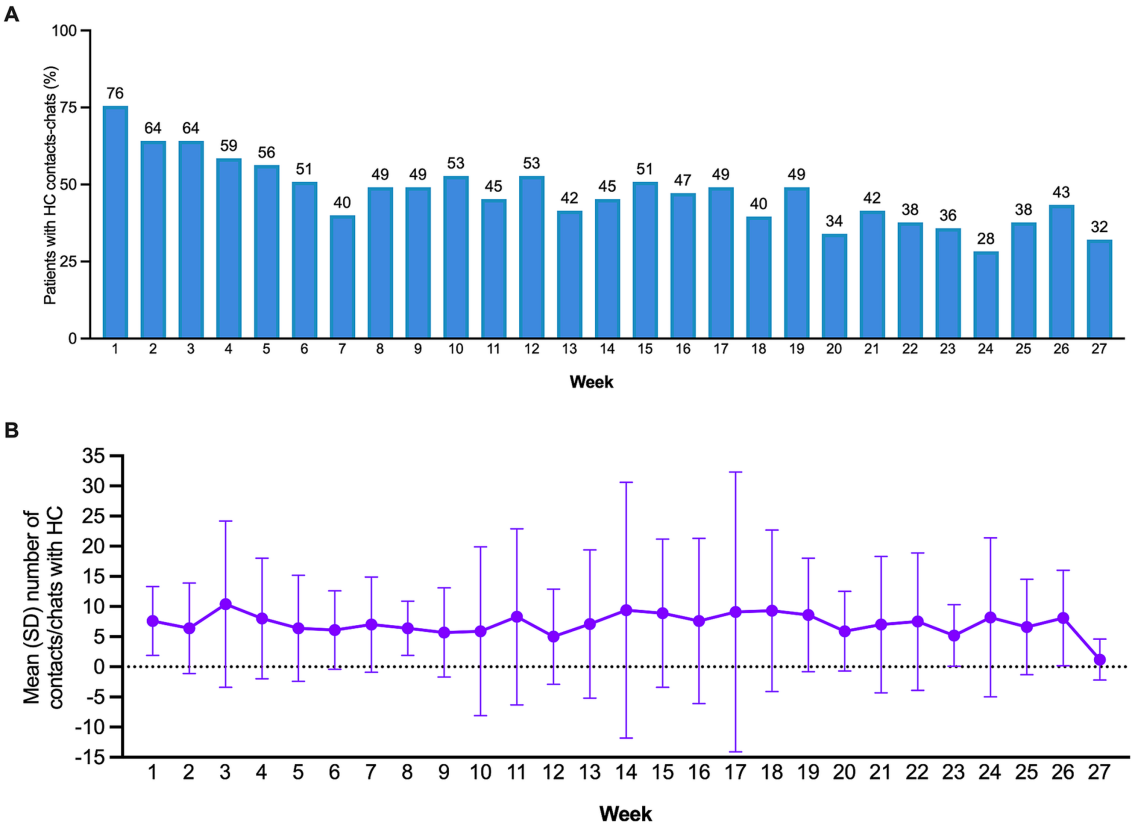

FIGURE 6
(A) Proportion of patients with contacts-chats with the health coach by month. **(B)** Mean number of chat lines per week.

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measures, disease severity, or disease-related signs and symptoms. However, the study revealed remarkably high levels of engagement, satisfaction, acceptability, and usability of the PAHCare™ platform.

The lack of significant improvements in health-related outcomes observed in our study could be attributed to various factors inherent to the study design. Firstly, due to the low prevalence of PAH, we opted for a single-arm pilot study without a comparison control group. This decision was made in order to maximise the number of patients who could benefit from the PAHcare™ platform intervention. Secondly, in addition to the limited sample size, the study lasted only 6 months, which may have influenced the ability to capture significant clinical changes. Indeed, given the chronic nature of PAH, longer-term interventions may be necessary to observe substantial shifts in parameters such as WHO functional class or 6MWDT. Thirdly, although we intended to include patients from all WHO functional classes, 96% of the enrolled participants were categorised as functional classes I and II. The skewed distribution across WHO functional classes may have had implications for the observed outcomes. The predominance of participants with relatively conserved functional capacity suggests that, at baseline, a majority effectively managed their condition with established coping mechanisms, treatment plans, and lifestyle adjustments. This pre-existing effective management likely contributed to the limited clinical changes observable during the relatively brief study period. Therefore, the possibility of a beneficial clinical effect in patients with lower functional capacity (WHO functional class III and IV) cannot be excluded. In these advanced cases, comprehensive pharmacological and non-pharmacological care has the potential to enhance disease symptoms and improve the overall QoL (5). Undoubtedly, making treatment decisions at these stages poses significant clinical challenges, as patients often suffer from psychological comorbidities such as depression and anxiety, conditions that substantially diminish the patient's HRQoL (28–30) and can also detrimentally affect treatment adherence and disease progression (31). Although we did not identify significant changes in the anxiety/depression dimension of the EQ-5D-5L questionnaire from baseline to the study's conclusion, we acknowledge the importance of a thorough evaluation of additional psychological factors. These could include aspects such as social support, self-efficacy, coping mechanisms, and the patient's confidence or perceived control over their health. Given the remarkable levels of engagement, retention, and satisfaction observed with the PAHcare™ digital platform, it is conceivable that a more comprehensive assessment of psychological factors might have revealed significant differences. In addition to the prevalence of patients experiencing only mild disease symptoms, it is noteworthy that the studied subjects exhibited a relatively high QoL at the outset of the study. However, our study lacks comprehensive data on comorbidities, such as ischaemic heart disease, hypertension, or sleep apnoea, which are known to adversely affect the overall HRQoL in individuals with PAH (3, 32). Lastly, although we do not have data on the pharmacological treatments, it is important to highlight that all patients in our study were treated at specialised PAH units in reference hospitals in Spain and had already stabilised their condition with a well-adjusted care and treatment plan. PAH requires a high level of expertise from healthcare providers, and clinical guidelines advocate for the referral of patients to Speciality Care Centres (SCCs) for optimal management (5, 33, 34). This approach has been consistently associated with improved patient outcomes, including reduced hospitalisations and mortality rates (35). In Spain, it has been estimated that there are currently 30–35 active PAH units (36). A recent survey conducted among physicians involved in the management of PAH revealed considerable variation between SCCs in terms of organisational models, diagnostic resource availability, and adherence to clinical practice guidelines (36). Furthermore, the survey highlighted several structural deficiencies within the PAH units. These included inconsistencies in the percentage of patients receiving health education, inadequate attention given to QoL assessments, and a frequent lack of access to support from social workers or psychologists (36). Additionally, it should not be extended to non-specialist PAH care centres that may possess varying levels of PH expertise and PH-specific resources, diverse multidisciplinary care approaches, different access to advanced diagnostic tools, availability of advanced therapies, distinct referral pathways, or supportive services (such as emotional support, disease management education, and guidance for coping with the challenges associated with living with PAH).

In addition to the essential objectives of promoting symptom monitoring, control, and improving the patient's QoL, mobile devices offer numerous additional benefits that are challenging to quantify but hold significant value for the healthcare system, providers, and patients. For instance, real-time communication between healthcare professionals and patients enhances patient engagement, promotes shared decision-making, and fosters collaborative care (6). Moreover, access to health education materials and self-management tools empowers patients to actively manage their disease (37, 38). In our study, we observed a notable level of app usage, with approximately half of the patients actively engaged with the chat/contact feature with their assigned HC throughout the follow-up period. Furthermore, 32% of the patients were still actively messaging their coach for support even after the study concluded. Patients also displayed significant interest in furthering their understanding of PAH by accessing magazines and educational programs offered on the platform. Lastly, the PAHCare™ platform received positive feedback from patients, with a high level of program satisfaction reported. Specifically, 92.1% of patients expressed satisfaction (either generally satisfied or definitely satisfied), and 84.2% felt that their needs had been effectively addressed. This underscores not only the patient's evident desire for comprehensive information and support but also demonstrates the platform's ability to effectively meet those needs, thereby facilitating a better understanding of the healthcare process and ultimately enhancing the overall patient experience.

All of the aforementioned factors probably played a crucial role in the platform achieving higher retention rates compared to other mHealth applications. Remarkably, studies indicate that approximately 80% of participants in mHealth interventions for chronic diseases only engage at a minimal level and fail to sustain long-term usage (39). Indeed, recent estimates suggest that approximately 72% of subjects launch healthcare applications five times or less, while 17% use them ten times or less within a span of 30 days (40). In contrast, patients used the PAHCare™ app on average at least once a day. Additionally, it has been estimated that the average 30 days retention rate for medical apps is 52% (79.2% in our study), dropping to 31–39% (69.8% in our study) after 90 days (41). A recent systematic review conducted to examine factors influencing adherence to mHealth apps found that personalised features such as tailored feedback and needs, along with ease of use and direct communication with healthcare professionals, positively influenced adherence to respiratory disease management applications (24). Additionally, the review found that adherence scores were significantly higher for apps provided exclusively as part of scientific studies, as opposed to those publicly available through app stores (39). The review also demonstrated that user engagement was higher for apps developed

by private app development companies compared to those created by public institutions or research groups (39). All these factors probably contributed to the attractiveness of the PAHCare™ platform and the sustained engagement and high retention rates observed in our study.

A recent review showed that Patient Support Programs (PSPs) designed with the aim of improving adherence and patient empowerment induced a positive impact on patient's adherence to medication, patient satisfaction, and HRQoL, and additionally showed that home therapy led to substantial cost savings (42). The main objectives of PSP are to ensure the correct delivery and management of medication, to improve healthcare professional's training and knowledge on treatment management, and to deliver very close patient care. In some countries, all this is taken care of by the PAH healthcare team, mainly by the specialised nurses, but in some cases externally provided additional support is needed. Mobile health platforms such as PAHcare can be used to deliver this patient support to patients in a straightforward and efficient manner. However, the observed increase in activity logs during the months corresponding to clinical follow-up appointments raises an interesting point. It is plausible that the additional motivation stemming from personal contact during these scheduled appointments contributed to heightened engagement with the PAHcare™ platform. Thus, the interaction with healthcare professionals during clinical follow-ups may have served as a catalyst, prompting users to actively participate and log more information on the platform. This finding suggests the potential synergistic effect of combining digital interventions with traditional, in-person clinical interactions.

Healthcare research requires different methodological approaches, such as qualitative and quantitative analyses, to understand the phenomena under study. Central elements of the qualitative method are that the object of study is constituted by perceptions, emotions and beliefs (43). Having seen that the high level of satisfaction shown by the study participants was not translated into a direct clinical benefit, the information gathered through the qualitative methodology may facilitate the understanding of critical points, barriers and facilitators that contribute to better management of PAH, considering the perspective of the patients and the health care team. Indeed, patient engagement goes beyond traditional activities in healthcare and extends to involving patients in designing and implementing care delivery systems, shaping health policies, and directing health research (6). In this context, the PAHcare™ digital platform emerges as a tool to collect patients' insights and experiences. These insights are crucial for aligning healthcare systems with the patient's needs, priorities, and preferences, ultimately enabling their active participation in governance decisions and defining management strategies. However, it's imperative to recognise that personalised support and user engagement in the context of mHealth apps also extends to privacy concerns and the willingness to share personal information (44). Thus, the development of a trustworthy application necessitates stringent measures to safeguard data from unauthorised access and uphold patients' rights to maintain control over their private health information and communications (45, 46). Finally, the importance of technical user-friendliness cannot be overstated, as it plays a crucial role in ensuring seamless and effective utilisation of digital health platforms (47), ultimately enhancing the overall user experience and maximising the potential benefits for patients. While our study lacked systematic data on technical support interactions and user-friendliness, it's crucial to consider these aspects in the broader context of our study's positive outcomes, including high levels of engagement, satisfaction, acceptability, and usability.

5 Conclusion

In summary, this pilot study demonstrates the feasibility and acceptability of the PAHcare™ digital platform as a promising mHealth intervention for patients with PAH. Although the clinical outcomes did not exhibit significant improvements, it is important to highlight the remarkable levels of engagement, satisfaction, acceptability, and usability experienced by participants. The platform's noteworthy user retention and sustained engagement underscore its potential to empower PAH patients. Through accessible educational resources, personalised health insights, and direct communication channels with healthcare professionals, the platform may facilitate active patient participation in their care, foster a sense of control over their health, and contribute to an overall enhancement in well-being.

The findings of this study provide a valuable basis for future research and development of mHealth interventions targeting PAH management. Further investigation with a larger sample size, longer follow-up period, and inclusion of patients across a broad functional spectrum is warranted to evaluate the clinical benefits offered by the PAHcare™ platform comprehensively. Qualitative research can also provide a more in-depth understanding of how the newly developed PAHCare™ solution is likely to address an unmet need.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the competing Ethics Committee of Hospital 12 de Octubre, Madrid, Spain, approved the study protocol V4.0 on March 22, 2022 (FPAH-CI-2101). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

GP: Investigation, Writing – review & editing. NO: Investigation, Writing – review & editing. JD: Investigation, Writing – review & editing. AM: Investigation, Writing – review & editing. ML: Investigation, Writing – review & editing. SC: Investigation, Writing – review & editing. FL: Investigation, Writing – review & editing. SG: Investigation, Writing – review & editing. CG-G: Investigation, Writing – review & editing. PR: Investigation, Writing – review & editing. JM: Investigation, Writing – review & editing. RA: Conceptualization, Investigation, Methodology, Supervision, Writing – review & editing. HM: Data curation, Methodology, Writing – review & editing. GB: Methodology, Writing – review & editing. PE: Conceptualization, Investigation, Methodology, Supervision, Writing – review & editing.

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Conflict of interest

PE has received consulting and lecture fees by Ferrer Internacional S.A. (Barcelona, Spain), Gossamer Bio., AOP Health, Janssen, and MSD. GP has received consulting fees by Ferrer Internacional S.A. (Barcelona, Spain). RA, HM, and GB are employees of Ferrer Internacional (Barcelona, Spain).

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2024.1335072/full#supplementary-material

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When all computers shut down: the clinical impact of a major cyber-attack on a general hospital

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Importance: Healthcare organizations operate in a data-rich environment and depend on digital computerized systems; thus, they may be exposed to cyber threats. Indeed, one of the most vulnerable sectors to hacks and malware is healthcare. However, the impact of cyberattacks on healthcare organizations remains under-investigated.
Objective: This study aims to describe a major attack on an entire medical center that resulted in a complete shutdown of all computer systems and to identify the critical actions required to resume regular operations.
Setting: This study was conducted on a public, general, and acute care referral university teaching hospital.
Methods: We report the different recovery measures on various hospital clinical activities and their impact on clinical work.
Results: The system malfunction of hospital computers did not reduce the number of heart catheterizations, births, or outpatient clinic visits. However, a sharp drop in surgical activities, emergency room visits, and total hospital occupancy was observed immediately and during the first postattack week. A gradual increase in all clinical activities was detected starting in the second week after the attack, with a significant increase of 30% associated with the restoration of the electronic medical records (EMR) and laboratory module and a 50% increase associated with the return of the imaging module archiving. One limitation of the present study is that, due to its retrospective design, there were no data regarding the number of elective internal care hospitalizations that were considered crucial.
Conclusions and relevance: The risk of ransomware cyberattacks is growing. Healthcare systems at all levels of the hospital should be aware of this threat and implement protocols should this catastrophic event occur. Careful evaluation of steady computer system recovery weekly enables vital hospital function, even under a major cyberattack. The restoration of EMR, laboratory systems, and imaging archiving modules was found to be the most significant factor that allowed the return to normal clinical hospital work.

KEYWORDS

computers in medicine, computer security, cyberattack, healthcare system resilience, patient electronic file, ransomware, safety

Introduction

It seems possible to imagine the modern world without computers. Medical care systems have advanced globally for many years. Currently, several of these systems are now paperless. Digitalization has significant advantages and allows access to all records in an online and real-time format. However, the dependency of healthcare organizations on digital computerized systems and the data-rich environment of these systems create vulnerability to cyber threats. Indeed, hacks and malware are a major concern in the healthcare sector (1).

Healthcare systems may be exposed to various types of cyber threats, which can be categorized as internal or external. Internal threats arise from inappropriate access to sensitive data by internal proxies, while external threats arise from external agents exploiting the vulnerability of healthcare information systems. External threats include data breaches, denial-of-service attacks, cybersquatting, critical infrastructure failure/breach, and cyberterrorism. Cybercriminals aim to steal or corrupt personalized health information, which in turn can harm patients, healthcare organizations, healthcare networks, and even the entire nation (2). The motivation is usually financial but may also be terrorism.

As healthcare systems become increasingly reliant on digital systems to deliver care, healthcare organizations' readiness to manage critical infrastructure failure/breach is crucial for the continuity of care and patient safety. Analyzing healthcare organizations responses to malfunctioning computerized systems can provide new insights that may be useful in the management of such future events.

Multiple cyberattacks have been reported in the medical literature, most of which describe the technical aspects of the cyberattacks or their impact on a single hospital service/department (3–5). However, the impact of hacks and malware on entire healthcare organizations remains under-investigated.

In what appears to be one of the largest medical cyberattacks in Israeli history, the Hillel Yaffe Medical Center (HYMC) major networks were hit with a major ransomware attack, by an unknown hacker group. As a consequence, the whole hospital was locked out of its entire digital systems. The ransom attack was declared as a major national incident. During the following 8 weeks, the hospital gradually resumed its regular activities, and total computer recovery was achieved.

This study aimed to identify and evaluate the direct and indirect impact of the cyberattack on the hospital's clinical activities and its organizational workflow. We explored the significance of the restoration of electronic medical records (EMR) and radiology archiving modules on normal hospital work.

Setting

HYMC is a general and acute care university teaching hospital. It is a non-profit, governmental-owned organization with a 546-bed capacity, including 35 different inpatient wards and ambulatory clinics. The hospital provides a wide range of medical services to a diverse population with various medical conditions. It serves a referral population of ~500,000 people. It is the only hospital in the area located 50 km from the nearest tertiary hospital. The hospital employs ~3,000 workers.

The hospital's information management is comprehensively computerized across all organizational levels, including clinics, administration, logistics, and communications. All hospital functions were disrupted. Computerized systems include core platforms, such as EMR (Chameleon, Elad Software Systems, Tel Aviv, Israel) connected to medical devices, admission, discharge, and transfer (ADT) and the main enterprise resource planning (ERP) system (ERP's Namer, SAP, Ra'anana, Israel), logistics (Mazor, SAP), Radiology Information System & Picture Archiving and Communication System (RIS/PACS, Phoenixville, PA, USA), IVF software (Eve Pro, OBG Soft, Israel), laboratory system (AutoLab and Softov, Softov Medical Systems, Kfar Saba, Israel), and a widespread communications network including Microsoft Outlook, an employee attendance system, a surveillance camera network, and additional security systems. The hospital is connected to the national community health patient record (HPR) interface—"Eitan" software, a computerized platform unique to Israel, which enables the sharing of online secure patient information between different healthcare providers and health insurance companies. In addition, the hospital management board uses a wide range of reports and data systems for obtaining online information on hospital activity status, control, supervision, and decision-making.

There are also about 100 different niche systems working across the hospital. In general, all organizational documentation is performed without paper documents and includes clinical treatment management, patient clinical data, measures, and follow-up, computerized physician order entry (CPOE), operating room (OR) module, patient education, laboratory, different protocols and reports, and communication between departments and services. Furthermore, during the COVID-19 period, the hospital added and upgraded remote e-work such as e-consultation services, remote home access, and other services.

Description of the cyberattack

On October 13, 2021, the Hillel Yaffe major networks were hit by a ransomware attack, known as DeepBlueMagic, by an unknown hacker group. All computer systems, at all levels of the hospital, were locked, without the option to log in. This denial-of-service attack locked completely the entire computer network by blocking access to most computers and encrypting most of the external and internal servers.

This particular type of ransomware attack utilized an innovative type of encryption. It is particularly dangerous because it manages to circumvent protection tools installed in the system to protect it. The attackers utilized a legitimate tool such as Microsoft BitLocker to disable all computers. The malware locks the system, and the hackers may demand a

ransom to release it, holding the information, and potentially the lives, of the hostage patients (1).

The attack was immediately recognized by an administration server and reported to the National Ministry of Health and the National Cyber Council. HYMC immediately locked the Internet access to prevent further damage, essentially blocking access to EMR, laboratory and imaging results, and other vital digital tools.

As a result of the attack, no access was available to any hospital computer. The staff did not even know which patients were scheduled for appointments nor the patient list on their respective wards. It influenced every aspect of medical services, both inpatient and outpatient. This included the loss of some documentation of patient data, EMRs, inpatient lists, information on upcoming outpatient appointments, laboratory services and reporting of results, imaging availability, and more. Also, the entire online staff communication system using intranet and e-mails came to a halt.

Methods

For the present manuscript analysis, the week of the DeepBlueMagik ransom attack was defined as week *X*. We performed two analyses (1). Data were collected during the 8-week period following the attack and compared to data from the parallel period in 2019. Data regarding the year 2020 were not examined due to the COVID-19 pandemic limitations (2). We compared the activity in the weeks following the cyberattack to the activity in the week of the attack.

The study was approved by the local IRB Committee, 0035-22-HYMC. The collected data did not include any patient personal or medical information. Research information was secured and saved in a suitable software for which access was limited to the study's investigators.

The case study method was used to describe the hospital's response to the massive cyber ransom attack. Data collection was based on the Ministry of Health information systems and activity reports extracted from HYMC information systems. All data collected manually during the attack were completely returned to the hospital computer systems. Data included visits to emergency departments (ED); the number of hospital admissions; hospital clinical activities, including urgent cases and elective procedures; the occupancy rate of pediatric, surgical, internal, and obstetric departments; and the number of visits to outpatient clinics.

Statistical analysis

The empirical analysis consisted of two steps. For this study, to maximally neutralize the potential impact of the COVID-19 pandemic and holidays, we collected data regarding hospital activities during the parallel 8-week period in 2019. This data served as a control for comparison. First, we compared the means of the two periods (2019 vs. 2021 across the postattack weeks), using the Mann–Whitney non-parametric test for two independent samples, that come from the same population to determine whether two sample means are equal or not. A complementary incidence rate ratio (IRR) analysis examined whether the rates remained unchanged across the two periods, that is, whether drops in the number of admissions, procedures, and outpatient visits were similar across different hospital departments and external services. Following the abovementioned analysis, the Mann–Kendall trend test was used to investigate the week-by-week difference, that is, the difference during each week through the duration of the attack (weeks X–$X+7$) (6–8). Sen's non-parametric slope measures were added. A graphical exposition was presented to show the change across weeks from large to no difference. For this analysis, we looked at different clinical time series, which covered hospital activity in all aspects, specifically, emergency room (ER) admissions, direct admissions to hospital departments, emergency admissions to hospital departments, total occupation rates, surgeries, cardiovascular catheterizations, number of births, and imaging services, i.e., CT, MRI, and x-rays.

Results

Immediate actions taken following the cyberattack

The top priority was to keep the patients safe. National news aired the issue, and prehospital emergency services were instructed whenever possible not to refer mild and moderate trauma patients to the HYMC emergency department. This was a critical decision that reduced the number of patients entering the hospital.

An immediate decision was made to stop all non-life-saving procedures, and many surgeries had to be rescheduled. Some patients had to be referred to other centers for various treatments. A decision was made to halt all elective surgeries and invasive procedures until guaranteeing that the hospital ventilators, all ICU monitors, operation rooms, and catheterization laboratory infrastructures have not been damaged.

During the first week, there was significant activity disruption throughout the hospital, both for the patients and for the healthcare staff. These disruptions included reverting to manual processes, e.g., reporting blood test results, paper documentation, writing and executing medical orders by handwriting, canceling outpatient appointments, and elective admissions and most surgical procedures (Table 1).

Computer system recovery

The system recovery efforts began from day 1 after the attack, first including the HPR interface, by distributing laptops with a secured cellular Internet connection to the national "Eitan" system, to restore the hospitalized patient health history. Laptops were distributed in the different wards and connected directly to printers (as there was no printer network) to allow clinical follow-up, the production of a Word document for discharge letters, and the writing of follow-up.

The first decisions taken by the local IT and national cyber experts were to build a completely new network for restoring the

TABLE 1 Challenges arising following the cyber attack.

Service affected	Sequela	Adaptation
Emergency room (ER)	A gradual decrease in visit numbers	The media reported cyberattack calling patients to turn to other ERs; ambulances referred patients to other ERs
Elective procedures	All elective procedures (hospital-wide) were postponed	Risk stratification was done on all elective procedures. Potentially complicated surgeries were referred to other hospitals
Loss of electronic medical records (EMR)	No historical data on patients from outpatient clinics, or previous hospitalizations	Within 2–3 days, a full set of Word formatted documents were available for ER visits (admission or discharge), interventional procedures, birth certificates, ward follow-up, and discharge letters
Labs	No previous or current laboratory results were available for patients in the ER or admitted	Only critical labs were done. Tubes were tagged using handwritten stickers and were sent manually to the laboratory. The results were first reported on the phone and within a few days were printed and delivered manually to the sending department.
Blood bank services	No historical data on the blood type of recurring patients. Risk of mislabeling patient blood type with increased risk of compromise to patient safety	Blood product transfusions were decreased to a minimum. Extra caution was implemented in rare cases when a blood product transfusion was needed.
Imaging	No remote access and historical images available	Selected imaging was done. Images were photographed using smartphones for radiological assessment
Decision-making	Change in policies for sending labs, imaging, and/or admission	Senior physicians or senior residents were placed to allow for better triage, deferring unneeded tests and preferring ambulatory care, whenever possible. Complicated cases (with potential risk for complications that will require complicated surgery or blood–product transfusion were deferred or referred to other medical centers. Admission was selected for low-risk patients who could not be discharged
Elective cesarean sections		Elective cesareans were allowed after risk management and case selection
Newborn identification	No digital authentication or digital birth certificates	Was done with double verification by two midwives, written manually on stickers and tagged to newborns and mothers
Outpatient clinics	The scheduled patient list was not available. No history or previous encounter data	Patients were treated based on "whoever arrives." Following encounters, patients were triaged: "uncomplicated" cases were referred to other clinics. Patients were encouraged to bring hard copies of their medical records
Archiving data	No data archiving. All data were manually written on paper	All data were assembled in the patient's binders. The first page included the order of papers from the admission letter, diagnosis list, follow-up, labs, fetal heart monitoring, etc. Every paper included a place for the date and hour and the physician's signature. Later all documents were scanned into the patient's EMR

data, disconnected from the Internet (with security layers), and installing the entire systems from scratch (without information restoration). New servers were installed, and a separate network was formed with new IP addresses for all the equipment. To reduce the occurrence of similar mishaps in the future, the local IT conducted password replacement in all systems, an examination, and elimination of permissions that were unnecessary. The same software were installed separately, and when possible, the data were restored and scanned for malware. After the imported data were installed in the new systems, each restored database was approved and only then allowed to be used. The local IT aimed to create a "new" and clean system. New layers of security and updated information security systems, such as antivirus, with the latest signatures were implemented to enable connection to the Internet and external connectivity to suppliers.

The laboratory system (LabOs) was restored in the first week after the attack ($X+1$), enabling the necessary work processes involved in laboratory testing. The ATD system was repaired in the middle of the second week following the attack ($X+2$), which restored the ability to properly register the hospital's population demography and patient flow. The second week ($X+2$) also included the restoration of the radiology module (RIS/PACS), which allowed image archiving, editing, distribution, and storage of patient radiological data. The administration and operation platform was restored after the fourth week ($X+4$) and enabled proper administrative ability. The EMR system, including all patients' histories that were saved in backup systems before the attack, was reinstalled in the fourth week ($X+4$), restoring the standard routine of electronic patient documentation and clinical data management. Finally, following 8 weeks ($X+8$), intranet and e-mail communication were restored. Week by week, partial recovery of the computer systems allowed the hospital's administration to carefully and gradually return to normal activity, along with meticulous evaluation of changes associated with this process.

Main study findings and outcomes

Drop in activity in 2021 compared with 2019

Descriptive statistics for the main time series across the two defined periods, followed by a non-parametric test of difference are presented in Tables 2, 3. Across the different time series, no statistical difference was found in the number of heart catheterizations ($U=-0.950$, $p=.370$; $U=0.306$, $p=.766$), as well as in the number of births and outpatient visits. In all other time series, the two periods differed, where the mean level of all other evaluated activities in the postattack period was lower in

TABLE 2 Comparison between 2019 and 2021 across various time series; weekly means.

	2019 mean ± SD	2021 mean ± SD	*p*-value
1. Total number of emergency room (ER) admissions[a]	2,479.8 ± 117.0	2,084.2 ± 284.2	.001
2. Total number of emergency direct admissions to hospital departments	661.8 ± 32.2	552.0 ± 99.8	.016
3. Hospital occupancy (percent of beds occupied)	83% ± 5%	64% ± 9%	<.001
4. Total number of ambulatory visits	6,640 ± 1,242.5	5,801 ± 1,163.4	.056
5. Births	86.3 ± 10.6	78.6 ± 5.6	.056
6. Total number of surgeries	243.1 ± 62.2	143.3 ± 102.4	.020
7. Heart catheterizations	26.9 ± 5.7	27.6 ± 6.5	.766
8. Total number of ambulatory imaging services	2,525.5 ± 198.8	2,013.6 ± 560.9	.016

[a]One excluded COVID admission.

TABLE 3 Analyses of the return to routine across various hospital indicators.

	Mann–Kendall trend test, *Z*	*p*-value	Sen's slope, 95% CI
Total number of emergency room (ER) admissions	−2.81	.002	−105.75,[−124.55, −86.95]
Total number of emergency admissions to hospital departments	−1.77	.038	−26.63, [−45.43, −7.83]
Hospital occupancy (percent occupied beds)	−0.52	.301	−0.01, [−18.81,18.79]
Total number of ambulatory visits	−0.31	.377	−70.83, [−89.63, −52.03]
Births	1.15	.126	1.92, [−16.88,20.72]
Total number of surgeries	−0.52	.301	−10.02, [−28.82,8.78]
Heart catheterizations	−0.94	.174	−1.74, [−20.54,17.06]
Total number of ambulatory imaging services	−2.19	.014	−188.08, [−206.88,−169.28]

Comparisons are based on differences across weeks X to $X+8$.

comparison to 2019. The complementary IRR test results indicated that the proportion of women admitted to the obstetric department and of children admitted to the pediatric department remained similar, regardless of the attack [the 2021–2019 ratio was 1.46 95% CI: (1.39,1.53); 1.10 95%-CI: (1.03,1.67), for women and children, respectively]. That is, in 2021, the proportion of women and children for all hospital admissions was higher, notwithstanding the attack.

The weekly number of ER admissions during 2019 and 2021 was analyzed, and the parallel weeks in the two periods were compared. Although administrative protective interventions were performed immediately, in certain time series, its impact was observed only as of $X+2$. The weekly differences were highly correlated with the 2021 level, as in 2019 the trend was relatively flat, as shown in Figure 1. The indication is that the trend took place mainly from week $X+2$ to week $X+6$. Assessment of the differences between 2021 and 2019 would be caught up to zero, or no difference. We found significant Mann–Kendall test results ($p=.002$) and a significant ($p<.05$) negative Sen's trend. The number of admissions dropped to slightly higher than 1,500 in week $X+2$ of 2021, compared with ∼2,500 in regular weeks. Based on Sen's slope calculation, we state that the difference was caught up by an average of 100 cases during the postattack period.

During the week of the ransomware attack, there was an overall small decrease in the number of deliveries, which remained stable during the 8 weeks that followed, representing a small drop compared to the average number of deliveries in the respective weeks in 2019 (86.3 ± 10.6 vs. 82.8 ± 11.2, 2019 and 2021, respectively). Visits to the obstetric ER demonstrated a decrease compared to $X-1$ and $X-2$, with a small difference compared to the average visits per week in the retrospective period in 2019. This remained stable up to $X+8$ (234.5 ± 19.5 vs. 225.7 ± 25.1, $p=0.00$, 2019 and 2021, respectively).

Return to activity compared to the week of the cyberattack

A final analysis is presented in Table 4. In this analysis, percent changes in numbers were calculated for different hospital activity measures. We found the actual change for these series and tested whether a significant change has occurred between the event (week X) and stages in the return to normal activity (week $X+2$, PACS + RIS; week $X+4$ and Chameleon system recovery; week $X+5$, full capacity). We estimated a trend across the 8 weeks that followed the event and found that aside from ambulatory visits, cardiovascular catheterizations, and ambulatory imaging services, the other six series showed a significant decrease in percent differences with respect to the earlier weeks of the event.

Discussion

In recent years, laptops and tablets have become as common in healthcare settings as stethoscopes, and for the young physician and nurse generation, working without computers seems impossible. The present study aimed to identify and evaluate the direct and indirect impact of the DeepBlueMagic cyberattack, which involved a complete computer and network shutdown, on the hospital's clinical activities and its organizational workflow. There was a need to install new servers and create a new network, and the first functions to return were the EMR and laboratory module and the imaging module.

The decision of a new network was recommended by the National Cyber Council, and the order of software installation was based on which systems were most crucial for the fast and safe return of clinical treatment and management of the patients in the hospital. There was a need to prioritize, and each system was released for use only after extensive checks and verification of all data. This took time but building the base was important to create a stable system.

Our results demonstrated that the attack impact differed according to the type of hospital activities. Most clinical activity was impacted apart from cardiovascular catheterizations, ambulatory outpatient visits, and ambulatory imaging services.

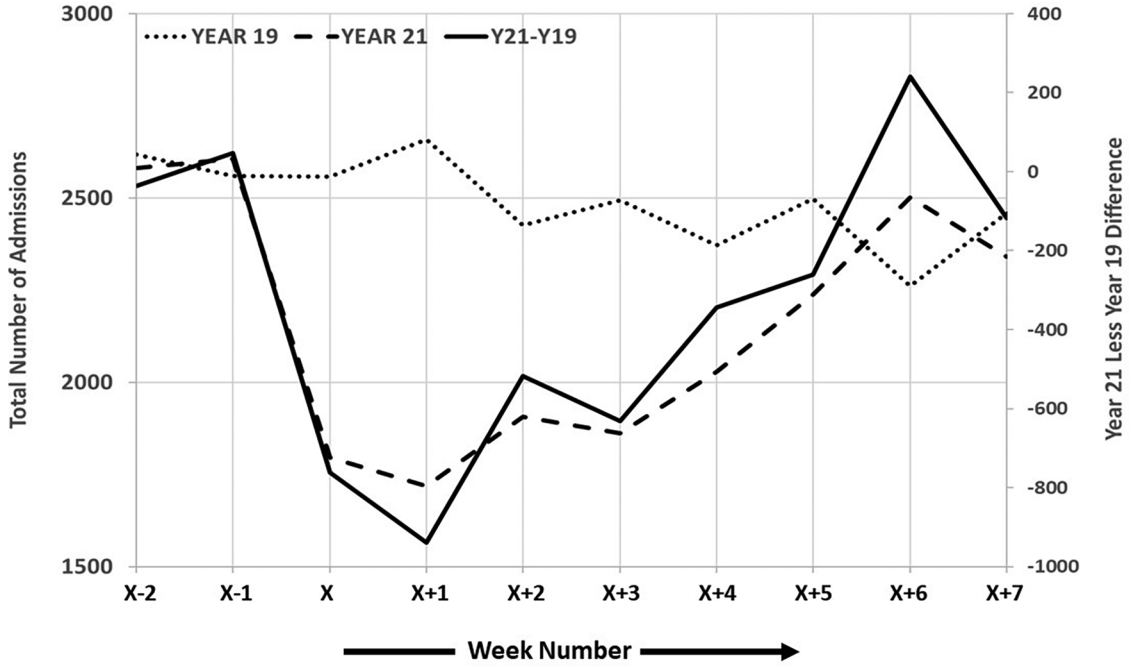

FIGURE 1
Graphical representation of the two periods with regard to total ER admissions.

TABLE 4 Tests of return to normal by significant events.

Percent change between weeks →	Trend	$X+2/X-2$	$X+4/X-2$	$X+6/X-2$	$X+2/X$	$X+4/X$	$X+6/X$
Hospital activity measure							
Emergency room (ER) admissions	−.04***	23.1%	18.2%	−0.9%	−6.2%	−13.0%	−39.4%
Emergency hospital admissions	−.05**	31.5%	25.9%	4.9%	6.0%	−1.8%	−30.7%
Regular hospital admissions	−.09**	46.3%	18.5%	−2.8%	42.0%	12.0%	−11.0%
Occupied beds	−.04*	35.2%	22.9%	17.3%	15.9%	0.0%	−7.2%
Ambulatory visits	−.02	35.7%	35.7%	16.7%	26.0%	26.0%	4.1%
Births	−.04*	35.4%	18.8%	−3.1%	33.5%	16.5%	−6.1%
Surgical procedures	−.06*	50.1%	24.1%	−0.6%	36.1%	2.7%	−28.8%
Heart catheterizations	.002	26.6%	19.1%	24.5%	15.9%	7.3%	13.4%
Ambulatory imaging services	−.05	40.0%	26.7%	−3.3%	5.3%	−15.8%	−63.2%
T-test results		12.49***	12.29***	1.64	3.59*	0.84	−2.36*

*$p < 0.05$.
**$p < 0.01$.
***$p < 0.001$.

The restoration of EMR, laboratory systems, and imaging archiving modules was found to be the most significant factor that allowed the return to normal clinical hospital work.

On the day of the cyberattack, all non-vital elective procedures were canceled. As expected, a drop was detected in all elective hospitalizations. Emergency services were asked to detour the hospital. There was a sharp drop detected in all admissions in the week of the attack. However, there was a complete return to the baseline hospitalization numbers in the internal medicine wards at week $X+7$. Yet, surgical emergency admissions did not return to the baseline even after week $X+8$. The total number of hospitalizations in the obstetrics and gynecology wards remained unchanged during the study period. It is easy to explain why there has not been a decline in gynecological interventions, as procedures such as caesarian sections and abortions cannot be canceled.

We demonstrated a significantly sharp drop in the number of admissions to the pediatric and psychiatric emergency wards in the week of the attack, accompanied by a consistent increase in these admissions after the first 7 days. This was regardless of interventions made by the hospital administration and the system recovery status. We assume this patient population, opted to return to the nearest hospital in any case. The gradual return to surgical activities was restarted at week $X+2$. In the beginning, the hospital administration considered performing surgeries in cases where the

consequences of a delay, outweighed the risk of the operation, according to the clinical judgment of the chief of the department.

In such a crisis, medical decision-making was crucial. The simple decision to send labs or admit/release to ambulatory care was based not only on guideline recommendations but also on risk stratification. This included, on the one hand, being aware of the potential damage to patients by human errors, delay of treatment, or suboptimal care and, on the other hand, enabling medical care when required. For example, the need for blood transfusion carries a special risk of human error (when taking the blood, tagging the tubes, forwarding them to the labs, retrieving a matching blood product, and transfusing it in the patient). Patients who were at high risk for complications during an intervention and who might need imaging services or interdisciplinary care were also postponed if possible or referred elsewhere.

Early indications suggest that the current "DeepBlueMagic," gained initial access by exploiting remote access software—a known Pulse Secure VPN vulnerability. The exploitation of network infrastructure is consistent with previously reported DeepBlueMagic activity, an unsurprising revelation given that many ransomware operators favor tried-and-tested exploits to acquire user credentials and/or gain privileged access to victim networks. It is also common for ransomware operators to terminate processes and services associated with backup and security tools, to evade detection and further thwart recovery and any application servers, and to ensure that files are not locked open.

This incident should act as yet another reminder as to why it is important to ensure that network infrastructure devices, all too often deployed and forgotten about, are included in robust patch management programs. Defenders will be reliant on the need to detect behavioral activity, both prior to the encryption phase, such as unusual user logon activity and privilege escalation, and during the encryption phase, such as the unexpected execution of these utilities or anomalous disk and file operations.

Moreover, despite the published recommendations and guidelines, there seems to be no single solution for managing cyberattacks, due to the complexity of such events and the differences between healthcare systems (9, 10). For example, a large regional orthopedic service in Ireland that was subjected to an attack decided to utilize inter-hospital transfers based on radiological hard copies and secure messaging systems and in some situations using the WhatsApp application (11). However, in the absence of clear formal or at least worldwide-accepted regulatory processes, it may create ethical concerns regarding patient privacy (12). For example, the Israeli data security laws prohibit such use. Furthermore, in comparison with evidence-based medicine, the solutions seem to be intuitive in many situations. Thus, during the major "WannaCry" attack, the National Health System (NHS) in England published a "Cyber Handbook" that reviewed the lessons learned and security standards and described ways to prepare for future events (13). However, this publication does not detail local cyber response activities in any depth. In addition, during the "WannaCry" attack, the authors reported no difference in the total level of activities across all the system trusts, but a statistically significant 6% drop in total admissions in the "infected" hospitals. However, this attack lasted only 1 week, and no single hospital-related volume analysis was performed (14).

As opposed to previous studies (14–21), the main effort in the current study was to evaluate the timing of problem identification and the different software installation and to investigate the decision-making processes with regard to different outcomes of hospital activities. The temporary conversion to a manual documentation process allowed the continuation of vital services and data collection. The hospital had to form a new network with new servers installed. The IT priority was to assist in the most important services: HRP, laboratories, and imaging. Some clinical services such as catheterizations were not influenced, but some took longer to recover. Some, as a result of rescheduling and waiting for a proper backup system to restore data, were destroyed by the attack.

According to a recent US Government interagency report, there have been 4,000 daily ransomware attacks on average since early 2016 (a 300% increase compared to the 1,000 daily ransomware attacks reported in 2015; US Government Interagency Guidance Document). The amount of data stored, which consists of financial information, health details, social security information, and others, its sensitivity, and the growing dependence of medical providers on technology have made hospitals a viable target for cyberattacks (16).

It is important to emphasize that this ransom attack was considered and treated by our organization as an emergency event. As part of the Israeli reality, which requires facing various emergencies, HYMC, similar to other Israeli healthcare organizations, created and constantly maintains preparedness for a variety of anticipated emergencies, one of which is a cyberattack/computerized systems overall shutdown. The components of an emergency preparedness and response program include planning, training, simulations, information management, communication, development of response, and contingency plans.

This is not the first time that a healthcare institution has been targeted, and undoubtedly not the last, given that some may consider them a soft target. The disruption caused by these financially motivated cyberattacks could result in a loss-of-life situation by delaying or preventing critical care. Several papers describe ways to prevent, recover, and analyze such attacks (22, 23). These studies emphasize the importance of monitoring computer and application use continuously in an effort to detect suspicious activities and identify and address security problems before they cause harm. There is a need to ensure adequate system protection by correctly installing and configuring computers and networks that connect them and to ensure more reliable system defense by implementing user-focused strategies, including simulation and training on the correct and complete use of computers and network applications. Finally, organizations need to respond adequately to and recover quickly from ransomware attacks and take action to prevent them in the future.

One limitation of the present study is that due to the retrospective design of this study, there were no data regarding the number of elective internal care hospitalizations that were considered crucial. Another major limitation is that this study describes a single-center experience with its own conclusions, which are not necessarily relevant to every institution in future cyberattacks.

TABLE 5 Main lessons for future events.

Checklist for a cyber incident	
Pre-established mechanisms for communication with healthcare teams	
Return to paperwork: pre-prepared sets of blank, hard-copy medical records in each department to enable uninterrupted charting and documentation	Templates for all scenarios should be readily accessible, with hard copies to allow workflow. This is important for patient safety and to ensure that all relevant patient details are recorded for later archiving
Staff training in the use of manual documentation and procedures for cyberattacks or other computer system losses (videos and simulations of work processes)	
Simulation of cyberattack	To detect the current situation in each organization
Safety first	Patient safety above all and considering the risk/benefit of each step
Decision-making	Senior physicians were allocated to every station to cope with both medical and ethical dilemmas. The decision for ambulatory care, referring to other hospitals, or even using the imaging services/labs was not based solely on medical recommendations but also took into consideration the complexity and risk of every evaluation needed
Laptop backup	To have enough laptops for urgent distribution
Communication and teamwork	e-mails or contact lists originally stored on hospital IT platforms were no longer available, it was essential to have an alternative route for communication, from managerial staff to all nurses and the last of the paramedical staff. Regular clear communication from the management proved critical for allowing essential patient care to continue
IT backup	This refers to having a backup for all essential information, having consistent parameter requirements across different vendor hardware and software, and having a plan for recovery and restoration of normal operations once the software is operational
Plans to support staff in a crisis and to maintain personal and organizational resilience	

Being prepared and simulating a cyberattack, when no computers function, may assist every institution in understanding the strengths and weaknesses they might have. Many daily life clinical examples can be detected with such a simulation, for example, how to locate the different forms such as consent forms and order sheets, how to connect to printers not through a network, how to send blood and other body fluid tests, how to receive the result and record them, and how to look at a CT scan or even a simple x-ray of a fractured bone—if there is no network or the option to burn a CD as there is no network. How can someone see a patient in the ambulatory outpatient clinic, when the physician is "blinded" to any clinical note, imaging test, laboratory, or pathology results or has no access to the ECG in the hospital's database? Simulation in each institute can find many additional points and detect weak areas, that one might face; but today—in the computer era—we do not think about it. Table 5 summarizes some additional points.

Conclusions

Hospitals must be prepared for cyberattacks just like any other emergency. The massive cyberattack had different impacts on various clinical hospital activities. The restoration of EMR and radiology archiving modules was found to be the most significant factor that allowed the return to normal hospital work. A selective approach to the decision-making process is needed to facilitate the provision of adequate patient care in different wards. Simulation of computer shutdown may assist in preparation for this kind of disaster and to be better prepared. It is recommended that healthcare providers at all levels have an available protocol for quick adaptation.

Summary points

In this paper, we describe the difficulties and lessons that should be shared for awareness and learning following a ransomware attack on a medical center that resulted in the complete shutdown of all computer systems.

Our study describes the challenges following a cyberattack, the steps taken, and how they influenced hospital recovery.

Healthcare systems at all levels should be aware of this threat and implement protocols once this catastrophic event occurs. The restoration of EMR, laboratory systems, and imaging modules was found to be the most significant factor that allowed the return to normal clinical hospital work.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the Hillel Yaffe IRB Committee, 0035-22-HYMC. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and institutional requirements.

Author contributions

BA: data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, validation, visualization, writing – original draft, writing – review and editing. BK: data curation, investigation, methodology, project administration, resources, validation, writing – original draft, writing – review and editing. MB: conceptualization, data curation, formal analysis, investigation, methodology, resources, software, supervision, validation, writing – original draft, writing – review and editing. RG-B: conceptualization, formal analysis, methodology, project administration, writing – original draft, writing – review and editing. DD: conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, validation, writing – review and editing. AO: conceptualization, data curation, formal analysis, investigation, methodology, resources, validation, writing – original draft, writing – review and editing. NG: data curation, formal analysis, investigation, methodology, project administration, resources, software, supervision, validation, writing – review and editing. AK: conceptualization, investigation, methodology, validation, writing – original draft, writing – review and editing. AR: conceptualization, data curation, formal analysis, investigation, methodology, project administration, resources, software, supervision, validation, visualization, writing – original draft, writing – review and editing. MD: conceptualization, funding acquisition, investigation, methodology, project administration, supervision, validation, writing – review and editing.

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Conflict of interest

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Facilitating patient portal engagement: a channel expansion and behavior change wheel perspective

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Introduction: Given the low patient portal adoption rates, the contradictory findings on the relationship between patient-provider communication and patient portal use, and the unclear mechanism of why doctor-patient communication might facilitate portal use as indicated in some existing studies, patient portal engagement warrants further examination.

Methods: Guided by the behavior change wheel framework and the channel expansion theory, this study examined the facilitators of patient portal engagement and tested the relationship between the facilitators (e.g., social opportunity and psychological capability) through analyzing the HINTS national survey data ($N = 1251$).

Results: We found that patient portal access (a physical opportunity) and physician advocacy (a social opportunity) were two significant predictors of portal engagement while educational attainment was not. We did not find any direct correlation between patient-centered communication (PCC) and patient portal engagement, but instead, found a significant indirect relationship between the two.

Discussion: To the best of our knowledge, this is the first study to employ the behavior change wheel and channel expansion theory to explain patient portal engagement. Theoretically, our study extended the behavior change theory by further explaining the relationship between the key components (e.g., capability, opportunity) of behavior change. Practical strategies to increase patient portal engagement were proposed.

KEYWORDS

patient portal engagement, the behavior change wheel, the channel expansion theory, patient-centered communication, patient portal access

Introduction

A patient portal is a secure online website that patients can use (e.g., to access personal health record) 24/7 from anywhere with Internet coverage (The Office of the National Coordinator for Health Information Technology, 2017). Despite the various potential benefits of patient portals (e.g., enhancing information sharing, improving patient safety, facilitating patient-provider communication, facilitating disease self-management, and empowering patients) (Miller et al., 2016; Rathert et al., 2017; Ammenwerth, 2018; Dendere et al., 2019), and despite the electronic health record (EHR) incentive programs to advocate and promote the meaningful use of EHRs to improve patient care (Ricciardi et al., 2013; Centers for Medicare and Medicaid Services, 2023), patient portal adoption rates have remained low, ranging from 37 to 54% (Anthony et al., 2018; Turner et al., 2020; Wright et al., 2022).

Among the empirical studies that have examined the facilitators of and barriers to online patient portal use, some conflicting results have been observed. For instance, some studies (e.g., Tieu et al., 2015) indicated that patient-provider communication is a facilitator while other studies (e.g., Zaidi et al., 2022) did not find such a significant relationship. The most prevalent barrier of portal use indicated by portal nonusers was the preference for in-person communication with providers (Anthony et al., 2018; Turner et al., 2020).

Even if patient-provider communication has a facilitating role, the mechanism of why the interpersonal communication (i.e., doctor-patient communication) can facilitate the computer- or technology-mediated communication (i.e., patient portal use) is unclear. Given the low patient portal adoption rates, the contradictory findings on the relationship between patient-provider communication and patient portal use, and the unclear mechanism of why doctor-patient communication might facilitate portal use as indicated in some existing studies, online patient portal use or engagement warrants further examination.

Guided by the behavior change wheel framework (Michie et al., 2011), the current research proposes that psychological capability (e.g., education attainment), physical opportunity (e.g., portal access), and social opportunity (e.g., physician advocacy) likely affect patients' levels of engagement in portal use. Also guided by the channel expansion theory (Carlson and Zmud, 1999), the current research proposes that patient-centered communication (PCC) likely affects portal engagement indirectly through levels of easiness in understanding the health information in patient portals. Therefore, the goals of the study are: (1) to test whether or not educational attainment, patient portal access, or physician advocacy predicts patient portal engagement, and (2) to find out the relationship between PCC and patient portal engagement.

Literature review

Functions of patient portals

Patient portals serve different functions. Basic functions include allowing patients to access their own medical information, such as medical history and records, immunizations, recent office visits. Other more advanced functions include enabling patients to schedule appointments, and exchange messages with healthcare their provider (Kruse et al., 2015). Some researchers have systematically reviewed the commonly shared functions among various patient portals. Bao et al. (2020) classified patient portal functions into two categories: clinical function and administrative function. Clinical function refers to outcomes that are directly related to patients' physical and mental health, such as viewing test results, messaging with health providers, scheduling an appointment. Administrative function is about how portal reduces the administrative burden on patients and health providers, such as updating insurance, resolving claims. Steitz et al. (2019) made a more detailed classification of patient portal's functions, which includes appointment, billing, document access, genetics, health results, immunization, medication, and messaging.

Patient portal engagement

Patient engagement is the process that patients themselves serve as an active member of the health care team and then build and maintain collaborative partnerships with health providers and provider organizations (Maurer et al., 2012). Patient portal engagement is a multi-step process, which goes from shallow to deep. Zhou et al. (2022) developed the patient portal engagement framework (PPEF) which summarized four levels of engagement: informing patients; involving patients; partnering with patients; and supporting ecology of care. Going through these four stages, a patient's role evolves from a passive information recipient to an active partner who collaborates with health providers. Portal engagement can generate some positive outcomes such as increasing medication adherence (Sarkar et al., 2014), empowering patients (Ammenwerth, 2018), reducing duplicate testing (Wakefield et al., 2020), significantly reducing patients' hospital visit times, and eventually decreasing hospitalization costs (Bao et al., 2020). However, though with various portal functions and the potential benefits, the adoption rates of patient portal, at least in the U.S., have remained low (Anthony et al., 2018; Turner et al., 2020). Given the low engagement rates, it is imperative to find out potential barriers to and facilitators of patient portal engagement.

The behavior change wheel and patient portal engagement

The behavior change wheel framework (Michie et al., 2011) can be used to systematically examine the facilitators of and barriers to patient portal engagement. According to the behavior change wheel (Michie et al., 2011, 2014), in order for the behavior of online patient portal engagement to happen, capability, opportunity, and motivation are necessary conditions (Michie et al., 2011). Capability includes physical capability (i.e., the physical skills or strength needed to perform a behavior) and psychological capability (i.e., the psychological skills or knowledge needed to engage in a behavior) (Michie et al., 2011). Patients with higher educational attainment will likely have more knowledge and skills needed for patient portal use. Studies indicated that education level (an example of psychological capability) (Sarkar et al., 2011; Osborn et al., 2013; Ancker et al., 2015; Sun et al., 2019) was a significant predictor of portal engagement. Therefore, we hypothesize that:

H1(a) educational attainment will predict patient portal engagement.

Motivation includes automatic motivation (i.e., automatic processes without much deliberate thoughts, such as wants and needs, impulses and emotions) and reflective motivation (i.e., reflective processes involving deliberate thoughts and mental processing, such as intentions and evaluations) (Michie et al., 2011). Lack of awareness or motivation (Goel et al., 2011; Turner et al., 2020) can inhibit a patient's portal use. Patients with stronger health emotions (an example of automatic motivation), and openness to new experiences (an example of reflective motivation) are more likely to use patient portals (Moqbel et al., 2020).

Opportunity includes physical opportunity (i.e., the physical environment external to an individual, such as resources, access) and social opportunity (i.e., the social environment and interpersonal relations that are supposed to influence people' perceptions of a behavior) (Michie et al., 2011). High income (an example of physical opportunity) was a facilitator of portal engagement (Ketterer et al., 2013; Osborn et al., 2013; Sun et al., 2019) while not having access to computer (another example of physical opportunity) is a barrier for patients' portal engagement (Osborn et al., 2013). Other factors related to physical opportunity were also mentioned in the existing literature. For instance, the levels of comprehensiveness of health data on patient portals (Fujioka et al., 2021) influence portal engagement whereas portal design features (Lazard et al., 2016) can influence portal acceptance by patients. Based on the definition, having access to online patient portal is a physical opportunity. Patients indicated that no patient portal access and lack of Internet access were barriers to patient portal use (Turner et al., 2020). Therefore, having access to online patient portal is likely to be a facilitator of portal engagement. We hypothesize that:

H1(b) patient portal access will predict patient portal engagement.

Provider advocacy of portal use is a social opportunity that has the potential to facilitate portal use. Some physicians do not hold a positive attitude toward a patient portal since they think it generates more workload (Miller et al., 2016). However, health providers' support can influence patients' trust on a portal (Goel et al., 2011). Providers can communicate the potential benefits of patient portals through interpersonal communication in a healthcare setting and promote the use of patient portals, which will in turn influence patients' perception of patient portals and facilitate portal engagement. The following hypothesis was proposed:

H1(c) physician advocacy of portal use will predict patient portal engagement.

Patient-provider communication and portal engagement

There are conflicting results regarding the relationship between patient-provider communication and patient portal engagement. Studies indicated that interest in the portal was predicted by dissatisfaction with the provider-patient relationship, and disinterest in the portal was predicted by satisfaction with the provider-patient relationship (Zickmund et al., 2008). National survey results indicated that preference for in-person communication with providers (Anthony et al., 2018; Turner et al., 2020) was one of the major barriers of patient portal use. While some studies (e.g., Zaidi et al., 2022) did not find a significant relationship between provider-patient communication and online portal use, some other studies (e.g., Lyles et al., 2013; Tieu et al., 2015) indicated that patient-provider communication is a facilitator of patients' online patient portal use. Patient-centered communication (PCC), a type of patient-provider communication, occurs when a provider takes a patient's needs, goals, and individual experience into consideration, gives the patient the opportunity to make decisions and participate in their care, and it will enhance doctor-patient relationship (Epstein and Street, 2007). Higher levels of PCC could make the patients feel that there is no motivation to use the portal (Zickmund et al., 2008) or could motivate patients to take care of their health by engaging in patient portal. Therefore, the following research question (RQ) was proposed:

RQ1: What is the relationship between PCC and patient portal engagement?

Portal-mediated communication vs. doctor-patient communication

Portal-mediated communication and interpersonal communication with providers have their distinctive characteristics, benefits or disadvantages, under different tasks or circumstances. First, we consider levels of synchronicity. According to media synchronicity theory (Dennis et al., 2008), it is better to use face to face communication which has the highest degree of synchronicity when a patient first sees a doctor to understand the diagnosis and discuss a treatment plan or when complex things need to be discussed. Some physicians hold that a portal was not able to handle complex communication (Laukka et al., 2020). The high immediate and interactive nature will facilitate the process to reach shared understanding of a patient's health conditions and disease management plans (Kashian and Mirzaei, 2019). Second, compared to face-to-face communication, patient portals, are mostly text based and lack of visual cues (An and Frick, 2006). Because of the lack of visual cues (e.g., body languages and gestures) that help facilitate understanding and convey emotions in patient portals, misunderstanding can happen (Slanetz et al., 2019) when patients use the portals. "Patients with advanced disease need the cues that come with direct interaction to help them along with their care" (Fuerst, 2017, para. 8). Third, portal-mediated communication lacks the ability to communicate empathy (Laukka et al., 2020). Fourth, the advantage of text-based communication is that it provides a written record of face-to-face communication (e.g., clinical notes), and information needed for patients to manage their health and coordinate healthcare (e.g., test results, patient education). Patients don't need to worry about forgetting important things in the interpersonal setting and later they have the opportunity to learn and reflect on the content provided in the portal (An and Frick, 2006). Fifth, another advantage of portal-mediated communication is that it is place and time independent (An and Frick, 2006). Patients can access their health information 24/7, with the access to the Internet and appropriate technology (e.g., smartphones).

Based on the previous discussion of the characteristics of the communication channels, according to media richness theory (Daft and Lengel, 1986), portal-mediated communication could be considered as a leaner medium, compared to face-to-face communication, because of the following four aspects: immediate feedback, multiple cues, language variety, and personal focus (Ishii et al., 2019). The perception that portal is a lean medium in medical context could be the reason of some peoples' preference of face-to-face communication and the low rates of portal adoption.

However, according to the channel expansion theory (Carlson and Zmud, 1999), perceptions and attitudes of a medium and its characteristics vary across users because of a variety of factors, such as experience (Timmerman and Madhavapeddi, 2008). Experience can be specified into four categories: "(a) experience with a particular channel, (b) experience with a particular topic, (c) experience with a particular communicator, and (d) experience with particular organizational contexts" (Ishii et al., 2019, p. 125). Based on the channel expansion perspective (Carlson and Zmud, 1999), if a patient has more experience with their healthcare provider through PCC, the patient will be more familiar with the communicator (e.g., doctors) as well as the topic (e.g., health conditions). As the experience increases, their levels of the perception of the richness of the channel (i.e., patient portal) increase, and patients would likely feel easier to understand the health information on the patient portal. According to behavior change wheel (Michie et al., 2011), as patients feel easier to understand the health information on portal (i.e., the increase of psychological capability), they are more likely to engage in patient portals. Therefore, the following hypotheses were proposed:

H2. Higher levels of PCC will make patients feel easier to understand the health information on patient portal.
H3. If patients feel easier to understand health information on patient portals, they are more likely to engage in patient portals.
H4. There is a significant indirect relationship between PCC and patient portal engagement.

Methods

HINTS dataset and study population

The Health Information National Trends Survey (HINTS), developed by National Cancer Institute (n.d.), is used to collect nationally representative data to monitor and study health communication and health information technology. HINTS data are reliable and informative, and the items were carefully tested before the survey to ensure its validity (National Cancer Institute, n.d.). The data used in this study, HINTS 5 Cycle 4 (N = 3,865), were collected in 2020, and were available in 2022. HINTS data were used in this study because of its focus on patient portal use and because of its national representativeness. Patients (N = 1,251) who filled out the questions related to patient-centered communication and online patient portals were the focus of the analyses.

Instrumentation

The HINTS survey questions related to our hypotheses and research question were included in our investigation. Patient portal engagement can be measured by frequency of access (e.g., Wallace et al., 2016). Similarly, in our study, patient portal engagement was operationalized as the frequency of portal access ("How many times did you access your online medical record in the last 12 months?"). PCC was measure by seven items which have been used as PCC measures in previous studies (e.g., Totzkay et al., 2017). The questions asked how often the health professionals (e.g., doctors, nurses) did each of the processes, such as "give you the change to ask all the questions you had" and "involve you in decisions about your health care as much as you wanted." Patient portal access was measured by asking participants: "Have you ever been offered online access to your medical records by your health care provider?" Physician advocacy was measured by the question: "Have any of your health care providers, including doctors, nurses, or office staff ever encouraged you to use an online medical record?" Educational attainment was measured by the question: "What is the highest grade or level of schooling you completed?" The level of easiness of understanding health information on patient portal was measured by the question: "How easy or difficult was it to understand the health information in your online medical record?"

Data analysis

In order to test hypotheses h1(a), h1(b), and h1(c), and answer the research question, multiple regression was used to analyze the data. Control variables included age, gender, health, race and ethnicity, household income. Gender, race, portal access, and physician advocacy were dummy coded. The mean score of the PCC items was used in the regression analysis. SPSS 27.0 (IBM Corp, 2020) was used for the regression analysis. Path analysis was used to test hypotheses 2, 3, and 4. In order to test the indirect effect, PCC was treated as a latent variable, and was the exogenous variable, the level of easiness of understanding health information on patient portal was a mediator, and portal engagement was the endogenous variable. Control variables included age, gender, health, race and ethnicity, household income. Bootstrapping technique, with the number of iterations being set to 5000, was used to obtain bias-corrected 95% confidence to test the indirect effect (Preacher and Hayes, 2008). Statistical software Mplus 8.0 (Muthén and Muthén, 2017) was employed to test the relationships.

Results

Participants' demographics

Participants' demographic characteristics were presented in Table 1. The mean age of the participants was 54.24. The majority of the participants were females (63.1%) and 80.7% of the participants were White. 38.4% of the participants reported to have very good health condition. 34.9% of the participants were college graduates.

Factors predicting patient portal engagement

Hypotheses 1 posited that educational attainment (H1a), patient portal access (H1b), and physician advocacy (H1c) predicted patient portal engagement. As shown in Table 2, a significant proportion of variance was predicted in portal engagement, $F_{(9,1,241)} = 7.94$, $p < 0.001$, $R^2 = 0.05$. Patient portal access ($\beta = 0.07$, $p < 0.05$) and physician advocacy ($\beta = 0.14$, $p < 0.001$) were significant predictors of portal engagement, but educational attainment ($\beta = 0.05$, $p = 0.10$) was not a significant

TABLE 1 Descriptive statistics.

Demographics	Number	Unweighted %
Age (years)	$M = 54.24$ (SD = 15.61, range: 18–98)	
Gender		
Male	461	36.9
Female	790	63.1
Race		
Non-white	242	29.3
White	1,009	80.7
Health		
Poor	25	2.0
Fair	139	11.1
Good	441	35.3
Very good	481	38.4
Excellent	165	13.2
Education		
Less than 8 years	5	0.4
8 through 11 years	13	1.0
12 years or completed high school	137	11.0
Post high school training other than college	74	5.9
Some college	260	20.8
College graduate	436	34.9
Postgraduate	326	26.1
Income		
$ 0 to $ 9,999	33	2.6
$ 10,000 to $ 14,999	40	3.2
$ 15,000 to $ 19,999	35	2.8
$ 20,000 to $ 34,999	114	9.1
$ 35,000 to $ 49,999	144	11.5
$ 50,000 to $ 74,999	223	17.8
$ 75,000 to $ 99,999	188	15.0
$ 100,000 to $ 199,999	346	27.7
$ 200,000 or more	128	10.2
Patient portal access frequency	$M = 2.06$ (SD = 1.05)	
Patient-centered communication	$M = 3.45$ (SD = 0.60, $\alpha = 0.92$)	
Patient portal access		
Yes	1,175	93.9
No	76	6.1
Physician advocacy		
Yes	1,063	85.0
No	188	15.0
Understanding of information on portal	$M = 3.34$ (SD = 0.66)	

TABLE 2 Regression analysis of portal engagement.

Variables	Portal engagement	
	B (SE)	*β*
Age	0.002 (0.002)	0.03
Health	0.199*** (0.04)	0.17
Sex	−0.002 (0.06)	−0.001
Income	−0.01 (0.02)	−0.02
Race	0.18*(0.08)	0.07
Portal access	0.29* (0.13)	0.07
Physician advocacy	0.40*** (0.08)	0.14
Education	0.04 (0.02)	0.05
PCC	0.06 (0.05)	0.03
R^2	0.05	
Adj. R^2	0.05	
F	7.94*** (9, 1,241)	

*p < 0.05.
***p < 0.001.

predictor of patient portal engagement. Therefore, hypotheses 1(b) and 1(c) were supported while hypothesis 1(a) was not supported. PCC was not a significant predictor ($\beta = 0.03$, $p = 0.25$) of portal engagement, meaning there was no direct relationship between PCC and portal engagement, and the research question was answered.

Indirect relationship between PCC and patient portal engagement

For the path analyses, the results for the overall fit of proposed model ($\chi^2 = 411.93$, df = 75, $p < 0.01$, RMSEA = 0.06, CFI = 0.93, TLI = 0.92, SRMR = 0.03) indicated acceptable fit to the data; although the *p*-value was significant. We used the following criteria to evaluate the model fit: values >0.90 for CFI and TLI, values smaller than 0.08 for RMSEA and SRMR (Browne and Cudeck, 1993; Hu and Bentler, 1998; McDonald and Ho, 2002). Higher levels of PCC ($\beta = 0.24$, $p < 0.001$) significantly predicted higher levels of easiness of understanding health information on patient portal. H2 was supported. Higher levels of easiness of understanding health information on patient portal ($\beta = 0.16$, $p < 0.001$) significantly predicted higher levels of patient portal engagement. H3 was supported. There was a significant indirect path from PCC to patient portal engagement [ES = 0.04, 95% CIs (0.02, 0.05)], and therefore, H4 was supported. The summary of the results is presented in Figure 1.

Discussion

This study was guided by the behavior change wheel framework (Michie et al., 2011) and the channel expansion theory (Carlson and Zmud, 1999). In this study, we found that patient portal access and physician advocacy were two significant predictors of portal

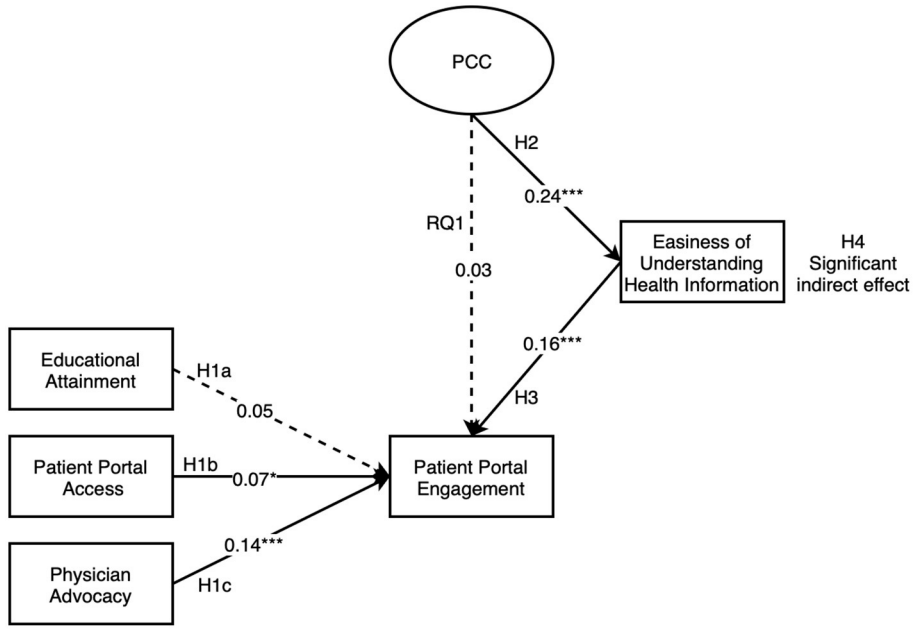

FIGURE 1
Summary of patient portal engagement results. *$p < 0.05$, ***$p < 0.001$; regression coefficients were standardized; dashed line represents non-significant result, solid line represents significant results.

engagement while educational attainment was not. We did not find any direct correlation between PCC and patient portal engagement, but found a significant indirect relationship between the two.

We found that physician advocacy was a significant predictor of portal engagement. This finding is in agreement with existing studies (e.g., Amante et al., 2014; Irizarry et al., 2015; Powell, 2017). For instance, in the systematic review (Powell, 2017) on patient-perceived facilitators of and barriers to portal use, they found that provider encouragement was indicated as one of the patient-perceived facilitators. Another study (Dendere et al., 2019) indicated that a lack of provider advocacy was a barrier of portal engagement. We found that portal access was another significant predictor of portal engagement. This is in agreement with the existing studies (e.g., Ancker et al., 2017) which demonstrated that the rates of portal adoption increased as more patients were offered the portal accounts.

However, we did not find a significant relationship between education attainment and portal engagement. This was in agreement with some existing studies (e.g., Woods et al., 2017). The finding implies that people with higher education levels do not necessarily possess higher health literacy skills (Wright et al., 2022) or digital skills (Heponiemi et al., 2022) needed to understand the information on patient portals. Some studies demonstrated that low health literacy inhibits patient's portal use behavior (Baldwin et al., 2017; Hoogenbosch et al., 2018). Therefore, future studies may operationalize psychological capability necessary for patient portal engagement as health literacy and/or digital skills, rather than educational attainment.

Existing studies are not in agreement with regard to the relationship between provider patient relationship and patient portal engagement. While some studies (e.g., Zaidi et al., 2022) did not find a significant relationship between provider-patient communication and online portal use, some other studies (e.g., Tieu et al., 2015) indicated that patient-provider communication is a facilitator of patients' online patient portal use. Interestingly, we did not find a significant direct relationship between PCC and portal engagement, but found a significant indirect relationship between the two. We provided some evidence to explain how interpersonal doctor-patient communication could influence technology-mediated communication in an indirect way, using the channel expansion theory (Carlson and Zmud, 1999). Through patient-centered communication in the face-to-face setting, patients will gain a lot of experience (i.e., visual cues such as body language and gestures, ways of expressing things) that will help patients understand the physician (the communicator) and their health condition (the topic) better. This type of experience and understanding will serve as context of the subsequent portal-mediated communication to avoid potential misunderstanding. As the levels of experience increase, and as their levels of the perception of the richness of the channel (i.e., patient portal) increase, patients will find the health information on portal easier to understand, and they will be more likely to engage with the medium (i.e., portal). This implies that people's perception of a patient portal can be changed and their engagement with portal can also be changed through that mechanism; PCC will facilitate easier understanding of health information on portal which in turn promote portal engagement.

Implications for theory and practice

To the best of our knowledge, this is the first study to employ the behavior change wheel (Michie et al., 2011) and the

channel expansion theory (Carlson and Zmud, 1999) to explain patient portal engagement. The two theories were employed to explain the mechanism of how interpersonal communication could influence technology-mediated communication. These findings indicated that the behavior change wheel framework (Michie et al., 2011) can be used as a guide to systematically examine the facilitators of and barriers of patient portal engagement. The three necessary components, capability, opportunity, and motivation, not only predict a behavior, but also interact with each other (Michie et al., 2011). For instance, capability and opportunity can influence motivation (Michie et al., 2011). Guided by the channel expansion theory (Carlson and Zmud, 1999), our study hypothesized the relationship between social opportunity (e.g., PCC) and psychological capability, and the indirect relationship between PCC and portal engagement. Our study provided some evidence to demonstrate that social opportunity (e.g., PCC) could influence psychological capability (e.g., perceived level of difficulty in understanding health information on patient portals) which predicts a behavior (e.g., portal engagement). In this sense, our study extended the theory by further explaining the relationship between the key components (e.g., capability, opportunity) of behavior change.

Practically, the behavior change wheel (Michie et al., 2011) has been applied as a framework to guide various interventions, for instance, mHealth interventions (Chiang et al., 2018). When it is used as a theoretical framework for designing interventions to promote portal adoption or engagement, the following dimensions can be considered: capability, motivation, and opportunity. Specifically, psychological capability, physical and social opportunity are important factors to be considered when designing an intervention to promote portal engagement. The behavior change wheel (Michie et al., 2011) also has provided strategies to facilitate capability, opportunity, and motivation, such as education, modeling, and enablement.

In our study, patient portal access was found to be a significant predictor of patient portal engagement, thus enhancing patients' digital access becomes an urgent and necessary effort. In the meantime, previous studies have revealed obvious disparities in digital healthcare service access, those with low socioeconomic status (SES) are less likely to use health technologies due to lack of access (e.g., Ahmed et al., 2020). Therefore, promoting patient portal access of people with low SES should be one focus of policy makers and healthcare providers' work in the future.

The results also provided important implications in terms of healthcare providers' key roles in facilitating patients' portal engagement. The following strategies can be used to facilitate portal engagement. First, during and/or after each doctor's office visit, healthcare providers can offer patient portal information (e.g., how to access portal online, how to use it) to patients who do not have access to patient portal to increase the rates of portal adoption and engagement. Second, physicians can briefly mention the benefits of a patient portal and encourage patients to use it. Moreover, the practice of PCC will potentially change patients' perception that a patient portal is a lean medium, and will also help patients understand better about the health information in the portal.

Limitation and future studies

There are several limitations of the study. One is that HINTS data did not have variables to measure channel perception. In future studies, we can conduct surveys to include participants' perceptions of the channel to test the relationships (i.e., from PCC to portal channel perception, to the level of difficulty in understanding health information on the patient portal, to patient portal engagement). Another limitation is that a limited number of variables representing limited categories of the behavior change model (Michie et al., 2011) were tested in this study. The model entails six categories (i.e., physical capability, psychological capability, social opportunity, physical opportunity, automatic motivation, and reflective motivation), and only three categories with one variable from each category were tested in this study. However, existing research has demonstrated a variety of variables (e.g., personal factors, health care delivery factors) influencing patient portal engagement (Irizarry et al., 2015). Future study could explore other categories of the behavior change model, such as reflective motivation. For instance, will including educational resources in patient portal (Johnson et al., 2023) promote reflective motivation, which then increases portal engagement? Another limitation is that because of the cross-sectional nature of the survey, no causal relationship can be demonstrated. Future research could use longitudinal surveys or experiments to test the relationships.

Conclusion

Guided by the behavior change wheel framework (Michie et al., 2011) and the channel expansion theory (Carlson and Zmud, 1999), this study examined the facilitators of patient portal engagement and tested the relationship between the facilitators. In order to test the relationships, HINTS national survey data ($N = 1{,}251$) were used. We found that patient portal access (an example of physical opportunity) and physician advocacy (an example of social opportunity) were two significant predictors of portal engagement while educational attainment was not. We did not find any direct correlation between PCC and patient portal engagement. However, we found a significant indirect relationship between PCC and portal engagement through levels of difficulty in understanding health information on the portals (an example of psychological capability). To the best of our knowledge, this is the first study to employ the behavior change wheel (Michie et al., 2011) and the channel expansion theory (Carlson and Zmud, 1999) to explain patient portal engagement, and to explain the mechanism of how interpersonal communication could influence portal-mediated communication. Theoretically, our study extended the behavior change wheel (Michie et al., 2011) by further explaining the relationship between the key components (e.g., capability, opportunity) of behavior change. Practical strategies have been proposed to increase patient portal engagement.

Data availability statement

Publicly available datasets were analyzed in this study. This data can be found at: https://hints.cancer.gov/.

Author contributions

WC: Conceptualization, Methodology, Writing—original draft, Writing—review & editing. XC: Writing—original draft, Writing—review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Operational disruption in healthcare associated with software functionality issue due to software security patching: a case report

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Despite many benefits, the extensive deployment of Health Information Technology (HIT) systems by healthcare organizations has encountered many challenges, particularly in the field of telemetry concerning patient monitoring and its operational workflow. These challenges can add more layers of complexity when an unplanned software security patching is performed, affecting patient monitoring and causing disruption in daily clinical operations. This study is a reflection on what happened associated with software security patching and why it happened through the lens of an incident report to develop potential preventive and corrective strategies using qualitative analyses—inductive and deductive approaches. There is a need for such analyses to identify the underlying mechanism behind such issues since very limited research has been conducted on the study of software patching. The incident was classified as a "software functionality" issue, and the consequence was an "incident with a noticeable consequence but no patient harm", and the contributing factor was a software update, i.e., software security patching. This report describes how insufficient planning of software patching, lack of training for healthcare professionals, contingency planning on unplanned system disruption, and HIT system configuration can compromise healthcare quality and cause risks to patient safety. We propose 15 preventive and corrective strategies grouped under four key areas based on the system approach and social-technical aspects of the patching process. The key areas are (i) preparing, developing, and deploying patches; (ii) training the frontline operators; (iii) ensuring contingency planning; and (iv) establishing configuration and communication between systems. These strategies are expected to minimize the risk of HIT-related incidents, enhance software security patch management in healthcare organizations, and improve patient safety. However, further discussion should be continued about general HIT problems connected to software security patching.

KEYWORDS

patient safety, healthcare quality improvement, software issue, training, system integration, system design, software update, workflow disruption

1 Introduction

"A software patch or fix is a quick-repair job for a piece of programming designed to resolve functionality issues, improve security, or add new features" (1). Software patching is a growing key aspect of today's computing environment (2), particularly in the healthcare environment (3) in which the volume, complexity, and number of configurations have increased considerably. A number of challenges associated with software security patching have been encountered in modern healthcare, including delayed patch applications (4), vulnerability scanning, assessment, and prioritization (5). The consequences of such problems due to software patching are enormous, such as causing delays in healthcare management and even risks to patient safety (4, 6). However, the underlying mechanism behind these issues is still unknown in most cases; for example, why and how delays occur while applying those patches (4). In addition, very limited research has been conducted on the study of software security patching, particularly in the context of healthcare.

HIT systems were deployed with the vision of making care delivery safer and more efficient by reducing adverse events and improving accuracy (7). The HITs have improved several dimensions of healthcare quality, such as enhancing the security and confidentiality of personal health information (8), improving patient safety, and increasing efficiency and effectiveness (9). Despite their numerous benefits, the introduction of HITs has encountered substantial problems, including planning, design, implementation, and management (10, 11).

Several studies of implementation science have indicated that the deployment of HIT systems might be successful in one setting but not in others (12). New and often unexpected problems arise, compromising the quality of healthcare and requiring diligent attention and awareness whenever a new technology or solution is introduced (13). Several pieces of evidence suggest that different HIT systems, such as radiology information systems (10, 11, 14) and e-prescribing systems (15), can pose serious consequences, ranging from workflow interruptions (16) and patient inconvenience (9) to multiple patient harm (17). Similarly, patient monitoring systems, such as an ECG monitoring system, can encounter various challenges, including system integration, complex computational needs, and patient/user resistance (18). While some studies suggested that the accuracy and reliability of remote patient monitoring systems can be questioned (19), others reported that security and privacy could also be the major challenges of these systems (20).

HIT systems, particularly those used in patient monitoring, such as central monitoring systems and alarm detectors, are commonly endorsed as the solution to many of the problems encountered by the Emergency Department or intensive care unit (21). Healthcare professionals, such as nurses, heavily depend on such systems, which allow them to monitor the vital signs of multiple patients on the same screen without being physically present in the patient room (22). While there is some evidence for the clinical benefits of this efficient system, there is reported evidence that patient monitoring systems can cause various challenges to patients, compromising healthcare quality (23).

The incident reporting process ensures reflection on what has happened, why it has happened, and how it might have been minimized (13). Sometimes, the incidents can act as an "early warning system" by identifying new issues before reaching the patient (24). They can be used as a basis for devising preventive and corrective strategies and strategies to prevent them from harming the patients (13). Incident reporting may also play a key role in improving the patient safety culture of a healthcare organization with the local follow-up of incidents (25). This necessitates qualitative analysis of the free-text narratives or anecdotes using inductive and deductive techniques. The inductive approach may include content analysis, whereas the deductive method may comprise the classification of the critical aspects of the qualitative data by feeding them into an existing framework, such as the HIT Classification System (HIT-CS) (26).

Since little research has been performed on software security patch management, there is an urgent need for qualitative analysis to explore the issue. Therefore, this case report will present how inappropriate planning of software patching can affect the patient monitoring system and cause disruption in day-to-day clinical operations and care delivery through the lens of an incident report. The report will also provide some useful insights for practitioners and researchers to understand what and where strategies are necessary to better support the patch management process.

2 Methods

2.1 Data collection

The incident (presented in Box 1) was reported in an electronic incident management database for medical devices, i.e., the reidarMTP. The reidarMTP aims to make essential information on medical devices readily available for the healthcare environment, primarily in Sweden and the Nordic countries, such as Denmark, Norway, Finland, and Iceland. The reidarMTP is operated by a voluntary association of Clinical Engineering departments in Swedish hospitals and is handled by certified staff trained to report such information into an open database. The information in the web database is anonymous and freely available to all healthcare professionals for quality improvement, education, and training (27, 28).

The incidents are generally categorized into several different fields, entailing different sets of information. The first category includes the date, day, and time of events, an incident description with a short subject line, for example, "patching software for patient monitoring does not work well." The second category is about the type of products involved in the incident, such as product name, manufacturer, software version, serial/batch number, etc. The third category comprises investigation, such as a summary of cause investigation, a summary of actions, and a summary of follow-up. The final and fourth categories consist of classification or risk assessment, including risk of medical damage and underlying cause.

BOX 1 This software security patching-related incident was reported to the reidarMTP by an anonymous user showing responses to the following categories of information.

Description of the incident

The program X, which is used, among other things, for security patching of patient monitoring systems, does not work well, which means problems when patching is to be done. Patching of Windows is done by Medical Technology to maintain high IT security.

During patching, restarts often occur, and during these restarts, no central patient monitoring can take place. This means that patching is carefully planned together with the business in order to disrupt as little as possible. These operational disturbances mean risks for telemetry patients in particular. Central monitoring and alarm detectors do not work during the patching, so the departments need to set aside extra resources to compensate for this.

X's job in patching is to schedule and initiate patching. The program indicates the client/monitoring centre patching status in green or red. During the last patching, you got a green light, meaning that the patching is complete and there is no pending restart. It was then assumed that the work was finished. The following morning, however, about half of the centres/clients handled the day before were red. This means that a further restart is needed, which is a major operational disruption for the departments that were unable to plan for this.

A major flaw in X is that Medical Technology cannot see when the patches are applied, how long this will take, how many patches will be applied, and whether they are applied at the same time or not. This makes it very difficult to make an assessment of how much operational disruption a patching will entail.

Summary of cause investigation

Patching of PC clients is done every six months, an interval deemed appropriate by Medical Technology. If patching was performed more often, not as many/large patches would have to be applied on each occasion, which could reduce the risk of what happened in this case. However, this would mean that the operations are affected by and need to plan for operational disruption more often.

Medical Technology's assessment is that patching more often overall would mean a greater impact on the operations.

The incident has been filtered and illustrated in Box 1 in two fields: "incident description," which was reported by anonymous healthcare staff, and "summary of cause investigation," i.e., an internal investigated narrative of the reported incident. The report was delivered in Swedish and translated into English by a linguistic expert who is proficient in both Swedish and English. The technical nature of the content through the translation process was taken into consideration with the help of consensus by the linguistic expert and the principal investigator. To maintain anonymity, the name of the software product has been masked by "X".

2.2 Data analysis

The incident was analyzed using both deductive and inductive approaches. The deductive approach included an existing framework proposed by Magrabi et al., i.e., the HIT-CS (26). The HIT-CS has particularly been tailored to address the issues arising from HIT in healthcare for deconstructing incidents, classifying HIT-related issues, and extracting meaningful information. Issues can be classified based on human or technical-related problems, whereas technical challenges can be grouped into hardware and software-related problems (26). The HIT-CS was used to identify the type of software issue, the type of consequence, and the contributing (human) factor. The inductive approach involved content analysis. The application of the existing framework, i.e., HIT-CS and content extraction analyses, were managed on a semantic level—the exact content of the incident was taken into consideration, and no assumptions were made about the latent underpinnings of the incident report. Both of these approaches helped develop a set of preventive and corrective strategies that could potentially minimize future occurrences of these risks.

3 Results

The HIT-CS was used for incident classification to enhance transparency and understanding. The incident was classified as a technical issue, i.e., "software functionality", and the consequence of the incident was categorized as "incident with noticeable consequence but no patient harm", and the contributing factor was "integration with clinical workflow".

Using the content analysis, the contributing factors, mitigating factors, and patient/ organizational outcomes were identified. The contributing factor was identified to be the software update, i.e., software security patching. Although the incident did not cause any harm to patients directly, the operational disruption was clearly indicated in the incident description. To mitigate such software issues, one has to be mindful not to use many or large patches if security patching is to be done frequently, i.e., every six months. Another mitigating factor was identified, i.e., a contingency plan for frequent operation disruption. There was

no patient outcome described in the narrative; however, the organizational outcome was determined to be severe disruptions in the clinical workflow for several weeks.

4 Discussion

The issue of software patching and the coordination of different components have become a common phenomenon in modern healthcare systems. The outcomes of these issues can cause workflow disruptions or delays in healthcare delivery and serious risks to patient safety (4, 6). For example, an empirical investigation in the healthcare sector indicated delays in applying software security patches, particularly in the patch deployment phase, due to coordination delays relating to technology, people, and organization (4). Another study proposed a similar theory, i.e., a lack of in-depth understanding of socio-technical aspects of the patching process and patching decisions causing delays in applying security patches (29). To mitigate such delays and maintain a timely security patch management process, the studies recommended coordination and interdependent software/ hardware components and the decisions made by multiple stakeholders involved. The delays can also be minimized by designing and developing computer-aided supportive tools (4, 29).

Jabin et al. demonstrated in 2019 that HIT incidents occurred at each step of the medical imaging workflow process and that human and technical factors play a role in problems related to patient details (16). Such disruptions in the workflow process cause significant delays in patient treatments, patient inconvenience, and risks to patient safety, including repeat images resulting in unnecessary radiation and even additional workload for radiographers, i.e., repeat reconstruction of radiographic images. A recent study indicated that approximately 41% of the total sample of incidents had a staff/organization-related outcome with a clear indication that workflow disruptions resulted in additional system/service/resource use and delays in using facilities/service/systems (7). These delays in treatment or procedure further cause delayed diagnosis, treatment initiation, impact, and monitoring. Such delays can even cause delays in the decision-making process regarding further treatment options—continuation, discontinuation, or change in treatment. This means that once an incorrect shred of information or document is initiated into the HIT system, an "automation bias" tends to be considered correct (30).

A robust mechanism of system resilience and high-reliability organizations must address system flaws or software-related issues, including software patches, in a timely manner (31). Ensuring a robust mechanism means that similar types of errors are not repeated in the future, which will further guarantee that preventive and corrective interventions are applied at a system level (32). Therefore, such a system-wide approach and reliable systems can quickly identify and fix the issues related to HIT systems, minimize the stress and dissatisfaction of healthcare professionals, and thus improve healthcare quality (33).

4.1 Implications for practice

Based on the system approach and through the lens of social-technical aspects of the patching process associated with HIT systems, such as the patient monitoring system, we propose the following 15 preventive and corrective strategies, which are grouped under four key areas (as outlined in Box 2). The key areas are (i) preparing, developing, and deploying patches; (ii) training the frontline operators; (iii) ensuring contingency planning; and (iv) establishing configuration and communication between systems.

(i) Preparing, developing, and deploying patches—software security patch management in large and complex systems like healthcare is a challenging process that engages numerous stakeholders and involves multiple interdependent socio-technical decisions. A number of steps need to be followed systematically (as outlined in Box 2) in order to overcome patching security vulnerabilities. A systematic review of software security patch management based on 72 included studies identified 14 socio-technical challenges and 18 solution approaches, tools, and practices mapped into the process of software security patch management (5). The study drew some conclusions on various opportunities for practitioners to adopt new solutions to overcome common challenges and understand the variations of common practices.

We recommend that the readers use this systematic review as a guide or handbook for software security patch management—preparing, developing, and deploying patches. Figure 1 presents a mapping of the findings to enable the readers to identify the relationships between challenges and proposed solutions (5).

(ii) Training the frontline operators—providing training and education to healthcare professionals, ideally in cooperation with HIT vendors, prior to deploying any patches will mitigate the risk of patient harm.

Several studies suggest that training healthcare staff should be included in the planning process to effectively respond to a disruption. For example, a study on HIT risk and resilience states that "an organization's ability to effectively respond to a disruption not only depends on how effective it was in the planning process, but also how effective it was with its preparation, trials, and the training of their staff, which is often neglected" (35). Another study by Jabin et al. in 2019 identified the need to set up a process for initial and ongoing training of the operators to minimize the risks associated with human factors-related errors and workflow interruptions (13).

(iii) Ensuring contingency planning—a greater focus on stakeholder engagement in all aspects of healthcare practice, such as care providers, practice, quality, and/or departmental managers; accreditors, IT staff, and professional associations who set the standards of practice should be in place. This should include appropriate backup and emergency plans/measures to minimize disruption to

BOX 2 Preventive and corrective strategies to mitigate and manage the risk of HIT incidents.

Preparing, developing, and deploying patches

- Understand the problem beyond what the reporter outlined and identify the source of the vulnerability before developing a patch.
- Work with the original developer of the system/component to ensure designing/creating the right fix.
- Carefully plan for a stable fix with full attention to security and without the loss of any functionality
- Create a deployable and installable (by end-user) package using automated patch management solutions and ensure the patches do not conflict with the previous patches in the same system/component.
- Establish a wide distribution of the patch quickly and efficiently to end users once the deployable package has been verified to fix the problem and all regression and compatibility testing has been secured.
- Track the status of the patch download and installation by the service/management tool to help determine if the patch is successfully installed or if it is initiating any compatibility issues with other applications.

Training the frontline operators

- Set up training for healthcare professionals prior to deploying any patches as part of preparing for situational awareness
- Provide professionals with training updates as part of professional development following software patches

Ensuring contingency planning

- Carefully plan any system changes to mitigate disruption to the regular workload and ensure contingency planning
- Ensure appropriate IT support and access to appointed IT experts in a timely manner in case of any unexpected failure within the facility
- Establish comprehensive plans and emergency operation modes for managing any new and unforeseen downtimes
- Set up a robust mechanism to communicate planned or unplanned power failure to all healthcare professionals involved in the service
- Ensure safety standards and sufficient escalation procedures to deal with the issues that cause patient harm

Establishing configuration and communication between systems

- Configure HIT systems (central monitoring system and alarm detectors) to ensure they are interoperable and communicate with each other.
- Ensure access to the care plan/history/details of telemetry patients at the time of operational disruption

regular care delivery, communicate unplanned power failure, and manage unexpected downtimes (33).

For example, a survey of US-based healthcare institutions focused on sharing HIT-related best practices and shared insight about Electronic Health Record (EHR)-related downtimes (36). The survey found that the majority of organizations experienced extended EHR-related downtimes, and most institutions implemented partial comprehensive contingency plans to mitigate the risks of unexpected EHR downtimes. The study concluded that "contingency planning" should be a routine part of all EHR-enabled healthcare organizations; we should eventually prepare for continuity of operations and ensure safe and effective healthcare.

(iv) Establishing configuration and communication between systems—configuration between different HIT systems, such as central monitoring systems and alarm detectors, should be considered at the time of design and purchase of systems (33).

Several other studies recommended to establish configuration and communication between systems as one of the strategies to overcome HIT-related issues and ensure safe and effective healthcare. For example, a study on e-prescribing-related challenges suggested ensuring software quality in an interfaced, networked healthcare environment since Lack of communication and appropriate configuration between systems was identified to be the major problem (15). Another similar study proposed that appropriate HIT configuration must be established to ensure access to prior studies, data integrity, and appropriate interfaces for record migration (17).

These strategies will be beneficial in improving healthcare quality and mitigating the risk of patient harm from issues with the HIT systems, such as the telemetry patient monitoring system. This recommendation guide will help set aside additional resources to compensate for any major operational disruptions; thus, the need for such a guide for healthcare professionals is urgent.

4.2 Strengths and limitations of the study

The major strength of this study is the use of both qualitative approaches, deductive (existing framework) and inductive (content analysis), permitting the investigator to obtain more detailed information from the incident report. Both of these approaches are most suitable due to their salient features for the qualitative data, i.e., free text narratives (17, 31); therefore, no other approach, such as Machine learning, could be applied.

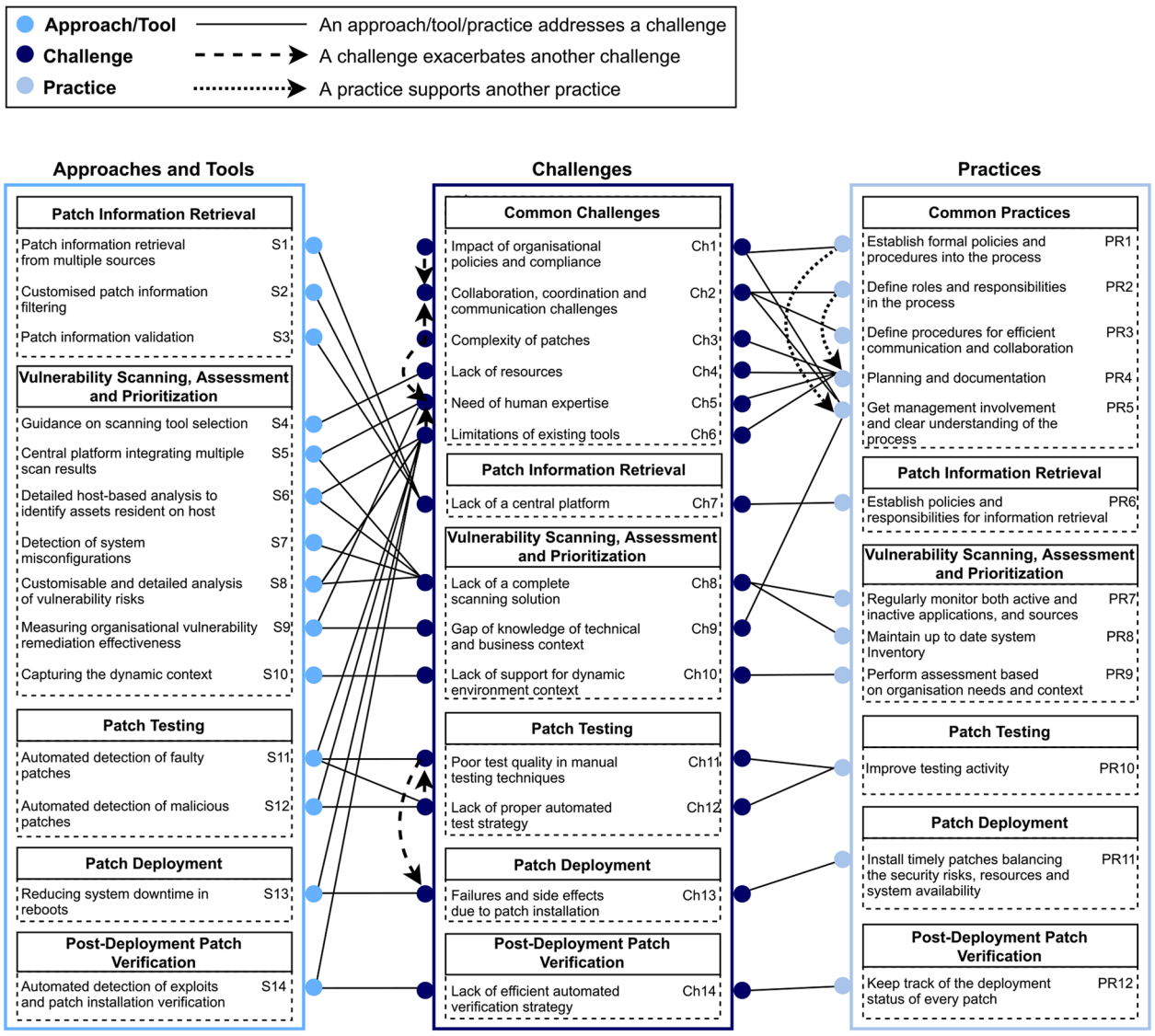

FIGURE 1
A mapping of challenges onto solutions. Reprinted with permission from Dissanayake et al. (34), licensed under CC BY 4.0, https://doi.org/10.48550/arXiv.2012.00544.

Although Machine learning could potentially extend the principle of qualitative analysis, offering a promising technique to scale up the coding process, one has to keep in mind that the study was on a single incident (not a set of incident reports) (37). Moreover, the application of both these approaches helps to minimize the potential subjective bias in devising 15 preventive and corrective strategies.

The incident report considered for this study was voluntary with its inherent limitations, including subjective bias, reporters' lack of knowledge of the HIT systems/ software security patching, or inclination to provide a comprehensive report. In addition, a follow-up communication to glean additional information could not be conducted due to the anonymity of the reporter. Notwithstanding these limitations, the findings and the devised strategies can be considered as alerts to enlighten healthcare digitalization in Sweden to adopt the culture of digital safety and effectiveness. This also implies that the lessons learned from this case report can be useful and pertinent to adopt elsewhere for overall healthcare quality improvement and patient safety (7, 17, 32).

5 Conclusion

Major operational disruptions in the clinical workflow for several weeks may take place as a result of insufficient planning and complex processes (many/large/frequent patches) of software security patching. Such workflow interruptions occur due to inadequate training for frontline operators for unexpected system failure, lack of foresight, and poor understanding of HIT system integration into practice. To mitigate the identified risk, the software security patch management must be aligned with the

context of clinical workflow. The first step of this alignment requires a proper understanding and consideration of proper planning, preparing, developing, and deploying patches. This should be followed by setting up the training process for healthcare professionals prior to any software patches and ensuring contingency planning to cope with any unexpected failures. The strategies should also include the configuration of HIT systems to ensure they are interoperable and communicate with each other.

As a multitude of settings, i.e., technology, people, and healthcare organizations, are potentially affected, it is challenging to specify in further detail. However, further discussion should be continued, emphasizing the need for adaptability in technology and healthcare practices and general HIT problems connected to software security patching. There is also a need to reinforce the necessity of systematic incident reporting as a fundamental practice for improving healthcare quality and patient safety.

Data availability statement

The incident data has already been presented in Box 1. However, the data presented in this study are available on request from the corresponding author.

Ethics statement

The studies involving humans were approved by Ethical Advisory Board in South East Sweden. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and institutional requirements.

Author contributions

MSRJ: Conceptualization, Data Collection, Formal Analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing.

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Conflict of interest

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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A study demonstrating users' preference for the adapted-REQUITE patient-reported outcome questionnaire over PRO-CTCAE® in patients with lung cancer

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Introduction: The use of patient-reported outcomes (PROs) has been shown to enhance the accuracy of symptom collection and improve overall survival and quality of life. This is the first study comparing concordance and patient preference for two PRO tools: Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®) and the adapted-REQUITE Lung Questionnaire.

Materials and Methods: Patients with lung cancer were recruited to the study while attending outpatient clinics at a tertiary cancer centre. Clinician-reported outcomes were generated through initial patient assessment with CTCAE v4.03. Participants then completed the PRO-CTCAE® and adapted-REQUITE questionnaires. Concordance between the 2 questionnaires was assessed by calculating Pearson correlation coefficient. PRO-CTCAE® and CTCAE concordance was demonstrated by calculating Pearson correlation coefficient from the linear predictors of an ordinal logistic regression. P-values were also calculated.

Results: Out of 74 patients approached, 65 provided written informed consent to participate in the study. 63 (96.9%) patients completed both PRO-CTCAE® and adapted-REQUITE questionnaires. Pearson correlation coefficient between PRO tools was 0.8-0.83 ($p < .001$). Correlation between CTCAE and PRO-CTCAE® ranged between 0.66-0.82 ($p < .001$). Adapted-REQUITE and CTCAE correlation was higher for all symptoms ranging between 0.79-0.91 ($p < .001$). Acceptable discrepancies within one grade were present in 96.8%-100% of symptom domains for REQUITE and in 92.1%-96.8% for all domains in the PRO-CTCAE®. 54% of the total participant cohort favored the adapted-REQUITE questionnaire due to reduced subjectivity in the questions and ease of use.

Conclusion: The adapted-REQUITE questionnaire has shown a superior correlation to clinician-reported outcomes and higher patient preference than the PRO-CTCAE®. The results of this study suggest the use of the REQUITE questionnaire for patients with lung cancer in routine clinical practice.

KEYWORDS

patient reported outcome, CTCAE, REQUITE, quality of life, symptoms, lung cancer

1 Introduction

Lung cancer is one of the most common cancers worldwide, with an incidence rate of 2.5 million cases in 2022 (1). Despite advances in cancer treatment and increased smoking cessation efforts, lung cancer remains the leading cause of cancer death, and its 10-year survival rate remains below 10% (2).

Treatment for lung cancer varies depending on the stage and type of cancer, and all treatment regimens are associated with significant side-effects (3). For example, platinum-based chemotherapy, used in patients with locally advanced and metastatic lung cancer causes significant side effects such as fatigue, peripheral neuropathy, and nausea/vomiting, and can have a negative impact on quality of life (4). For patients receiving radiotherapy, the most associated dose-limiting toxicity is radiation pneumonitis which is predicted to affect between 13-37% of patients (5, 6). Surgery is also an important treatment option, particularly for those patients with early-stage lung cancer. Common complications include lung collapse, bleeding, irregular heartbeat, infections at the surgical site or in the lungs, air leakage from the lungs and difficulty breathing (7–10).

Adequate assessment and reporting of patient symptoms and adverse events are required to manage patients with cancer effectively. Assessment of symptoms is especially important for patients with lung cancer, as research suggests up to 75% of lung cancer patients will experience symptomatic disease progression (11). Traditionally, clinicians monitor patients for side effects and manage adverse events (AEs) based on their perceived severity. The current gold standard for reporting AEs, particularly in the context of clinical trials, is the National Cancer Institute (NCI)'s Common Terminology Criteria for Adverse Events (CTCAE) (12). It features a bank of 790 items and provides a severity grading scale from 1 to 5. Due to its comprehensive nature, the CTCAE is used in routine clinical practice for patient symptom assessment since its inception in 1983 (13).

The use of the CTCAE has numerous limitations. A large body of evidence shows that clinician-reported AEs may miss or underreport up to 50% of symptoms that patients experience during treatment (14–19). Discrepancies between patient and physician reporting tend to be satisfactory for objectively measurable symptoms such as vomiting; however, large discrepancies exist in subjective symptoms such as nausea and fatigue (16). Therefore, there is an unmet need to incorporate patients' perspectives into AE reporting.

Over the last decade, patient-reported outcomes (PROs) have found increased utility in clinical trials, and there is an increased effort to incorporate PROs into routine clinical practice. Large-scale randomized controlled trials have reported that incorporating PROs into clinical practice decreases hospital admission, improves anti-cancer therapy compliance, improves quality of life, and increases overall survival (20–23). Furthermore, PROs have been shown to guide follow-up consultations, allowing comprehensive management of patients, mental status, cancer, and adverse events from treatment (24). The collection of PROs has also been described by the Food and Drug Administration (FDA) and the European Society of Medical Oncology (ESMO) as the gold standard of symptom collection (25, 26).

Noting the need to incorporate PROs into symptom assessment, NCI developed a patient-reported version of the CTCAE (PRO-CTCAE®). The PRO-CTCAE® questionnaire is a library of 124 questions evaluating 78 toxicities mapped to the CTCAE (27). The questionnaire features up to three questions per AE item, assessing different symptom attributes: frequency, severity, interference, amount, and presence/absence. The PRO-CTCAE® uses a 5-level severity grading scale from 0 to 4, except for the presence/absence attribute which uses 0 to 1. The PRO-CTCAE® questionnaire has proven utility in a large multi-national clinical trial (28).

Another PRO tool that was integrated in a multi-national study is the questionnaire developed as part of the European Union funded REQUITE study (29, 30). It features a direct lay translation of the CTCAE for symptoms commonly experienced during lung cancer radiotherapy and chemotherapy. Symptoms are graded based on severity from 0 to 4. The REQUITE questionnaire has been formally validated at The Christie NHS Foundation Trust (31). By way of example, Table 1 compares how CTCAE, PRO-CTCAE® and REQUITE grade the severity of anorexia (27, 29, 32).

Both PRO-CTCAE® and adapted-REQUITE questionnaires have strengths and limitations. The PRO-CTCAE® severity grading scale offers a subjective grading approach open to interpretation. On the other hand, the REQUITE questionnaire features a direct lay translation of CTCAE and detailed, objective descriptions for each grade. There is therefore an unmet need to compare existing PRO tools and assess patients' preference in the context of routine clinical practice.

TABLE 1 Reporting difference between CTCAE, PRO-CTCAE® and REQUITE for anorexia.

Grade	CTCAE v4.03 Anorexia	PRO-CTCAE® In the last 7 days, what was the SEVERITY of your DECREASED APPETITE at its WORST?	PRO-CTCAE® In the last 7 days, how much did DECREASED APPETITE INTERFERE with your usual or daily activities	REQUITE Have you lost your appetite?
0	None	None	Not at all	I have not lost my appetite
1	Loss of appetite without alteration in eating habits.	Mild	A little bit	I have lost my appetite, but I eat as I normally would
2	Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated.	Moderate	Somewhat	I have lost my appetite and lost weight. I have been prescribed food supplements.
3	Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated.	Severe	Quite a bit	I have lost my appetite and lost weight. I have been getting extra fluids or nutrition with a tube or a drip.
4	Life threatening consequences; urgent intervention indicated.	Very Severe	Very much	I have been in hospital with severe/life-threatening weight loss.

CTCAE, Common Terminology Criteria for Adverse Events; PRO-CTCAE®, Patient-Reported Outcomes version of Common Terminology Criteria for Adverse Events; TPN, Total parental nutrition.

This study compared the PRO-CTCAE® and REQUITE PRO tools in conjunction with clinician-reported outcomes and explored patient preference through surveys. The aim was to identify the most appropriate questionnaire to use in our institution in a clinical practice setting.

2 Materials and methods

This was a single-site, prospective questionnaire-based study conducted at The Christie NHS Foundation Trust. Approval for this study was obtained from the Health Research Authority, London – City and East Research Ethics Committee, and The Christie Research and Development Division. To identify the most appropriate questionnaire to use at our institution, this study had three primary objectives: 1) to conduct correlation analyses between clinician-reported CTCAE and each PRO tool, 2) to assess the correlations between both PRO tools, and 3) to determine patient preference between these PRO tools.

Patients with lung cancer at outpatient clinics were approached and recruited to the study with written informed consent. Any individuals aged over 18 years who could provide informed consent with a confirmed histological or clinical diagnosis of lung cancer were included. All patients, with or without prior surgical invention, were either undergoing radiotherapy, chemo-radiotherapy, systemic anti-cancer treatment, or were in post-treatment follow-up. Those patients who could not read or understand English were not recruited into the study.

Upon obtaining written informed consent, symptoms were assessed verbally by a clinician using CTCAE v4.03, which consisted of 8 domains: performance status, shortness of breath, chest pain, dysphagia, cough, hemoptysis, reduced appetite, and fatigue. The Adult Comorbidity Score 27 (ACE-27) was additionally completed for all patients by their clinicians. Each patient was provided with two PRO tools to complete in a paper format: the PRO-CTCAE® questionnaire and the adapted-REQUITE Lung questionnaire. The latter questionnaire was adapted from a questionnaire developed as part of the European Union funded REQUITE project (29). The adapted-REQUITE Lung questionnaire featured 8 questions assessing 8 domains: performance status, shortness of breath, chest pain, dysphagia, cough, hemoptysis, weight loss, and fatigue (See Supplementary Material). The PRO-CTCAE® questionnaire included adverse events and symptoms commonly experienced by patients with lung cancer during treatment or follow-up. It consisted of 12 questions assessing 6 symptom domains: shortness of breath, chest pain, dysphagia, cough, reduced appetite, and fatigue (See Supplementary Material).

An evaluation questionnaire was also given to determine which PRO tool patients felt best described their symptoms, the ease of filling out the questionnaires, and their overall preference between the two PRO tools. Patient data (including age, gender, disease staging, histology, ECOG performance status, ACE-27 score, and smoking history) and treatment data were collected from structured forms included in the electronic patient records.

A power calculation was performed to determine the sample size required for the study using a conservative correlation coefficient of 0.3. The calculation set a target sample size of 86 patients. Data obtained from CTCAE and both PRO tools were assessed for its distribution by visual inspection. Correlation between CTCAE and adapted-REQUITE was calculated using the Pearson correlation coefficient for linear relationships between variables, which was reported together with the corresponding p-value. The correlation between CTCAE and PRO-CTCAE® was assessed via an ordinal logistic regression analysis since one question on the CTCAE related to multiple questions on the PRO-CTCAE®. The linear predictor from the ordinal logistic regression analysis was used to calculate the Pearson correlation coefficient and

corresponding p-value. Correlation analysis was only performed for symptoms at least 3 patients reported having. All analyses were conducted in R v3.4.1, and statistical significance was set at p-value <.05.

3 Results

3.1 Patient recruitment

Patients were recruited in June 2018. Out of 74 eligible patients approached to participate in the study, 9 declined to participate in the study. The reasons for declining were as follows: 4 patients reported anxiety related to their appointments, 3 patients mentioned time constraints, 1 patient expressed concern about questionnaire complexity, and 1 patient did not provide a specific reason. A total of 65 patients provided written informed consent to participate in the study. Subsequently, 2 patients withdrew their consent following their consultation, one due to receiving bad news and the other due to not receiving the requested pharmaceutical agent. Overall, the final study cohort comprised 63 patients. The recruitment workflow is depicted in Figure 1.

3.2 Patient characteristics

Patient characteristics are presented in Table 2. There was no missing data. The median age was 68 years, ranging from 47 to 89. Among the study population, 63.5% were female, and 57.1% were ex-smokers. The predominant diagnosis and disease stage was stage IV non-small cell lung cancer (NSCLC) (44.4%). Clinician-evaluated ECOG performance status ranged from 0 to 3, with the majority having a score of 1 (52.4%). As patients were recruited from different oncology clinics, patients underwent various types of cancer treatment. This was categorized as chemotherapy, radiotherapy, systemic therapy, which includes targeted therapies and immunotherapy agents, and post-treatment follow-up.

3.3 Correlations between CTCAE and PRO tools

The clinician-reported CTCAE symptom assessment and the patient-reported adapted-REQUITE and PRO-CTCAE® symptom assessment are included in Supplementary Tables 1-3. The most common clinician-reported CTCAE symptoms of any grade were fatigue (68.3%), shortness of breath (65.1%) and cough (57.1%). Shortness of breath was the only grade 4 symptom reported. The most common patient-reported symptoms on the adapted-REQUITE questionnaire were fatigue (71.4%), shortness of breath (66.6%) and cough (57.1). Again, only one grade 4 symptom was reported, which was shortness of breath. The most common patient-reported symptoms on the PRO-CTCAE® questionnaire were fatigue (69.8%), shortness of breath (65.1%) and cough (50.8%). Across six symptom domains, including dysphagia, chest pain, shortness of breath, cough, reduced appetite, and fatigue, a higher number of grade 3-4 severity were reported in PRO-CTCAE® (8.99%) compared to adapted-REQUITE (1.84%).

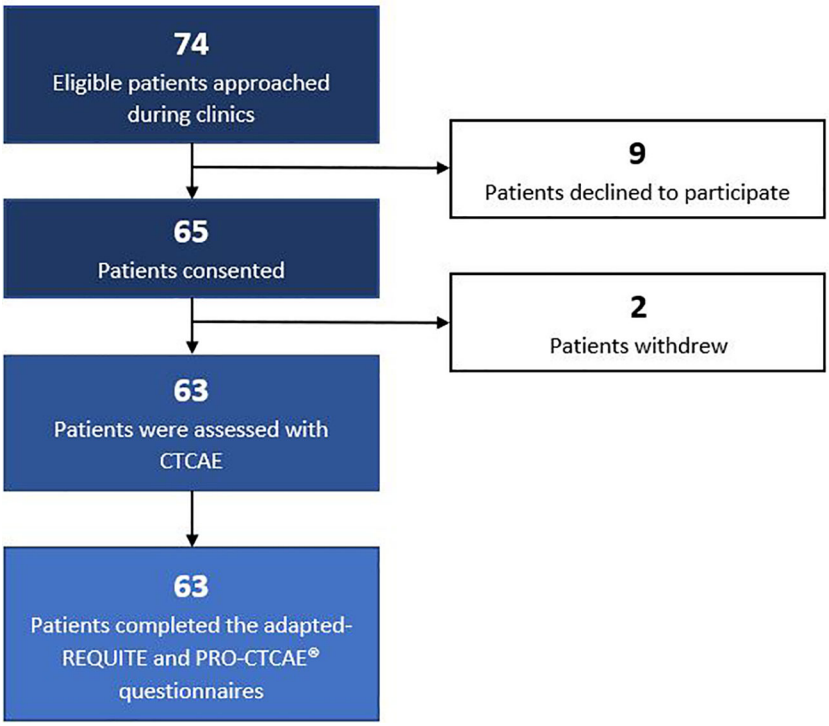

FIGURE 1
Patient recruitment flow.

TABLE 2 Baseline patient characteristics.

	All patients (n=63)
Age in years, median (range)	68 (47–89)
Gender, n (%)	
Male	23 (36.5)
Female	40 (63.5)
Diagnosis and staging	
NSCLC	51 (81.0)
I	10 (15.9)
II	3 (4.8)
III	10 (15.9)
IV	28 (44.4)
SCLC	12 (19.0)
Limited	6 (9.5)
Extensive	6 (9.5)
NSCLC histology	
Adenocarcinoma	37 (58.7)
Squamous cell carcinoma	9 (14.3)
Unknown	5 (7.9)
Smoking status	
Ex	36 (57.1)
Current	14 (22.2)
Never	13 (20.6)
Pack years	
<15	2 (3.2)
15-30	16 (25.4)
31-45	14 (22.2)
46-60	12 (19.0)
>60	3 (4.8)
Unknown	4 (6.3)
ECOG Performance status	
0	17 (27.0)
1	33 (52.4)
2	9 (14.3)
3	4 (6.3)
ACE-27	
0	14 (22.2)
1	23 (36.5)
2	11 (17.5)
3	7 (11.1)
Unknown	8 (12.7)
Patients on treatment	
Chemotherapy	10 (15.9)
Radiotherapy	21 (33.3)
Systematic therapy	19 (30.2)
Patients on follow-up	13 (20.6)

Systemic therapy included tyrosine kinase inhibitors and immunotherapy agents. NSCLC, Non-Small Cell Lung Cancer; SCLC, Small Cell Lung Cancer; ECOG: Eastern Cooperative Oncology Group; ACE-27, Adult Comorbidities Evaluation 27.

Supplementary Table 4 reports the grading differences between clinician-reported CTCAE and patient-reported adapted-REQUITE. Exact grade matching ranged from 69.8% (shortness of breath) to 84.1% (performance status). Discrepancies within one grade were present in 96.8% to 100% of symptom domains. For all domains, there were no discrepancies over two grade differences. Supplementary Table 5 reports the grading differences between CTCAE and PRO-CTCAE®. Exact grade matching ranged from 49.2% (fatigue) to 85.7% (dysphagia). Discrepancies within one grade were present in 92.1% to 98.6% of symptom domains. For all domains, there were no discrepancies over two grade differences. Symptom grade agreement was higher between CTCAE and adapted-REQUITE (>69.8%) than PRO-CTCAE® (>60.3%).

Table 3 presents the correlation between CTCAE symptoms and symptoms reported through adapted-REQUITE or PRO-CTCAE®. Statistical analysis was conducted on symptoms reported by enough patients. The correlation between CTCAE and adapted-REQUITE symptoms ranged from 0.72 (reduced appetite) to 0.91 (performance status). The correlation between CTCAE and PRO-CTCAE® symptoms ranged from 0.63 (reduced appetite) to 0.82 (shortness of breath). All CTCAE and PRO-tool symptoms had statistically significant positive correlations ($p < .001$).

3.4 Correlations between PRO-CTCAE® and adapted-REQUITE

Table 4 presents the correlation between two PRO tools, PRO-CTCAE® and adapted-REQUITE. There was a high correlation between PRO-CTCAE® and adapted-REQUITE symptoms (0.80-0.83, $p < .001$).

3.5 Patient preference

The results from the patient evaluation questionnaire are presented in Table 5. 51% of patients felt adapted-REQUITE better described their symptoms, compared to 11% for PRO-CTCAE. 38% found both questionnaires described their symptoms equally, although most of these patients scored zero in all domains in both questionnaires. Regarding ease of completion, 38% expressed no preference, while 37% and 25% found adapted-REQUITE and PRO-CTCAE® easier to complete respectively. When asked which questionnaire patients preferred overall, more than half (54%) favored adapted-REQUITE, with 24% having no preference and 22% favoring PRO-CTCAE. The reasons patients prefer adapted-REQUITE or PRO-CTCAE® are included in Supplementary Tables 6, 7. The most common reason for preferring adapted-REQUITE was that it better described their symptoms while for PRO-CTCAE® was that it was easier to complete.

4 Discussion

This study has several key findings. Firstly, both PRO tools showed a strong correlation with clinician-reported outcomes using CTCAE, with the adapted-REQUITE questionnaire showing a higher correlation than the PRO-CTCAE® questionnaire. Secondly, the adapted-REQUITE questionnaire also showed higher levels of exact grading agreement and agreement within one grade up to 100%. Thirdly, most patients expressed an overall preference for adapted-REQUITE over PRO-CTCAE® as more patients found the adapted-REQUITE questionnaire better described their symptoms.

TABLE 3 Correlation between CTCAE clinician-reported symptoms and adapted-REQUITE or PRO-CTCAE® patient-reported symptoms.

Symptoms	CTCAE vs adapted REQUITE		CTCAE vs PRO-CTCAE®	
	Correlation (95% CI)	P-value	Correlation (95% CI)	P-value
Performance Status	0.91 (0.86, 0.94)	<.001		
Shortness of Breath	0.79 (0.67, 0.87)	<.001	0.82 (0.72, 0.89)	<.001
Fatigue	0.79 (0.67, 0.87)	<.001	0.66 (0.49, 0.78)	<.001
Cough	0.77 (0.65, 0.85)	<.001	0.73 (0.59, 0.83)	<.001
Reduced appetite	0.72 (0.57, 0.82)	<.001	0.63 (0.45, 0.76)	<.001

CTCAE, Common Terminology Criteria for Adverse Events; PRO-CTCAE®, Patient-Reported Outcomes version of Common Terminology Criteria for Adverse Events; CI, Confidence Interval.

To our knowledge, this is the first study comparing the PRO-CTCAE® and adapted-REQUITE PRO tools for concordance and overall patient preference in a lung cancer population. Both PRO tools have been previously validated and have proven utility in the clinical environment (31, 33, 34). This study further demonstrates the feasibility of incorporating PRO tools in routine clinical practice. Overall, both PRO questionnaires were received very well by the patients and their clinicians, as the study had a high uptake of participants. The two PRO tools were completed by all 63 patients, and an average of 21 patients were recruited per week. Only 9 patients refused to participate, and 2 patients withdrew their consent due to external factors unrelated to the study.

In this study, a strong correlation was observed between clinician-reported CTCAE and patient responses to both PRO tools. The correlation was statistically significant with p <.001 for shortness of breath, fatigue, cough, and reduced appetite. Pearson rho values range from 0.66 to 0.82 for PRO-CTCAE® and 0.79 to 0.91 for the adapted-REQUITE questionnaire. Furthermore, the agreement between each PRO tool and clinician-reported symptoms using CTCAE was also high. The PRO-CTCAE® questionnaire had an exact grading agreement of 49.2% to 85.7%, and agreement within one grade ranged from 92.1% to 98.4%. The adapted-REQUITE questionnaire demonstrated a higher exact grading agreement for symptoms of 69.8% to 84.1%, with agreement within one grade ranging from 96.8% to 100%. Importantly, neither questionnaire displayed discrepancies higher than two grades. This study's findings align with existing literature that discrepancies between patient and clinician reporting are notably higher for subjective symptoms (16). The weakest correlation for both PRO tools was observed for fatigue and reduced appetite. However, even for these symptoms, discrepancies within one grade remained above ninety percent in both questionnaires.

As already mentioned, the correlation levels observed between CTCAE and both PRO tools were high. However, the findings of this study suggest that the adapted-REQUITE questionnaire has a superior correlation to CTCAE than the PRO-CTCAE® in most variable domains, except shortness of breath. Therefore, the adapted-REQUITE questionnaire is superior to the PRO-CTCAE® in this study. It should be noted that the study was powered with a conservative correlation of 0.3, generating a target size of 86 patients. The trial sponsorship was significantly delayed due to factors beyond the control of the study investigator; as a result, recruitment time was cut to three weeks, limiting the total number of patients that could be recruited. However, the correlation between the PRO tools was significantly higher than the correlation used in the power calculation, and the total of 63 recruited participants was sufficient for statistical analysis.

The correlation between the clinician-reported outcomes and PRO tools in this study surpasses the correlations reported in other studies. For instance, the correlation for fatigue was 0.66 with the PRO-CTCAE® questionnaire and 0.79 with adapted-REQUITE. For shortness of breath, the values were reported as 0.82 and 0.79 for the PRO-CTCAE® and adapted-REQUITE questionnaires respectively. A 2006 study by Basch et al. involving 400 patients found a correlation of 0.55 for fatigue between clinician-reported CTCAE and patient-reported syntactically modified CTCAE (15).

TABLE 4 Correlation between PRO-CTCAE® and adapted-REQUITE patient-reported symptoms.

Symptoms	Correlation (95% CI)	P-value
Shortness of breath	0.82 (0.72, 0.89)	<.001
Fatigue	0.80 (0.69, 0.87)	<.001
Cough	0.83 (0.73, 0.89)	<.001
Reduced appetite	0.83 (0.73, 0.89)	<.001

PRO-CTCAE®, Patient-Reported Outcomes version of Common Terminology Criteria for Adverse Events; CI, Confidence Interval.

TABLE 5 Patient evaluation questionnaire.

	Adapted-REQUITE	PRO-CTCAE®	No preference
Which of the two PRO tools best describes your symptoms?	51%	11%	38%
Which of the two questionnaires did you find easiest to complete?	37%	25%	38%
Overall which questionnaire did you prefer?	54%	22%	24%

PRO-CTCAE, Patient-Reported Outcomes version of Common Terminology Criteria for Adverse Events.

Another study reported a correlation for fatigue as low as 0.3 between clinician-reported CTCAE and the European Organization for Research and Treatment Cancer's Quality of Life questionnaire (EORTC QLQ-C30) completed by patients (35). When comparing PRO-CTCAE® to EORTC QLQ-C30, there was a correlation of 0.74 for fatigue and 0.47 for shortness of breath (34). In our study, there was no time limit for questioning patients and determining CTCAE grading. The study also took place in a private room separate from busy lung cancer clinics. Therefore, the factors of time pressures and busy clinic environment that traditionally affect clinician reporting may have been absent here.

As the level of correlation between the two PRO tools is very high, patient preference is a significant factor when determining overall superiority. Patient preference was broken down into three categories: those that preferred the adapted-REQUITE questionnaire (54%), PRO-CTCAE® (22%), and those that stated the tools were equal (24%). The largest group of participants stated that they preferred the adapted-REQUITE questionnaires overall. The most commonly stated reason was that the descriptions of the grades removed the subjectivity present in the none-to-severe grading of the PRO-CTCAE®. One patient who had suffered from significant dysphagia stated that grading subjectively would require interpretation by clinicians as his response did not sit accurately in one domain. Such situations may create some subjectivity and lead to clinicians under- or overestimating the severity of patient symptoms. A minority of 22% of patients stated they preferred the PRO-CTCAE®. The most common reason people stated for PRO-CTCAE® preference was that the subjective approach was more straightforward to complete. It should be considered that PRO tools will often be completed during a time of increased anxiety; therefore, simplicity and ease of completion are significant factors for patient preference. The questionnaires for this study were completed in the clinical environment, and some patients were particularly anxious about their scan results.

There are some limitations in this study. It was a single-site study with a limited yet diverse patient population. The inclusion of individuals undergoing different treatments and at various stages of their disease introduces variability to the findings; the number of patients reporting certain symptoms such as chest pain, dysphagia, and hemoptysis was insufficient for analysis, underscoring the need for further research to establish correlations for these symptoms. Notably, the study participants were relatively younger, with a median age of 68, while more than half of patients diagnosed with lung cancer are 70 years and above (2). Additionally, the proportion of female patients was larger than the national estimates (63.5% in our study versus 48% nationally). Finally, deprivation index data was not available in this study and we therefore cannot confirm the diversity of socio-economic backgrounds.

Several participants required assistance to complete the questionnaires. The adapted-REQUITE questionnaire is shorter than the PRO-CTCAE® in terms of the number of questions. However, the volume of reading required meant that some participants still needed assistance from their families or the study investigator to complete the questionnaire. The main issue was that the grade descriptions were quite long; therefore, some patients struggled due to poor literacy skills or eyesight. For 7 patients, the study investigator had to read the questionnaire to the patient. Approximately 5 patients required help from their relatives either to read or to interpret the questionnaire; however, the exact number, although low, was not recorded. Several of the issues could have been rectified using electronic questionnaires. This would have allowed the participants to enlarge the question font size so that patients who required reading glasses may have been able to have more autonomy when completing the questionnaires. The questionnaires could also have been linked to electronic health records enabling doctors to review the questionnaire responses.

In 2019, after this work had been completed, The Christie NHS Foundation Trust, a large tertiary cancer center in the United Kingdom, launched its electronic patient-reported outcome measures (ePROMs) service 'MyChristie-MyHealth,' integrating ePROMs questionnaires into routine clinical practice (36). This service was initially rolled out to patients with lung cancers, and the adapted-REQUITE lung questionnaire was integrated into the ePROMs platform. The EQ-5D quality of life questionnaire was also added to the questionnaire (37). A study conducted at The Christie by Crockett et al., including 1,480 patients with lung cancer who completed ePROMs questionnaires between January 2019 and December 2020, adds to the evidence supporting the feasibility and practicality of incorporating the REQUITE questionnaire in routine clinical practice (38). This service has been expanded beyond lung cancer to multiple disease sites. At the time of writing this paper, it has enrolled over ten thousand patients with more than thirty-five thousand completed electronic questionnaires featuring the direct lay translation of CTCAE. Both patients and clinicians have responded positively to this service due to its benefits in enhancing care (39).

In recent years, the routine adoption of PROM services has increased worldwide, with a growing emphasis on enabling remote or electronic completion (40–43). This effort effectively bridges the gap between the benefits identified in landmark randomized controlled trials and the application in real-world clinical practice. The benefits around improved consultation, symptom control and clinic efficacy have been realized, as many PROM services are designed to align with clinic appointments. An anticipated advantage identified that has yet to be fully realized involves the ability of PROMs to trigger alerts for clinicians when there is a change in patients' symptoms from baseline. This could lead to early patient reviews or prompt referrals to urgent services, increasing overall survival. This service is presently being developed at The Christie (36). Therefore, it is of importance that PRO tools facilitate consistent and high-quality symptom reporting, given its increased role in modern healthcare.

As this is the first study to investigate the concordance of these two PRO tools, there is a need to further validate the study findings. Future studies should address the limitations identified in this study, including the inclusion of larger sample sizes accounting for socioeconomic status. It is recommended to conduct longitudinal studies that evaluate PROs at various time points, starting before treatment and continuing through the follow-up period after treatment. This approach provides valuable insights into how patients' symptoms and quality of life evolve over time.

Additionally, challenges remain for clinicians to establish if a change in patients' symptoms is caused by the disease progression, adverse events related to treatment, or an exacerbation of their existing comorbidity. Hence, further research is required to assess the impact of patients' comorbidities on PROs to improve the quality of symptom reporting.

5 Conclusion

The adapted-REQUITE questionnaire has shown a better correlation to clinician-reported outcomes and higher patient preference than the PRO-CTCAE®. The results of this study have led to the adoption of the adapted-REQUITE questionnaire for patients with lung cancer in routine clinical practice at our institution.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material. Further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by the Health Research Authority, London – City and East Research Ethics Committee, and The Christie Research and Development Division. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

TJ: Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing. TN: Visualization, Writing – original draft, Writing – review & editing. IF-W: Visualization, Writing – original draft, Writing – review & editing. RC: Investigation, Resources, Writing – review & editing. JC: Investigation, Resources, Writing – review & editing. MH: Investigation, Resources, Writing – review & editing. HM: Formal analysis, Methodology, Writing – review & editing. PT: Investigation, Resources, Writing – review & editing. DW: Investigation, Resources, Writing – review & editing. CF-F: Conceptualization, Investigation, Methodology, Project administration, Supervision, Validation, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fonc.2024.1328871/full#supplementary-material

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Analysis of the effect of digital hospital efforts on paper savings in inpatient procedures and on the duration of nursing care services

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Background: This study has two primary objectives. Firstly, it aims to measure the time savings achieved through the digitization of paper forms filled out by nurses in the inpatient care process. Secondly, it seeks to reveal the financial savings resulting from reduced paper consumption due to the digitalization. The Health Information Management System Society (HIMSS)—Electronic Medical Record Adaption Model (EMRAM), which makes stage-based (0–7) evaluations, serves as a tool to measure the rate of technology utilization in public hospitals in Turkey. The study is based on the HIMSS EMRAM criteria for 2018. Bahçelievler State Hospital, a public hospital in Turkey, was chosen as the research facility. In 2017, it was accredited as Stage 6 with HIMSS EMRAM. However, not all its wards have been digitalized. Initially, pilot selected wards were digitized. Therefore, digital and non-digital wards serve together. In this context, 4 wards were randomly selected and time, paper and toner savings before and after digitalization were measured.

Method: A table was created in Microsoft Excel,listing the forms used by nurses in inpatient care and the time required to fill them out.The time spent for filling paper-based forms and digital-based forms was measured in randomly selected wards.

Result: The analysis showed that digital forms saved more time, paper and toner. For example, filling out the patient history form took 45 min when using paper, compared to 12 min in digital environment. Approximately 27% time savings are achieved only for the patient history form. The total time savings delivered by digitalization for 1,153 inpatients during the year were found as 117 care days, and the savings on total paper consumption was 41.289 pages. For 1,153 inpatients throughout the year, the total time savings from digitalization was 117 care days and the total paper consumption savings was 41,289 pages. In addition, in 4 wards with a total bed capacity of 25, annual paper savings of $1,705.86 and toner savings of $283,736 were achieved.

Discussion: This study reveals the benefits of digitalisation in hospitals for nurses. It saves the time that nurses allocate for filling out paper forms with digitalised forms. Thus, it is a good practice example in terms of using the time allocated for form filling for patient care.When we extend this study to Turkey in general, it can be considered that the time savings achieved by nurses by

digitizing inpatient forms varies between 10.8% and 13%. The number of nurses working in public hospitals in Turkey is approximately 160,000. Assuming that 60% of the nurses work in the inpatient ward, it is understood that the annual savings achieved by digitizing the forms corresponds to a range of 398–559 nursing hours.

KEYWORDS

healthcare costs, health informatics, medical record, nursing care, time study

Introduction

Nursing is a dynamic profession that has transcended its traditional boundaries and continues to develop unique theories. Nursing/midwifery is a profession that directly engager with and serve individuals. The field of health differs from other business lines because individuals living under intense stress, namely patients, are served, and personnel working in this field often confront stressful situations (1). The job descriptions of nurses encompass a variety of responsibilities, includingcollecting patient data, assessing patient needs,, performing nursing diagnosis, developing and implementingcare plans, monitoringmedication administration, training patients and their relatives, and arranging patient transfers when necessary (2).

Considering that all these processes are carried out on paper, and there are often not adequate nurses, it has been observed that nurses spend a pretty long time for each patient record they make in hardcopies. This being the case, the use of electronic health records in nursing processes has come to the fore, and it is considered that hospital information and management systems will help increase the care time to be allocated to the patient by reducing the time allocated to stationery operations (3).

It has been stated that if the nursing forms and work processes are fulfilled through Hospital Information Management System (HIMS), this will result in enhanced health care quality, decreased paperwork, reduced paper consumption, and increased nursing performance and satisfaction induced by reduced workload (4). The willingness of nursing staff to embrace digital technology is generally high. For example, the integration of medical devices with the hospital information management systems accelerates the work of nurses. Studies areseen that the efficiency and motivation among nurses increase significantly with digitalization (5).

This study aims to compare the time nurses spend in inpatient services when the records (filled forms) of health care are kept in the form of hardcopies and electronic media and to measure the change in paper consumption when electronic systems are used.

Effect of electronic systems on health service quality, nurse performance, and satisfaction

A wide variety of high-level information is produced in health care delivery and treatment processes. Therefore, it becomes necessary to use information technology-supported systems to record this information, use it in the treatment process, facilitate retrospective access to information and manage the treatment process in a quality manner. The systems used by health institutions for this purpose are called Hospital Information Management Systems (HIMS). A valuable, and well-designed HIMS is highly correlated with health care quality (6).

It is seen that hospitals which are using information systems have come a long way in terms of quality. It is observed that the quality of health services has increased in organizations that keep up with the changing health technologies, make investments for this purpose and actively use the technologies in the field. In 2009, Kilinc investigated the effect of information technologies on improving the service quality. Based on the questionnaire results applied to 165 patients from 4 different hospitals in Konya province, a strong relationship was determined between the quality of the service provided and the use of technology (7).

Another study on this subject was conducted by Banet et al., where nurses were caused to use HIMS for 12 months. The measurement was conducted using a questionnaire with 55 nurses before and after 1 year. It was observed that the time spent by the nurses for recording decreases, and the time they allocate the patients' care increases since nurses record all treatment and care processes electronically and avoid using paper. In addition, it was determined that the performance of nurses increased due to the decrease in the time allocated to nursing work and procedures (8).

The results of the HIMS usability questionnaire for nurses were analyzed in the study conducted by Yılmaz and Demirkan, which evaluated the effect of electronic systems on nurse satisfaction and assessed the usability of hospital information and management systems. Nurses were asked to present their opinions about HIMS, practical usability, learnability, assistance, safety, customization, design, satisfaction, and ease of use. In this study, the concept of satisfaction was defined as the satisfaction of the healthcare personnel using the HIMS with the software, their feeling of content with the speed and accuracy of the software, and the assistance provided by the software to allow them to do their jobs faster (9).

Nurses are direct users of HIMS. The usability of the HIMS interface is of great importance for nurses due to the complex structure of nursing work and operations. It is predicted that a HIMS that warns and helps nurses when faced with adverse circumstances, is not obstructive but suggestive in decision-making, organizes nursing workflows, and has a user-friendly interface will enhance satisfaction from nursing services (10). The study conducted by Saluvan, which supports the conclusion that

the use of information technologies is required to improve quality, concluded that the use of information technologies could positively affect the quality of care since health services have a complex structure (11).

The purpose of usability is to produce products that are compatible with the information and usage habits of the user. To increase the usability of HIMS, the expectations of users from the product and the product itself should be designed to meet the user's needs. Thanks to the information systems designed considering the information and usage habits of the user, the effectiveness, efficiency, and user satisfaction delivered by the product increase (12).

A study by Yorgancioglu et al., investigated the effect of innovation studies on health service delivery. A questionnaire was applied to a total of 143 patients treated at Eskisehir State Hospital. Based on the research results, the technological system and hardware infrastructure in the hospital increase the quality of the health service offered. Additionally, this induces a positive effect on patients. At the same time, it was determined that some elements, such as electronic records, physician and nurse electronic documentation, use of technology in clinical decision-making, and electronic medication management and administration, affect the quality perception among patients positively (13).

In a study conducted by Nokay et al., which deals with the effect of electronic systems on nurse performance, a questionnaire was applied to 307 healthcare professionals to determine the effect of electronic systems on institutional performance. Based on the survey study results, the operating speed and performance of healthcare personnel using electronic systems are elevated (14). Interventions used to facilitate nurse education and training on electronic health records are also important. Inadequate education and training can threaten the adoption of electronic health records and negatively affect the quality of nursing documentation. Therefore, as well as the digitization of nursing forms, nurses need to be taught how to complete these forms (15). With the digitalization of nursing forms, it was observed that the transition from paper-based documentation to computerized documentation was easier, nurses using the electronic nursing documentation system received more approvals, and complaints about its content in the practice environment were minimized (16).

Another study suggesting that digitalisation in healthcare institutions increases patient care and safety was conducted by Vida et al. When a digitalisation strategy is determined for healthcare institutions, it has been observed that its effect on patient safety and care is positive (17). A study conducted in Australia in 2017 investigated the use of digital technology in healthcare settings. Interviews were conducted with nurses and the barriers to nurses' access to digital technology were discussed. It was observed that nurses could not use technology in patient care because they did not know how to access technology. In interviews with nurses, it was concluded that the use of technology will benefit health care services (18). In the study conducted by Krick et al., the existence, use and benefits of digital technologies in nursing care were discussed with a literature review. In particular, it was observed that studies on the use of technology in the field of nursing are quite rare (19).

This study proved the benefits of digitalizing nursing forms in the literature. It is seen that questionnaire and time study are used as measurement methods in the studies. In this study, time study was preferred as a method. With the survey method, the satisfaction of nurses about solid and digital system applications can be analysed comparatively. This study determines the effect of electronic filling of nursing forms instead of paper in inpatient procedures within the scope of digital hospital studies on the duration of nursing care services and measures the cost-effectiveness of filling out the forms electronically on paper consumption.

Methods

This study is based on the data of 1,153 patients hospitalized in the Internal Medicine, Infection, Chest Diseases, and Neurology ward of Bahcelievler State Hospital between January 2023 and January 2024. Two types of data were collected within the scope of the study. The first type of data recordedthe time nurses spent filling out paper forms during inpatient services. The second type of data capturedthe time nurses spent filling out the same forms using the Hospital Information Management System (HIMS). Personal Data Protection Law No. 6698 was taken into consideration during the data acquisition, and the distinctive identity data of the patient was completely removed from these data before they were used. Also, informed consent and assent were obtained from the patients. Patients were informed about the scope of the study.

This study consists of two separate analyses. In the first analysis, the researcher used an observation method and compared the time spent by nurses in filling out paper forms vs. electronic forms in the wards under study. A Microsoft Excel file was created to collect these data. The Excel file consisted of the following columns:

- Patient name
- Ward of admission
- Names of nursing forms
- Time spent on filling out paper forms
- Time spent on filling out electronic forms

First, the time spent by nurses on filling out paper forms was recorded by the researcher using a stopwatch. Then, the time spent by nurses on filling out electronic forms while entering data into the Hospital Information System (HIS) was calculated. Thus, data were collected to compare both situations. It should be noted that variations in forms used based on the ward of admission were not considered in this study. Only forms used universally across all patients were taken into account. The time required for nurses to fill out the forms (paper/electronic) was determined based on the number of days patients were admitted, and the total time spent by nurses in filling out forms was calculated accordingly.

In the second analysis, the potential paper savings from digitizing paper forms and active use of the HIS were calculated. Another Microsoft Excel file was created to collect these data. The Excel file consisted of the following columns:

- Form name
- Number of pages per form
- Frequency of form usage

Some forms were filled out only once, while others were repeated throughout the duration of the patient's admission. Therefore, calculations were made taking into account the number of days the patient was admitted and the number of pages for forms that were repeated.

The information regarding the number of days patients were admitted and the number of pages for forms was provided by the hospital management. Subsequently, the total paper consumption was calculated by multiplying the number of days each patient was admitted by the number of pages for forms used during that period, considering eight nursing forms included in the study.

The forms filled out by the nurses contain the following patient information:

- Patient Admission Number
- Date of Admission
- Hospitalization Release Date
- Number of Hospitalized Days
- Type of Discharge
- Details of the Ward Where the Patient Is Hospitalized

The forms included in the research were selected from those filled out by the service nurses for each patient in the inpatient wards.Nurses using the digital system and nurses using the paper-based system were randomly selected. Because paper and digital forms used for inpatients throughout the hospital are the same. The completed forms for a particular age group or disease were excluded (e.g., geriatric forms, diabetes forms).

1. **Forms included in the scope of the study**

   (1) Nursing History Form
   (2) (Itaki) Adult Patient Fall Evaluation and Follow-up Form
   (3) Nurse Observation Form
   (4) Form Nrs2002
   (5) Pressure Sore Risk Assessment Form (Norton Scale)
   (6) Das (Behavioural) Pain Rating Scale
   (7) Patient and Companion Training Form
   (8) Nurse Follow-up Form (Care Plan)

In this study, the researcher used the observation method and recorded the paper-based form-filling times of the nurses by observing them one-on-one on-site. A table was created in Microsoft Excel for this calculation. The names of the patients, their wards, the names of the forms filled in and the time of filling in the forms were included in this table. Nurses' form filling times were monitored and calculated with a stopwatch. The digital-based form filling times of the nurses were calculated through the Hospital Information Management System. Thus, it was possible to make comparisons. In this study, it was not taken into account that the forms used varied according to the ward in which the patient was hospitalised. Printed forms used for all patients were taken into consideration. For inpatients, the time required to fill in the forms used by the nurses (according to the electronic/paper form) was determined. Basing the patients' hospitalization period, the nurses' total time spent filling out the forms was calculated. Another data collected within the scope of this study is the paper savings achieved when electronic-based forms are used instead of paper-based forms. For this purpose, the number of patients hospitalized in the selected wards and the number of days of hospital stay were determined. Then, the total paper consumption was calculated by multiplying the number of hospitalization days for each patient and the number of form pages used over the eight nursing forms used in inpatient services.

Ethical considerations

Ethical approval was taken from the local ethics committee on 25/07/2018 with number 430. The approval was received from İstanbul Medipol University Health Science Ethical Committee.

Results

Time analysis

As seen in Table 1, the fill-out times and time differences for the nursing forms were filled out in digital media, and hardcopies were recorded starting from the patient's admission to the ward. The time spent on the forms during the observation was recorded in seconds. The time difference between digital and paper forms filled out by nurse A for one patient during the year was 13.7 min. Similarly, this value was calculated as 11.67 min for nurse B, 11.58 min for nurse C, and 11.55 min for nurse D.

Table 2 shows the nurses' time on the forms for each patient hospitalized during the year. The nursing history form is filled out only once during admission to hospitalization. Other forms are the forms that are used repetitively every day during the hospitalization of the patient. The nurse observation form includes vital sign measurements repeated three times a day. The recurrence time was also considered when calculating the times spent to record the nursing observation form on paper and digitally, and the time spent for the recording process was calculated by multiplication by 3.

In Table 3, the savings on time resulting from the conversion of nursing forms of 1,153 hospitalized patients from hardcopy forms to digital forms are analyzed by nurses. For example, the time difference for nurse A to fill out the the patient's account of their medical history form in hardcopy and digital forms is 175 s, as given in the previous table. Considering that the patient's account of their medical history form is filled out only once for each patient, the savings on time provided by Nurse A were

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TABLE 1 Comparison of time spent for a patient.

	A Nurse			B Nurse			C Nurse			D Nurse		
	Total time for digital forms	Total time for hardcopy forms	Total time difference	Total time for digital forms	Total time for hardcopy forms	Total time difference	Total time for digital forms	Total time for hardcopy forms	Total time difference	Total time for digital forms	Total time for hardcopy forms	Total time difference
Total time spent for forms filled out during hospitalization (s)	558	1.380	**822**	410	1.110	**700**	498	1,193	**695**	462	1,155	**693**
Total time spent for forms filled out during hospitalization (min)	9.3	23	**13.7**	6.83	18.5	**11.67**	8.3	19.88	**11.58**	7.7	19.25	**11.55**

Bold values show total difference values.

multiplied by the total number of inpatients, and the total time savings during the year was determined as 201,775 s.

(1) 400–225 = 175 (Time difference when filling out hardcopy forms and digital forms)
(2) 175 × 1,153 = 201,775 s (Time difference multiplied by the total number of inpatients)
(3) 201,175/60 = 336 min (Converted from seconds to minutes)
(4) 336/60 = 56 h (Converted from minutes to hours)
(5) 56/8 = 7 days (Total working hours were determined as 8 h and regarded as 1 day. The total day savings were determined by dividing the total hours by 8)

The same table indicates the savings on time achieved by switching the repetitive nursing forms used during the hospitalization from hardcopy to digital. For example, the times for completion of 7 forms mentioned above in hardcopy form and digital form by Nurse A are given in the previous table. Considering that other forms are repetitively used every day during the hospitalization, the total time savings achieved by nurse A during the year were multiplied by the total number of care days, which was found as 3,603.143 s.

(1) 980–333 = 647 (Time difference for seven forms when filling out in hardcopy and digital formats)
(2) 647 × 5,569 = 3,603.143 s (Time difference multiplied by the total number of care days)
(3) 3,603,143/60 = 60,052 (Converted from seconds to minutes)
(4) 60,052/60 = 1,000 (Converted from minutes to hours)

Paper consumption analysis

The patient's account of their medical history form given in Table 4, which is filled out during the admission of the patient to any of the Internal Medicine, Infection, Chest Diseases, and Neurology wards, consists of 2 pages. The seven forms, which are utilized for daily follow-up after admission and repetitively used at certain intervals, consist of 7 pages in total.

Total paper consumption measurement

Table 5 gives a total of 5,569 days of care provided for 1,153 hospitalized patients between January 2023 and January 2024. The number of pages in the nursing the patient's account of their medical history form, which was filled out and was not repetitively used during hospitalization, was found to be 2,306 pages when multiplied by the total number of care days. The total number of pages of the seven forms, which were repetitively used daily during hospitalization, was found to be 38,983 pages when multiplied by the number of days of care. Additionally, it was determined that the total number of papers consumed for 1 year was 41,289 for 1,153 patients.

TABLE 2 Comparison of time spent by nursing forms in seconds.

Reviewed forms	A Nurse		B Nurse		C Nurse		D Nurse		Average	
	Time for hardcopy forms (s)	Time for digital forms (s)	Time for hardcopy forms (s)	Time for digital forms (s)	Time for hardcopy forms (s)	Time for digital forms (s)	Time for hardcopy forms	Time for digital forms (s)	H.copy form (s)	Digital form (s)
Nursing services patient history form (The patient's account of their medical history)	400	225	280	120	328	163	310	160	330	167
(Itaki) adult patient fall evaluation and follow-up form	130	45	90	35	110	40	95	37	106	40
Pressure sore risk measurement form (Norton scale)	65	45	33	15	45	25	50	32	48	30
das (behavioural) pain assessment scale	50	20	30	10	45	17	36	17	40	16
Nurse observation form	370	85	356	93	325	76	336	65	346	80
Nursing process care plan	180	75	162	70	155	67	166	63	166	68
Patient and companion training form	90	38	75	27	95	60	82	44	85	42
NRS2002 form	95	55	4	40	92	50	80	44	68	48
Total	1,380	558	1,110	410	1,193	498	1,155	462	1,210	482

TABLE 3 Calculation chart for 1-year time savings.

		Nurse A	Nurse B	Nurse C	Nurse D	Average
Nursing services patient history form (The patient's account of their medical history)	Time savings (s)	201,775	184,480	190,245	172,950	
	Time savings (min)	336	307	317	288	
	Time savings (h)	56	51	52	48	
	Time savings (day)	7	6.37	6.5	6	**6.5**
(Itaki) adult patient fall Evaluation and follow-up form Pressure sore risk measurement form (Norton scale) Das (behavioural) pain assessment scale Nurse observation form Nursing process care plan Patient and companion training form NRS2002 form	Time savings (s)	3,603.143	3,007,.60	2,951.570	3,023.967	
	Time savings (min)	60,052	50,121	49,192	50,399	
	Time savings (h)	1,000	835	819	839	
	Time saving (day)	125	104,375	102,375	104,875	**110**

Bold values show average of time savings (day) for nurses forms.

Total number of reams consumed

Based on Table 5, it is provided that the total amount of reams (each ream contains 500 pages) consumed for 1 year is 82.57 for 1,153 patients.

Total number of toners consumed

Table 5 shows that 25.80 packs of toners were used in total, considering that one pack of toner can be used for 1,600 pages, and the total number of pages is 41,289.

Paper consumption cost

The information obtained from technology stores determined the average price of a 2,500-page A4 Paper box as 21,06$. Table 5 shows that the total annual paper cost for 1,153 patients is 1,705.86$.

Total cost of toners consumed

Based on the information obtained from technology stores, the cost of a pack of toner, which can be used for 1,600 pages, is 103.07$.

TABLE 4 Number of forms used and number of their pages.

	Forms filled out only once during hospitalization	Forms used repetitively every day
Number of forms	1	7
Number of pages in a form	2	7

TABLE 5 General analysis of the study.

Number of care days	Number of pages in a form filled out only once during hospitalization	Number of pages in forms used repetitively every day	Overall total
5,569	2,306	38,983	**41,289**
Total number of pages in forms	Number of one ream of A4-size paper	Total number of A4 packs consumed	
41,289	500	82.57	
Total number of pages in forms	Number of usable papers per pack of toner	Total number of toner packs used	
41,289	1,600	25.80	
Total number of pages in forms	Number of usable papers per pack of toner	Total number of toner packs used	
41,289	1,600	25.80	
Total number of pages in forms	Price of a A4 box (2,500 pages) in $	Total paper cost	
41,289	21.06$	1,705, 86$	
Total number of pages in forms	Price of a toner (1,600 p. black) in $	Total toner cost	
41,289	103.07$	2,837,36$	

Bold value shows overall total value for 3 columns.
According to the Central Bank, the average dollar exchange rate on a level basis for 2023 is 23.74.

Table 5 shows that the total annual cost of toners for 1,153 patients is 2,837.36$.

Turkey-scale projection

Considering the 90% bed occupancy rate in Bahcelievler State Hospital, it is understood that 22.5 of 25 beds in 4 wards are occupied at all times. In line with the study conducted with four nurses, it is seen that one nurse provides continuous care for 5.5 beds. Given the time each nurse spends for the forms and the time differences, we can determine how much of the total working time is allocated to documentation. The example given in Table 6 shows that nurse A spent 18 min on the hardcopy forms that she filled out for one patient, totaling 99 min for 5.5 patients. It was found that nurse A spent 20% of her 8-h shift filling out hardcopy forms. After digitalization, we see that nurse A spent 6.18 min on the digital forms she filled out for one patient, totaling 34 min for 5.5 patients. It was determined that nurse B spent 7% of her 8-h shift filling out a digital form. In line with all this information, it was established that nurse A saved 13% on time spent filling out forms after digitalization. When making the same calculations for other nurses, it was determined that nurse B saved 11% on the same time, followed by nurse C with 11% and nurse D with 10.8%.

TABLE 6 Rate of total working hours saved based on nurses after digitization.

	Rate of time spent on hardcopy forms	Rate of time spent on digital forms	Rate of total working hours saved
Nurse A	20%	7%	13%
Nurse B	16%	5%	11%
Nurse C	17%	6%	11%
Nurse D	17%	6.2%	10.8%

Since the the patient's account of their medical history form is a form that is filled out only once, the time saved by a nurse while filling out each the patient's account of their medical history form is divided by the total hospitalization days after calculation. The subsequent value found was summed up with the time savings delivered for other forms. Thus, the repetition of the time spent on the the patient's account of their medical history form was avoided.

After digitalization, it is seen that the total rate of savings in an 8-h working period ranges between 10.8% and 13%.

Considering the cost of paper consumption derived from our study for 25 beds, it is possible to note that a paper cost savings of approximately 533,287.18$ per year will be achieved in a service offering with 135,340 beds if we build a projection throughout Turkey.

Discussion

Informatics skills are increasingly becoming a necessity for nurses. Nurses will use technology more frequently in the future and must be adequately prepared to document patient care and analyze data. Therefore, they will be expected to improve their informatics skills throughout their ongoing education. In a study conducted at the California School of Nursing, a simulation study was conducted with third- and fourth-year nursing students on using electronic health records. In this study involving 38 nursing students, the students were given simulated training on using electronic health records for two terms in total. At the end of the study, the students stated that the use of electronic health records in hospitals establishes a bond of trust between the patient and the nurse and added that it is easier to access the patient's history by recording the data and responding to the patient inaccurately is avoided with the help of the clinical warnings created (20).

A study conducted in the US investigated whether electronic health records are effective in the varying health conditions of patients in an intensive care unit. During face-to-face interviews with nurses, nurses were asked how they used the electronic health record to assess patients' conditions. In the study involving 18 nurses, 47% of the nurses stated that they were able to regularly monitor the patient's vital signs through the electronic health record, and thus, they could make healthier and stronger decisions during the care process. On the other hand, 32% of the respondents find the use of clinical templates useful

and think that it accelerates data recording and access to data (21). A similar study by Pabst et al., measured the effect of electronic systems on nursing documentation time. According to the study, nurses using electronic systems could reduce the time they allocate to documentation and lengthen the time they allocate to the patient (22).

The literature includes few studies that measure the effect of using electronic health records on time. In a study by Poissant et al., the effect of using electronic health records on the time efficiency of physicians and nurses was investigated. Based on the study, which examined and compiled a total of 23 publications, it was observed that using electronic health records in nursing work processes allows nurses to save time by 23.5% (23).

In parallel to our study, a study conducted by Banner et al., observed before and after the electronic use of nursing forms. The study's results established that the time spenton nursing documentation decreased by 12% after digitalization (24). The master's thesis study conducted in 2019 measured the annual time and paper savings achieved after digitalization in intensive care units. Based on the study conducted with two nurses, after the digitalization of the daily forms in intensive care units, it was determined that nurse X saved 48 min per day and nurse Y 65.50 min per day. It was determined that the annual time savings achieved were 248.20 care days for nurse Y and 181.44 care days for nurse X (25). In this study, the time spent by nurses for care in partial digital (ward using both paper and digital forms) and digital clinic was compared. It was observed that 129.1 min were spent for indirect care practices in the full digital clinic and 404.4 min in the digital clinic. In addition, in the partially digital ward, 281.5 min were wasted due to medication preparation in the treatment room, preparation/use of paper-based documents, double entry of some procedures, nurses collecting data from both digital and paper systems, and additional e-order entry for medications prescribed by doctors. This study supports our study in terms of proving that when nurses use paper forms, the time allocated to patient care is shortened (26).

Similar results were derived in our study based on a total of 5,569 care days of 1,153 patients hospitalized in the Internal Medicine, Infection, Chest Diseases, and Neurology wards at Istanbul Bahcelievler State Hospital between January 2023 and January 2024. In the process that started with the patient admission to the ward, the routine procedures fulfilled by the nurses were followed, and the forms used as a standard for each patient were reviewed individually. The forms filled out in hardcopy format before the digitalization process were also reviewed in the electronic environment after digitalization. The electronic and manual fill-out times of the forms were observed upon the researcher's involvement in the environment of the researched subject. Based on this observation, the times required to fill out the forms electronically and manually were determined. Upon the observational measurement conducted with four ward nurses, the savings on time delivered for 1 year regarding the given forms were calculated as 117 working days (1 day was calculated as 8 h). The four wards we examined have a total of 25 beds, with four nurses working. Likewise, the results of our study based on 5,569 care days of 1,153 patients demonstrated that 1.76 nurses were saved after digitalization.

For the Turkey-scale projection; it is understood that the annual savings in Turkey correspond to a nursing time ranging between 398 and 559, based on the projection made in consideration of the minimum 10.8% and maximum 13% savings indicated by our study. When reviewing similar studies in the literature, the effect of electronic health records on nursing documentation time has been emphasized, but the paper savings achieved upon the digitalization of forms have not been measured. Additionally, our study measured the paper and toner savings achieved due to the digitalization of nursing forms. Based on our study carried out in 4 wards with a total bed capacity of 25, the paper savings achieved by switching eight nursing forms filled out for 1,153 hospitalized patients to digital format during the year are 41,289 pages. In addition, the savings on toner costs amount to $ 2,837.36. Based on a study conducted in the intensive care unit in 2019, which measured the paper savings achieved after digitalisation, papers worth $707.29 and toners worth $4,977.02 were saved annually in a 22-bed intensive care unit, as similarly indicated by our study (25).

Conclusion

Patient loyalty can be evaluated as a continuation of this study. Satisfaction with the patient care process carried out with paper forms and satisfaction with the patient care process carried out with digital forms can be compared. Thus, a new contribution to the literature will be provided. It is a fact that data that are not recorded and analysed electronically do not contribute to any academic research. In today's conditions, producing academic studies from data on paper takes a lot of time and requires labour force. Information kept on paper cannot become data and cannot be analysed. Considering that a total of 41,289 pages of paper is consumed in 1 year for 1,153 hospitalised patients, retrospective examination and analysis of these documents for academic studies is a heavy burden. For healthcare organisations, digitalisation is very important not only in terms of patient care but also financially. The use of paper creates a financial burden when evaluated on a country basis. Digitalisation is a measurement tool especially for the health ministries and policy makers of countries. With digitalisation, access to patient data becomes easier, the time allocated to the health care process of patients increases and the potential of patients to access health outcomes increases.

The study covers a period of only 1 year. It is not thought that the result may change when spread over a longer period. Because currently, hospitals in Turkey still use a dual system. While some hospitals have completely switched to the digital system, some hospitals use both the raw digital system and the paper system together. The forms used in hospitals in Turkey are determined by the Ministry of Health. Therefore, the same forms are used in public hospitals throughout the country. Therefore, it makes it easier to generalise across the country. However, a limitation of

the study is the size of the hospital. Hospital size is determined depending on the number of beds. In such a case, the number of forms used in a hospital with a high number of beds will increase and financial calculations will be different. As a continuation of this study, the use of paper forms and digital forms according to hospital size can be discussed comparatively.

As a result, considering the potential benefits of digitalisation in healthcare institutions for all stakeholders, the concept of digital hospital should be expanded and all processes should be carried out electronically.

Future research could explore the long-term effects of digitalization on patient outcomes, healthcare costs, and overall quality of care. Additionally, comparative studies across different healthcare systems or countries could provide valuable insights into the scalability and generalizability of digital hospital initiatives.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

This study was approved by the Medical Ethics Committee of Istanbul Medipol University of Medical Sciences (ethics code: 108400986040.01.01-E53566EKN:420). The study followed accepted ethical standards, as outlined in the Declaration of Helsinki. The purpose of the study was explained to the participants and a written informed consent was obtained.

Author contributions

EV: Conceptualization, Data curation, Formal Analysis, Writing – review & editing, Investigation, Methodology, Resources, Writing – original draft. İK: Data curation, Formal Analysis, Methodology, Project administration, Software, Validation, Writing – original draft, Writing – review & editing. SC: Conceptualization, Data curation, Formal Analysis, Writing – review & editing. ÖE: Conceptualization, Formal Analysis, Resources, Validation, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Asking questions that are "close to the bone": integrating thematic analysis and natural language processing to explore the experiences of people with traumatic brain injuries engaging with patient-reported outcome measures

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Introduction: Patient-reported outcomes measures (PROMs) are valuable tools for assessing health-related quality of life and treatment effectiveness in individuals with traumatic brain injuries (TBIs). Understanding the experiences of individuals with TBIs in completing PROMs is crucial for improving their utility and relevance in clinical practice.

Methods: Sixteen semi-structured interviews were conducted with a sample of individuals with TBIs. The interviews were transcribed verbatim and analysed using Thematic Analysis (TA) and Natural Language Processing (NLP) techniques to identify themes and emotional connotations related to the experiences of completing PROMs.

Results: The TA of the data revealed six key themes regarding the experiences of individuals with TBIs in completing PROMs. Participants expressed varying levels of understanding and engagement with PROMs, with factors such as cognitive impairments and communication difficulties influencing their experiences. Additionally, insightful suggestions emerged on the barriers to the completion of PROMs, the factors facilitating it, and the suggestions for improving their contents and delivery methods. The sentiment analyses performed using NLP techniques allowed for the retrieval of the general sentimental and emotional "tones" in the participants' narratives of their experiences with PROMs, which were mainly characterised by low positive sentiment connotations. Although mostly neutral, participants' narratives also revealed the presence of emotions such as fear and, to a lesser extent, anger. The combination of a semantic and sentiment analysis of the experiences of people with TBIs rendered valuable information on the views and emotional responses to different aspects of the PROMs.

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Discussion: The findings highlighted the complexities involved in administering PROMs to individuals with TBIs and underscored the need for tailored approaches to accommodate their unique challenges. Integrating TA-based and NLP techniques can offer valuable insights into the experiences of individuals with TBIs and enhance the interpretation of qualitative data in this population.

KEYWORDS

traumatic brain injury, patient-reported outcome measures, natural language processing, sentiment analysis, artificial intelligence, healthcare development

1 Introduction

1.1 Traumatic brain injuries and the use of routine outcome measures to inform care decisions

The World Health Organization (WHO) defines Traumatic Brain Injuries (TBIs) as "an acute brain injury resulting from mechanical energy to the head from external physical forces", excluding manifestations related to "drugs, alcohol, medications, caused by other injuries or treatment for other injuries (e.g., systemic injuries, facial injuries or intubation)". It also excludes manifestations linked to "other problems (e.g., psychological trauma, language barriers or coexisting medical conditions) or caused by penetrating craniocerebral injury" (1). TBIs are a leading cause of death and disability worldwide, and their global incidence is rising (2) to the extent that TBIs are commonly referred to as "the silent epidemic" (3–5). Recent estimates (6) indicate that in 2019, there were 27.16 million new TBIs reported and a prevalence of 48.99 million TBIs worldwide. Nonetheless, exact figures on the incidence and prevalence of TBIs are difficult to retrieve due to missing data, methodological inconsistencies in epidemiological studies, out-of-hospital deaths, and lack of comprehensive, comparable and regularly updated epidemiological data (6–9).

Furthering our understanding of TBIs and their effects is essential in light of the remarkable impairment and severe limitations they can have on people's lives, particularly as TBIs are considered a life-long condition that affects individuals' functioning and quality of life, as well as the wellbeing of their loved ones and society as a whole (10–14). In England and Wales, it has been calculated that ~1.4 million patients per year attend hospital following head injury, and TBIs are the most common cause of death under the age of 40 years, with yearly costs estimated at €33 billion in Europe and £15 billion in the UK (0.8% of GDP) (15–17).

Given the intricate interplay between brain function and psychological health, assessing and evaluating mental health outcomes in individuals with TBIs becomes paramount for effective intervention and rehabilitation strategies (16, 18). A crucial role in guiding assessment and intervention is played by Patient-Reported Routine Outcome Measures (PROMs). PROMs are standardised tools and instruments designed to systematically assess and evaluate patients' progress and outcomes of interventions over time (19). They are routinely used in standard care for TBI patients to assess the presence and intensity of common mental health conditions associated with TBIs, such as anxiety and depression, and inform therapeutic choices and evidence-based decision-making in clinical and research settings (20–23). In the UK, the national PROMs programme mandates that all hospitals utilise PROMs as part of healthcare interventions (24), with the aim of facilitating clinical decisions that are evidence-based, ensuring high care standards and promoting service development (25).

1.2 Key areas of evaluation via PROMs in individuals with TBIs

In the context of mental health in individuals with TBIs, PROMs have been repeatedly used in clinical and research practice to assess domains that are commonly negatively influenced by TBIs. These include, for example, global functioning, neuropsychological impairment, adjustment problems, and/or mood disturbances (26), with particular relevance given to the evaluation of anxiety and depression as common TBI comorbidities (12, 27, 28). A growing number of studies increasingly highlighted the importance of taking into account patients' perspectives when assessing these domains and when planning and evaluating treatment outcomes (29–31).

Focusing on the experiences and views of patients when administering and scoring PROMs can serve different purposes, including supporting patients' understanding of their symptoms, enhancing communication and treatment management and facilitating discharge planning (30, 32). Despite the advantages of PROMs, their implementation in the context of TBIs is not without challenges. Issues such as variability in injury severity, cognitive impairments, and the need for specialised measures present hurdles that may necessitate careful consideration and adaptation of PROMs (26, 33). More specifically, among others, barriers to completing PROMs for TBI patients include cognitive demands associated with PROMs completion, memory issues that can alter the possibility of accurately recalling symptoms, potentially impaired self-awareness, and cognitive biases (11, 34–36).

Additionally, literature on barriers and facilitators to PROMs completion identified both patient-related and professionals-related barriers. The former include issues with the contents of the PROMs, for example, if the questions are perceived as too generic and non-personal, or too complicated to be completed

independently, without the help of healthcare professionals (30, 37, 38). Other studies reported that service users might be discouraged from completing PROMs if they feel that they have not received appropriate explanations as to their role and functions, or how the data collected will be used and safely stored (39–42). Language barriers and issues with PROMs questions perceived as ethically and/or culturally insensitive were also reported as factors potentially affecting PROMs completion rates (43, 44). Additionally, a plethora of studies also outlined professionals-related barriers to PROMs completion, including, for example, concerns about additional work and time commitment (e.g., need to be trained in PROMs administration and scoring), the perceived burden of having to educate patients on the value and uses of PROMs, and following-upon non-responders (8, 45–47).

In light of these considerations, the current study aimed at exploring the views, opinions and experiences of completing PROMs in a sample of individuals with TBIs referred to the Clinical Neuropsychology Department of the Salford Royal NHS Foundation Trust (SRFT), a large hospital located in the Northwest of England (UK).

2 Methods

2.1 Rationale

TBI patients referred to the SRFT Clinical Neuropsychology Department routinely complete a set of PROMs (for a complete list, see Table 1. below), both before their first appointment and again following discharge from the service. Patients receive the PROMs via post at their home address on both occasions, together with a pre-paid envelope to be able to return the PROMs once completed. An internal service evaluation conducted by Peak et al. (48) highlighted very low completion rates in the said department, with pre-intervention PROMs completed only by 30% of service users referred to the service, and post-intervention PROMs returned only by 7% of service users. As the authors (48) pointed out, these findings warranted further investigation into service users' lived experiences of receiving and engaging with PROMs as part of their care. Therefore, the current study set out to:

- Explore the lived experiences of individuals with a TBI engaging with PROMs as part of their care pathway;
- Understand the factors acting as barriers and facilitators to the completion of pre-intervention and post-intervention PROMs;
- Evaluate potential challenges linked to 'indirect aspects' of PROMs that may affect completion (e.g., provision of paper-based copies, sent to service users via post).

2.2 PROMs used to assess mental health and global adjustment in TBI patients

Table 1 below shows the PROMs routinely used to assess global functioning and TBI-related neurological and psychological symptoms in service users with a TBI accessing the SRFT Clinical Neuropsychology Department.

2.3 Participants

A purposive sampling method was used to recruit sixteen participants from the SRFT Clinical Neuropsychology Department. Full demographic information is purposedly not provided to protect participants' anonymity. All participants had received a diagnosis of TBI and had been referred to the service to access psychological support to manage the effects of the TBI on their daily life (e.g., return to work) and/or to improve their mental health and wellbeing. A list of participants accessing the service was provided to the research team members, who utilised the following criteria to select service users to be invited to take part in the study: ≥18 years old; having mental capacity to consent to participation; having accessed the SRFT Clinical Neuropsychology

TABLE 1 Description of PROMs used in the SRFT Clinical Neuropsychology Department.

Routine outcome measures (ROMs)	Characteristics and psychometric properties
Patient health questionnaire [PHQ-9; (49)]	The PHQ-9 measures the frequency of symptoms of depression using nine items on a 4-point Likert scale, ranging from 0 (not at all) to 3 (nearly every day). A total score comprised between 0 and 27 is obtained by summing all items; ordinary mean substitution is used for missing items if less than one-third (less than three items) are missing. Based on the total score of PHQ-9, the depression symptoms severity are categorised into minimal (0–4), mild (5–9), moderate (10–14), moderately severe (15–19), and severe (20–27) (49).
General anxiety disorder 7-item scale [GAD-7; (50)].	The GAD-7 is a brief self-report scale for symptoms of General Anxiety Disorder [GAD, (50)]. Seven items assess the frequency of anxiety symptoms on a 4-point Likert scale ranging from 0 (not at all) to 3 (nearly every day). A total score (min 0, max 21) is obtained by summing all items; ordinary mean substitution is used for missing items providing less than one third (less than two items) are missing. The total score is categorised into minimal (0–4), mild (5–9), moderate (10–14), and severe (15–21) anxiety symptoms (50).
Work and social adjustment scale [WSAS; (51)]	The WSAS is a five-item self-report scale of functional impairment assessing individual levels of functioning in everyday activities, including work, home management, family and relationship interaction and social and private leisure activities. Each of the five items is rated on a 9-point scale ranging from 0 (not at all a problem) to 8 (very severely impaired). The total scores range between 0 and 40, with high scores indicating higher levels of impairment.
TBI health checklist	The TBI health checklist is a measure developed ad hoc as part of the SRFT services provided to TBI patients taking part in this study. It assesses pre- and post-TBI conditions related to a variety of neurological and psychological domains, including neurological conditions (e.g., epileptic seizures), sensory difficulties (e.g., difficulty with vision and hearing), chronic pain and sleep disturbances. Respondents are asked to indicate the presence of such conditions (before and after reporting a TBI) using yes/no response options. A final open-ended question asks respondents about types of medication-if any-taken at the time of completion of this measure.

services and having been sent copies of PROMs, although completion was not essential. This latter choice was due to the main aim of this study being to understand lived experiences of PROMs completion, including the barriers that may have hindered it.

Potential participants thus identified were contacted via phone call to inform them of the study and propose participation. If interested in participating, they were sent a copy of the Participant Information Sheet (PIS) and Consent Form (CF) via email or post, depending on their preferences. They were given a timeframe of at least one week to carefully consider participating in the study and allow them to ask any questions they may have had before participating. A suitable date and time were subsequently arranged for interviews to take place. Interviews were conducted until "theoretical saturation" was achieved (52–54), defined as "the point when no additional issues are identified and the codebook begins to stabilise" (52).

2.4 Data collection

Data for the current study were collected using semi-structured interviews conducted via phone calls, with each interview lasting about one hour. Interviews were audio recorded, and recordings were transcribed verbatim.

2.5 Ethics

The study received ethical approval from the SRFT Research & Innovation Department (approval n. S18HRANA45) and the Manchester Metropolitan University Research Ethics & Governance Committee (ns. 17158/9). All participants obtained written information (via PIS and CF) to be fully informed about the study and withdraw their participation. Audio-recorded consent was collected before the interviews and stored electronically, separately from the interview recordings, to ensure further protection of participants' anonymity. Pseudonyms were assigned to participants at the start of each interview, and personal information was removed from the final copies of the transcripts. The study was conducted in agreement with the Code of Ethics of the Declaration of Helsinki (55).

2.6 Data analysis

The data for this study were analysed using different methods with the aim of capturing a wide range of semantic and structural features in the participants' narratives. There is growing interest in the combination of more traditional analytical methods of qualitative data (e.g., thematic and interpretative phenomenological analysis) with innovative methods underpinned by machine learning (ML), such as Natural Language Processing (NLP) (56–59). Conventionally, the application of ML techniques, including NLP to text-based data, relied on large data sets for the algorithm to elicit meaningful themes. More recently, though, ML-based analysis of qualitative data yielded interesting results even on smaller data sets (60). This considered, the current study aimed to merge the potential of analysing data thematically and using NLP.

2.6.1 Thematic analysis

The data collected were analysed utilising Thematic Analysis (TA), following Braun & Clarke's principles (61, 62). Codes and themes were identified inductively, using NVivo version 14 (63), a form of computer-assisted qualitative data analysis software (CAQDAS) that may help to advance the robustness of research findings (64). Investigator triangulation, defined as "the participation of two or more researchers in the same study to provide multiple observations and conclusions" (65), was used to enhance the methodological rigour and trustworthiness of the analytical process (66). To this aim, three research team members (DDB, SL and PM) analysed the corpus of data independently. Codes and themes were then collectively revised, and a final set of themes was agreed upon by consensus.

2.6.2 Natural language processing

The term Natural Language Processing (NLP) refers to a subfield of computer science and artificial intelligence concerned with the automatic analysis, representation and understanding of human language (67). NLP typically focuses on written texts, processed and formatted for interpretation by a computer, such as the transcripts analysed in our research. Sub-fields of NLP include topic modelling (i.e., identifying common themes within a corpus of data by clustering words or sentences frequently appearing as connected) and sentiment analysis, which assigns meaning to words, phrases or other text units by matching them to their categorical sentiment (68–70). In recent years, NLP has been increasingly used in combination with qualitative methods of data analysis (56, 57, 71–73). The combination of these methods allows to achieve a textual and semantic analysis that integrates symbolic and statistical approaches (68, 74). Findings from studies utilising such a blending of researcher-driven qualitative analysis and NLP yielded valuable insight and complex interpretation of the data, showing the enhancing potential of combining these methods to analyse textual data (57, 59, 75, 76). Additionally, techniques that aim to predict the content -such as hate speech- or highlight the presence of emotional language in text-based data are routinely used in NLP to identify text characteristics that can subsequently be explored further within qualitative analysis (57, 77, 78). In light of this, integrating NLP with more traditional methods of qualitative data analysis could enhance the possibility for qualitative researchers to analyse larger amounts and more diverse data types, thus increasing the chance to appreciate the richness and complexity of human experience as portrayed by text-based data (79).

NLP tools make use of the same transformer-based large language models that are powering the current wave of interest in the AI field (80). The transformer model is a large neural network relying on the self-attention mechanism (81). This is particularly well suited for text analysis as the attention mechanism prioritises appropriate elements (e.g., words) of a sequence (e.g., a sentence) to make an overall classification (e.g., whether the text is positive or negative). The GPT architecture is best known for its use in conversational applications (82). In this configuration, a causal language modelling (CLM) objective is used to predict the next

words forming a response to a user. However, in our case, we used Bert-based models (83) still relying on the transformer architecture using a Masked Language Modelling (MLM) objective. These models are particularly designed for the purpose of sequence classification, which was our goal.

We used two tools for our NLP analysis. Both of these tools take text as input (in this case, the sentences from the interviews). Prior to running our tools, we pre-processed the input text to separate the text into sentences and to distinguish between dialogue acts between the interviewer and the participant. We ran each tool separately on all sentences from the interviewer and the participant and aggregated the results using the mean average within each document. We used a pre-trained sentiment analysis tool based on the BERT architecture and an emotion recognition pipeline based on the RoBERTa architecture (83, 84). Both tools were downloaded from the HuggingFace repository and applied to our data corpus using an Apple MacBook M2 Pro with 16GB of RAM.

3 Results

3.1 Thematic analysis

The process of inductive TA generated six overarching themes (displayed in Figure 1 and illustrated below with exemplary quotes), which captured different opinions and experiences of TBI service users receiving copies of the PROMs.

3.2 Theme 1: barriers to completion of PROMs

Sub-themes:

3.2.1 Lack of detailed information about how PROMs will be used

One of the main barriers to completing PROMs reported by participants was related to the perceived lack of sufficient information regarding the purposes and potential outcomes of completing PROMs. Many highlighted the need for more precise explanations about how their responses would be utilised within the healthcare system. On this note, participant twelve noted:

> *It doesn't really say why it's useful or what it's helpful (…). I think maybe you could do with putting a little more information for context (…) I think if (…) I understood why it was important and why it was helpful to more than just me (…)—it was helpful to others in general, I would have been more inclined to fill it in* (P12)

One of the service users who did not complete the PROMs commented that having more information on the PROMs would have made them feel more "in control", thereby increasing their motivation to complete them.

> *I like to feel in control of everything that's going on in a very uncontrolled time, um, I think it [having more information*

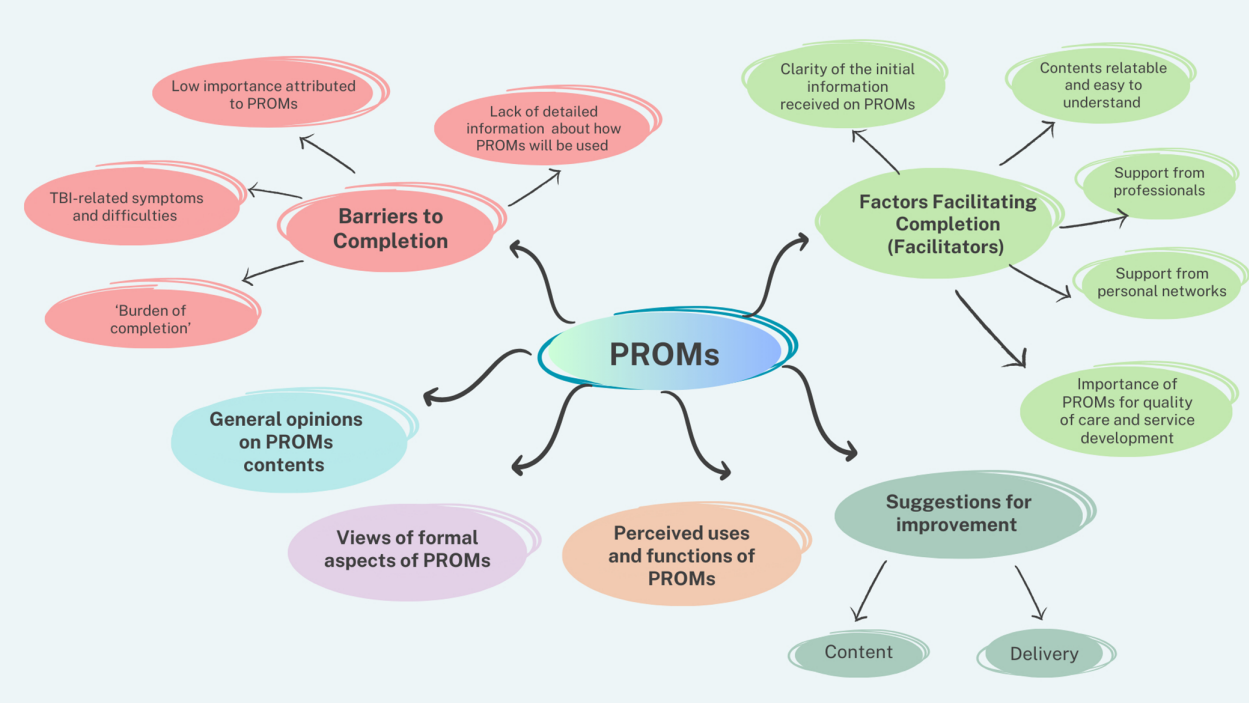

FIGURE 1
Map of themes identified using Thematic Analysis.

> *about the uses and relevance of PROMs] would solidify my desire to complete them, yeah* (P12)

Moreover, a lack of clear information about the uses and functions of PROMs might lead service users to draw incorrect inferences as to why PROMs are used, which in turn might represent a barrier to engaging with them:

> *Other people will think oh their judging me or they want, they're rating me—you know-* (P7)

> *'Cause you just think it's another form to fill in. Nobody will… They'll just put it in a filing cabinet and it will be stored* (P11)

3.2.2 Low importance attributed to completing PROMs

Some of the interviewees reported a lack of perceived relevance or benefit of completing PROMs, which, in some cases, represented a barrier to completion. This was particularly true for participants who had received support for their TBI-related difficulties and had completed their treatment journey, as participants ten and eleven explained:

> *Especially if you've been discharged like once you've been discharged it becomes… It starts becoming a little bit like unimportant, cause you're sort of gone* (P10)

> *From my point of view I didn't think, I didn't feel as if it was helping me, cause I've gone past all of that bit* (P11)

3.2.3 Potentially upsetting questions

Some participants reported discomfort or distress when faced with questions that touched upon sensitive topics such as suicide, or the impact that their TBI-related difficulties had on their families and loved ones. In some cases, this emotional burden acted as a barrier to completing PROMs. More specifically, when asked about the questions that may discourage people from completing PROMs, service users often mentioned the ones related to suicidal thoughts and the feeling of disappointing loved ones due to TBI-related issues.

> *I would say uhm (…) "that you've let your family down" is quite a hard one. (…) because I think even if you didn't think about letting your family down that question would definitely make you think about it (…) Which can be a little bit sad sometimes.* (P1)

Interestingly, however, the vast majority of service users reported that they felt it was important to ask these questions and to use straightforward language to do so, as they reflected relevant aspects of the experiences of people with TBIs. This was reported by some of the participants as follows.

> *I know that they're the most important too you know it's funny in a way. (….) [and] No, I wouldn't ask them differently.* (P3)

> *These things are always going to be a little bit close to the bone (…) If you ask anyone: "Oh have you felt like harming yourself", do you know what I mean it's like a, I don't think there's any way you can ease someone into that sort of question* (P12)

> *There have been times when those thoughts have been present, and having to answer that um question, honestly is quite hard (…) but I honestly don't know how you would ask it any other way either. Because it's an important piece of information that a practitioner needs to know, so yeah, I don't think, I think its worded as well as it can be* (P15)

3.2.4 TBI-related symptoms and difficulties

Participants cited cognitive impairments resulting from their TBI as obstacles to accurately completing PROMs, with memory impairments and concentration problems being among the most frequently reported.

> *The only problem I'd have is, if you ask a question, sort of before the accident, I can't remember, or after the accident—if you know what I mean* (P13)

> *I know it's only nine questions but actually nine questions for some people especially seeing as question number seven is "do you have trouble concentrating on things such as reading the newspaper or watching television", well actually some people would have trouble getting through nine questions* (P7)

> *Over two weeks it's like, two weeks I can't even remember what happened (…) two days ago, never mind two weeks ago (…) at the time I wouldn't know if it would have been easy or not to fill it [the PROM] in. 'Cause I can't even remember, you know, much about it really* (P9)

3.2.5 "Burden of completion" (time and effort required to complete PROMs)

Some participants expressed frustration with the time-consuming nature of completing PROMs, particularly when dealing with physical or cognitive limitations that increased the effort required. Both participants eight and nine described this concept using the term "*overwhelming*" and participant ten added that the length and multiple iterations of the PROMs increased the burden of completion, thus representing a potential barrier.

> *That just seems like a bit of a mare [Laughs]. A bit long. [Laughs]. (…) Uhm, if I was getting that very often then towards the end of it, I'd stop responding because it would get a bit tedious* (P10)

3.2.6 Unclear how to best answer PROMs questions

Some participants struggled with understanding the intent behind specific questions or determining the most appropriate response, leading to uncertainty and dissatisfaction with the process and ultimately, to disengaging from PROMs.

> *I generally just missed the questions that I don't really understand out (…) I would miss the ones that weren't specific enough or weren't for me to answer because I don't have that kind of information.* (P10)

When asked whether not understanding how to answer could impact the likelihood of completing the PROMs, participant eight replied:

> *It could do. I think I would still carry on, but I can see how with other people they might just think "yeah, I don't understand it, I can't do it"* (P8)

For some service users, the main difficulty laid in discerning the changes in their cognitive functions and mental health before and after the TBI, which affected their ability and willingness to engage with questions on such changes.

> *It was quite difficult to differentiate between before my injury and after because everything on that list was impacted by my mental health prior to the events which led to my injury* (P15)

3.3 Theme 2: factors facilitating completion of PROMs

Sub-themes:

3.3.1 Clarity of the initial information received on PROMs

Whilst some service users felt that the lack of clear information about the aims and uses of PROMs questions hindered their completion, the majority felt that receiving clear and comprehensive information about the purpose, relevance, and potential benefits of completing PROMs positively influenced their willingness to engage with these measures.

> *I remember reading through it all and it was quite clear that it was important to do it uhm cause obviously it was for my benefit.* (P1)

One aspect that emerged as encouraging completion was receiving appropriate information on the ethical treatment of their data, including who would have access to their responses and how the confidentiality of their data would be protected.

> *I know it's all in, um, kept secret anyway* (P13)

> *It matters to me, cause confidentiality is you know, personal data, data protection.* (P13)

3.3.2 PROMs contents perceived as relatable and easy to understand

Participants appreciated PROMs that used language and concepts they could easily grasp, enhancing their confidence in providing accurate responses. Furthermore, some of the interviewees reported being more inclined to complete PROMs if they felt that questions were appropriately capturing their symptomatology, rather than being too broad and generic.

> *I think they're all quite (…) uhm not too difficult to answer, they're pretty straight forward and uh, I think it encompasses most of the things you feel when you've had an injury like this, I was quite happy with them* (P4)

Some of the interviewees also commented on the time ranges indicated on the PROMs being helpful in supporting a more accurate recall and evaluation of their symptoms.

> *I found useful is where it says "over the past two weeks", so it's giving an instruction, (…) not to think of things as a whole, but in that short space of time prior to completing it. Because I think that if it hadn't said that, I would've felt very overwhelmed* (P15)

3.3.3 Importance of PROMs for quality of care and service development

Participants recognised the value of PROMs in improving the quality of care and advocating for their needs within the healthcare system, motivating them to complete these measures. In this regard, participant eleven highlighted the need to provide information on how PROMs can help to improve services, as a way to enhance completion rates.

> *People need… (…) I think people need to know why they're doing it. (…) Because otherwise there doesn't seem to be much point. And if it's too help them change stuff, people are more likely to fill them in* (P11)

The participants' narratives also indicated that the motivation to complete PROMs could be increased by knowing the perceived benefits for oneself, other service users, and the service as a whole.

> *It was quite clear that it was important to do it uhm cause obviously it was for my benefit* (P1)

> *You'd fill it in because you think you're helping somebody else. And I think that's what most people think. Only because again (…) I don't want anybody else to go through what I've gone through* (P11)

3.3.4 Support from caregivers and personal networks when completing PROMs

Participants emphasised the importance of emotional and practical support from family members, friends, or support networks in facilitating their completion of PROMs.

> *My partner was here (…) when I first got the letter, and you know she (…) spoke throughout when I was completing it* (P4)

The same participant also remarked that caregivers of people with TBIs can not only support completion, but also offer valuable help to evaluate pre- and post-injury changes, which might be challenging to assess in case of memory issues.

> *It's better to get somebody else's view who understands the situation and has seen how you've been really (…) it's better with another point of view as well, you know, to give the wider picture* (P4)

3.3.5 Support from healthcare professionals

Some service users emphasised that encouragement, guidance, and assistance from healthcare professionals were instrumental in overcoming barriers to engaging with PROMs.

> *I know for a fact that anything I've ever been given to or told by the doctors personally rather than the letters sent to my address, I'm more likely to take an automatic interest in* (P12)

> *I find… It's best if I sit there and talk to the doctor. We have a good conversation she's a very good doctor* (P3)

Participant seven also mentioned the possibility of receiving support from non-clinical staff as a potential factor that would facilitate PROMs completion.

> *Even like the reception staff could have some understanding of them and then if people need to ring up for clarification—you know they could ring and—you know-say: "look I've been given this to fill in but I don't understand this, is any chance you could explain it to me?"* (P7)

3.4 Theme 3: general opinions on PROMs contents

Participants provided varied feedback on the content of PROMs, with the vast majority expressing satisfaction with the comprehensiveness and relevance of the questions.

> *It's quite hard to put into words how you're feeling and everything that you've listed sort of in those questions, at some point you will, you will feel like that. So I would say yeah, you've hit the nail in the head with all of them* (P1)

Some of the participants felt that the content of the questions proposed, although generally relatable, did not allow them to give sufficient voice to the subjective experience of living with a TBI.

> *Umm everybody is different when they suffer from low mood and depression* (P4)

> *Everybody's experience or feelings are different (…) It's hard to put into words because the feeling of it was, you're all individual (…) and I get they've got to group them as a whole to get everything together, but, there's no individuality. If that makes sense?* (P11)

Nonetheless, others had a clearer understanding of the PROMs as tools aiming to gather data which need to be comparable within and across services and service users, and therefore, need to entail validated questions capturing common TBI symptoms.

> *If you want information analysing you've got to have a questionnaire that uhh… (…) perhaps addresses you know the most likely things that people are experiencing* (P2)

3.5 Theme 4: views of formal aspects of PROMs

Participants shared their perspectives on the formal aspects of PROMs, including the format, layout, terminology, and response options. Participant one commented on the layout of the questionnaires being clear, and their length being appropriate to gather sufficient information on different aspects of the physical and mental health of TBI patients.

> *The layout's quite clear, so, you're not gonna get overwhelmed by you know loads and loads of questions* (P1)

When asked whether printing PROMs in colour would have influenced the motivation to complete them, participants unanimously indicated that it would not have made any significant difference:

> *Um I think, colour doesn't massively matter to people but, I don't really think unless you're trying to get kids* (P12)

Some of the questions asked were also related to the scoring system (yes/no answers, or Likert scales) used in the measures composing the PROMs. Although there was some heterogeneity of views on the scale range (e.g., the GAD-7 four-point Likert scale) and labels (e.g., "several days") of such measures, service users generally agreed that the response options and format were clear and easy to understand.

Lastly, a few participants pointed out that some of the terms used in the PROMs would benefit from more clarification, enabling respondents to understand their meaning better and provide more accurate answers. In this regard, participant seven remarked:

> *I guess some of them, "other neurological condition" or "other mental health difficulties" (…) I guess that, the "other mental health difficulties" does that make it sound like a TBI is a mental health difficulty and you might have other mental health difficulties, other than you TBI? I don't know why the word "other" is there* (P7)

Participant eight echoed this point as follows:

> *"Other neurological conditions" that… This may be confusing say if nobody's ever suffered a head injury before and know anything about it* (P8)

3.6 Theme 5: perceived uses and functions of PROMs for service provision

Participants discussed their perceptions of how PROMs could be used to improve service provision, including personalised care planning, monitoring treatment progress, and identifying areas for service development and improvement.

> *You want to know who you're dealing with and what their problems are* (P5)

> *I would imagine that it would be that um, the person that's receiving these-that's doing the consultation would be able to initially see maybe what course of treatment or action would be needed* (P15)

Participant nine felt that PROMs were mostly useful to healthcare professionals "*to see if you're doing a good job*" (P9)

When asked specifically about the perceived functions of the follow-up PROMs, sent after discharge from the service, participant seven commented:

> *I guess to hopefully make sure that they feel that there has been an improvement in their [the service users'] condition through attending neuropsychology* (P7)

3.7 Theme 6: suggestions for future improvements

Sub-themes:

3.7.1 Content improvement of PROMs

Some participants suggested revisions to the content of PROMs, mostly to capture a wider range of subjective experiences and symptoms associated with TBIs. However, an almost equal number of interviewees expressed awareness about the difficulty of appropriately adapting standardised measures (such as the ones composing PROMs) to capture the variety of challenges individuals with TBIs may face. In participant seven's words:

> *You get such a broad range of patients with varying levels of difficulty, (…) do you change the entire system for the minority?* (P7)

Another participant also expressed scepticism on whether adding open-ended questions would improve the quality of the information retrieved via PROMs:

> *Even if you would actually put like a big gap for people to write stuff, they won't write things. Because they just don't want to. They're just not in the mood to do it. (…) Because then they've got to start thinking. And they've got other things to think about* (P11)

A smaller number of participants suggested minor changes in the contents of the questions, to make them more accurate and informative. For example, participant two suggested:

> *The fifth question, "because of my injury my ability to form and maintain close relationships with others". I'm not quite sure about that question you know (…) to receive this question a few weeks after a traumatic brain injury, you aren't really going to be able to assess that. Uhm perhaps it would be more relevant to (…) "the way I think about the relationships with my loved ones or those I live with has changed"* (P2)

3.7.2 Improving the delivery of PROMs

Recommendations for enhancing the delivery of PROMs included providing additional support and guidance to patients and offering alternative formats and platforms for completion. This last aspect—the need to provide a range of different formats for PROMs- emerged in many of the service users' interviews.

> *I know for a fact if it was me and I got a letter through saying "you can either fill this out, get a phone call or go and have an appointment", I probably would have done the phone call to be honest. (…) So yeah, just give people the option really I would say* (P1)

> *In a different um, service, using similar PROMs type questionnaires, (…) I was actually given an iPad before my first appointment when I got there, to complete it and then I was asked at the end of my last appointment if I would stay behind for ten minutes* (P15)

> *A large majority of us are online now (…) and communicate by email, and you could save up a lot of money a lot of paper and a lot of you know (…) by just simply sending out the information in an email* (P2)

A subgroup of interviewees indicated that the current way of sending PROMs (in paper copies, sent via post) might be the most appropriate for people with TBIs, who may struggle with engaging with PROMs delivered digitally (e.g., via a web link or email).

> *I think post… Something as comprehensive as these the post is, is a good system. Email sounds… Makes it easier for the sender, it doesn't necessarily make it easier for the receiver.* (P5)

> *I just forget things me because of my memory, I just forget, so yeah, post them and then, anything that comes through to the house, you know (…) NHS is opened* (P6)

Lastly, Participant fifteen suggested the option to ask people to complete PROMs in clinical settings to increase the availability of support and, in turn, completion rates.

> *If somebody does feel they need that further input (…) potentially, setting somewhere aside for them to do that within the clinic setting* (P15)

3.8 Sentiment and emotion analysis

The sentiment and emotion analysis of the corpus of data rendered interesting findings related to the emotional connotations characterising the interviewers' and service users' discourses on engaging with PROMs. An overview of the findings for each interview is reported in Figure 2 below.

Figure 2 shows the results related to the polarity classification of sentences as positive or negative based on patterns of sentiment learnt from previous examples, as expressed by interviewers and participants (service users) taking part in the interviews. The results suggested that the sentiments expressed by interviewers were positive, with some variations of intensity across interviews. More heterogeneous, instead, were the sentiment connotations related to service users, with most of the interviews showing low levels of positive sentiments. Some of these interviews (i.e., participants three, seven, eleven, fourteen and sixteen) also showed a clear negative polarisation in the overall sentiment underpinning the participants' narratives. Although the interviews addressed the service users' experiences of engaging with PROMs, the low levels of positive sentiment and the presence of negative sentiment connotations might at least partly be due to the emotional challenges linked to discussing TBI-related challenges and possible changes in health-related quality of life.

Figure 3 below offers a more in-depth breakdown of the emotions retrieved via the NLP analysis of the participants' experiences.

The majority of patient-reported experiences of engaging with PROMs were predominantly "neutral". However, emotions of fear, disgust, anger and sadness also seemed to emerge frequently across all interviews. In this context, and in line with other studies using NLP techniques to analyse text-based data (85, 86), "disgust" is to be intended as "venting out", expressing criticism and displeasure/complaint, rather than in a literal sense as "being disgusted". More positive emotions (e.g., surprise and joy) were also present, albeit to a lesser extent.

4 Discussion

The current study explored the lived experiences and opinions of TBI service users receiving PROMs questionnaires as part of their routine healthcare. The sentiment analysis of the participants' narratives about their engagement with PROMs and, more generally, about living with a TBI, revealed a generally low positive emotional tone in their narratives, with some participants expressing more polarised negative feelings. Further analysis of the emotions expressed during the interviews highlighted an overall "neutral" emotional tone. Interestingly, however, service users' narratives also showed a connotation of negative emotions such as fear, disgust/disappointment and anger. Taken together, these findings call for the need to pay closer attention to the "emotional experiences" of TBI patients engaging with PROMs, as they may play a pivotal role in understanding how to improve their experiences with outcome measures and, in turn, increase completion rates.

The TA of participants' narratives suggested that overall, people with TBIs had positive experiences of completing these

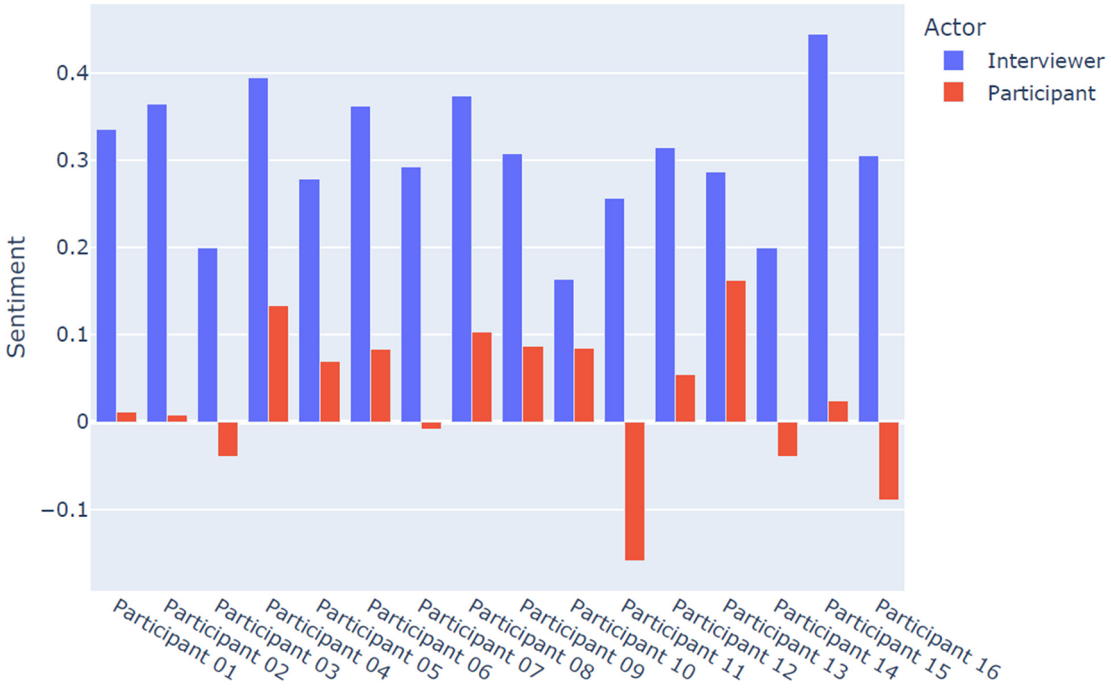

FIGURE 2
Sentiment analysis of participants and interviewers.

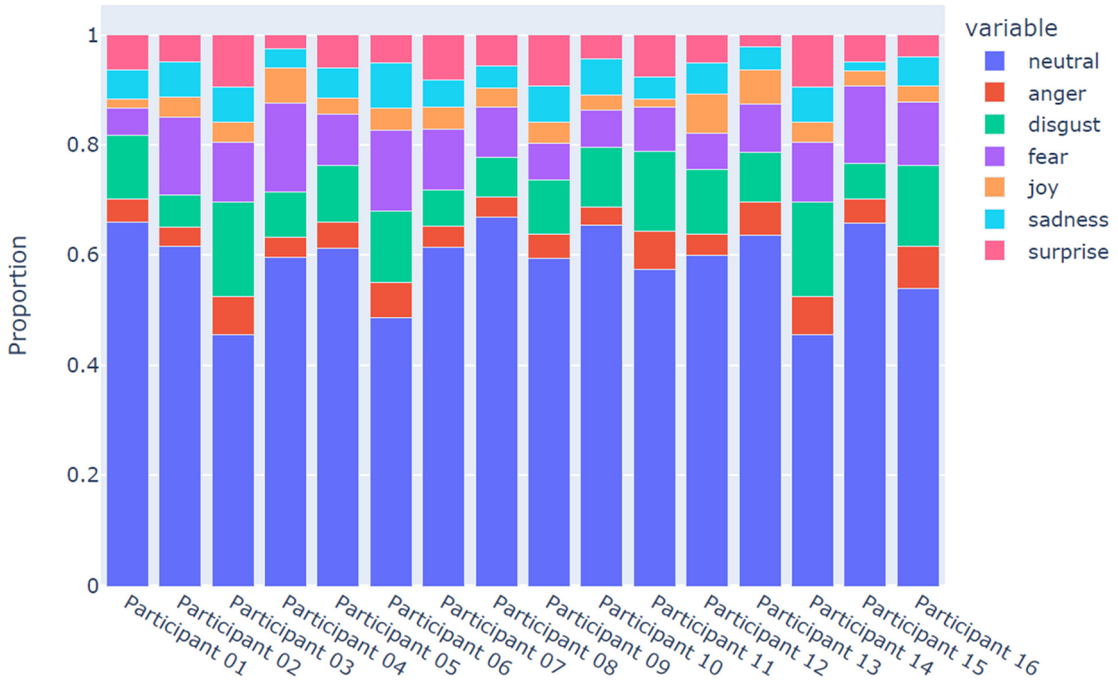

FIGURE 3
Emotional analysis of participants' narratives.

measures and found them generally clear and easy to engage with. These positive views also encompassed aspects such as the layout and response format of the questionnaires composing the PROMs. Nonetheless, a few participants pointed out that some of the response options (e.g., "most days") and questions asked (e.g., presence of chronic pain and "other general neurological conditions") would have benefitted from further clarification, to allow for more appropriate answers and a more user-friendly experience of engaging with these measures.

The findings also highlighted a set of barriers to the completion of PROMs that ought to be considered by clinicians and policymakers. Among the barriers mentioned by participants, there were aspects related to the difficulty in completing PROMs and the need for more information on their role and importance for service provision and improvement. The difficulties affecting completion were mostly related to TBI symptoms, such as memory impairment and response fatigue, which are commonly reported by individuals with TBIs (87–89). This calls for the need to keep PROMs conceptually relevant but also accessible and easy to understand, particularly in consideration of the cognitive challenges that might create an additional burden to people with a TBI engaging with self-reported outcome measures (90, 91). Strategies to address these barriers may include, for example, providing clear instructions on the aims and uses of PROMs and using accessible formats.

Conversely, participants also identified factors that facilitated their engagement with PROMs. These included personalised support from caregivers and healthcare providers, PROMs questions perceived as relatable and easy to understand and high importance given to PROMs to improve their overall treatment and recovery process, as well as for service provision and development. Literature on TBIs previously highlighted the importance of caregivers' support in different aspects of people's lives (92–94), and the findings from this study indicated that caregivers (close friends and family members) can play a pivotal role in influencing the completion of PROMs. Therefore, it appears to be essential for services to facilitate the involvement of service users' networks when administering these measures. This is in line with the findings of a recent review (95) suggesting that caregiver-led support can prove to be useful in managing TBI-related difficulties, including the ones (e.g., cognitive deficits) that the current study identified as potential barriers to PROMs completion. Nonetheless, it is also crucial to recognise that the involvement of caregivers during PROMs completion would need to be limited and, where possible, monitored by services and professionals, as the administration of PROMs by proxies has the potential to introduce bias (96). Some participants pointed out that a potential facilitator to PROMs completion would be receiving support from healthcare professionals. If implemented, this type of support might call for the need for specific training, as professionals' level of knowledge and confidence about using outcome measures can deeply influence their attitudes towards PROMs, which might, in turn, influence the quality of support offered (30, 97).

A further factor enhancing service users' likelihood to engage with PROMs was the perception that the data collected would have been handled according to ethical regulations (e.g., safe storage and protection of patient identity) and used to inform care pathways and service development. This is coherent with previous literature on the

barriers and facilitators to PROMs completion in different clinical populations (98, 99), indicating that when patients perceive PROMs as key for service quality and improvement, they are likely to be more motivated to engage with them.

Lastly, service users reported valuable suggestions for improving PROMs, such as incorporating open-ended questions to capture nuanced experiences, allowing for customisation of PROMs based on individual preferences and needs, and integrating technology-based solutions (e.g., using tablets) to enhance accessibility and user experience. Implementing these suggestions could enhance the relevance and utility of PROMs in clinical practice.

Our study combined TA and NLP analysis, incorporating sentiment analysis and emotion analysis. We were able to identify common themes in both analyses, and both analyses demonstrated that participants experienced distress during the interviews. The TA can provide context to this, suggesting that the questions asked by the interviewers (particularly around risk and the impact of TBI-related changes on families) can be a cause of distress. The NLP analysis allows us to quantify these factors for each participant in the study. In the future, the combination of TA and automated analysis could be used to give quantified yet meaningful insights into participant experiences.

Lastly, it was interesting to note that the sentiment of the interviewers was more positive than that of the participants. This finding is at least partly motivated by the fact that interviewers were acting in a professional capacity whilst participants were discussing their lived experiences entailing emotionally loaded topics (as demonstrated by the emotion analysis). Nonetheless, the experiences of both these groups, reflected in the positive and negative sentiments evidenced, provide valuable insights into the "positionality" of these "actors" (interviewer and interviewee). Further research combining TA and NLP should focus on the mutual links, if any, between the affective and emotional connotations expressed by the two "actors" in an interview setting, as this could inform "best practices" on how to conduct interviews addressing sensitive topics with people with complex clinical conditions, including but not limited to TBIs.

In summary, our study contributes to a deeper understanding of the lived experiences of individuals with TBIs completing PROMs, highlighting both the challenges and opportunities for optimising their use in clinical practice. Future research should focus on implementing participant-centred approaches to PROMs development and evaluation, as well as evaluating the impact that the emotional experiences of engaging with PROMs might have on their completion rates.

5 Limitations

Despite the promising benefits of combining NLP and traditional methods of qualitative data analysis (72), it is important to recognise that there are still some challenges related to the joint application of these methods. For example, there is a longstanding tradition of tools and strategies used within the qualitative research domain to ensure the rigour and trustworthiness of the themes retrieved and interpretations provided. These include, among others, triangulation, peer review or debriefing, member-checking, and external audits (the process by which researchers get audited by external researchers) (100, 101). Although these methods of ensuring quality are not entirely exempt from criticism (102–105), it is undeniable that similar debates on the rigour, trustworthiness and replicability of data analysis performed via NLP are still in their infancy (106, 107). In this regard, emerging debates highlight that not all NLP tools and methods that are consensually used have gone through systematic and comprehensive standardisation processes to ensure their validation and integrity (108, 109). In light of this, one of the salient challenges of the growing application of NLP methods in the research context will be to ensure a rigorous evaluation and optimisation of data analysis processes and transparency in the way results are obtained and explained (110). Being an integral part of these debates will allow qualitative researchers to contribute to shaping the so-called "computational turn", i.e., the process by which new techniques and methodologies drawn from computer science (including but not limited to NLP) are implemented in the humanities and social sciences (109).

Future research combining NLP and more conventional qualitative data analysis methods will need to strive to achieve "a delicate balance between capitalising on digital advantages and upholding research integrity" (109, p. 577). As for any other research paradigm, one of the main goals of mixed-methods research integrating NLP methods will be to abide by high methodological standards, minimising the risk of bias and maximising the accuracy and credibility of research results (111). To do so, researchers will need to strive for rigour by adopting a coherent application of analytical methods and clear standards of honesty and transparency in reporting the study results (112, 113).

Data availability statement

The datasets presented in this article are not readily available because of the need to protect participants' anonymity and the confidentiality of their data, as the qualitative nature of the dataset might expose them to the risk of being identified. Requests to access the datasets should be directed to d.dibasilio@lancaster.ac.uk.

Ethics statement

This study involving humans was approved by Research & Innovation Department of the Salford Royal Hospital [Northern Care Alliance NHS Foundation Trust] (approval n. S18HRANA45) and the Manchester Metropolitan University Research Ethics & Governance Committee (approval n. 17158/9). The study was conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

DDB: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Project administration, Resources,

Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. LK: Conceptualization, Investigation, Project administration, Resources, Supervision, Writing – original draft, Writing – review & editing. SL: Data curation, Formal Analysis, Resources, Writing – original draft, Writing – review & editing. PM: Data curation, Formal Analysis, Resources, Writing – original draft, Writing – review & editing. MS: Conceptualization, Data curation, Formal Analysis, Methodology, Resources, Software, Visualization, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fdgth.2024.1387139/full#supplementary-material

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A case report of system configuration issue in medical imaging due to system upgrade– changes in hardware and software

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Although the rapid growth in the efficiency of medical imaging is undeniable, the expansion of health information technology (HIT) into medical imaging has not been as seamless or well-integrated as it was thought to be. The socio-technical complexities in medical imaging associated with HIT systems can cause risks to patient harm and inconvenience, both individually and collectively, often in new, unforeseen, and unexpected ways. This study reflects a retrospectively collected single incident report related to medical imaging HIT systems, aiming to develop a set of preventive and corrective strategies. A combination of multiple deductive approaches (existing frameworks), i.e., HIT Classification Systems and 18-step medical imaging process workflow and inductive method (content analysis), were used to analyze the incident. The incident was identified as a "system configuration"-related software issue, contributed by system upgrade–changes in hardware and software. The incident was determined to occur during steps 10–12, i.e., "study selection and retrieval," "calling up of patient's referral," and "image review and interpretation," causing severe disruptions in the clinical workflow for several weeks. We propose 16 preventive and corrective strategies grouped under four key areas based on the socio-technical aspects associated with HIT systems. The key areas are (i) preparation and integration for upgraded systems, (ii) training for medical imaging specialists, (iii) contingency planning/immediate backup system, and (iv) system design and configuration. These strategies are expected to help healthcare staff, analysts, reporters, researchers, and relevant stakeholders improve care delivery and patient safety in medical imaging in the context of any system upgrades.

KEYWORDS

picture archiving, patient safety, healthcare quality improvement, software issue, training, system integration, system design

1 Introduction

Over the last four decades, medical imaging modalities such as x-rays, CT scans, MRI, and techniques like Deep Learning (1, 2) and Federated Learning (2) have progressed rapidly alongside the immense advancement of modern medicine (1–3). Undeniably, the rapid growth in the efficiency of medical imaging, largely driven by recent advances

in Deep Learning and Federated Learning and the use of larger and more diverse training sets, is a testament to collective efforts and achievements in modern medicine (4). It is crucial that the efficiency of medical imaging meets the expectations of the healthcare staff, whose additional hours spent with dysfunctional devices and systems not only lead to frustration but also underscore the urgent need for improvement (4, 5).

Meanwhile, healthcare quality improvement and patient safety have increasingly been the top priority over the last 40 years, with the progressive realization that the delivery of care in medical imaging can itself harm patients (6). It is also important to remember that the person who is to be imaged is often in a vulnerable state and out of their comfort zone. The role of medical imaging technicians is not just to produce a high-quality image but also to facilitate patient care throughout the imaging process (7). Medical imaging in the healthcare system now comprises truly sociotechnical complexities despite its many benefits and strengths. It can also cause risks to patient harm and inconvenience, both individually and collectively, often in new, unforeseen, and unexpected ways (6).

Health information technology (HIT) has been defined as: "hardware or software that is used to electronically create, maintain, analyze, store, receive (information), or otherwise aid in the diagnosis, cure, mitigation, treatment or prevention of disease and that it is not an integral part of an implantable device or medical equipment" (1, 2, 8). The merging of medical imaging and HIT systems, such as Radiology Information Systems (RIS) and Picture Archiving and Communication Systems (PACS), has been introduced to modern healthcare to improve efficiency (9). The HIT systems have been promoted to streamline operations and optimize available technology to be safe and effective (4). Nevertheless, the expansion of HIT into medical imaging has not been as seamless or well-integrated as it was thought to be.

Multiple issues are associated with HIT systems in socio-technical contexts, such as hardware and software-related issues, system upgrades—hardware and software modifications (6, 9). Software-related challenges associated with HIT systems can be of different types, such as software functionality, system configuration (problems with default settings), increased volume of transactions, interface with software systems or components, and viruses/malicious attacks (10–12). The hardware issues may involve "device down or slow", issues related to data capture or output peripheral, data storage and backup, and power failure (6). In addition, a study on the analysis of 436 medical imaging-related HIT incidents indicated that around 10% of the total sample was associated with "system upgrades". These upgrades involved upgrading the PACS software, scanner software, server software, and RIS system. The consequences of these issues could range from patient inconvenience to patient harm or workflow interruptions to single or multiple facilities or even the entire healthcare (5, 6, 13, 14).

For example, Jabin et al. demonstrated an analysis in 2019 of how 436 HIT incidents occur infrequently at each of the 18 steps of the imaging workflow process, contributed by either human or technical factors, with the consequences of outcomes sporadically reported—often not evident or not yet occurred at the time of (14). Several outcomes were associated with the imaging workflow, such as interruptions in patient treatments, patient inconvenience, delays in delivery of care, and risks to patient safety, including repeated or unnecessary radiation to patients. The patient outcomes were misdiagnosis, missed diagnosis, and delayed diagnosis, whereas the staff and organisational outcomes were delayed reporting and confusion among imaging staff, particularly during image review and interpretation (5, 6, 13, 14). The major problem of these incidents affecting the workflow is that once a wrong piece of information or document is initiated into any HIT system, an "automation bias" tends to consider it correct (15, 16).

Collecting information after something goes wrong, such as incident reports, may help understand the underlying mechanism for how and why they go wrong. This necessitates qualitative research—collecting qualitative data in the form of free-text narratives or anecdotes. This form of study, in turn, allows us to understand the healthcare context, identify and characterize the risks, contributing factors, consequences of the risks posed, and actions taken to manage the risks (9). The approaches to analyzing the qualitative free-text narratives are inductive (extracting themes in the narratives) (17) and deductive techniques. The deductive method comprises the classification of the critical aspects of the qualitative data by feeding them into an existing framework, such as the HIT Classification System (HIT-CS) (18) and 18-steps of the medical imaging process workflow (14). The HIT-CS was developed to map a conceptual framework for understanding and classifying things that go wrong in healthcare associated with HIT systems (19). In comparison, the 18-step imaging process workflow was framed to inform the analysts where preventive and corrective strategies should be addressed.

Since limited research has been conducted on system configuration issues in medical imaging, there is an urgent need for qualitative exploration of such problems. Therefore, it is essential to analyze retrospectively collected medical imaging incident reports to illuminate patient safety issues in Swedish healthcare and characterize the problems associated with their human and system-based causal factors. This report will address some practically applicable insights for medical imaging professionals, researchers, and analysts to understand where preventive and corrective strategies could be addressed to better support the issues associated with system upgrades– changes in hardware and software. The report explores the following research questions:

1. What is the reported issue involving the HIT system used in medical imaging?
2. What were the contributing factors and consequences of that HIT issue related to medical imaging?
3. What potential preventive and corrective strategies would be used to reduce the risks associated with the HIT systems used in medical imaging?

2 Methods

This is a qualitative study in which data was collected from an organization responsible for the healthcare incident repository. The data, i.e., free-text narratives, was then analyzed using both multiple deductive and inductive approaches.

2.1 Data collection

As presented in Box 1, this case report is a medical imaging-related HIT incident report extracted from the reidarMTP, i.e., an electronic database for registering incidents related to any medical devices and/or their use in the healthcare environment. The incident has been presented in three fields: "incident description," i.e., reported by an anonymous healthcare professional, "summary of cause investigation," i.e., an internal investigation analysis after reporting the incident, and summary of measures, i.e., actions taken to manage risks. The reports are anonymous and freely available for quality improvement, education, and training to all healthcare professionals. The database is operated by a voluntary association of clinical engineering departments in Swedish hospitals and is managed by certified trained staff (20, 21).

The reports are generally categorized into multiple different fields, comprising various sets of information. The first category includes the date, day, and time of events, as well as an incident description with a short subject line, such as "problems in the imaging workstation". The second category is about the type of products involved in the incident, such as product name, manufacturer, software version, serial/batch number, etc. The third category entails a thorough investigation, including a summary of cause investigation, a summary of actions, and a summary of follow-up. The final category involves classification or risk assessment, including risk of medical damage and underlying cause (22). The incident in Box 1 has been filtered and illustrated in three fields: "incident description," which was reported by anonymous healthcare staff, "summary of cause investigation," i.e., an internal investigated narrative of the reported incident, and a "summary of measures". The name of the software program/product has been kept anonymous, and the incident has been filtered before being presented in Box 1.

The report was provided in Swedish and later translated into English by a linguistic expert who has proficiencies in both languages, i.e., Swedish and English. To ensure the accuracy and credibility of the report, the technical nature of the content was carefully considered with the help of consensus throughout the translation process by the linguistic expert and the principal investigator.

2.2 Data analysis

The following incident was analyzed using both inductive (content analysis) and deductive approaches (existing framework).

BOX 1 This medical imaging-related HIT incident was reported to the reidarMTP by an anonymous user showing responses to the following categories of information.

Incident Description

Digital imaging systems, i.e., PACS, had been struggling for several weeks. We could not see or display examinations; the work was slow, and we had to improvise different solutions and try to find examinations in image viewers that we were not used to (and so on). It was not acceptable from a work environment point of view, and there was a risk that patient safety had been threatened. Today, there were two emergency patients who did not have their images available before acute surgery.

Summary of Cause Investigation

In this case, general problems occurred with the PACS workstation, which was previously used within the hospital. In connection with a change of hardware, server operating system, and database manager, large deteriorations in the systems' performance occurred.

After several weeks of troubleshooting, the supplier found a configuration that was missing from the application. This missing configuration caused the system to spend a lot of time updating image files without really needing to. This, in turn, resulted in examinations being locked and inaccessible. After the setting was adjusted, the systems worked better.

The reason was also connected to the fact that a planned failover (change of active data center) in the image archive was carried out at 11:55 on the same day. Soon after, error reports began to come in, where it appeared that a number of newly produced examinations were not available.

After various troubleshooting by the supplier during the afternoon, it turned out that there were a number of examinations that had not been replicated (copied) from the previously active part of the image archive to the part that was made active at 11:55. Synchronisation work began and continued approximately until midnight. Information is posted on the intranet.

Part of the reason the vendor was unaware that the two halves of the image archive were not fully synchronized since one of the tools showed 100% synchronized data, but it was actually a rounded value.

Summary of measures

Adjustment of configuration in X and synchronization of the imaging archive.

The deductive approach included multiple existing frameworks—an existing classification system proposed by Magrabi et al., i.e., the HIT-CS (18), and a framework used by Jabin et al., i.e., the 18-step of medical imaging process workflow (14). The HIT-CS is helpful in deconstructing HIT-related incidents and categorizing types of problems, contributing factors, and consequences to extract meaningful information (18). The 18 steps of the medical imaging workflow-based classification system are useful as they orientate the reporters, researchers, and analysts to the tasks at each stage. It also helps inform the analysts as to where preventive and corrective strategies could be addressed to overcome the specific problem in question (14).

The HIT-CS was used to identify the type of system issue and the type of consequences associated with the incident. The 18-step process workflow, combined with the content analysis, was used to understand the underlying mechanism of what went wrong, why it went wrong, and at which stage of the imaging process it went wrong. The ultimate purpose of using all these analyses was to devise a set of preventive and corrective strategies that could eventually mitigate the risk of similar incidents occurring in the future.

3 Results

Using the HIT-CS, the incident was categorized as a software issue (technical problem), i.e., "system configuration", and the consequence of the incident was classified as an "incident with noticeable consequence but no patient harm".

Using the framework of 18 steps medical imaging process workflow, the incident was identified to occur during steps 10–12 (as indicated by the dotted lines in Figure 1), i.e., "study selection and retrieval", "calling up of patient's referral", and "image review and interpretation".

Using the content analysis, the contributing factors for the incident were changes in hardware and software, such as the database manager and server operating system. The mitigating factor was multiple improvised solutions to retrieve the examinations from the image viewers; however, those improvised solutions were not clearly indicated in the incident description. Although the incident did not cause any harm to patients directly, two emergency patients were found to be at risk of patient safety since their images could not be retrieved in a timely manner. Therefore, the patient outcome was delay in patient treatment, and the organizational outcome was determined to be severe disruptions in the clinical workflow for several weeks. The actions taken to manage the risk were a correction of the missing configuration and synchronization of the PACS.

4 Discussion

Although medical imaging HIT systems have improved effectiveness and efficiency, their design, use, and implementation can negatively impact patient care and safety (6, 14). Any changes in or errors due to HIT systems can even contribute to regular workflow interruptions (14). Several pieces of evidence suggest that software-related challenges are common phenomena in various types of HIT systems used in modern medicine, such as e-prescribing systems (10), patient information systems (11), and medical imaging systems (6, 13). These issues can trigger serious consequences, ranging from staff organizational outcome (5) to patient inconvenience (13) and patient harm (5, 23). Among all software issues, software functionality, and system configuration have been the most common software-related challenges (10, 11), including in medical imaging HIT systems (6).

Jabin et al., in 2023, reported different types of system configuration issues, such as "system not designed to support the decision" and "system not designed to give any warning/alert" (11). These issues posed severe risks to patient safety, which were later escalated to maximum severity and priority to meet the required system criteria. On the other hand, multiple studies reported that even a perfect system configuration might become challenging due to changes in system environments or workloads, such as hardware changes, environment changes, resource exhaustion, and software upgrades (24, 25). Hardware changes comprised 18% of the root cause of configuration errors (25).

In this report, we examined things that had gone wrong with respect to medical imaging as a basis for devising a set of preventive and corrective strategies for managing similar issues in the future. It is of utmost importance to overcome the ongoing socio-technical challenges that healthcare face in their daily routine, particularly in the context of medical imaging HIT systems. Therefore, we propose a set of strategies through the lens of socio-technical aspects associated with HIT systems, the reflections arising from the literature and the findings, and stakeholder engagement (led by authors) comprising specialists in medical imaging from the Region Gävleborg, The proposal includes 16 preventive and corrective strategies, which are grouped under four key areas. The key areas are (i) preparation and integration for upgraded systems, (ii) training for medical imaging professionals, (iii) contingency planning/immediate backup systems, and (iv) system design and configuration. We believe these recommendations will help healthcare staff, analysts, reporters, researchers, and relevant stakeholders to improve the delivery of care and patient safety in medical imaging in the context of any system updates or changes. The details of these strategies are presented in Box 2.

It is important to note that this study has a few limitations that may impact the interpretation of the findings. For instance, the study does not follow a protocol for the usual qualitative method used in medical imaging research, such as observation or interviews. Understanding these limitations is crucial for a comprehensive assessment of the research (26–28). The major limitation is that it is a retrospectively collected single anonymous incident report; therefore, it was not possible to follow up with the reporter to extract more details about the event. Moreover, data collection from voluntary incident databases has inherent limitations with the accuracy and specificity of reported data, combined with limited content knowledge, i.e., reporters' lack of expertise in HIT systems and

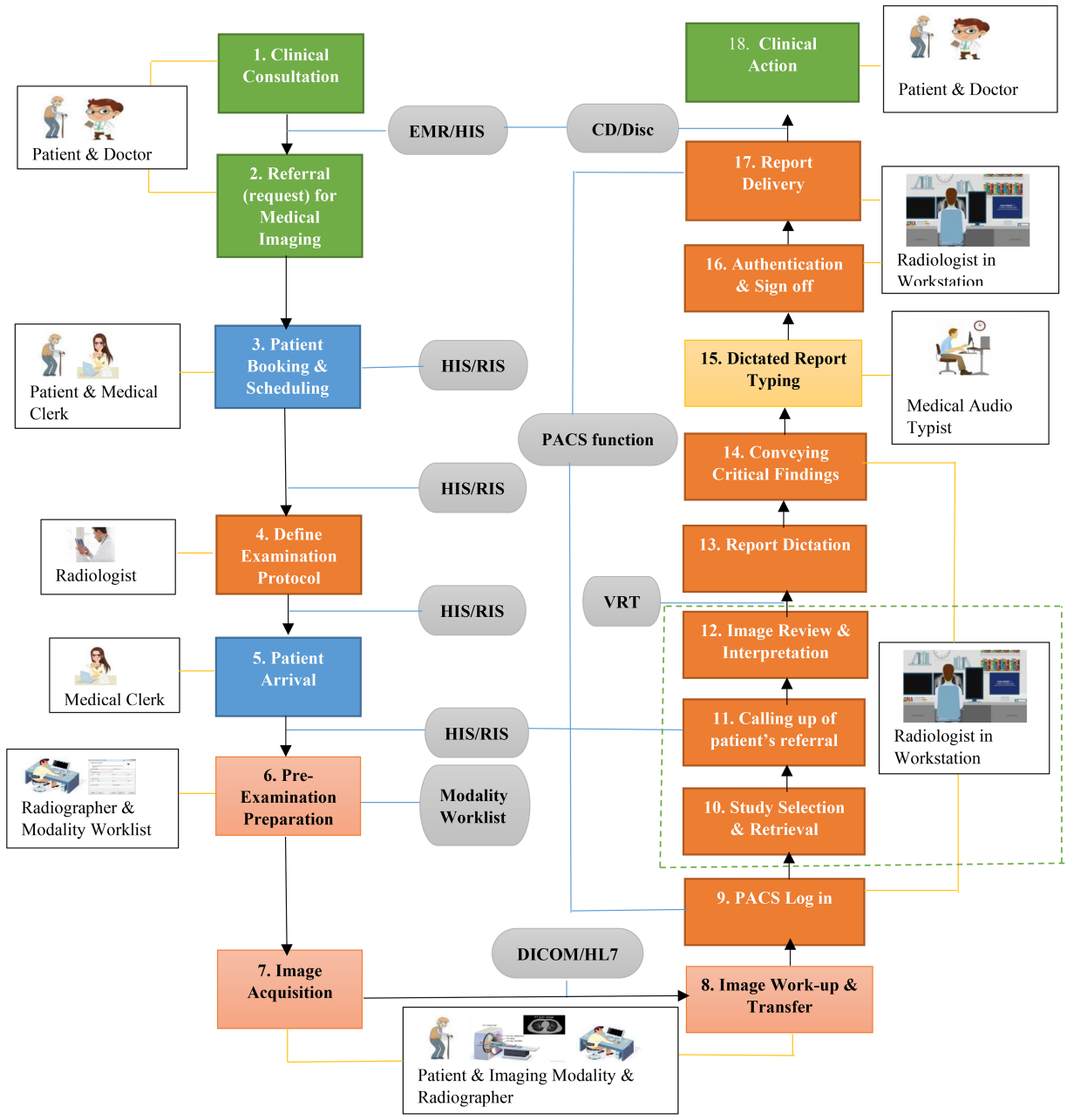

FIGURE 1
Medical imaging process workflow showing the 18 sequential steps and the HIT systems by which they are mediated.

technologies. However, this limitation was overcome by utilizing the additional fields of information, "summary of cause investigation" and "summary of measures." Moreover, the incident was scrutinized through multiple lenses—two deductive approaches and an inductive method. This helped obtain a detailed picture of what went wrong and how it went wrong and devise a set of preventive and corrective strategies to overcome such future configuration issues in medical imaging.

The conclusion based on the results of this single incident should be treated with caution, as this case report does not offer any insights into quality improvement interventions or how to measure their effects. One must remember that the risks to patient safety existed even after developing and implementing various radiological interventions, such as the Correct Patient, Correct Site, and Correct Procedure (3Cs) Protocol in 2004 (29). This is mainly because the volume and complexity of the workload in radiology practice have also increased; for example, the daily average volume of medical imaging examinations read by radiologists has increased sevenfold in the last 7 years (29). Therefore, the complications in workload management in this

BOX 2 Preventive and corrective strategies to mitigate and manage the risk of medical imaging-related HIT incidents.

Preparation and integration for upgraded systems

- Establish close cooperation between the vendors of both the new and "legacy" systems to understand the needs of the facility or service through extensive ongoing consultation and advice-seeking and obtain the right systems in the first place
- Work closely in association with vendors to ensure proper and applicable integration of multiple medical imaging systems, such as RIS and PACS, in the facility
- Perform robust testing or regression protocol in the system development phase prior to system deployment to avoid or mitigate the occurrence of software functionality and system configuration issues
- Plan carefully for any system (hardware and software) changes, local fixes, and system transition to mitigate disruption to regular workflow and ensure contingency plans (see below)

Training for medical imaging professionals (radiologists and radiographers)

- Train imaging professionals with adequate paid time, jointly organized by healthcare organizations and HIT vendors prior to implementation or deploying any new system
- Provide radiologists and radiographers training updates as a refresher and following any hardware changes, environment changes, resource exhaustion, and/or software upgrades

Contingency planning/immediate backup system

- Ensure immediate backup system and contingency procedures are part of any contract for any high-stakes operations, such as medical imaging in healthcare
- Establish sufficient escalation procedures to deal with any new and unforeseen issues that may potentially cause patient harm
- Arrange timely access to appointed IT personnel who are adequately trained in all facets of HIT use, monitoring, evaluation, and optimization
- Set up a robust mechanism for communicating any unexpected downtimes to all healthcare professionals in the facility

System design and configuration

- Design and configure medical imaging HIT systems, such as RIS and PACS, so that they are interoperable and coordinate with each other
- Design standard user-interface features and functions and develop well-established standards for safety-critical software
- Develop and design the HIT systems that fit with the clinical workflow
- Synchronise terminologies, exposure indicators, proprietary coding systems, and information systems while implementing or operating systems from various vendors
- Ensure decisive information is displayed for decision-support interventions using standardized terminologies and color schemes
- Secure access to previous images—prefetching algorithms and display protocols (as mentioned above)

complex sociotechnical system add a layer of other obstacles (3). Moreover, thousands of patients are processed, transported, treated, and examined by hundreds of radiologists and radiographers in daily clinical practice, and the risks for such failures are enormous. Notwithstanding these limitations, the findings and devised preventive and corrective strategies can be generalized and considered as alerts to inform healthcare digitalization and pertinent elsewhere for patient safety and quality improvement studies. Our study's findings, which establish a clear connection between HIT system issues and clinical outcomes, are significant. They not only contextualize the study's significance but also provide a crucial direction for future research efforts. The ultimate purpose of using all these analyses was not just to understand what went wrong and how it went wrong but also to proactively devise a set of preventive and corrective strategies that could eventually mitigate the risk of similar incidents occurring in the future.

5 Conclusion

Although medical imaging efficiency has improved, if those HIT systems are not supported by adequate contingency planning or backup system, appropriate system integration, design, and configuration, unforeseen consequences such as delays, corruption of information, workflow disruption, and patient harm can ensue. Therefore, collecting information after they have gone wrong should be a routine part of clinical practice to provide a basis for improvements for preventing issues and improving such practice. However, an ongoing

discussion should be carried out about general HIT problems related to system upgrades– changes in hardware and software.

Data availability statement

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by Ethical Advisory Board in South East Sweden. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and institutional requirements. The studies involving humans were advised by the Ethical Advisory Board in South East Sweden.

Author contributions

MJ: Conceptualization, Formal Analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing, Data curation. DW: Conceptualization, Methodology, Writing – review & editing. AH: Conceptualization, Data curation, Formal Analysis, Investigation, Validation, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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Attitudes of nurses toward telenursing and influencing factors in resource-limited settings: Northwest Ethiopia 2022

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Background: The worldwide scarcity of nurses is a pressing concern, with the World Health Organization predicting a deficit of 5.9 million nurses globally by 2025. Notably, 89% of this shortage is expected to impact low- and middle-income countries. To address the growing demand for nursing professionals, the concept of telenursing care is being considered. However, there is limited evidence regarding nurses' attitudes towards telenursing care in Ethiopia. This study aims to understand how nurses feel about telenursing care and the factors related to it at a specialized teaching referral hospital in northwest Ethiopia.

Method: We conducted a cross-sectional study at a specialized teaching referral hospital, employing a simple random sampling technique to gather information from 423 nurses. The study took place from July 28 to December 19, 2022/23. Descriptive statistics, including tables and bar graphs, were utilized. Additionally, a binary logistic regression analysis was conducted with 95% confidence intervals and a significance level of $P < 0.05$ to identify factors influencing nurses' attitudes toward telenursing.

Result: Out of the total 416 nurses who responded, representing a response rate of 98.35%, 39.7% exhibited favorable attitudes towards telenursing care. Factors associated with nurses' attitudes included awareness, source of information, social media use, knowledge, computer access, digital training, internet access, and computer training.

Conclusions: The findings indicate a low level of positive attitudes towards telenursing care among nurses. To enhance future acceptance, use, and implementation, policymakers, higher education institutions, and other stakeholders should collaborate to improve nurses' attitudes toward telenursing care, taking into consideration various factors and user preferences.

KEYWORDS

attitude, nurse, Ethiopia, telenursing, telenursing care, Statistical Package for Social Science (SPSS), variance inflation factor (VIF), World Health Organization (WHO)

1 Introduction

yIn the present-day context, the demand for nursing services has evolved rapidly and become more complex (1, 2). Globally, among the most pressing challenges for public health systems and the nursing community is the increasing shortage of nurses (3). Many countries today grapple with various health issues, including an aging population, the need for home care, a shortage of nursing staff for direct patient care services at home or remotely, the challenges posed by pandemic diseases like COVID-19, and conflicts (4–7).

Before the outbreak of the coronavirus disease (COVID-19), the global nurse shortage was widely recognized. In 2020, the World Health Organization (WHO) published its first' State of the World's Nursing' report, revealing that 27.9 million nurses were working worldwide. The report predicted a shortage of 5.9 million nurses in low- and middle-income countries, accounting for 89% of these shortages, with notable regional differences (8, 9).

The primary objective of healthcare facilities in Ethiopia is to deliver high-quality healthcare to patients. The quality of nursing care significantly influences overall healthcare quality, especially as nurses play a crucial role in providing direct primary healthcare in rural and remote areas, as well as delivering outstanding care to patients in hospitals (10, 11). So, nurses play crucial roles in managing the quality of treatment and enhancing healthcare outcomes, as they are the most essential component in developing nations for providing high-quality healthcare (10, 12, 13). However, the availability of resources, nursing documentation, technology, and interactions with patients and other healthcare providers all have an impact on the standard of nursing care (10, 13).

Additionally, nurses constitute the largest group of healthcare providers in Ethiopia. As of 2016, there were a total of 50,604 nursing professionals, and it is anticipated that this number will increase to 127,299 professionals by 2025 (11, 14). According to a 2018 World Bank estimate, Ethiopia had a nurse and midwife density of 0.7135 per 100,000 population (15).

Notably, the majority of healthcare facilities in Ethiopia lack a retention plan, leading to significant nurse turnover. Consequently, the nurse-to-patient ratio varies from 1:6 to 1:12, depending on the institution (10). As an essential linkage in the delivery of medical services between patients, doctors, and other nursing medical practitioners, nurses contribute significantly to the preservation of public healthcare because of their high relevance for interventions and treatment in developing countries (7, 16–18).

Nevertheless, a global shortage of nursing practitioners persists in the present day (3, 7). Nurses contribute to a growing field of specialists by incorporating novel technologies into the healthcare procedure (1, 2, 4, 19). The emergence of telehealth nursing is a significant innovation that fundamentally transforms the delivery of nursing healthcare (4, 7, 19–21). To address the expanding need for nursing professionals, the exploration of new technologies, such as telehealth nursing (telemedicine in nursing), is underway as a solution to meet the demands for patient care (22).

Telenursing integrates nursing with computer and information sciences for the handling and exchange of data, information, and knowledge within nursing practice (7, 23). The term "telenursing" also encompasses a method of remotely providing nursing care or services using devices such as smartphones, computers, or other advanced technologies capable of capturing, saving, processing, sharing, and disseminating information, including text, photographs, and videos through telecommunication (4, 19–21, 24–28). In 1974, Mary Quinn delivered telenursing care to patients at Logan Airport, marking the inception of this practice in the medical industry (7, 20–22).

Innovative technical advancements have brought about significant changes in various fields, impacting both the progress of medicine and the delivery of healthcare services (4, 5, 12, 20, 21). As nurses increasingly enhance and redefine their roles and responsibilities through telehealth nursing, which involves the technology-based application of providing nursing care (16, 18), this emerging field of medical services requires collaboration among clinical professionals, hospitals, health centers, and financial and clinical experts in a digital environment. This collaboration aims to ensure the equitable distribution of medical services, maintain service quality, and enhance the affordability of healthcare (4, 5, 12, 20, 21, 29).

Also, telenursing technologies boost how well patients follow their treatment plans, improve access to nursing care, enhance patient safety at home and other health facilities, and facilitate communication with healthcare providers (4, 12, 19–21). Such an innovative and advanced form of nursing care delivery (telenursing care) allows for the development of new, innovative nursing care

Abbreviations

BSc, Bachelor of Science; CI, confidence intervals; COVID-19, coronavirus disease 2019; DDCF, Doris Dukes Charitable Foundation; FMoH, Federal Minister of Health; ICT, Information and Communication Technology; IPH, Institute of Public Health; OR, odd ratio; SPSS, Statistical Package for Social Science; VIF, Variance Inflation Factor; WHO, World Health Organization.

models that can enhance nursing healthcare service delivery (1). Since technology influences the quality of nursing care, it is better to include innovative technologies like telenursing, telemedicine, telemonitoring, etc. that enhance and boost the quality of nursing care within the nursing field. Therefore, many research projects can be used to develop, apply, and integrate such types of new technology into nursing practice (1, 2, 7).

Amidst various challenges, the rapid advancement of technology and escalating healthcare costs have prompted the nursing team to leverage technology for enhanced patient care (5, 7, 30). To tackle these challenges, streamline healthcare systems, minimize costs, alleviate the isolation of healthcare personnel, and concurrently enhance patient care outcomes, the healthcare sector is increasingly adopting digital health technologies (5, 7, 31).

Despite growing interest in digital health technologies, there is a notable absence of empirical evidence regarding the attitudes of nurses toward telenursing in resource-limited settings, particularly in Northwest Ethiopia. This gap is significant because understanding the level of telenursing attitudes among nurses plays a crucial role in the adoption and implementation of such technologies. Various studies have indicated that positive attitudes are a key determinant in the successful integration of digital health innovations (32, 33).

However, current literature lacks specific insights into how nurses in resource-limited settings perceive telenursing. Understanding these perceptions is essential for policymakers and planners who aim to implement telenursing effectively within the nursing domain. Without this understanding, efforts to promote telenursing may face unforeseen challenges and resistance. Addressing this research gap is of paramount importance for several reasons:

It provides policymakers and healthcare planners with crucial evidence on nurses' attitudes towards telenursing, which is essential for designing interventions and creating training programs and support systems tailored to nurses' perceptions and needs. Understanding the factors that influence nurses' attitudes can help in creating a more favorable environment for the adoption of telenursing. Positive attitudes can lead to higher acceptance and more effective utilization of telenursing technologies, ultimately improving patient care and outcomes (32, 33).

In resource-limited settings, efficient allocation of scarce resources is critical Evidence-based insights into nurses' attitudes can guide investments. These investments might include technology, training, and support infrastructure. This ensures that resources are used effectively to support the transition to telenursing. Nurses' attitudes towards telenursing can directly impact the quality of patient care. Positive attitudes are likely to result in more enthusiastic and effective use of telenursing. This leads to better patient monitoring. Communication and overall care delivery especially in remote or underserved areas, are also enhanced by positive attitudes. The evidence demonstrates that fostering positive attitudes towards telenursing among nurses is crucial for successful integration. This is significant for effective delivery. Patient care is particularly improved, It is especially important in resource-limited settings. Underserved settings benefit greatly (4, 34, 35).

Conducting this research in Northwest Ethiopia will contribute to the local evidence base, providing context-specific data that can inform regional and national health policies. This localized evidence is essential for tailoring interventions to the unique challenges and opportunities within the region. In conclusion, exploring and addressing nurses' attitudes toward telenursing in Northwest Ethiopia is vital for the successful implementation of this technology in resource-limited settings. It will provide the necessary evidence to support informed decision-making, promote the adoption of telenursing, and ultimately enhance the quality of healthcare services in the region.

To realize these benefits, it is crucial to introduce innovative technologies such as telenursing, into the healthcare sector. Therefore, this study aims to address this gap by exploring nurses' attitudes toward telenursing care and associated factors at a specialized teaching referral hospital in the Amhara region of northwest Ethiopia.

2 Methods

2.1 Study design, area, and period

This research adopted an institutional-based cross-sectional study design, focusing on nurses employed at two specialized teaching referral hospitals situated in the Amhara Region, northwest Ethiopia. The investigation took place over a period spanning from July 28 to December 19, 2022. The University of Gondar Comprehensive Specialized Referral Hospitals and Tibebe Ghion Specialized Teaching Referral Hospitals were chosen as they were the sole teaching and specialized facilities in the Amhara region during the study. These hospitals were selected based on their comparability in terms of personnel composition and the spectrum of services they provided.

2.2 Source and study population

The source population for our study encompassed all nurses employed at Tibebe Ghion and the University of Gondar Specialized Teaching referral hospitals, both situated in the Amhara regional state. Meanwhile, the study population specifically consisted of all nurses actively engaged in delivering nursing care within the confines of the University of Gondar and Tibebe Ghion Specialized teaching referral hospitals during the designated data collection period.

2.3 Eligibility criteria

Our study included nurses who were employed at the two teaching, specialized referral hospitals and those who willingly volunteered to participate. However, individuals who lacked permanent employment status were not actively working during the data collection period, or faced difficulties reporting to work at the specified time were excluded from participation. This ensured a focus on nurses with consistent employment and availability during the study period.

2.4 Determination of sample size and selection procedures

During the study period in the Amhara region, only two specialized teaching referral hospitals, all specialized teaching referral hospitals in the region were considered for inclusion in the study and approached accordingly.

Since there is no evidence or no study was conducted on the telenursing attitude specifically among nursing professionals in the study area we utilized a single population proportion formula to establish the required sample size by considering key factors, such as the standard normal deviation (with $Z\ a/2 = 1.96$) for a 95% confidence interval (CI), P, proportion of telehealth nursing attitude ($P = 0.5$), a margin error ($d = 0.005$), and the final sample size (n). This factor was chosen due to the absence of a previous study in the same area. A precision level (margin of error) of 5% was targeted, resulting in a calculated sample size of 384.

$$n = \frac{(z_{\frac{a}{2}})^2 * pq}{d^2}$$

Where n represents the required sample size, d is the margin of error, the proportion reflecting attitudes toward telenursing, and $q = 1 - p$.

$$n = \frac{(z_{\frac{a}{2}})^2 * p(1-P)}{d^2} = n = \frac{(1.96)^2 * 0.50(1-0.50)}{(0.05)^2} = 384$$

To account for a 10% non-response rate, the final total sample was determined to be 423 participants. The selection of study participants involved a two-step process: initially using a straightforward random sampling method and then implementing proportional allocation.

2.5 Study variables

This study examined nurses' perspectives on telenursing care, focusing on various factors. The independent variables encompassed demographic aspects like age, gender, job experience, education, and marital status. Additionally, variables included social media/internet use, experience with online patient interactions, internet access at home, preferred platforms, and the source of information. Professional factors such as access to personal computers/desktops, digital training, ICT infrastructure, availability of technical support staff, internet access at the workplace, computer-related training, and nurses' awareness and knowledge of telenursing care were also considered in this research.

2.6 Operational definitions

Attitude toward telenursing care is an outcome variable that reflects nurses' behavior and thinking, categorized as either poor or good based on previous studies. It was assessed using a 5-point Likert scale with 19 questions, scoring from "1" (strongly disagree) to "5" (strongly agree), resulting in a minimum score of 19 and a maximum of 95. A poor attitude is indicated for participants scoring below the median, while those scoring above the median are considered to have a good attitude, as indicated in prior studies (4, 5, 26, 36–44).

Awareness of telenursing care serves as an explanatory variable, representing the extent to which nurses are acquainted with or informed about telenursing care. This awareness was gauged through a set of ten 5-point Likert scale questions, where respondents rated their agreement on a scale from "1" (strongly disagree) to "5" (strongly agree), resulting in individual scores ranging from 10 to 50. Upon a thorough examination of prior studies, these ten questions were utilized to classify nurses into two groups based on their telenursing care awareness. Nurses scoring below the median were identified as having limited awareness, while those scoring above the median were deemed to possess a substantial understanding of telenursing care (4, 7, 26, 38–42).

Knowledge of telenursing care is an explanatory variable representing nurses' comprehension of the purpose and advantages of telehealth nursing (telenursing). This understanding is determined by ten questions categorized as indicators of poor or good knowledge. The evaluation involved a set of "yes" or "no" questions, with answers rated as "0 = no" or "1 = yes," resulting in a score range from "0" to "10".

Participants were classified as having either poor or strong knowledge based on their median scores. A review of prior studies indicates that participants scoring below the median generally demonstrated poor knowledge of telenursing, while those scoring above the median exhibited a stronger understanding (5, 7, 26, 31, 36–40, 43, 45–49).

2.7 Data collection procedures and tools

Data were collected using a pretested, well-structured, self-administered questionnaire. Before developing the data collection tool, a review of relevant literature was conducted (4, 5, 7, 19, 26, 31, 37–49). The questionnaire, designed for self-administration, consisted of a mix of question types. These included a binary "yes" or "no" question, a Likert scale ranging from 1 to 5, and a set of questions categorized into six groups, covering socio-demographic, technological, organizational, awareness, knowledge, and attitude-related aspects.

2.8 Data quality management

Before initiating the actual data collection process, both supervisors and data collectors underwent training. Five individuals assigned to data collection from study participants and two supervisors responsible for supportive supervision during data collection received a two-day training session. The training encompassed the study's objectives, relevance, data confidentiality, respondents' rights, informed consent, and data collection techniques.

Overall, our study adapted and verified the questionnaire using a methodical procedure to increase the reliability of our

results. First, a review of the existing literature on telenursing and nurses' attitudes towards digital health technologies was done to ensure the items were relevant. Then, expert consultation with healthcare professionals and academic researchers in the field was done to refine the questionnaire and enhance its content validity. Next, the questionnaire was pre-tested on 41 nurses (10% of our total sample size) at Felege Hiwot Specialized Referral Hospital in Bahir Dar City to identify and correct any ambiguities or issues in the questions. Finally, statistical validation methods including Cronbach's alpha were done based on the pre-test results. The results were high, Cronbach's alpha for attitude, knowledge, and awareness questions were 0.946, 0.930, and 0.923 respectively. This thorough adaptation and validation process ensures our results are trustworthy.

2.9 Data analysis and processing

We utilized Epi-data version 4.6 for data entry, ensuring daily checks for questionnaire completeness during the data collection period. The collected data underwent coding, and its completeness, absence of missing values, and clarity were verified by both the principal investigator and supervisor at the time of entry.

For analysis, the data was exported to Statistical Package for Social Science (SPSS) version 27. We employed descriptive and inferential statistical analyses, presenting the results through pie charts, bar charts, frequency tables, and percentages. To identify factors influencing nurses' attitudes toward telenursing, we applied a binary logistic regression model.

Correlation strength between dependent and independent variables was measured using adjusted odds ratios with a 95% confidence interval. Initially, a bivariate analysis assessed the significance of each independent variable, considering a cut-off point (p-value less than 0.2) to establish relationships (7, 31, 50–53).

Next, a 95% confidence interval and a p-value less than 0.05 were used to pinpoint factors significantly associated with nurses' attitudes toward telenursing care. A multi-collinearity test confirmed no significant issues, as all variables showed variance inflation factors (VIF) ranging from 1.047 to 7.611 (7, 31, 54). Finally, model fitness was gauged through the Hosmer and Lemeshow test, with a p-value greater than 0.05 indicating statistical significance.

2.10 Patients and public involvement

Patients or the public were not involved in the study.

3 Results

3.1 Socio-demographic characteristics

A set of 423 structured self-administered questionnaires was distributed among nurses at two specialized teaching referral hospitals. The response rate was notable, with 416 completed and returned questionnaires, accounting for 98.345% of the distributed surveys.

Upon analyzing the demographic and personal background data from the participants, it was observed that a substantial portion, specifically 232 individuals (55.8%), belonged to the age group of 23–30 years, with a mean age of 30.0 ± 4.285 years. The academic background of the majority of participants (254, 61.1%) indicated possession of a BSc degree. Additionally, marital status revealed that 198 participants (47.6%) were unmarried, while religious affiliation showed that 204 participants (49.0%) identified as Orthodox Christians (Table 1).

3.2 Technological related factors

Among study participants, 295 (70.9%) had personal computers, and the majority of them (75.0%) used social media, with 64.6% and 35.7% of them usually using Facebook and Telegram, respectively (see Table 2).

3.3 Study participants' sources of information

The primary sources of information for the majority of study participants were friends, accounting for about 91.6%, and coworkers, accounting for 78.6% (see Figure 1).

3.4 Organizational related factors

Out of the total study participants, 193 (46.4%) underwent computer training, 190 (45.7%) nurses had desktop access in their

TABLE 1 Shows the sociodemographic details of the nurses in Northwest Ethiopia in 2022–2023 (n = 416).

Socio demography factors	Attribute	Frequency	Percent
Age in a year	23–30 Year	232	55.8%
	above 30 Year	184	44.2%
Sex	Male	192	46.2%
	Female	224	53.8%
Educational statues	Diploma	79	19.0%
	Degree	254	61.1%
	Master	83	20.0%
Marital status	Married	175	42.1%
	Unmarried	198	47.6%
	Divorced	23	5.5%
	Windowed	20	4.8%
Religion	Orthodox	204	49.0%
	Muslim	104	25.0%
	Protestant	59	14.2%
	Catholic	29	7.0%
	Josh	20	4.8%
Monthly salary in ETB	4,609–6,193 ETB	187	45.0%
	6,194–9,056 ETB	151	36.3%
	Above 9,056	78	18.8%
Working experience in a year	0–3 Year	195	46.9%
	4–7 Year	132	31.7%
	Above 7 Year	89	21.4%

TABLE 2 Technological factors influencing telenursing attitudes Among nurses in North-west Ethiopia (2022/23) ($n = 416$).

Technological factors	Response	Frequency	Percent
Personal Computer Utilization	No	295	70.9
	Yes	121	29.1
Internet Use OR Social Media Use	No	104	25.0
	Yes	312	75.0
Social Media Usage Patterns	Facebook	242	58.2
	Telegram	148	35.6
	Twitter	86	20.7
	Instagram	83	20.0
	Email	81	19.5
Interact with patients through social media using the internet at home	No	291	70.0
	Yes	125	30.0
	No	285	68.5
	Yes	131	31.5

TABLE 3 Organizational factors influencing telenursing attitudes Among nurses in North-west Ethiopia, 2022/23 ($n = 416$).

Organizational factors	Response	Frequency	Percent (%)
Access to desktop computers at work	No	226	54.3
	Yes	190	45.7
Organizations facilitate online instruction	No	245	58.9
	Yes	171	41.1
The organization's ICT infrastructure	No	82	19.7
	Yes	334	80.3
ICT Technical Support staff in your organization	No	92	22.1
	Yes	324	77.9
Access to the Internet within the organization	No	223	53.6
	Yes	193	46.4
Computer Training in the organization	No	223	53.6
	Yes	193	46.4

workplace or organizations, and 334 (80.3%) and 324 (77.9%) participants reported the availability of ICT infrastructure and technical support in their organization, respectively (see Table 3).

3.5 Level of telenursing care awareness, knowledge, and attitude among nurses

In this study, 49.8%, 45.9%, and 39.7% of nurses demonstrated good awareness, knowledge, and attitudes toward telenursing care, respectively (see Figure 2).

3.6 Analysis of binary logistic regression to identify variables related to nurses' attitudes toward telenursing care

In the bivariable analysis, nurses' attitudes toward telenursing care demonstrated significant associations ($p < 0.2$) with various factors, including awareness, knowledge, age, sex, educational level, job experience, monthly salary, social media/internet use, personal computer access, preferred social media platforms, experience of online patient contact, source of information, internet access at home, digital training, desktop computer access at workplaces, internet access in organizations, and computer-related training.

Upon examining the final multivariable logistic regression model, it was observed that several variables continued to exhibit a statistically significant association with nurses' attitudes toward telenursing care. These variables included awareness (AOR = 4.24; 95% CI: 1.99–9.041), knowledge (AOR = 2.45; 95% CI: 1.10–5.46), job experience (4–7 years: AOR = 2.74; 95% CI: 1.72–4.37, and above 7 years: AOR = 3.46; 95% CI: 2.05–5.85), personal computer access (AOR = 2.66; 95% CI: 1.26–5.63), social media and internet use (AOR = 6.24; 95% CI: 2.06–18.92), organizational computer access (AOR = 2.25; 95% CI: 1.12–4.51),

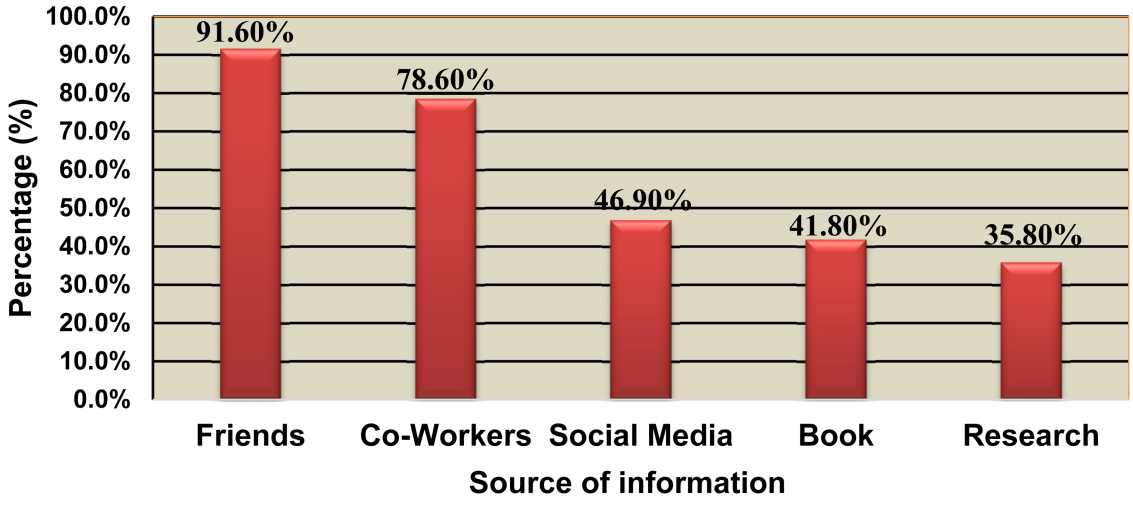

FIGURE 1
The major source of information for nurses in Northeast Ethiopia in 2022/23 ($n = 416$).

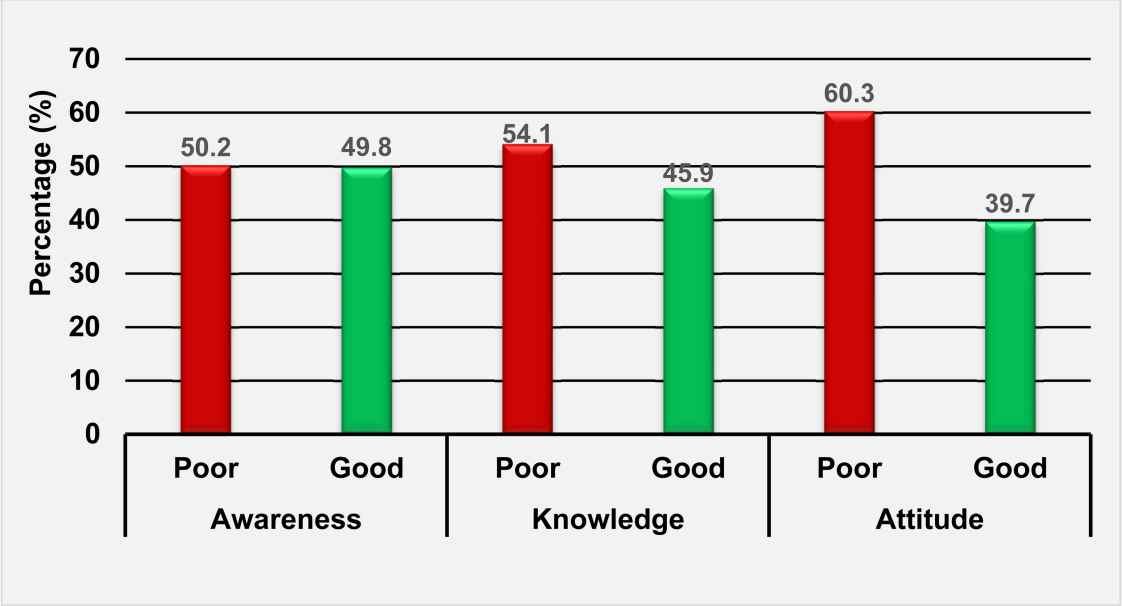

FIGURE 2
Nurses' awareness, knowledge, and attitude toward telenursing care in North-west Ethiopia, 2022/23 (*n* = 416).

digital training (AOR = 3.32; 95% CI: 1.65–6.66), internet access in the organization (AOR = 6.10; 95% CI: 3.02–12.33), and computer-related training (AOR = 4.01; 95% CI: 2.06–7.78) (Table 4).

4 Discussion

This study investigates nurses' attitudes toward telenursing care and the factors influencing these attitudes in northwest Ethiopia. The results reveal that 39.7% (95% CI: 35.1%-44.5%) held a positive view of remote nursing assistance (telenursing). This aligns with a similar study in India, where 61% and 39% demonstrated low and high attitudes, respectively, toward telehealth (26).

In contrast, our findings differ from research in northwestern Ethiopia, where 64% of healthcare professionals favored telemedicine (5). This discrepancy may be attributed to variations in the included health professionals, the study's scope covering three hospitals, and differences in sample sizes.

Previous investigations in Egypt and Iran reported diverse attitudes toward telemedicine among healthcare professionals. In Egypt, 24.6% and 75.4% of dermatologists had poor and good attitudes, respectively (44). In Iran, about 36% and 63% of health professionals expressed unfavorable and favorable attitudes, respectively, toward telemedicine at Isfahan University of Medical Science (38). Another study in Iran found that a significant 73% of healthcare workers had a positive attitude toward telemedicine (41, 42). Similarly, a study in Poland found that 71% of university nursing students had a favorable view of telehealth and telenursing (4).

These variations may stem from differences in technology utilization, internet access, personal computer availability, and institutional computer accessibility. Notably, only 61.2% of our study participants had personal computers, and 50.4% had internet access at home, contrasting sharply with the study in Iran where 99.2% could use a computer and access the internet (41, 42).

Among participants with a positive attitude toward telenursing care, 46.2% used social media/internet in their daily activities, while 48.7% sourced information from social media. This is consistent with a study in Iran where 52.6% of participants obtained information from public media and the Internet (41, 42). In our study, 33.7% of nurses agreed to use telenursing in the future, slightly higher than the study in Iran where only 30.4% were willing. Additionally, 36.7% of nurses in our study acknowledged that utilizing telenursing could enhance the efficiency of nursing staff, aligning with a similar study in Iran (4, 19).

Approximately 30% of the respondents in our study believe that telenursing may enhance nursing care services, a perspective contrasting with an Australian study where 52% agreed that e-health can improve nursing practices (47). However, only 39.4% of the nurses in our study agreed that telenursing may enhance nursing care quality, a figure significantly lower than the Polish study where over 70% believed in its utility across medical specialties (4, 19). This difference may arise from variations in educational systems, technology use, and internet access across countries. In contrast, 44.2% and 31.1% of the participants in our study agree that telenursing may improve nursing communication and decrease unnecessary travel costs, respectively, aligning with findings from research conducted in Ethiopia (5) and India (26).

About 29.3% of participants agree or strongly agree that telenursing improves nursing clinical decision-making, while 24.7% believe it may threaten information privacy. This finding

TABLE 4 Regression analysis, both bivariable and multivariable, of the variables linked to nurses' attitudes about telenursing care in Northwest Ethiopia 2022/23 ($n = 416$).

Variable	Category/responses		Level of telenursing attitude		OR (95%, CI)	
			Good No (%)	Poor No (%)	COR (95% CI)	AOR (95% CI)
Awareness	Poor		28 (13.4)	181 (86.6)	1	1
	Good		137 (66.2)	70 (33.8)	12.65 (7.74–20.68)	**4.24 (1.99–9.041)****
Knowledge	Poor		37 (16.4)	188 (83.6)	1	1
	Good		128 (67.0)	63 (33.0)	10.32 (6.49–16.42)	**2.45 (1.10–5.46)***
Educational level	Diploma		23 (29.1)	56 (70.9)	1	1
	BSc. Degree		97 (38.2)	157 (61.8)	1.50 (0.87–2.60)	1.52 (0.48–4.84)
	Master		45 (54.2)	38 (45.8)	2.88 (1.51–5.52)	2.57 (0.15–45.30)
Job work experience in the year	0–3 Year		51 (26.2)	144 (73.8)	1	1
	4–7 Year		65 (49.2)	67 (50.8)	**2.74 (1.72–4.37)****	2.28 (0.5–9.31)
	Above 7 Year		49 (55.1)	40 (44.9)	**3.46 (2.05–5.85)****	2.57 (0.43–15.48)
PC/Laptop computer access	No		91 (30.8)	204 (69.2)	1	1
	Yes		74 (61.2)	47 (38.8)	**3.53 (2.27–5.49)****	**2.66 (1.26–5.63)***
Social media/Internet use	No		21 (20.2)	83 (79.8)	1	1
	Yes		144 (46.2)	168 (53.8)	**3.39 (2.0–5.74)****	**6.24 (2.06–18.92)****
Social media usually used	Facebook	No	52 (29.9)	122 (70.1)	1	1
		Yes	113 (46.7)	129 (53.3)	**2.06 (1.36–3.10)****	1.39 (0.49–3.90)
	Telegram	No	92 (34.3)	176 (65.7)	1	1
		Yes	73 (49.3)	75 (50.7)	**1.86 (1.24–2.80)****	0.51 (0.21–1.25)
	Twitter	No	120 (36.4)	210 (63.6)	1	1
		Yes	45 (52.3)	41 (47.7)	**1.92 (1.19–3.10)****	1.32 (0.44–3.93)
	Instagram	No	118 (35.4)	215 (64.6)	1	1
		Yes	47 (56.6)	36 (43.4)	**2.38 (1.46–3.88)****	1.81 (0.58–5.69)
	Email	No	126 (37.6)	209 (62.4)	1	1
		Yes	39 (48.1)	42 (51.9)	1.54 (0.945–2.51)	0.33 (0.10–1.08)
An experience in contacting online		No	102 (35.1)	189 (64.9)	1	1
		Yes	63 (50.4)	62 (49.6)	**1.88 (1.23–2.88)****	0.61 (0.29–1.29)
Internet access at home		No	99 (34.7)	186 (65.3)	1	1
		Yes	66 (50.4)	65 (49.6)	**1.91 (1.25–2.91)****	0.53 (0.25–1.13)
Source of Information	Friends	No	9 (25.7)	26 (74.3)	1	1
		Yes	156 (40.9)	225 (59.1)	2.0 (0.91–4.39)	1.50 (0.48–4.68)
	Social Media	No	70 (31.7)	151 (68.3)	1	1
		Yes	95 (48.7)	100 (51.3)	**2.05 (1.38–3.05)****	0.91 (0.40–2.08)
	Research Articles	No	70 (26.2)	197 (73.8)	1	1
		Yes	95 (63.8)	54 (36.2)	**4.95 (3.22–7.62)****	1.87 (0.85–4.09)
Desktop computer access at the workplace		No	46 (20.4)	180 (79.6)	1	1
		Yes	119 (62.6)	71 (37.4)	**6.56 (4.24–10.16)****	**2.25 (1.12–4.51)***
Organizations facilitate digital training		No	53 (21.6)	192 (78.4)	1	1
		Yes	112 (65.5)	59 (34.5)	**6.88 (4.44–10.66)****	**3.32 (1.65–6.66)****
Internet access in the organization		No	39 (17.5)	184 (82.5)	1	1
		Yes	126 (65.3)	67 (34.7)	**8.87 (5.63–13.99)****	**6.10 (3.02–12.33)****
Computer Training in the organization		No	56 (25.1)	167 (74.9)	1	1
		Yes	109 (56.5)	84 (43.5)	**3.87 (2.55–5.86)****	**4.01 (2.06–7.78)****

*p-value < 0.05; **p-value < 0.01.

contrasts with a study in North West Ethiopia, where 54.0% and 66% expressed agree and strongly agree on the positive impact of telemedicine on clinical decision-making quality and its potential threat to information confidentiality (5).

Approximately 73.6% of nurses in our study indicate that telenursing technology demands more effort, consistent with a study in North West Ethiopia, where 72.6% believed that Telemedicine technology required increased effort (5).

Similarly, a study in Iran found that 76.2% of participants perceived telemedicine as complex, requiring substantial mental effort (4).

The results indicate that nurses' awareness (AOR = 4.24, 95% CI: 1.99–9.041) and knowledge (AOR = 2.45, 95% CI: 1.10–5.46) were significantly associated with positive attitudes toward telenursing care. This aligns with previous studies that have highlighted the importance of awareness and knowledge in shaping healthcare professionals' perceptions and acceptance of telemedicine technologies (55, 56). This might be due to increasing nurses' awareness and knowledge of telenursing and its capabilities, benefits, and applications in healthcare increasing their perception of telenursing technology for use in nursing clinical care.

The findings suggest that nurses with 4–7 years (AOR = 2.74, 95% CI: 1.72–4.37) and over 7 years (AOR = 3.46, 95% CI: 2.05–5.85) of job experience were more likely to have positive attitudes toward telenursing. This could be attributed to experienced nurses' familiarity with technological innovations and their ability to recognize the potential benefits of telenursing in resource-limited settings (57, 58). Potential Reasons for the Findings are Experienced nurses are more familiar with technological innovations in healthcare. As they have worked in the field for longer, they have likely seen the introduction and adoption of various new technologies. This familiarity may make them more open to and appreciative of the potential of telenursing, experienced nurses can better recognize the benefits of telenursing, especially in resource-limited settings. With their extensive experience, they understand the challenges of providing quality care with limited resources. They may see telenursing as a way to expand access to care and improve outcomes in these settings, and more experienced nurses may be more comfortable with the autonomy and independence that telenursing can provide. As they progress in their careers, they may value the ability to work remotely and have more control over their schedules.

The study revealed that personal computer access (AOR = 2.66, 95% CI: 1.26–5.63), social media and internet use (AOR = 6.24, 95% CI: 2.06–18.92), organizational computer access (AOR = 2.25, 95% CI: 1.12–4.51), and internet access in the organization (AOR = 6.10, 95% CI: 3.02–12.33) were all significantly associated with positive attitudes toward telenursing. These findings are consistent with previous research, which has highlighted the importance of technological infrastructure and access in the successful implementation of telemedicine (55, 56). By addressing these technological barriers and providing nurses with the necessary tools and support, healthcare organizations can create an environment that is conducive to the acceptance and implementation of telenursing services.

The study found that digital training (AOR = 3.32, 95% CI: 1.65–6.66) and computer-related training (AOR = 4.01, 95% CI: 2.06–7.78) were also significantly associated with positive attitudes toward telenursing. This aligns with existing literature, which suggests that providing targeted training and skill development opportunities can enhance healthcare professionals' confidence and willingness to engage with telemedicine technologies (56, 58). The potential reason for this fact is that comprehensive training programs for healthcare professionals facilitate the successful implementation and adoption of telenursing technologies. By equipping nurses and other healthcare providers with essential digital and computer-related skills, organizations can create a more positive and receptive environment for integrating telenursing into clinical practice.

5 Strengths and limitations of the study

This research examines the current attitudes of nurses toward telenursing care in Ethiopia. The findings represent the first exploration of nurses' perspectives on telenursing care within the country's nursing practice. The significance of this research extends to policymakers, program developers, and project planners in the nursing sector, providing a foundational reference for future researchers with similar interests. However, the study has limitations. It does not extensively explore the challenges and barriers to the implementation of telenursing in resource-limited settings. Additionally, the study is an institution-based cross-sectional survey conducted exclusively in two dedicated educational referral hospitals within the Amhara region, thereby excluding other referral hospitals. Consequently, the results are only applicable to these specific institutions.

6 Conclusion

The results of this survey indicate that a significant portion of nurses hold a negative opinion regarding telenursing services. This can be attributed to their limited awareness, insufficient knowledge, and a lack of training in computer and digital health-related aspects. The utilization of technology in nursing practice involves various considerations, such as the ability to engage in online communication and the accessibility of computers and the Internet.

Moreover, a nurse's attitude towards telenursing care is intricately connected to factors such as education level, knowledge, access to computers and the internet, and training in digital health. In light of these findings, it is imperative for key stakeholders, including Federal Ministers of Health (FMoH), institutions of higher education such as universities or colleges, and both governmental and non-governmental organizations engaged in nursing care, to collaborate. This collaborative effort aims to enhance nursing practices by addressing and improving nurses' attitudes toward the acceptance, utilization, and implementation of advanced technology in the nursing domain.

Data availability statement

The data analyzed in this study is subject to the following licenses/restrictions: the data generated during the course of this study will be made available upon reasonable request from the corresponding author. However, due to the nature of the study area being one of the surveillance sites in the country, we are unable to publicly release the data. Access to the data is restricted by the University of Gondar, College of Medicine and Health Sciences, which owns the data. Therefore, interested parties can request access to the data and supplementary information by contacting the surveillance site coordinator office at the University of Gondar, College of Medicine and Health Sciences via email. Requests to access these datasets should be directed to kassahuna@yahoo.com.

Author contributions

FB: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation,

Visualization, Writing – original draft, Writing – review & editing. BT: Conceptualization, Data curation, Funding acquisition, Project administration, Writing – original draft, Writing – review & editing. BE: Conceptualization, Data curation, Methodology, Project administration, Validation, Visualization, Writing – original draft, Writing – review & editing. AS: Formal Analysis, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. AC: Conceptualization, Formal Analysis, Validation, Visualization, Writing – original draft, Writing – review & editing. AG: Formal Analysis, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. MR: Conceptualization, Data curation, Validation, Writing – original draft, Writing – review & editing. GK: Conceptualization, Formal Analysis, Funding acquisition, Validation, Visualization, Writing – original draft, Writing – review & editing. TN: Conceptualization, Formal Analysis, Validation, Visualization, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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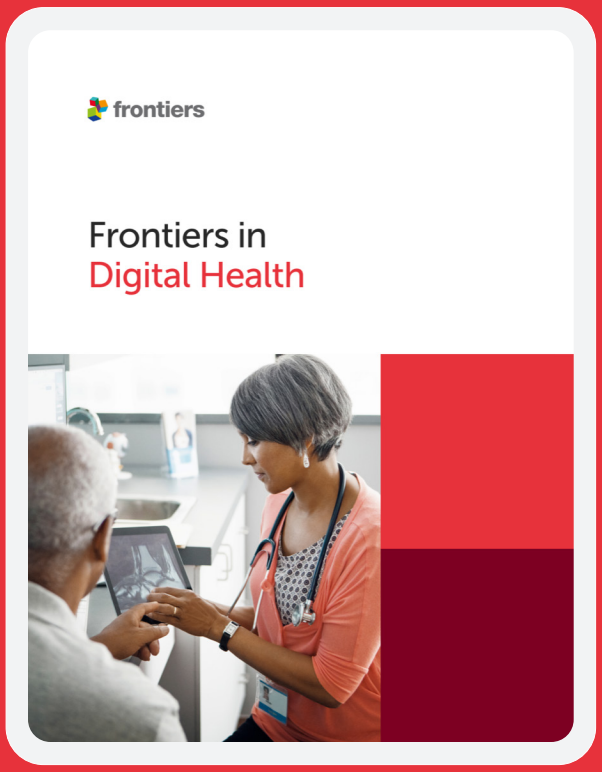

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