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Digital health applications: acceptance, benefit assessment, and costs from the perspective of patients and medical professionals

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Digital health applications: acceptance, benefit assessment, and costs from the perspective of patients and medical professionals

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Editorial: Digital health applications: acceptance, benefit assessment, and costs from the perspective of patients and medical professionals

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Editorial on the Research Topic
Digital health applications: acceptance, benefit assessment, and costs from the perspective of patients and medical professionals

Digital health services have witnessed a growing prevalence in healthcare systems around the world, with diverse levels of implementation and hurdles to surmount. Germany took the lead in creating the possibility for prescribing digital health applications (DHAs) as CE-certified digital medical devices with costs covered by the national health system, a trend that has been emulated by other countries, such as France and Belgium (1). Nonetheless, digital healthcare services continue to be perceived as innovations in most healthcare systems, encountering challenges due to the absence of well-established reimbursement channels. In healthcare systems where statutory health insurance covers the costs of healthcare services, patients are often reluctant to pay for digital health services privately. Additionally, both patients and service providers lack initial experience with these innovations (2–4), giving rise to skepticism and requiring time for the innovation to integrate into healthcare.

To secure health insurance coverage for these services, clear evidence of patient benefits is generally required, involving substantial costs and time investment, which smaller innovative companies may find prohibitive. To expedite the integration of DHAs into healthcare systems, several countries have instituted measures to address these barriers. For instance, Germany has adopted a two-phase market entry process, in which an initial pilot study grants market access and reimbursement by the national health system, followed by a confirmatory study to definitively demonstrate the benefits (5). What started as an innovative tool to give patients quick access to DHAs, especially for psychological indications where therapist waiting times are often long, has unfortunately become a very complex system. The requirements for studies to prove a benefit for patients are now much higher, making the studies time consuming and very expensive, so that hardly any new DHA is made available (6).

In recent years, digital health services have gained substantial momentum, revolutionizing healthcare delivery and presenting new opportunities for patient care. In this research topic the contributing authors present a variety of perspectives on the digitalisation of the health care sector. For example, Giebel et al. developed the DiGA-Care Path, a step-by-step analysis of DHA supply in Germany. This approach comprises a "main path," concentrating on the supply environment, and a "sub-path," illustrating the supply delivered by the DHA. This methodology assists in identifying problems and potential quality improvements in the current DHA supply and can serve as a guidance for international policymakers and stakeholders.

Stapelfeldt et al. performed a systematic assessment of DHA intended to treat obesity (7). The study concluded that most apps partially meet guideline recommendations and exhibit adequate to good quality based on the MARS score. However, evaluating the quality of mobile health applications remains challenging for patients, despite their low-threshold accessibility.

Naemi et al. designed and evaluated an Electronic Health Record (EHR) for amblyopia patients in Iran, aiming to enhance information management and reduce treatment costs. A usability evaluation showed that over 90% of users rated the web-based EHR system as very good or good, demonstrating high patient acceptance. Implementing an EHR for amblyopia has the potential to improve care quality and facilitate complication control.

Tischendorf et al. examined the sustainable integration of digitalization in nursing education, pinpointing trends in digitalization-related training and emphasizing the importance of involving nursing professionals in digital technology development. The literature review suggests that discussions on this topic in German-language literature lag behind those in the international context, highlighting the need for collaboration between nursing professionals and nursing sciences.

Arabian et al. investigated patients' understanding of electronic prescriptions in Iran, underscoring the necessity for improved patient comprehension of the potential consequences of such technology on their relationships with healthcare providers. Active patient engagement and positive attitudes toward electronic prescription systems can enhance healthcare service quality, increase acceptance, and simplify system usage.

In conclusion, the aforementioned studies of this research topic, accompanied by numerous other investigations, provide valuable insights into the acceptance, benefit evaluation, and cost implications associated with digital health services. As the ongoing proliferation of innovations persistently reconfigures global healthcare infrastructures, it is indispensable to eradicate prospective obstacles and facilitate egalitarian accessibility to superior care, thereby engendering unprecedented possibilities through the utilization of, and access to, data derived from digital health applications among other resources. Collaborative efforts among stakeholders, including policymakers, healthcare professionals, and developers, will be vital in overcoming these barriers (8).

Author contributions

TonS: Conceptualization, Writing – original draft, Writing – review & editing. TomS: Conceptualization, Writing – original draft, Writing – review & editing.

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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Integration of digital health applications into the German healthcare system: development of "The DiGA-Care Path"

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Introduction: Since 2019 people who have insured in the German statutory health insurance are entitled to use certified apps called the Digitale Gesundheitsanwendungen [Digital Health Applications (DiGAs)]. The prerequisite for this is that an app certified as DiGA and suitable for their diagnosis exists. The DiGA can then either be prescribed by a physician or psychotherapist or requested by the patient from the statutory health insurance fund. Given the novelty of this type of healthcare, the implementation of a DiGA should be closely monitored to identify potential weaknesses and achieve quality improvements. To enable an analysis of the supply of DiGAs step-by-step, we aimed to create the DiGA-Care Path.
Methods: We conducted three steps to create the DiGA-Care Path. First, a knowledge base was created based on a structured literature research matched with knowledge gathered from the superordinate research project "QuaSiApps" funded by the German Federal Joint Committee. Second, we aimed to create an "ideal-typical" DiGA-Care Path using a flowchart. Third, based on the first path, a final path was developed using the graphical modeling language "Event-Driven Process Chain."
Results: The DiGA-Care Path was developed to depict the supply of DiGAs in Germany. The final path is constituted by a "main path" as well as a corresponding "sub-path". While the "main path" focuses more on the supply environment in which a DiGA is used, the "sub-path" depicts the supply delivered by the DiGA itself. Besides the process itself, the paths include relevant actors to indicate responsibilities for individual process steps.
Discussion: The DiGA-Care Path helps to analyze the current supply of DiGAs step-by-step. Thereby, each step can be investigated in detail to identify problems and to detect further steps where quality improvements can be enabled. Depending on the perspective, focused either on the supply environment, or the supply delivered by the DiGA itself, the "main path" or the "sub-path" can be used, respectively. Besides the potential of the DiGA-Care Path to improve the current supply of DiGAs, it can help as an orientation for international policymakers or further stakeholders either to develop their own integration of apps into healthcare systems or for international manufacturers to consider entering the German market.

KEYWORDS

digital health application, DHA, Digitale Gesundheitsanwendungen, DiGA, care path, mHealth, mobile app

1 Introduction

Since the introduction of the Apple iPhone in 2007, mHealth apps are on the rise and permit multiple patient benefits. These benefits can be achieved in five domains: educational health applications, applications to contact healthcare professionals, applications to check the personal health records, personal care applications, and social networking applications (1).

To help patients benefit from opportunities through mHealth apps, the German Bundestag passed the Digital Care Act (DVG) in 2019. This act established specific mobile as well as web apps also known as Digitale Gesundheitsanwendungen [Digital Health Applications (DiGAs)] as an integral part of the German healthcare system (2). Other European countries such as France and Austria are also considering establishing similar concepts (3). In addition, efforts are being made at the European level to establish a harmonized authorization (4).

DiGAs are not limited to mobile apps; they can also exist in the form of web applications or include other devices [such as virtual reality (VR) glasses]. To become a DiGA, an app has to go through a testing procedure, the "Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V" (5, 6). The basic requirements for a DiGA tested in this process are as follows: (1) The app must be a European conformity (CE)-certified medical product (risk class I or IIa); (2) the main function of the app is based on digital technologies; (3) the app supports the recognition, monitoring, treatment, or alleviation of diseases or the recognition, treatment, alleviation, or compensation of injuries or disabilities [§33a Social Code Book V (SGB V)]. An approval for apps focused on primary prevention is not provided. After passing the Fast-Track Process, the app will be registered in the DiGA directory managed by the Federal Institute for Drugs and Medical Devices (BfArM) and is reimbursable by the German statutory health insurance.

In general, there are two categories of listing in the directory: (1) DiGA with a provisional listing or (2) DiGA with a final listing. The decision depends on the availability of a comparative study that is suitable to prove a positive healthcare effect. If such a proof exists, a DiGA can directly be final listed in the directory. If manufacturers cannot present a suitable study, they can apply for provisional listing. Nevertheless, all listed DiGA must fulfill requirements such as security, functional capability, quality, data protection, and information security, regardless of their listing status (provisional or final). A corresponding study to prove the positive healthcare effect can be carried out retrospectively as part of a trial phase lasting up to 1 year. If there is a prospect of evidence, a decision may be made at the request of the manufacturer to grant a maximum of a further 12 months for the proof (5, 6).

There are two valid types of positive healthcare effects: Either in the form of a medical benefit or in the form of a patient-relevant improvement of structure and processes (§139e Abs. 2 SGB V). Prior to the approval study, a target patient group has to be determined according to the International Classification of Diseases (ICD-10). Reimbursement for a DiGA is only provided for this designated patient group (5, 6).

The DiGA prices are regulated within §134 SGB V. They differ between the first year and subsequent years. In the first year, the manufacturer is free to determine a price. However, fixed reference price groups must be taken into account depending on the indication and the category of positive healthcare effect. From the 13th month, prices apply that are negotiated between the manufacturer and the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband). If no agreement is reached, an independent arbitration board decides on the price.

Once listed, the manufacturer still has some obligations. In case of significant changes to the DiGA, the BfArM has to be informed. Furthermore, the manufacturer must ensure that information in the DiGA directory, in the distribution platform, or on the application website, is up-to-date and complete. With regard to further requirements, continuous maintenance, reassessment, and further development of the technical and organizational data protection and information security measures must be ensured. This also includes penetration tests. Further requirements are listed within the guide for manufacturers, service providers, and users provided by the BfArM (5, 6) or the Digital Health Applications Ordinance (DiGAV) (7).

Currently, the DiGA directory includes 56 DiGAs. Thereof, 24 DiGAs are provisionally listed and 32 DiGAs are final listed. Six DiGAs could not prove their positive healthcare effect and were subsequently delisted. DiGAs are approved for a broad range of diseases, such as mental illnesses, cardiovascular diseases, cancer, diseases of the muscles, bones, and joints, or hormonal or metabolic diseases (8). Overall, the demand for DiGAs is increasing. While the health insurance funds reimbursed just under 40,000 DiGAs in the first year (October 202 –September 2021), the number rose to over 200,000 reimbursements last year (October 2022–September 2023) (3).

Although safety and clinical performance are tested in the context of the medical device approval process [*Medical Device Regulation (MDR)*, Annex I Chapter 1] and further test criteria such as data protection, information security, interoperability, and further quality requirements are part of the Fast-Track test procedure (5, 6), several problems can emerge within the use of a DiGA. These were found in 10 different categories: (1) validity, (2) usability, (3) technology, (4) use and adherence, (5) data privacy and security, (6) patient–physician relationship, (7) knowledge and skills, (8) individuality, (9) implementation, and (10) costs. On a more abstract level, these are problems concerned either with the DiGAs themselves or their integration into the healthcare system (9).

To address these existing problems and to ensure a high quality of DiGAs, we established the QuaSiApps project with the aim to develop a comprehensive, continuous quality assurance system for DiGAs (10, 11). The project is funded by the German Federal Joint Committee (12).

According to the International Organization for Standardization (ISO) 9000 standard, quality is "the degree to which a set of inherent characteristics fulfills requirements" (13). Thus, a fundamental need to determine the quality of a DiGA and its supply is to know the requirements and gain clarity

about the exact procedures and the respective tasks of the concerned parties. One way to guarantee such clarity is the visualization in the form of a care path as the ideal-typical path for the defined patient groups with its decisive diagnostic services in chronological order (14).

Care paths are a methodological basis for the development of quality assurance procedures. Despite some indifferent results, it is now well documented that care paths—or their implementation as a control and standardization instrument for processes—are effective and useful in the context of quality management and quality assurance (15, 16). However, the requirements for the creation of care paths are complex, especially because the fundamental question of care paths: "Who does what with whom at what time" (17) is complex and challenging with regard to the various interfaces (including service providers, payers, and patients). We searched for a clear definition, and a precise depiction, of the ideal-typical care path in the context of DiGAs to build on our quality assurance system. Since our research on guidelines or care paths for DiGA did not result in any eligible results, we determined to create the actual DiGA-Care Path by ourselves. In addition to the benefits that the DiGA-Care Path brings to our project, it can also help national and international stakeholders and interested parties to understand the German DiGA-Care System and look at it in detail.

Hence, the aim of this research was twofold. First, we collected available evidence on the supply of DiGAs in Germany to create a clear understanding of the process, and second, we developed the DiGA-Care Path upon this base.

2 Materials and methods

We pursued a three-stage process to develop the DiGA-Care Path. First, we conducted a structured literature research to identify relevant articles and legal standards describing the supply of DiGAs. Therefore, we searched in scientific databases such as MEDLINE via PubMed and Embase for websites of DiGA-relevant stakeholders in the German healthcare system as well as relevant laws and acts in the context of healthcare supply and especially DiGAs. Hereby, the aim was not to conduct an exhaustive research identifying all the relevant literature in the context of these apps but to gain a broad and reliable knowledge base on which the DiGA-Care Path can be developed further.

Second, a first version of the DiGA-Care Path (see Supplementary Figure S1) was developed. It summarizes the ideal-typical path of DiGA patient groups with decisive services in the chronological sequence. In addition, the actors involved and the DiGA interventions (e.g., the performance of a DiGA application anamnesis) are depicted.

This first care path is based on various sources of knowledge that were generated both within the QuaSiApps project and with the help of external literature. A flowchart was modeled based on: (1) statements of patients (18) and experts from a qualitative survey within the project; (2) a case-based problem outline of medical ethical implications in the use of a DiGA (19); (3) the four medical ethical principles of autonomy, care, non-harm, and justice (20); and (4) the model professional code for doctors working in Germany (21).

Based on this draft, we discussed and decided that the model would benefit from a modeling language that enables a more complex branching than "yes/no-decisions." We also wanted to add the relevant application software (in our context, the DiGA) and the relevant organizational unit (e.g., patient, DiGA manufacturer, or service provider) to the respective process steps in the path. Since the Event-Driven Process Chain (EPC) modeling language developed at the Institute for Information Systems (IWi) at the University of Saarland, Germany (22), offers these possibilities, we used it.

To depict the processes, the EPC uses alternating events and functions that are connected through arrows, showing what is called the "Control Flow." In case a function can be followed by different "Events," "Connectors" are used to branch the "Control Flow." In our case we used "XOR (Either-or)" and "OR (And-or) Connectors."

To clarify which executing body is responsible for a function, we modeled the respective "Organizational Unit" to each function. Where indicated, we added the DiGA as an "Application Software." To indicate the conjunction between a main- and a sub-path, an interface was implemented by a "Sub-process" (cf. Figure 1).

To implement the DiGA-Care Path, we used Lucidchart (23), a web-based diagramming application from Lucid Software Inc. that allows visualization of charts and diagrams, organizational structures, and especially processes.

Finally, after developing the DiGA-Care Path, we sent it out to independent DiGA-experts without conflicts of interest with the research project and asked them after 1 week within an online meeting to evaluate whether the path is correct and intuitive to understand.

3 Results

To develop the DiGA-Care Path, we started with the structured literature search yielding four legal standards (cf. Table 1), six articles (9, 19, 24–27), the QuaSiApps project accompanying working paper (10), a book about DiGAs (28, 29) as well as the Fast-Track Process for DiGA (5, 6) (cf. Table 2).

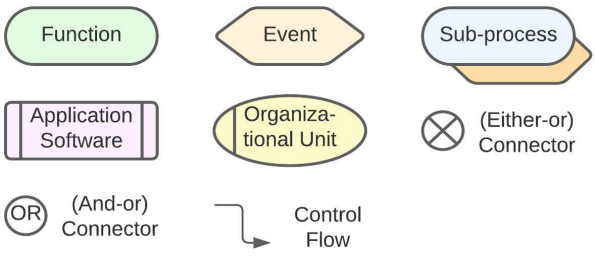

FIGURE 1
Basic components of the event-driven process chain.

TABLE 1 Legal standards relevant in the context of DiGA.

Reference	Description
§33a SGB V	Statutory anchoring of DiGA contains the legal definition and regulates the entitlement of persons with statutory health insurance to the use of DiGA.
	According to the paragraph, DiGA are defined as low-risk class (I or IIa) medical devices whose primary function relies substantially on digital technologies and which are intended to assist in the detection, monitoring, treatment, or mitigation of disease or the detection, treatment, mitigation, or compensation of injury or disability in the insured or in the care provided by healthcare practitioners.
	Furthermore, it includes the procurement channels either through a healthcare practitioner or the authorization by the health insurance. A fundamental requirement for DiGA use irrespective of the procurement channel is a medical indication.
§134 SGB V	Regulation about the remuneration for DiGA use.
§139e SGB V	Regulates the way in which manufacturers can apply for a listing of their medical apps in the DiGA-directory. The basic requirement is a proof of evidence in three areas: (1) the app meets the requirements for safety, functional capability, and quality, including the interoperability of the medical device; (2) the app meets the requirements for data protection and ensures data security in accordance with the state of the art; and (3) the app has a positive healthcare effect.
DiGAV	Determines how the Digital Care Act (DVG), which has incorporated DiGA into the SGB V, is to be implemented. The DiGAV describes in more detail than the DVG how manufacturers can prove that they or their products meet the legal requirements. For example, the ordinance contains specific checklists that manufacturers must use to verify that IT security requirements are met. In contrast to the law, the ordinance also regulates the costs, the procedural sequence, and the precise contents of the DiGA-directory (30).

TABLE 2 Sources included from the structured research that were used to build the DiGA-Care Path.

No.	Author(s)/law	Description	Language
1	Kuhn et al. (19)	A case-based problem outline of the medical–ethical implications of DiGA use.	German
2	Giebel et al. (9)	A review of problems and barriers that have and might have an impact on the supply of DiGAs.	English
3	Börchers and Kampka (10)	A working paper including a detailed description of the QuaSiApps project, FAQs in the context of the project as well as a comprehensive project glossary.	German
4	Schelling (27)	A handout of the association of Statutory Health Insurance Physicians, Bavaria, with advice and recommendation for the avoidance of liability in the context of DiGA.	German
5	BfArM (5, 6)	A Guide for Manufacturers, Service Providers, and Users for the Fast-Track Process for DiGAs.	English/German
7	Sauermann et al. (26)	An article describing basics in the context of DiGAs.	English
8	Geier (24)	An article that describes the status quo in 2021 and recent as well as prospective challenges.	German
9	Brönneke et al. (28, 29)	A comprehensive book about the integration of DiGAs into the German healthcare system.	English/German
10	Haserück and Lau (25)	A short article about the integration of DiGAs into the healthcare supply and the viewpoint of physicians.	German

Based on the included articles and the knowledge generated within the QuaSiApps project, authors KB and BK developed a first DiGA-Care Path (September 2022) as a basis for discussion. After a project meeting that served for a discussion on the consortium of gathered ideas, corrections and improvements were highlighted and we consented to rework the path and implement it in more detail.

Mainly the need for an either–or branching after an activity or function led to the decision to choose another more comprehensive modeling language. Thus, we chose the EPC allowing this modeling.

To reduce the complexity, we decided to separate the DiGA-Care Path into a main path as well as a sub-path contained therein. The main path represents the supply environment in which the DiGA is used (cf. Figure 2). The sub-path includes the supply by the DiGA itself (cf. Figure 3). According to the consensus, the final paths were iteratively modeled with feedback loops including the whole consortium.

Once the paths were developed, we sent them to four independent experts for review. We then held an online meeting together with the experts to discuss the accuracy and comprehensibility of the DiGA-Care Paths. Both paths were judged to be easily understandable as well as correct in content. Nevertheless, it was suggested to emphasize the most frequently followed path within the DiGA-Care Path. To find this, we used the DiGA-Report 2022 from Germany's largest health insurance company. According to the report, 85% of users receive their DiGA via a prescription and 15% receive it via a direct request to their health insurance company (31).

The final paths are represented in Figures 2, 3. Since they were judged to be self-explanatory, only a short, written description of the process is given here.

3.1 Supply environment in which DiGAs are used

The "Supply environment in which DiGAs are used" is depicted in care path 1 (cf. Figure 2). Care path 1 is the higher-level process that includes the "Supply by the DiGA itself" (cf. Figure 3) as a sub-process.

The starting point of DiGA supply is always the diagnosis of a disease made by a healthcare practitioner for which a DiGA exists. After the diagnosis, the healthcare practitioner and patient together develop a concept of therapy that can either include a DiGA or not. If the healthcare practitioner estimates the risk–benefit assessment positive, he offers to inform the patient about the use of the DiGA. If the patient is already experienced with the appropriate DiGA, he can waive the medical information. If the patient declines the use of the DiGA at any point, the app does not become part of the healthcare supply.

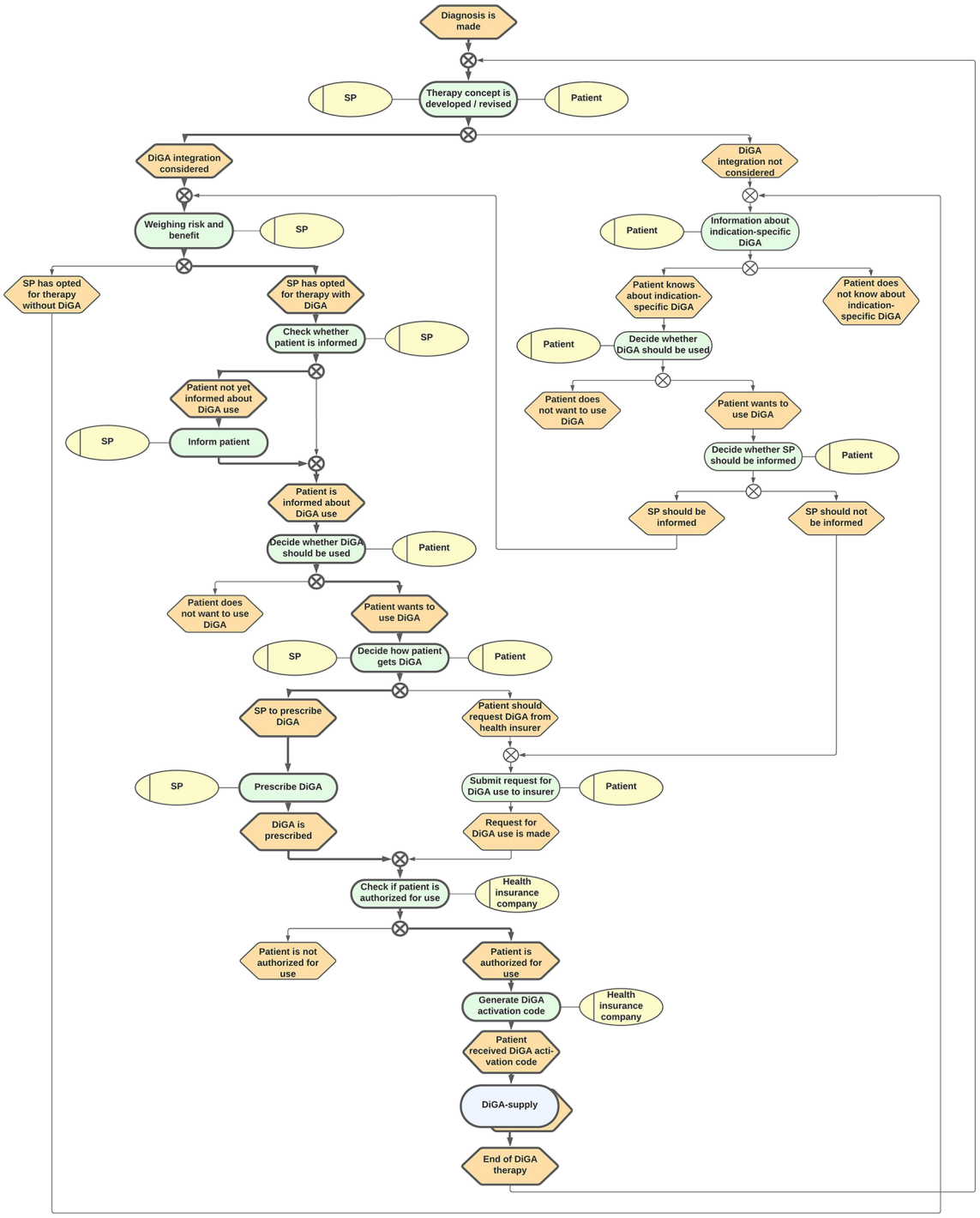

FIGURE 2
DiGA-Care Path 1: supply environment in which DiGAs are used. SP, Service provider (either physician or psychotherapist); DiGA, Digitale Gesundheitsanwendung (Digital Health Application).

If the patient and healthcare practitioner both decide to integrate DiGA into the therapy, the usual path will continue with a prescription made by the healthcare practitioner. Subsequently, the health insurance company of the patient will check if the patient is entitled to use the DiGA or not. If their review results in a positive assessment, the patient receives an activation code to use the DiGA.

Otherwise, if either the healthcare practitioner is not aware of the DiGA or declines its usage within the concept of therapy, the patient himself can request for the DiGA when given the suitable

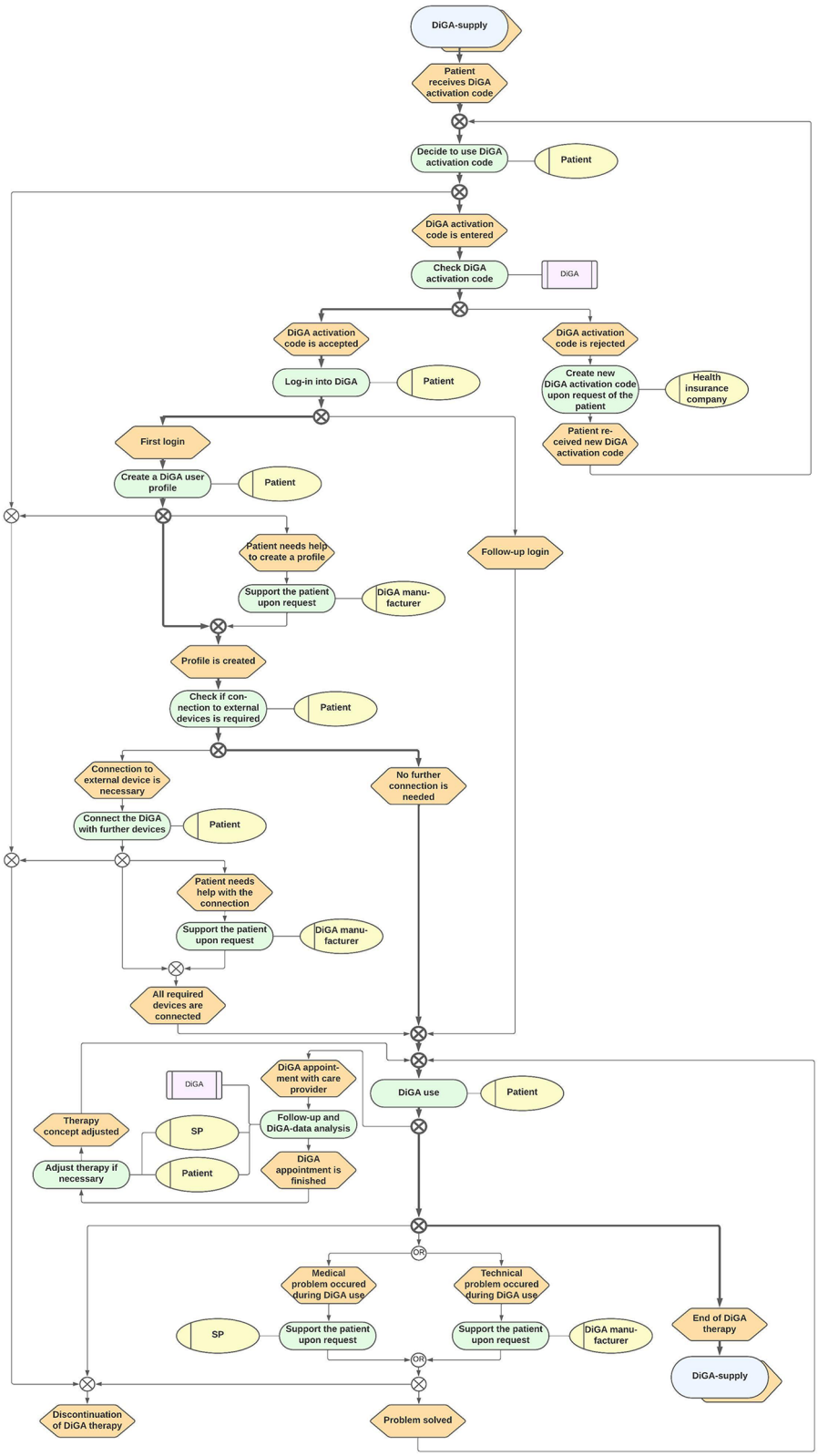

FIGURE 3
DiGA-Care Path 2: supply by the DiGA itself. SP, Service provider (either physician or psychotherapist); DiGA, Digitale Gesundheitsanwendung (Digital Health Application).

diagnosis (and no relevant contraindications) directly from his healthcare insurance company.

Irrespective of the way of procurement, the patient always has the option to ask or inform the healthcare practitioner about the DiGA use.

3.2 Supply by the DiGA itself

The supply provided by the DiGA itself is shown in care path 2 (Figure 3). This path is a sub-process of the supply environment process. After the patient receives his activation code, he decides whether to use it or not. If he does not use it, the DiGA therapy is canceled. Otherwise, the code is checked by the DiGA automatically. Once the code is accepted and the user creates a profile and connects any additional devices, the patient can use the DiGA. In case of any appointments due to the use, the healthcare practitioner and patient analyze the DiGA data and possibly adjust the DiGA therapy concept. If there are any medical or technical problems during use, the patient should get support from his healthcare practitioner or the manufacturer, respectively. If the problem is solved, the patient can continue the use. At the end of the "DiGA utilization period," the patient is redirected to the care path 1 and should evaluate (alone or together with the healthcare practitioner) whether a further use is indicated or not.

4 Discussion

4.1 Principal findings

The DiGA-Care Path was developed to depict the supply of DiGAs in the German healthcare system. It enables researchers, policymakers, and further stakeholders to analyze the supply of a DiGA step-by-step, to identify the parties involved in each case and to locate potential weaknesses, problems, and quality indicators at individual points.

In principle, it can be assumed that the German healthcare system improves through the integration of DiGAs. This assumption is mainly based on two reasons: (1) A DiGA must prove either a medical benefit or a patient-relevant improvement of structure and processes (§139e Abs. 2 SGB V), and (2) the positive attitude of outpatient-care general practitioners, physicians, and psychotherapists (32) as well as physical therapists, occupational therapists, and speech-language pathologists (33) toward DiGAs. Nevertheless, there are several problems and barriers that might impede the prescription and use of a DiGA (9, 32). To face those challenges as well as to optimize the integration and maximize the subsequent positive effects of DiGAs, different approaches should be pursued. One is the implementation of quality assurance. The starting point for quality assurance should be a clear understanding of the care process. Therefore, we gathered and analyzed laws, literature, and project knowledge to build on the DiGA-Care Path.

Even if the high quality of the DiGA itself and its optimal integration into existing care are factors that affect patient benefit, other factors such as the actual use of the app must be taken into account. To verify the actual patient benefit, a new law provides the implementation of application-related performance measurements. This law, the "Act to accelerate the digitalization of the healthcare system" [Digital-Gesetz (DigiG), not yet in force] (34) will also bring further changes such as a closer integration of DiGAs into existing processes and the extension of the risk class of DiGAs to class IIb according to the MDR.

Even if the developed path correctly represents the theoretical requirements for the supply, at some points in the supply reality, the supply of DiGAs could deviate from the path. Such an example we know from focus groups with patients (18) within the QuaSiApps project: In some cases, younger, tech-savvy family members take on the role of DiGA manufacturers and support users with technical questions.

Especially, the closer integration into existing processes is welcomed by many stakeholders because concerns were raised that DiGAs should not be used without integration into the standard care provided by physicians and psychotherapists [e.g., the German Psychotherapists Association (35), the German Diabetes Society (36), the Professional Association for Orthopaedics and Trauma Surgery e.V (37), or Heidel et al. (38)]. Nevertheless, insufficient reimbursement of medical services in the context of DiGAs might be a problem or barrier toward the prescription of DiGAs by physicians or psychotherapists (9, 32, 38). Such changes should always be kept in mind when using the DiGA-Care Path. From time to time, it should be reflected if the DiGA-care is changing and if subsequent changes should be implemented in the DiGA-Care Path.

Furthermore, even if not regulated yet, other stakeholders such as physical therapists, occupational therapists, and speech-language pathologists might play a role in the supply of DiGAs. Thus, for example, a survey with 150 therapists found that 87.3% indicated a positive intention to use a DiGA. In addition, it was to be expected that patients would use DiGAs incorrectly and that errors could therefore occur during training with an app. Therefore, it is necessary to examine to what extent a DiGA can replace an in-person therapy, or whether supplementary or partial replacement use is preferable (33).

Even if apps are becoming more ubiquitous in healthcare systems all over the world, most countries, however, did not or only rudimentarily regulate their integration and use. Also, the European Union only dictates that apps must fulfill the criteria of the MDR to become medical products and to receive admission to healthcare systems and in the secondary healthcare market. Further regulations about how apps should be integrated into care do not exist on this level. Germany took it one step further and created a legal basis for the integration of distinct apps (DiGAs).

But even if there is a legal basis, the integration of DiGAs into care paths is uncertain. Therefore, the National Association of the Statutory Health Insurance Funds emphasized: "DiGA must be integrated into the care paths. To this end, the potential for digitalization in treatment and networking across service sectors

must be exploited" (39). While we depicted the general DiGA-Care Path that is independent of indication, the integration of DiGAs should also be considered in the context of disease-specific care paths, especially by medical professional societies.

4.2 Limitations

DiGA-care in Germany is a very complex system. Nevertheless, we aimed to illustrate it as clearly organized as possible. Therefore, we had to neglect some aspects. Such an aspect is especially the contact between the patient and the healthcare practitioner. Even if we depicted this contact at some points of our path, it should be emphasized that the patient should always have the option to contact the respective healthcare practitioner at any time during the DiGA-Care Path.

We decided to use the EPC to represent the German DiGA supply. Even if the EPC was originally developed to model business processes (22), it proved to be the right modeling language for our purpose. This was mainly because it provides the possibility to use Either–Or Connectors, which were necessary to detail the complex system, and because of the easy readability. Since there is a variety of other modeling languages (e.g., the BPMN), translating the DiGA-Care Path into other forms of representation could also be considered.

The DiGA-Care Path was reviewed by four independent DiGA-experts. It can therefore be assumed that in principle it correctly maps the supply of DiGAs. Nevertheless, the review did not include a broad range of different stakeholders. Further stakeholders, such as patients, physicians, manufacturers, or policymakers, should also be asked about their assessment of the appropriateness of the path. Hence, the path should be subject to further discussion and could therefore be subject to change in the future.

A further limitation was the non-systematic evidence collection we used to develop the DiGA-Care Path. We did not conduct a systematic literature review or a systematic survey of experts. Therefore, there is a risk that the evidence is incomplete. Nevertheless, we are convinced that based on the knowledge gathered during the project, together with the literature and the review by the four experts, our DiGA-Care Path adequately represents the DiGA-care.

5 Conclusions

We analyzed and subsequently visualized the DiGA-Care Path using the graphical modeling language EPC. Thereby, the DiGA-care process becomes transparent and can be further investigated in detail. The developed DiGA-Care Path serves as a solid foundation to examine the weaknesses of the current situation as well as to indicate areas where one can start to improve care. Furthermore, it provides an overview of the German DiGA supply. Thus, the DiGA-Care Path can either be used as an inspiration for policymakers or further stakeholders to develop their own integration of mHealth apps into healthcare systems, or for international manufacturers to consider entering the German market.

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

Ethical approval was not required for the study involving humans in accordance with the local legislation and institutional requirements. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent to participate in this study was not required from the participants in accordance with the national legislation and the institutional requirements.

Author contributions

GG: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing. CA: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Validation, Visualization, Writing – review & editing. KB: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Validation, Visualization, Writing – review & editing. BK: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Validation, Visualization, Writing – review & editing. SN: Conceptualization, Funding acquisition, Validation, Writing – review & editing. HC: Data curation, Formal Analysis, Validation, Writing – review & editing. FP: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Validation, Visualization, Writing – review & editing. JW: Funding acquisition, Project administration, Supervision, Validation, Writing – review & editing. NB: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing – review & editing.

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Conflict of interest

KB and BK were employed by QM BÖRCHERS CONSULTING+.

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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Corrigendum: Integration of digital health applications into the German healthcare system: development of "The DiGA-Care Path"

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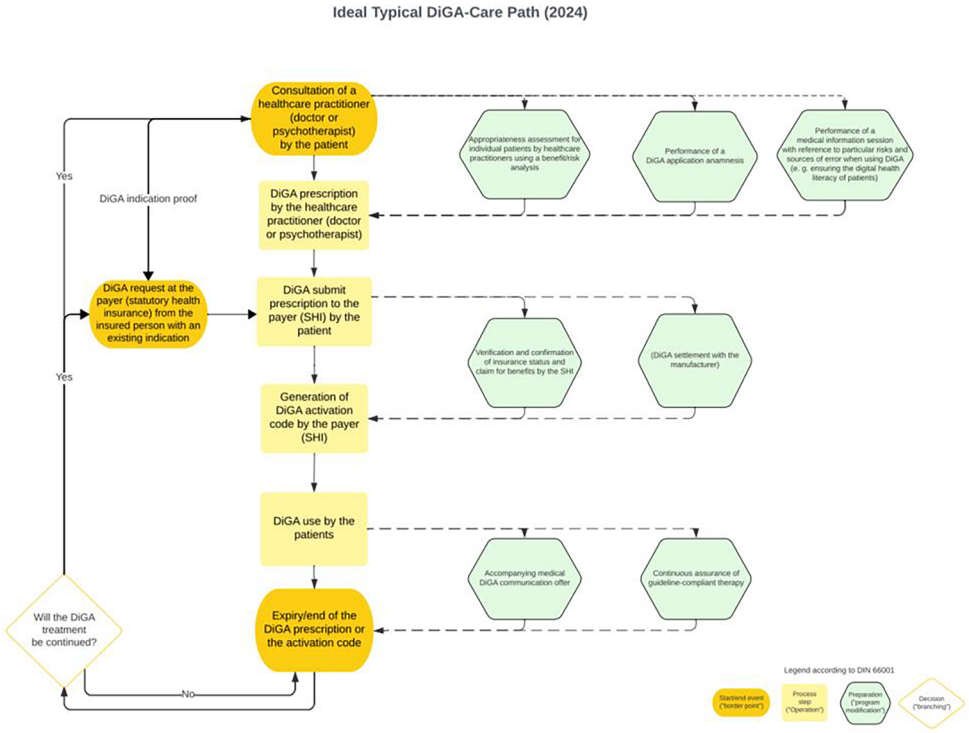
In the published article, there was an error in Supplementary Figure S1. A preliminary, German-language version of the attachment was uploaded by mistake. The correct and final version of Supplementary Figure S1 appears below.



The authors apologize for this error and state that this does not change the scientific conclusions of the article in any way. The original article has been updated.

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Design and evaluation of a web-based electronic health record for amblyopia

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Introduction: Amblyopia, or lazy eye, is a type of visual impairment in which the eyesight is not complete, even with the use of glasses. For the treatment of this disease, accurate and continuous examinations are needed. Nowadays, patient-centered care, by relying on web-based electronic records for amblyopia, has the potential to reduce treatment costs, increase the quality of care, and improve the safety and effectiveness of treatment. Therefore, the purpose of this study is to design and evaluate an Electronic Health Record (EHR) for patients with amblyopia.

Methods: The present study is applied developmental research. Using a Morgan table as a sampling tool, a straightforward random sampling technique selected 150 records from 1,500 records that were free of flaws. The design of the electronic version proceeded in a cascading manner so that after the design of each part, it was presented to the amblyopia experts, and if approved, the next part was designed. To design this EHR, the C# programming language and MySQL database were used. A system evaluation was performed by entering and recording patient information. For this purpose, the standard Questionnaire of User Interaction Satisfaction (QUIS), consisting of 18 questions, was used.

Results: According to the amblyopia EHR data elements, the data of physician and patient, examinations, website members, and members' roles were determined. After defining the fields and classes that explain the tables, the EHR was designed. The usability evaluation of the system showed that the mean selection of very good and good options by the users of EHRs was over 90%, indicating the patients' acceptance of web-based EHRs.

Conclusion: The design of an EHR for amblyopia is an effective step toward integrating and improving the information management of these patients. It will also enable the storage and retrieval of patients' information to reduce and facilitate the control of amblyopia complications.

KEYWORDS

amblyopia, electronic health record, design, evaluation, usability test evaluation

1 Background

Eyes and sense of sight are very important in the perception of the environment, and any eye problem will have social and psychological consequences, so taking care of the eyes and paying attention to diseases that affect the eyes' health are vitally important (1, 2). Amblyopia, or lazy eye, is a type of vision disorder that causes a decrease in central vision in an apparently healthy eye (3). In this case, although the external structure of the eye is healthy, the vision is not perfect, even with the use of glasses. When the development of vision in one eye is normal and abnormal in the other eye, the eye with poor vision becomes lazy (4). The most common cause of amblyopia is strabismus, and the less common cause is anisometropia (refraction difference between two eyes). It may also be caused by a combination of strabismus, anisometropia, or visual deprivation (5). Although the pathophysiology of amblyopia is not fully known, regardless of the type of amblyopia, many ophthalmologists have recommended that its treatment should be started as soon as possible (6). Improvement of vision after treatment has a good probability of success only at the age of less than 6 years.

In studies conducted in Iranian universities, the prevalence of amblyopia has been reported between 1.03 and 1.2 (7, 8). With the prevalence of this amount of eye laziness and the importance of its treatment, the need for a database to record the information about this disease is felt, and today hospital management information systems are considered one of these tools in the health sector (9). On the one hand, the need for these systems has raised due to the increasing complexity of processes and information in the health field, and on the other hand, their supply has been combined with significant diversity and innovations (10, 11).

In recent years, investment and implementation of information technology application plans in the health sector have been the main priorities of advanced countries (9, 12, 13), and this importance has also been emphasized by the World Health Organization (WHO) (14). It can be concluded that treatment and follow-up of any disease require storage and retrieval of information (15), so the use of efficient information systems to improve the efficiency, effectiveness, and quality of services and customer satisfaction is an undeniable necessity (16–19). One way to access information in the best possible way is to use an Electronic Health Record (EHR). The EHR is an important tool for providing high-quality care through the sharing of health information. The benefits of EHR increase when patient-recorded information is available and used by all those involved in patient care (20, 21). Healthcare providers electronically record, verify, and share patients' information in the EHR system. The important administrative clinical data pertinent to the patient's care under a specific provider is included in this system. This data includes demographics, progress notes, problems, medications, vital signs, past medical history, vaccinations, laboratory results, radiology reports, genetic and phototype information, and more (21). Timely access to reliable information improves the quality of service delivery and treatment processes and speeds up decision-making, implementation of preventive activities, monitoring of the disease process, early detection of complications, and timely treatment (22, 23). Paper-oriented records are not reliable sources of health information due to their inherent limitations, such as handwriting errors, misspelled words, increased costs of printing, and the need for a large volume of folders, archives, and specialized manpower (24).

The design and use of a web-based EHR for patients leads to integrated data collection, prevention of information loss and dispersion, illegibility of written instructions, reduction of unnecessary actions, as well as improvement of workflow, efficiency, and reduction of medicinal costs (including reduction of medical errors, drug side effects, and so forth.) (24–27). Additionally, the use of EHRs is crucial for the treatment of illnesses, particularly those like amblyopia for which there is no known cure. This is because improved access to patient medical records allows medical staff to diagnose patients more accurately, leading to the provision of more appropriate treatment. They also avoid repeated and pointless tests and prescriptions and are informed about the patient's records by the physicians. The price of tests and medications can be greatly reduced by using EHR system. The use of digital and smart technologies has greatly advanced case design in recent years. A blockchain-based EHR system can be developed and validated as part of clinical projects. The purpose of such systems is to enhance medical record storage and enable provider-to-provider data sharing. They also aimed to reduce environmental uncertainty (28).

Healthcare professionals are primarily responsible for compiling data within an EHR, and only specialists have exclusive access. Furthermore, it is important to note that only a single healthcare practitioner has the capability to furnish information for an EHR. A novel software application, referred to as a Centralized Electronic Medical Record System (CEMRS), has been developed. The primary objective of this program is to offer a comprehensive and secure EHR system, facilitating healthcare providers access to patient medical records at any given time and from any location (29). Effective, efficient and satisfactory use of the system to perform assigned tasks is called EHR usability (30). Studies indicate that the use of EHR systems will be associated with the poor ability of adverse results in the provision of health services, including low participation, job dissatisfaction, medication errors, mortality, and readmission (30). Increasing safety, appropriately managing patients, and enhancing cognitive function are all correlated with better system usability (31–33). The usability and beneficial implementation of the product in the complex and real-world clinical environment are fostered by the user-centered design process of the EHR and the evaluation of system usability during design and implementation (34). It has been suggested that ways to improve the system's added value and make the EHR more user-friendly include standardizing notes, employing reminders in place of memory, creating a dashboard to track patients' treatment progress and connect relevant data, and automatically computing information (35). Considering that so far, no research has been done in Iran to design and evaluate a web-based EHR for amblyopia, the researchers in this study aimed to design and evaluate this system in Farabi Hospital of Tehran University of Medical Sciences to provide quality services, prevent the progression of this disease and introduce an important resource for education and research.

2 Materials and methods

The current investigation is classified as an applied-developmental study that was conducted in two distinct stages. The initial phase encompassed the actual design of the web-based EHR using the extracted Minimum Data Set (MDS). Determining the MDS needed to design the web-based EHR is performed in the previous work of

the authors (36). The second phase entailed evaluating the effectiveness and functionality of the designed web-based EHR for amblyopia. The principal two phases of this research are presented in the following:

2.1 Designing the web-based EHR

By studying the clinical records of patients with amblyopia in Farabi Hospital and related articles, software, systems, and electronic records, a web-based EHR for patients with amblyopia was designed. Samples were taken from the Amblyopia Clinic of Farabi Hospital. The main elements to be completed in the EHR were identified in the previous study (36). The design of the electronic version proceeded in a cascading manner so that after the design of each part, it was presented to the amblyopia experts, and if approved, the next part was designed. Corrections were applied to the electronic version of the system. In the design phase of the web-based EHR for amblyopia patients, MS SQL Server software, ASP.NET MVC web programming language, and C# basic programming language were used to design the database tables and manage the system database. HTML5, JQuery, and CSS technologies were also used to design the appearance and appeal of the pages. Entity Framework was used for database connections, and IIS Virtual Server was utilized for setting up, running, and testing the system. Also, since the EHR for patients with amblyopia was designed to be web-based, there was a need for the researcher to purchase a dedicated domain from hosting companies.

2.2 Evaluating the web-based EHR

A descriptive-analytical study was used in the evaluation phase. The research population during the evaluation phase included the amblyopia experts and the fellowships, residents, and nurses of the Amblyopia Clinic of Farabi Hospital, whose opinions were used through a questionnaire. At this stage, a strategy similar to experimental conversion was applied, and the EHR was used experimentally in the Amblyopia Clinic of Farabi Hospital. A Morgan table was used for sampling and 150 records without defects were selected from 1,500 records by a simple random sampling approach. Then, the information of patients with amblyopia was entered into the web-based EHR and its software and outputs were evaluated. The QUIS standard questionnaire was used to assess the system's usability. In other studies, the reliability and face validity of the Persian questionnaire have been confirmed. This questionnaire was customized by the research team in this work (37, 38). Notably, we adjusted the items of the chosen standard questionnaire to increase the cooperation of the recruited physicians (See Supplementary Appendix Table A1). This modified questionnaire consists of 18 questions in five sections. The first section includes five questions related to the general use of the system; the second section, with three questions, is related to the display screen; and the third section, with three questions, is related to the system terminology and information. The fourth section, with four questions, is related to EHR learning capability, and the fifth section, with three questions, is related to the overall capabilities of the EHR. To answer the question, five options—very good, good, average, bad, and very bad—are considered. The sampling method was a census, and there are 20 ophthalmology residents, fellowships, specialists (professors), and nurses of the Amblyopia Clinic of Farabi Hospital who are included in the sample of this research. After distributing 20 questionnaires among the research community, their responses to the questionnaire and the results of the questionnaire were analyzed. The participants who took part in this evaluation included four amblyopia specialists, three fellowships, seven ophthalmology residents, and six nurses working at Farabi Hospital.

3 Results

To answer the question of designing and evaluating a web-based EHR for amblyopia and achieving the research objectives, the findings were divided into four main parts:

3.1 Database table design

In this step, according to the findings of the first step (determining the MDS required to design the electronic record of amblyopia patients on the web), the fields of the electronic record database tables were determined. The distribution of table fields was done according to the needs of system users and the existence of connections between fields. The desired tables include the patient information table, the attached record information table, the examination information table, the site member information table, the role definition table, and the role assignment table for members. An example of a patient information table is shown in Figure 1.

3.2 Final design with related codes

At this stage, according to the amblyopia EHR data elements, the data of physician and patient, examinations, website members, and members' roles were determined. After defining the fields and classes that explain the tables, the database was created. The "Entity Framework Code First" was used to create and work with the database in this project. In this method, tables are defined as classes and then a database can be created and manipulated by creating a context class. Each table in the database requires a class, and these classes are located in the model folder in the Doctor Model section. The first class was the patients' table creation class. In this class, the table fields were defined as properties, and since each patient could have multiple examinations, the relationship between this class and the examination class was defined as Virtual & ICollection. The examination class contained the data of examinations performed by physicians. This table had a one-to-one ratio with the patient and physician tables and a one-to-many ratio with the attachments table. The next class was the physician class, which is used to store the information of website users. To determine the table's primary key, the Annoticate was used as the key. The examination field was expressed as a set. This means that each physician is able to register several examinations in own name. Attachments are also recorded in the attachments table, the definition class of which is as follows:

The first part of the codes of the site pages will examine the pages related to membership and the entry and exit of site members. In the previous section, a separate class was defined for each of the database tables. These classes were only useful for creating the database and

	Name	Data Type	Allow Nulls
🔑	Id	int	☐
	Name	nvarchar(50)	☑
	LastName	nvarchar(50)	☑
	FatherName	nvarchar(MAX)	☑
	National	nvarchar(MAX)	☑
	Age	int	☑
	Gender	int	☑
	BirthDate	datetime	☐
	Acceptance_Number	int	☐
	Home_Address	nvarchar(MAX)	☑
	Phone_Number	nvarchar(MAX)	☑
	NextExamDate	datetime2(7)	☑
	Register_User_Id	int	☐
	Doctor_Id	int	☑
	RegisterDate	datetime	☐

FIGURE 1
Patient information table.

Pseudo code for the class definition

```
[Table ("Attachment")]
Public partial class Attachment
[Key, DatabaseGenerated (DatabaseGeneratedOption.Identity)]
Public int f_id {get; set;}
Public string FileName {get; set;}
Public string date {get; set;}
Public string FilePath {get; set;}
Public int? Size {get; set;}
Public virtual Exam exam {get; set;}
```

accessing the fields of the database tables. Now the desired model classes must be rewritten. With this, error control can be placed on the fields of the Annoticate class. In the AccountViewModel class located in the Model folder, the desired class for the membership section is as follows:

3.3 User interface of designed EHR

By entering the address http://ambly.hisapps.ir, you can access the electronic record of amblyopia patients on the web. By entering this address, the first page viewed is the login page, which can be seen in the middle of the main page, with the password and password sections. If a password and username have already been defined for the user, he can access the electronic record by entering them (Figure 2).

The program menu is in the form of a black bar in the Persian part on the right side and in the English part on the left side, which includes sections such as physicians, patient lists, new patient registration, user and management, which includes all users and creating a new user, clinical information, sensory tests, physicians' prescriptions, treatment plans, reports, and charts.

In the search section, you can access the history of the disease, the history of eye diseases, the history of drug use, the history of eye surgery, the patient's main complaint, the time of the disease's onset, and the causes of the disease. The section on visual examinations includes examinations with glasses, examinations without glasses, refraction of the eye with eye drops, and refraction of the eye without eye drops for both eyes, in which the eye score can be selected. The next part is the type and pattern of strabismus, which are determined after eye examinations. By specifying the following, the registration option is selected at the end and a record is created for the patient. The deviation of the eye is determined by the physician and information about the type of deviation in the patient's eye is recorded and maintained. The treatment plan includes items such as determining surgery along with muscle type, closing the eyes (patching), eye exercises, prescribing glasses, and prescribed drugs, which are added to the patient's record after registration. In the reports section, the number of treated patients by attending physician, the referral date and patient's gender can be obtained. Finally, the patient's eye photos are stored in the EHR and the physician presents treatment plan according to the patient's issues (Figure 3).

3.4 Evaluation of the web-based EHR

After designing and programming the system, the usability and user satisfaction of the EHR were evaluated with the experimental conversion strategy. Table 1 shows the demographic information of the research community. The frequency distribution of the participant's answers to the questions in each section is presented in separate figures. As seen in Figure 4, most of the evaluators' comments on working with EHR were very good or good. Several physicians suggested some corrections to the latest version of the system. The second section of the questionnaire to evaluate the usability of the EHR was related to the screen capabilities of the EHR on the web of amblyopia patients, and the frequency distribution of the responses of amblyopia specialists, fellowships, residents, and nurses is presented in Figure 5. The views of subspecialty physicians, fellowships, residents, and nurses of the strabismus clinic on

Pseudo code for the registration page

```
public class RegisterViewModel
    {
        [Required]
        [Display(Name = "UserName")]
        public string UserName {get; set;}

        [Required]
        [StringLength(100, ErrorMessage = "The {0} must be at least {2} characters long.", MinimumLength = 6)]
        [DataType(DataType.Password)]
        [Display(Name = "Password")]
        public string Password {get; set;}

        [DataType(DataType.Password)]
        [Display(Name = "Confirm password")]
        [Compare("Password", ErrorMessage = "The password and confirmation password do not match.")]
        public string ConfirmPassword {get; set;}
        public string Name {get; set;}
        public string Family {get; set;}
```

the terminology and information used in the web-based EHR for amblyopia are shown in Figure 6. The fourth section of the questionnaire was related to assessing EHR learning ability. Participants evaluated the usability of web-based EHR for amblyopia as very easy and efficient and finally considered it an effective tool in integrating patient information and helping to improve patient's condition.

The fifth section of the questionnaire is related to the general capabilities of the EHR and users evaluated the general capabilities of the system as very easy and efficient. The analysis of the data obtained from the questionnaire showed that the research community answered all the questions with "good" and "very good" options, and the web-based EHR for amblyopia was fully approved by the experts of the Amblyopia Clinic (Figure 7).

4 Discussion

In developing countries like Iran, we still face problems using EHR, and patients' records are paper-based. Since accurate recording of patients' information in medical records is one of the minimum requirements for providing high-quality treatment, the main goal was to design and evaluate an electronic health record for patients with amblyopia. To achieve this goal, at first, we determined the MDS, defined data characteristics in the data dictionary, defined the type and number of characters, and created structured forms for data entry that can improve the exchange of information and the quality of clinical care (36); in the following step, the designed web-based EHR is evaluated for its usability. In the present study, the web-based EHR of amblyopia patients was developed using the ASP.NET programming language and the new Visual Basic database SLOcalDB (SQL Server 2014 Express). To use the EHR, the admin of the web-based EHR defines the users in the program and provides them with a username and password, and physicians can access the EHR on the web in real time. In the web-based EHR for patients who visit the clinic for the first time, there is a page where all the patient's demographic information, surgical records, drug use, family diseases, eye diseases, the patient's main complaint, and the date of the patient's first examination are recorded. After that, the examination of the patient is done according to the entered items in the EHR. Finally, the images of the patient's eyes are stored in the EHR and the physician presents a treatment plan according to all the patient's issues. This EHR had an easy and user-friendly interface, and users were able to easily enter the patient's demographic and clinical information and ophthalmic images into the EHR and view this information in an integrated manner.

Updating information in the healthcare environment or settings has been possible through advanced information technology to enable continuous quality improvement in complex areas. Therefore, information can be stored, processed, searched for, and retrieved in healthcare organizations with the help of web technology (39).

Scientifically speaking, both structured and unstructured data are typically present in EHRs. Many statistical techniques can be applied with relative ease to structured data processing. Nevertheless, structured data by itself does not offer all of the details regarding the entire clinical context. On the other hand, unstructured data can offer additional, useful information, but the analytics procedures involved in using it are laborious, time-consuming, and involve a lot of manual labor. Effective use of both structured and unstructured data is necessary for a well-designed diagnosis and decision-support tool to extract valuable information and produce better results. The benefits of combining structured and unstructured data have been demonstrated by numerous studies (40). During the process of data integration and reconstruction in the EHR systems, combining structured and unstructured data can be done early or late (41).

In the present study, a web-based EHR for amblyopia was designed using the ASP.NET programming language, and a SQL Server database was also used to enable physicians and users to obtain a username and password to access the EHR. In line with

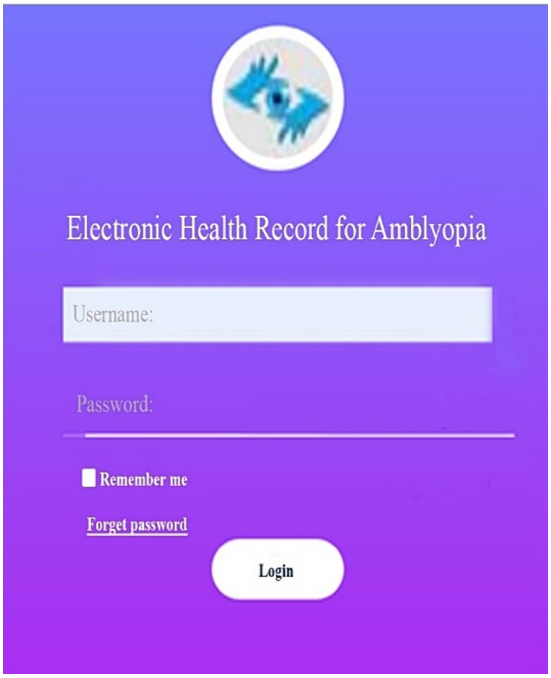

FIGURE 2
The login page.

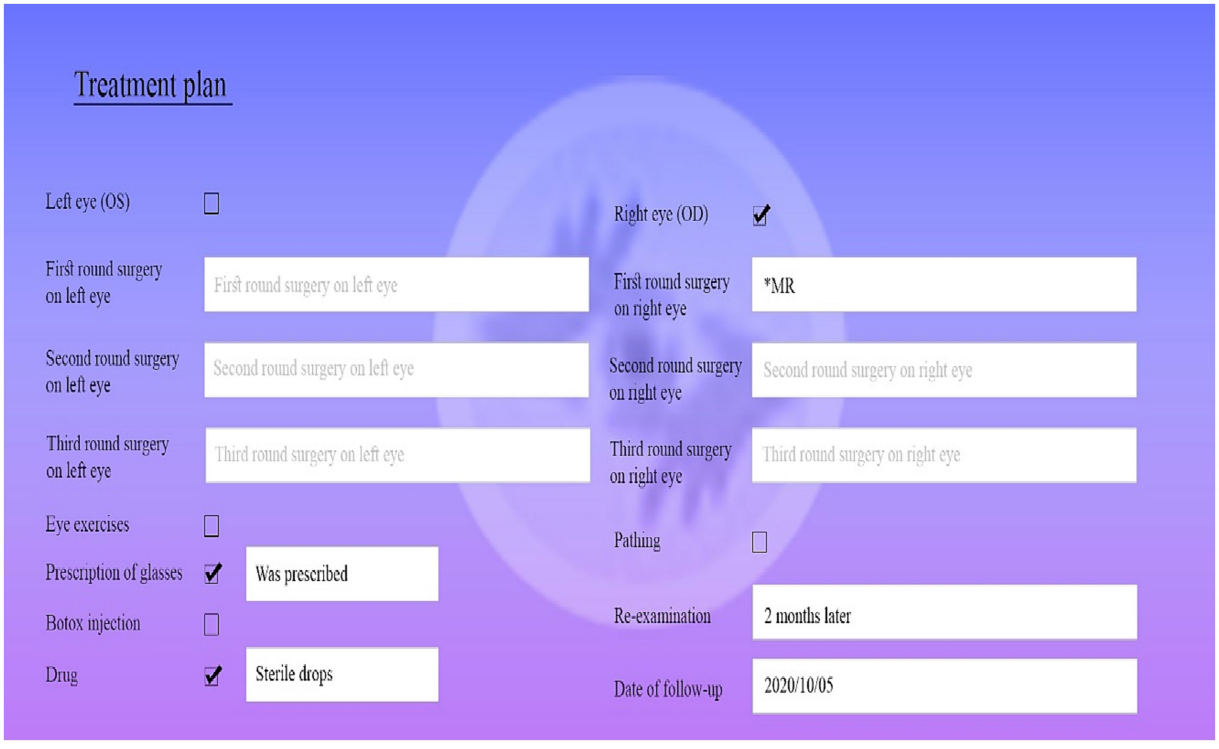

FIGURE 3
The page of treatment plan.

our study, in the study of Ibrahim et al., the web-based ASP.NET framework was used to provide a data exchange model for patients' records to reduce patients' time and cost and enable physicians to obtain up-to-date and accurate information from patients' records (39). In the study of Lee et al., ASP.NET was used to set up a platform for displaying, transferring data, accepting databases,

TABLE 1 Frequency distribution of demographic information of participants in the study.

Demographic information		Frequency	Percentage
Gender	Female	5	25%
	Male	15	75%
Scientific ranking	Subspecialty physician	4	20%
	Fellowship	3	15%
	Resident	7	35%
	Nurse	6	30%
Work history	Under 5 years	9	45%
	5–10 years	3	15%
	10–15 years	4	20%
	15 years and over	4	20%

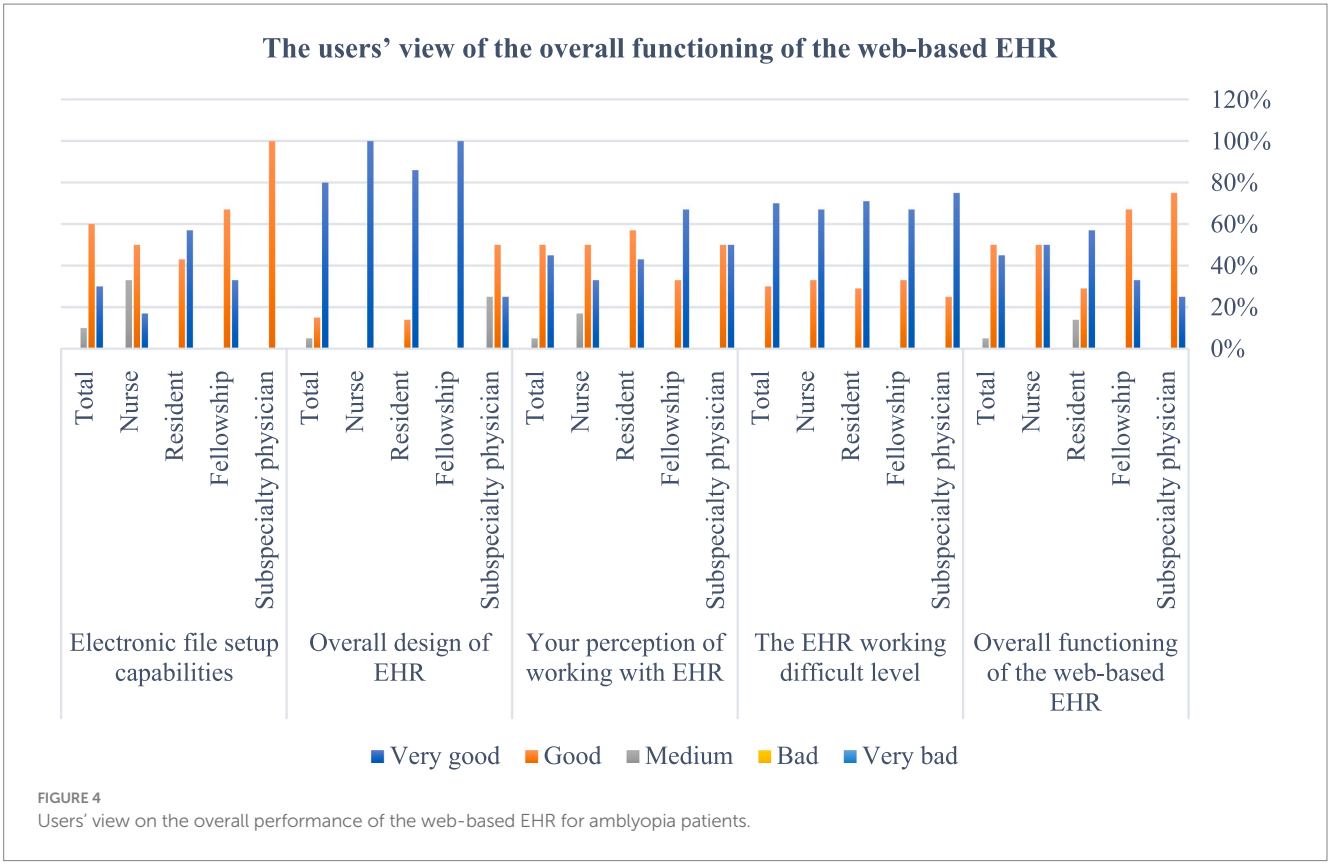

FIGURE 4
Users' view on the overall performance of the web-based EHR for amblyopia patients.

and converting personal health record formats (42). Studies have shown that web-based EHRs allow access to and exchange of information such as patient name, history, illness, physical examination, health assessment, patient condition, quality of life, and patient care (43). Therefore, due to the web-based nature of the program and the features of the ASP.NET programming language, this language was optimal to develop a web-based EHR for amblyopia.

A large amount of heterogeneous data has posed a huge challenge to evidence-based decision-making. The use of data warehouse technology is an effective solution for aggregating and analyzing different health data. In the study of Nero et al., a data warehouse was created to investigate various factors affecting obesity. In this study, SQL Server was used to generate reports in appropriate formats to extract, convert, and load data. Analysis of health data can identify unknown links between different types of health factors and also evaluate the effectiveness of different medical methods using new data mining techniques (44).

In the present study, the SQL Server program was used to create the database and Visual Studio software was used to design the EHR. John Beazley acknowledged that the most important factor in designing an EHR is to pay attention to the user interface because it is the first place that the users encounter, and the second factor is how the users use the EHR (45). In the current study, however, the user interface was created by the researcher multiple times on paper and then presented to the users for feedback and necessary adjustments. Ultimately, the evaluation findings demonstrated that the majority of users rated the user interface as "very good" or "good." In the area of

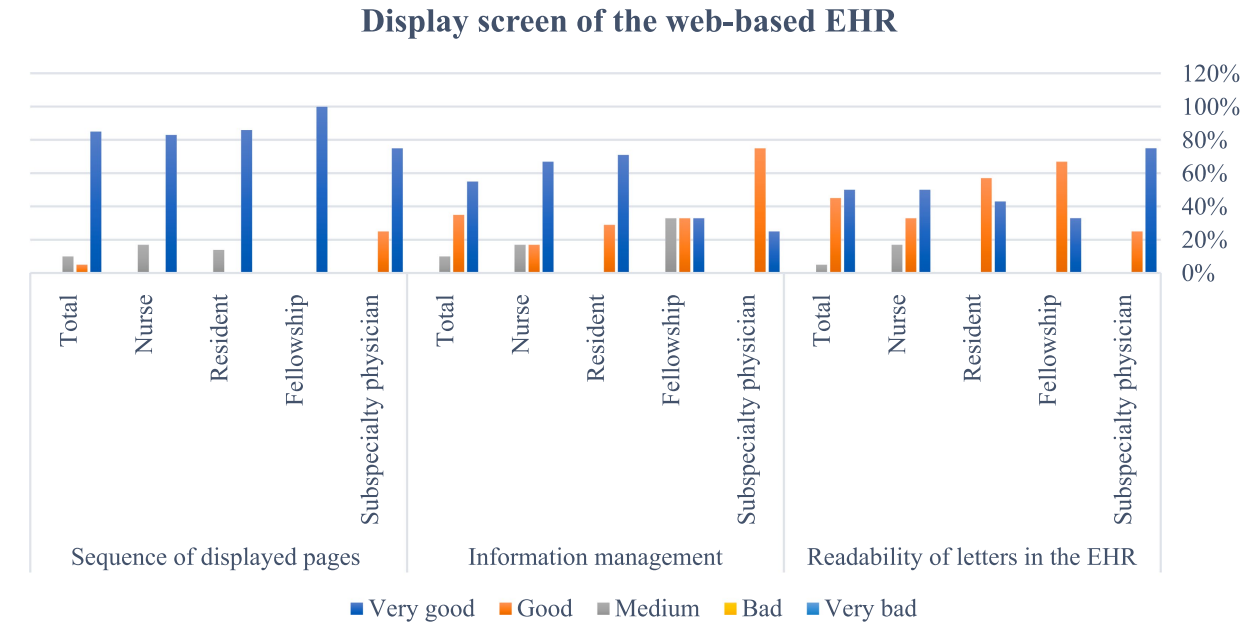

FIGURE 5
Users' view on the display screen of web-based EHR.

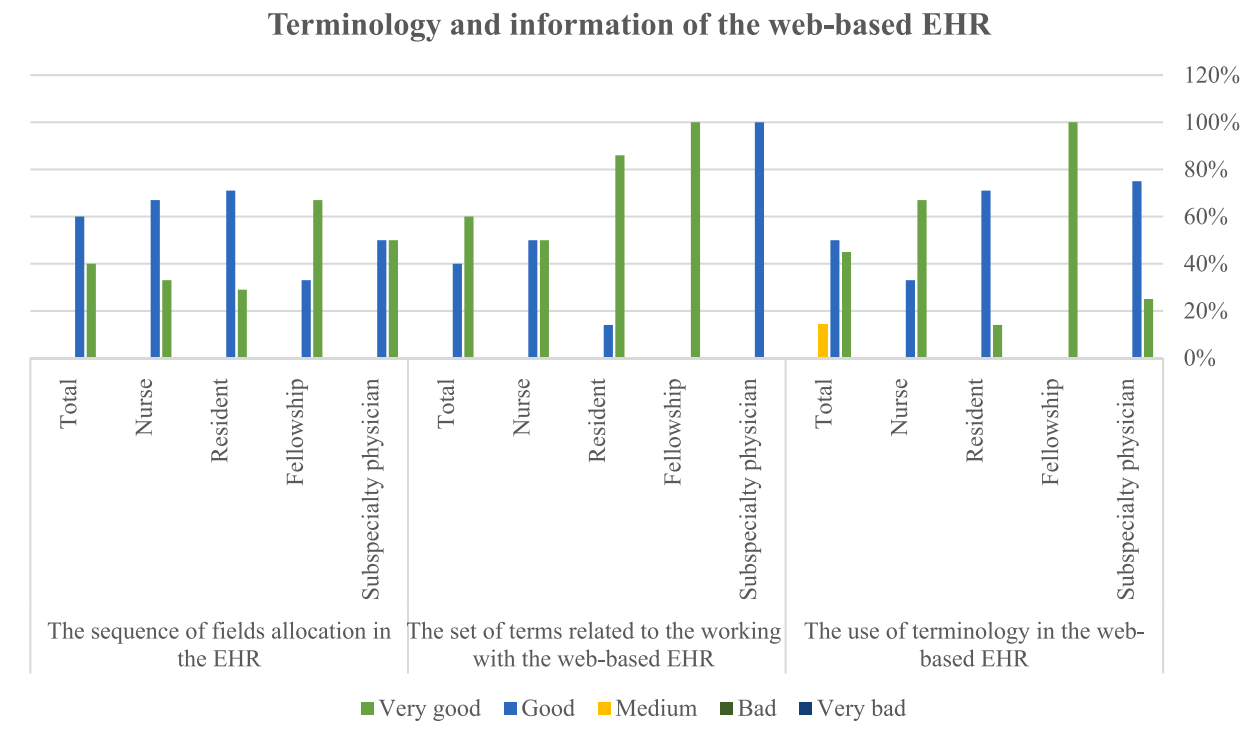

FIGURE 6
Users' view on the terminology and information used in the web-based EHR for amblyopia patients.

applied, scientific, and repeatable evaluation of various stages of EHR system development, not many high-quality studies have been published. The usability of an EHR is influenced by a number of factors, such as personnel, workflow, hardware, software, organizational culture, and communication (34). Lack of formal and standard reporting of usability assessment is the main cause of knowledge gap (46). Large number of usability problems can affect effectiveness, efficiency, user satisfaction and patient safety (47). According to Joukes, the expectations and attitudes of end users during the implementation of EHR should be examined by surveys and questionnaires. The EHR usability, EHR alignment with work processes, in-service and post-implementation support, EHR training,

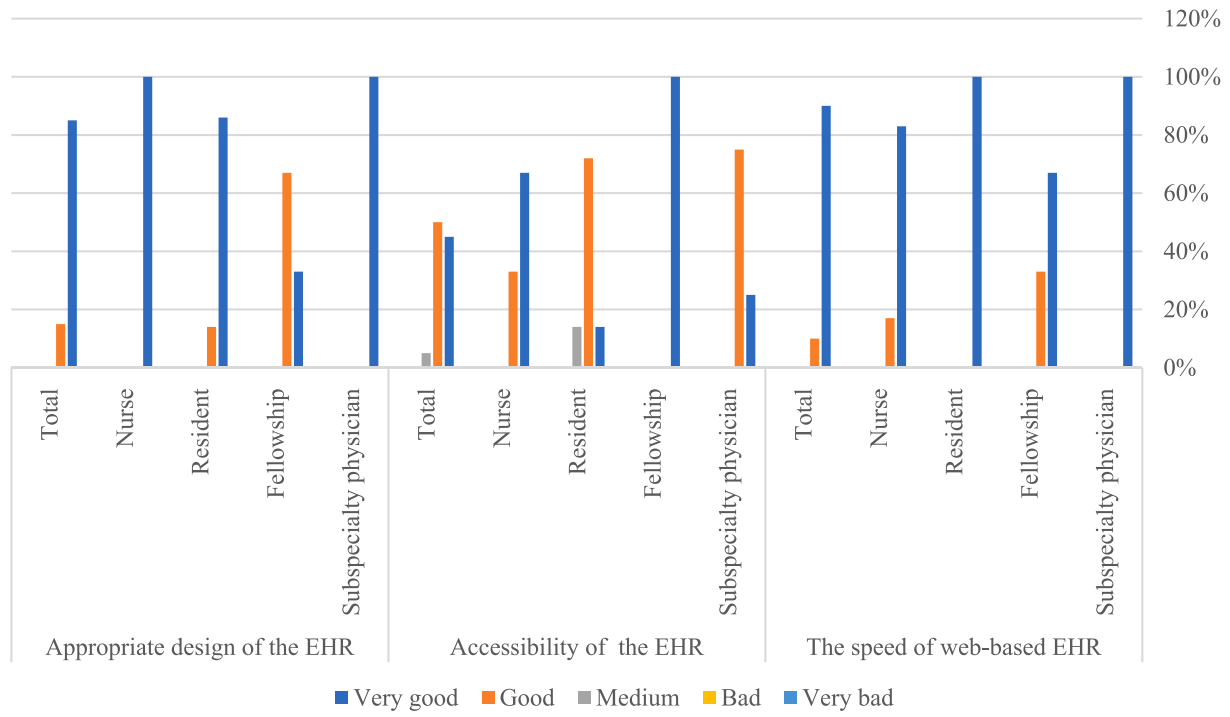

FIGURE 7
Users' view on the overall capabilities of the web-based EHR for amblyopia.

and use of other centers' experiences are among the important factors in EHR success (48).

A think-loud approach was used to evaluate the functionality of the HER; in this method, the EHR was provided to the users and while working with it, they expressed their opinions, and the researcher wrote down the appropriate comments and applied them to the final version. A study by Eric et al. examined the attitudes of ophthalmologists at the University of Michigan after the implementation of the EHR system. The survey questions focused on satisfaction, efficiency, and documentation of the EHR. Ophthalmologists commented on their ability to produce high-quality documents and the impact of EHR on patient interaction. They also did not report a significant change in documentation time or clinic efficiency. The results of this study determined the physicians' areas of interest, the need for physician training, and the customization of EHR software and implementation (49). In the present study, in order to evaluate the EHR, a questionnaire was distributed among the research community and the analysis of participants' responses showed that all participants approved the system. The participation of end users in the process of preparation and implementation of EHR helps to meet the needs of users, create a sense of ownership of participation in the project and accept the system (10). Therefore, in the present study, from the stage of determining the minimum required data to the stage of designing and evaluating the system, the opinions of the end users were examined and applied to the project. It is obvious that customizable EHR with an emphasis on users' needs will be effective in improving patient safety. The use of technology in healthcare in the form of EHRs is considered the most important and necessary issue to foster the quality of healthcare and research has shown that it is not only a method for integrating information and representing the condition of patients and a dynamic source for health care, but also leading to access to information and clinical records, educational electronic communication and comprehensive management and ultimately improving the level of public health.

4.1 Strengths and limitations

The strength of our study is the survey of clinical records of patients with amblyopia in Farabi Hospital in the first stage to identify the information elements of the EHR, which led to the generalization of our work. It is noteworthy that surveys of records were conducted in one of the country's most advanced ophthalmology centers. This study has ethical approval number IR.TUMS.SPH.REC.1398. 290 is from Tehran University of Medical Sciences and owns the registered data of Farabi Hospital in Tehran.

This study has several limitations. The evaluation of the system was conducted at Farabi Hospital with 20 ophthalmology assistants, fellowships, and specialists (professors). Overall, the study was performed in a single center with a limited number of healthcare providers. Using this system on a larger scale requires more investigations, identifying challenges, and providing solutions. Specifically, this study focused on designing a web-based EHR and evaluating its usability by healthcare professionals. The EHR was only available to users of the amblyopia department of Farabi Hospital in Tehran and was not available to all service providers. Therefore, consent was not obtained from patients to store their data on a

web-based platform. End-user concerns about data security and patient and physician privacy have not been addressed about the features of the designed EHR.

Another obstacle of the study is not examining the effect of the EHR of amblyopia on the workload and fatigue levels of end users. Considering its effect on the efficiency, productivity, acceptance, and success of the system, it is necessary to study the impact of the designed system on the workload of end users and propose re-engineering of the work. It is suggested to investigate the interventional evaluation of the usability, such as designing a dashboard to observe the patient's treatment process and link related data, using reminders instead of relying on memory, standardizing notes of the amblyopia EHR system and its impact on the workload and cognitive performance of doctors in future studies.

5 Conclusion

By and large, to quickly access patients' information, eliminate the shortcomings of paper records, and improve the quality of health services, the need for a web-based EHR for patients with amblyopia is evident. EHR is one of the most important tools for monitoring the disease process and integrating and improving the information management of patients with amblyopia. The use of a web-based EHR, in addition to facilitating access to patients' information, makes it possible to retrieve the required information to reduce and facilitate the control of amblyopia complications. The designed system has high capabilities and users can easily record and store patient information in the system. It is suggested that the web-based EHR for amblyopia patients be upgraded by designing a mobile phone educational application for amblyopia patients. The design and implementation of a management dashboard for required reports and statistics are also suggested. Furthermore, the design of EHR for other eye diseases, such as diabetic retinopathy and congenital orbital diseases, as well as self-care applications for eye diseases and remote ophthalmic systems for chronic eye diseases like amblyopia are suggested for future research.

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 authors.

Ethics statement

The studies involving human participants were reviewed and approved by the Ethics committee of Tehran University of Medical Sciences (Ethics approval number: IR.TUMS.SPH.REC.1398.290). Verbal informed consent was obtained from the participants or legal guardians to participate in this study.

Author contributions

RN: Data curation, Investigation, Writing – original draft, Writing – review & editing. MA: Conceptualization, Data curation, Investigation, Methodology, Software, Validation, Writing – original draft, Writing – review & editing. ME: Conceptualization, Data curation, Writing – original draft. LS: Conceptualization, Data curation, Investigation, Methodology, Writing – original draft. BM: Conceptualization, Data curation, Methodology, Supervision, Writing – review & editing. SR: Conceptualization, Investigation, 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/fmed.2024.1322821/full#supplementary-material

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Sustainable integration of digitalisation in nursing education—an international scoping review

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Introduction: Trainees and teachers at nursing schools as well as nursing professionals are increasingly facing new challenges as a result of the digital transformation. Opportunities for the entire care system exist in the improvement of care quality and communication between those involved. However, this change also harbours risks, such as the use of immature digital applications in the care sector, data theft and industrial espionage. In order to be able to exploit the potential of digitalisation despite these risks, it is necessary to integrate relevant aspects such as digital skills into nursing training. The aim of this study is to investigate the extent to which the sustainable integration of digitalisation in nursing education is discussed.
Methods: The methods of the systematic literature and database search were carried out in the form of a scoping review according to the PRISMA scheme. The PubMed and CINAHL databases were used for this purpose. The search period covered the years 2017–2023.
Findings: After screening the titles and abstracts using inclusion and exclusion criteria, 13 studies were included in the synthesis of findings. The international literature focuses on content areas that highlight trends in digitalisation-related training in nursing. These focal points include concept development, considering the heterogeneity of demand constellations, as well as the reflexive reorientation of existing competences, whereby the technological competence of teachers is not disregarded. Other focal points relate to the initiation of digital skills in training and maintaining the employability of older nursing staff through professional development.
Discussion: The literature research shows that there is a rudimentary discussion about digitalisation and curricular developments in nursing training in an international context, while the discourse in the German-language literature is less advanced. Among the sustainability desiderata derived from the literature is the involvement of nursing professionals in the development, testing and implementation of digital technologies. Only through active cooperation between nursing professionals and nursing sciences can the topic of digitalisation be integrated into the education and training of professional nursing in a targeted and future-oriented manner, whereby the focus should always be on the ability to deal with digital technologies and the associated change.

KEYWORDS

digitalisation, professional care, education, digital competencies, sustainability—nachhaltigkeit

Introduction

Health and healthcare systems around the world are undergoing change as a result of advancing digitalisation (1). Digital innovations in the healthcare system can make a decisive contribution to improving healthcare. In an international comparison, Germany is only making insufficient use of this digitalisation potential (1). Referring to a study by the Bertelsmann Foundation, it shows that many other European and Western countries are significantly more advanced in the application and use of digital applications in areas such as healthcare. The challenges in the context of digitalisation include not only compliance with data protection requirements, but also the availability and further development of digital skills and an overview of the variety of different technologies and approaches. With a view to the future challenges in professional care, the integration of digital possibilities into training is becoming increasingly important. Digitalisation offers the opportunity to make the care process more efficient by facilitating access to relevant information and optimising administrative processes (2). It also improves patient care by offering precise and individualised care, which also reduces the diverse workload of nursing staff (ibid.). Finally, there is a need to promote data-driven research and innovation in nursing science in conjunction with the potential of digitalisation, which in turn can lead to more advanced nursing practices and methods (3).

New technologies in nursing are discussed in numerous publications. However, the approaches to digitalisation in nursing vary widely, digital tools operate at different levels, and a current structured classification of development and digitalisation in nursing is hardly possible. A large part of publications deals with robotics and robotic systems (4, 5). The research literature reports on the use of service and logistics robotics in care contexts, social robotics, assistance robotics, mobilization robotics (4–7). Furthermore, the use of artificial intelligence in nursing is discussed (8). This can help improve the organisations of patient processes and treatment plans and/or provide all relevant information that physicians and nurses need to make correct decisions and/or help with repetitive or routine care tasks or medication management (3, 9). Other digital developments are being researched in the context of information and communication technologies, including projects such as telemedicine, telehealth, telenursing, computer-assisted documentation, or specific apps to support people with dementia (e.g., for cognitive stimulation) (2, 10, 11). Various publications also test digital monitoring and sensor technologies for behavioral analysis, fall and pressure ulcer prevention, or measurement of vital signs, etc. (12).

Opportunities for the entire healthcare system exist in the improvement of the quality of care as well as the communication between the stakeholders. However, this change also entails risks, such as the use of immature digital applications in the care sector as well as dealing with cyber attacks, data theft, and industrial espionage, which require an awareness of the sensitive data infrastructure. In order to exploit the potential of digitalisation despite these risks, it is necessary to integrate corresponding aspects into nursing training. The competencies and expertise of nurses in the use of digital technologies are therefore of central importance in order to integrate the roles, relationships, and responsibilities of all professional and personal groups involved in health care as well as ethical and professional dilemmas (13). As a result, nursing professionals need to acquire digital competencies in order to appropriately apply new digital tools in health care. Along with other basic skills such as reading, arithmetic, and writing, the European Union defines digital literacy as one of the eight key competencies for lifelong learning (14). According to Ferrari (15), digital literacy includes: knowledge, skills, and attitudes that enable people to use information and communication technologies and digital media to complete tasks, solve problems, communicate, manage information, create and share content, and thus create a knowledge base and use it appropriately, effectively, creatively, and at the same time critically, autonomously, and ethically. International studies (16, 17), among others, emphasize teachers' technology acceptance in educational contexts. The focus should be on both the use of technology in teaching and the inculcation of critical reflective competence in nursing practice.

The aim of this article is to evaluate the discourse on the sustainable integration of digitalisation for nursing education in the field of nursing science. In doing so, possible connections, obstacles and perspectives resulting from the integration of digitalisation into nursing education, especially with regard to sustainability aspects, will be examined in detail. The primary research question aims to determine to what extent and in what form sustainable integration of digitalisation for nursing education becomes a topic in nursing science. In addition, the article aims to identify key areas that arise from these discussions and that may have implications for initial, continuing and further training in nursing as well as for nursing research.

Methodology

The systematic literature and database search methodology followed the PRISMA scoping review process (18). The National Library of Medicine PubMed and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases were used for the search. Another hand search was conducted in the Educational Resources Information Center (ERIC) journal database, the Fachinformationssystem Bildung (FIS Bildung) [Specialised information system for education] of the Fachportal Pädagogik, the funding database of the German Research Foundation (GEPRIS), and the Federal Ministry of Health in Germany. A supplemental search was conducted using Google Scholar.

The database search was conducted in the period from March to April 2023. Various search strategies were implemented using appropriate search terms and Boolean operators. German terms and their English equivalents were used, with the terms occasionally shortened:

(Pflegewissenschaft OR nursing science) AND (Pflege OR nursing) AND (Digitalisierung OR digitalisation) AND

(Nachhaltigkeit OR sustainability) AND (Vorteile OR advantages) AND (Nachteile OR disadvantages).

Studies from 2017 to 2023 were included and used flexibly according to the filtering capabilities of the databases to narrow down literature findings that were too large. The start of the search period in 2017 is based on the assumption that the research topics covered in the studies reflect the currently established use of digital technologies in care. This also justifies the lead time required for the published studies and meta-studies. The filters used were:

- set filters in PubMed: exclusion of preprints, studies in the period 2017–2023
- filters set in CINAHL: presence of abstracts, studies in the period 2017–2023

In the identification phase, 19,620 literature finds were organised in the PubMed and CINAHL databases and 931 literature finds were organised by hand searching additional sources using the Citavi 6 literature management and knowledge organisations program. A total of 20,551 sources were searched for duplicates using the program, and the duplicates were removed accordingly. This left us with 20,066 publications. A total of 152 publications were included in the preselection. The pre-selection from the 20,066 publications was made by reading the headings according to the predefined inclusion and exclusion criteria. In addition to the reference to the research question, studies that met the following criteria were included in the pre-selection (Table 1).

After completing the pre-selection, the included texts were thoroughly assessed for their relevance to the research questions and adherence to the inclusion and exclusion criteria. Studies were excluded if they were written in neither German nor English and fell under the exclusion criteria in Table 1. In order to accomplish this, the full texts were downloaded from the respective databases or publishers' websites. Initially, abstracts were reviewed if they were available, and if no abstract was available, a cursory reading of the full text was conducted. The second step was the detailed reading of the full texts. Out of the 152 literature records included in the pre-selection, 13 sources were ultimately included in the analysis (Figure 1).

Findings

A total of 13 studies were identified to answer the research question (Table 2). Of these, five were published in German and a further eight in English.

TABLE 1 Overview of the predefined inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Published language: • English or German	Published language: no English or German
Topics: • Reference to nursing • Reference to teachers at nursing colleges	Other topics: • no reference to nursing or nursing science • no relation to teachers at nursing colleges • focus on social media

The Study 1 by Bleijenbergh et al. (20) aims to define elements of digital adaptability for healthcare professionals. Through an exploratory Delphi study, they identified a total of 29 topics covering personal attributes, interpersonal attributes and ethical aspects. Given the rapid progress in eHealth, healthcare professionals are expected to keep pace with digital developments. The study provides a concrete list of elements that reflect the digital adaptability skills of healthcare professionals and helps to transform the abstract concept of digital adaptability into a more pragmatic concept. These topics on digital adaptive competence according to Bleijenbergh et al. (20) are presented in Table 3.

In Study 2 Brice and Almond (21) identified four topic areas, each containing three to four categories. The first topic area denotes change management with the categories of professionalism, education, professional standards, and non-technical skills. In the second topic area, "User Application", three categories (User Development, Holistic Care, Participation) were identified. The third topic area includes the categories of Technological Skills, Technological Competence, and Managing Technology. The fourth topic area includes the categories of Innovative Practice, Innovative Behavior, and Applied Innovation. Overall, the authors conclude that Professional Digital Competency Frameworks require refocusing on currently known skills and competencies rather than rewriting them. They combine this approach with a focus on the identified topic areas and avoiding a one-sided perspective on skills/competencies isolated from one another (ibid.). These aspects need to be viewed holistically as interconnected aspects (ibid.).

In the third study, Brown et al. (22) were able to identify the following overarching themes from the included literature of their integrative review based on Whittemore and Knafl (33): 1. expertise and competence on the user side, 2. patient-centered access to data, 3. nurse concerns, and 4. investment in implementation. The top theme 1 links the factors that relate to nurses' informatics expertise in their clinical practice and can be associated with competency development (ibid.). The improvement of digital competencies in nursing is already addressed in nursing studies and through continuing professional education and training. However, the latter is less likely compared to the educational situation in the degree program for nurses working close to patients (34), cited by (22). The authors link access to evidence, on the one hand, and access to electronic health documentation, on the other hand, to the superordinate theme 2 (ibid.). Access to evidence-based information and data in electronic form facilitates decision making in the clinical context due to easy as well as efficient access to information in patient-centered care (ibid.). This is also reflected in access to electronic health documentation, as (almost) paperless documentation increasingly accompanies care (ibid.). The third overarching theme points to the fact that the impact of digital technologies on clinical outcomes is a key driver for their inclusion in the repertoire of actions (ibid.). However, there are concerns among nurses about the time-consuming use of digital technologies, which could limit the amount of time available for patient-centered care (ibid.). At the same time, stress and

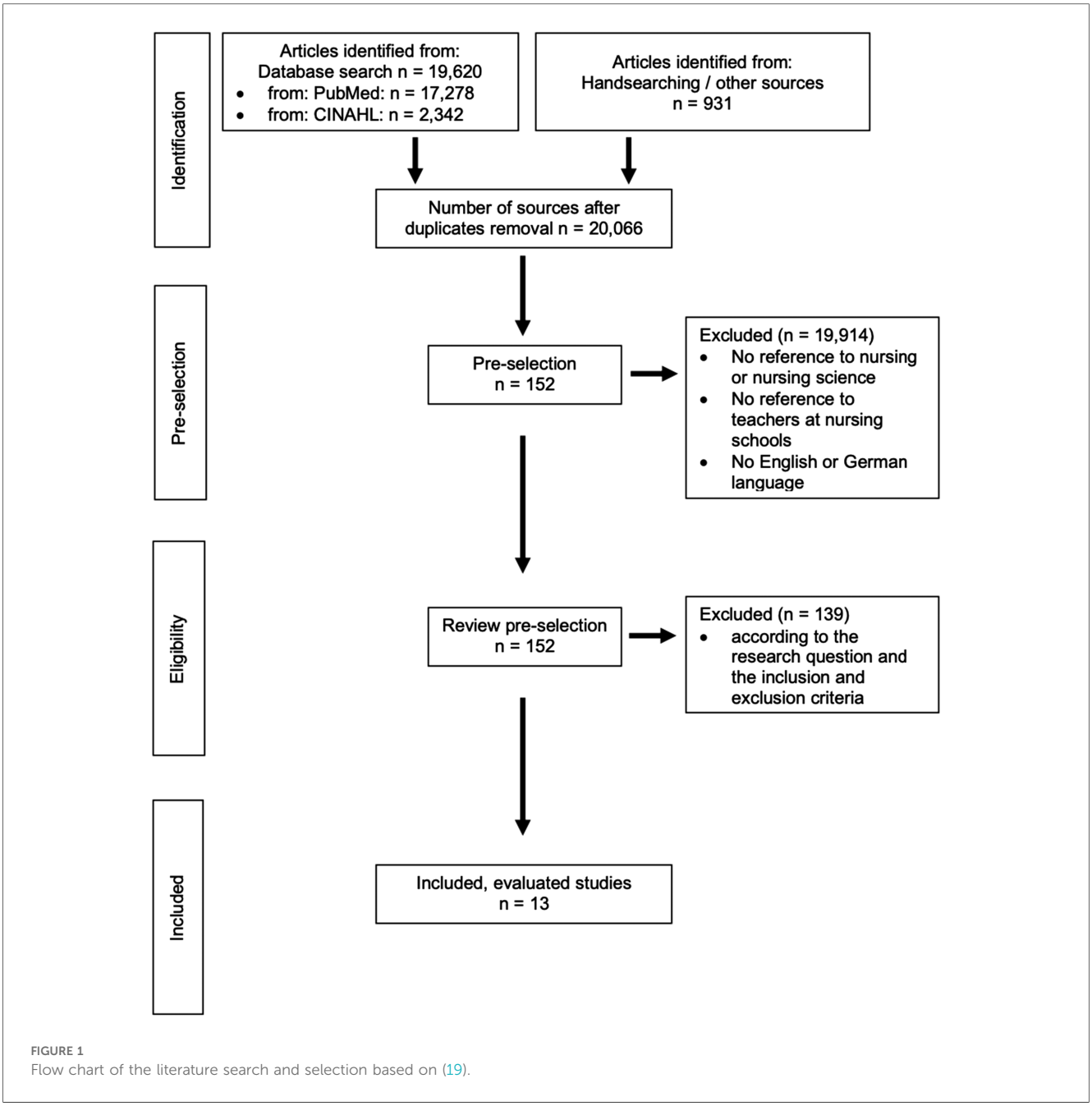

FIGURE 1
Flow chart of the literature search and selection based on (19).

frustration are also associated with the use of digital technologies or their functionality, especially when the technology has not served its purpose (ibid.). In this case, nurses would revert to analog paper-based solutions (ibid.). Top topic 4 elaborates on the existing discourse in the literature regarding implementation. This refers to the removal of barriers or issues that may stand in the way of implementation (ibid.). Overall, Brown et al. (22) elaborated implications for practice, policy, and education in linking the themes. In terms of practice, 1. allocating time for nurses to explore and use digital platforms in patient-centered care, 2. offering help and support services for nurses in the event of technical glitches and problems, 3. offering patient-centered access to evidence-based information as well as support in identifying appropriate clinical information, 4. broad use of electronic records and documents as a means to improve quality and safety of care (ibid.). The implications for policy are formulated by Brown et al. (22) as follows: 1. involving nursing leaders, nursing informaticists, and clinical nurses in the development of digital platforms and systems, 2. developing policies regarding patient confidentiality and privacy as well as other sensitive information, and 3. a thorough implementation strategy with commitment and an appropriate time corridor for implementation of new technologies. With regard to education, five implications are elaborated (ibid.): 1. incorporation of curricular content to build digital literacy already established in education, 2. continuous professional development to build and

TABLE 2 Overview of included literature.

Study 1	Bleijenbergh, R., Mestdagh, E., Timmermans, O., van Rompaey, B., Kuipers, Y. J., 2023. Digital adaptability competency for healthcare professionals: a modified explorative e-Delphi study. In: Nurse education in practice 67, S. 103563. DOI: 10.1016/j.nepr.2023.103563.
Study 2	Brice, S., Almond, H., 2020. Health Professional Digital Capabilities Frameworks: A Scoping Review. In: Journal of multidisciplinary healthcare 13, S. 1375–1390. DOI: 10.2147/JMDH.S269412.
Study 3	Brown, J., Pope, N., Bosco, A. M., Mason, J., Morgan, A., 2020. Issues affecting nurses' capability to use digital technology at work: An integrative review. In: Journal of clinical nursing 29 (15–16), S. 2801–2819. DOI: 10.1111/jocn.15321.
Study 4	Buhtz, C., Paulicke, D., Hofstetter, S., Jahn, P., 2020. Technikaffinität und Fortbildungsinteresse von Auszubildenden der Pflegefachberufe: eine Onlinebefragung [Affinity for technology and interest in continuing education among nursing trainees: an online survey]. In: HEILBERUFESCIENCE 11 (1/2), S. 3–12. DOI:10.1007/s16024-020-00337-5.
Study 5	Eiben, A., Mazzola, R., Hasseler, M., 2018. Digitalisierung in der wissenschaftlichen Weiterbildung im Bereich Gesundheit und Pflege. Herausforderungen und Chancen unter besonderer Berücksichtigung des Blended Learning Formates [Digitalisations in Continuing Academic Education in Health and Care. Challenges and opportunities with special consideration of the blended learning format]. In: Zeitschrift Hochschule und Weiterbildung (1), S. 31–37. DOI: 10.4119/zhwb-240.
Study 6	Evans, M., Kemper, J., Kucharski, A., Seyda, S., Hickmann, H., Pierenkemper, S., 2022. Gestaltungspfade und Gestaltungspraxis der Digitalisierung in der Altenpflege in NRW [Design paths and design practice of digitalisations in geriatric care in NRW]. Cologne (IW-Report. 2022,15). Online available at: https://ideas.repec.org/p/zbw/iwkrep/152022.html.
Study 7	Meissner, A., 2017. Technisierung der professionellen Pflege. Einfluss. Wirkung. Veränderung [Technicisations of professional nursing. Influence. Effect. Change.]. In Nomos Verlagsgesellschaft mbH & Co. KG eBooks, S. 153–172. doi: 10.5771/9783845279435-153
Study 8	Koch, D., 2021. Age Management in der ambulanten Pflege: Unterstützung älterer Pflegekräfte bei Digitalisierungsprozessen [Age Management in Outpatient Care: Supporting Older Caregivers in Digitalisationals Processes]. Gelsenkirchen (Institut Arbeit und Technik. Forschung aktuell. 2021,2). Online available at: http://hdl.handle.net/10419/231384; https://hdl.handle.net/10419/231384.
Study 9	Longhini, J., Rossettini, G., Palese, A., 2022a. Correction: Digital Health Competencies Among Health Care Professionals: Systematic Review. In: Journal of medical Internet research 24 (11), e43721. DOI: 10.2196/43721/ Longhini, J., Rossettini, G., Palese, A., 2022b. Digital Health Competencies Among Health Care Professionals: Systematic Review. In: Journal of medical Internet research 24 (8), e36414. DOI: 10.2196/36414.
Study 10	Mohr, J., Riedlinger, I., Reiber, K., 2020. Die Bedeutung der Digitalisierung in der Neuausrichtung der pflegerischen Ausbildung - Herausforderungen für die berufliche Pflege im Kontext der Fachkräftesicherung [The importance of digitalisation in the reorientation of nursing training - challenges for professional nursing in the context of securing skilled workers]. In: Evelyn Wittmann, Dietmar Frommberger und Ulrike Weyland (Hg.): Jahrbuch der berufs- und wirtschaftspädagogischen Forschung 2020. Opladen, Berlin, Toronto: Verlag Barbara Budrich, S. 165–182. Online available at: https://nbn-resolving.org/urn:nbn:de:0111-pedocs-206610.
Study 11	Gonçalves Nes, A. A., Steindal, S. A., Larsen, M. H., Heer, H. C., Lærum-Onsager, E., Gjevjon, R. E., 2021. Technological literacy in nursing education: A scoping review. In: Journal of professional nursing: Official journal of the American Association of Colleges of Nursing 37 (2), S. 320–334. DOI: 10.1016/j.profnurs.2021.01.008.
Study 12	Tacke, D., 2017. Chancen und Risiken computergestützter Pflegediagnostik [Opportunities and risks of computer-assisted nursing diagnostics]. In: Hagemann, T. (Hg.): Gestaltung des Sozial- und Gesundheitswesens im Zeitalter von Digitalisierung und technischer Assistenz. Baden-Baden: Nomos Verlagsges, S. 207-216. Online available at: doi: 10.5771/9783845279435-207
Study 13	Zelt, T., Weidner, F., Hülsken-Giesler, M., 2017. ePflege - Informations- und Kommunikationstechnologie für die Pflege [Information and communication technology for nursing]. Study on behalf of the Bundesministerium für Gesundheit. Cologne: Roland Berger GmbH, Deutsches Institut für angewandte Pflegeforschung e.V., Philosophisch-Theologische Hochschule Vallendar.

TABLE 3 Items of personal characteristics, interpersonal characteristics and ethical aspects.

The healthcare professional…	
• - "…shows interest in eHealth", • - "…uses eHealth for data retention", • - "…uses eHealth as a supportive tool in care delivery", • - "…uses eHealth as a tool to improve care", • - "…is able to use the software/programs to access patient data", • - "…feels confident in using eHealth to make care-related decisions", • - "…is aware of the benefits provided by eHealth", • - "…critically evaluates the reliability of data collected with eHealth applications", • - "…supports the person in need of care to benefit from eHealth", • - "…encourages the person in need of care to use eHealth", • - "…adapts eHealth approaches according to the needs of the person in need of care", • - "…behaves professionally in the use of eHealth", • - "…is competent in the use of eHealth in relation to clinical reasoning", • - "…feels that the use of eHealth in most situations improves the quality of life of the person in need of care", • - "…has the skills to communicate with other health professionals via eHealth", • - "…has the basic skills to use appropriate technologies such as the computer or a smartphone",	• - "…knows where to reliably gather information using eHealth", • - "…understands the impact of eHealth on improving the quality of health care", • - "…communicates professionally with individuals seeking care through eHealth", • - "…presents information gathered via eHealth in a manner that is understandable to individuals seeking care", • - "…has skills via eHealth to communicate with individuals in need of care", • - "…discusses the advantages and disadvantages of eHealth with individuals in need of care", • - "…provides health-related counseling in the use of technology evidence-based care tools", • - "…communicates in a professional manner with other health professionals via eHealth", • - "…uses eHealth in personal routines", • - "…proactively and regularly obtains consent from individuals in need of care to access personal information", • - "…recognisess ethical dilemmas that may arise when integrating technology in health care and ethical principles." • - "…discusses ethical dilemmas with the person in need of care that may arise due to ethical principles and the integration of technology in health care." • - "…updates their knowledge of developments in health technologies through (continuous) learning".

maintain digital literacy in nurses, 3. separate time frame for orientation into the topic and (continuing) education in everyday professional life, 4. identification of support persons and their assignment to support the development of digital literacy in nurses, and 5. patient and family education with regard to the use and forms of digital technologies used in care.

The Study 4 by Buhtz et al. (23) conducted an online survey on the use of low-threshold technical solutions in the area of home care and the experiences in dealing with these at schools for geriatric and nursing care in the eastern German states. They found out that part of the trainees showed a strong willingness to participate in educational programs related to digital and assistive technologies. The respondents also saw a need for such offerings (ibid.). Accordingly, there is a high degree of openness to this topic, although their own knowledge was assessed as low (23, 35). However, concerning the integration of technical applications in the homes of individuals receiving nursing care, respondents had no difficulties in identifying these problems (23, 35). At the same time, most of the technologies for home use (medication dispenser, videophone, height-adjustable washbasins, daily calendar with reminder function) were unknown (23). Thus, from the authors' perspective, the imagination of the respondents is limited in the direction of beneficial use of technologies (ibid.). Overall, their perspective gives the impression that the ability to assess needs, the (competence-related) self-confidence in dealing with technologies and the integration of technologies should be questioned (ibid.). They justify this with the lack of knowledge about assistive systems and their inherent complexity (ibid.). Buhtz et al. (23) highlight that training programs and educational opportunities need to be integrated into training, as there are already care scenarios for technical aids. There is thus a need for the integration of teaching units on digital and assistive technologies into nursing education (23, 35).

In Study 5 Eiben et al. (24) interviewed a total of 32 nursing professionals participating in continuing education courses offered by various universities implemented in a blended learning format. In the evaluation results, the uncertainty of the target group becomes clear when it comes to the use of digital tools in the context of the events, such as the use of the learning platform, video tutorials, or even technical difficulties in setting up access to online-supported teaching. The results indicate that the participants tend to use learning strategies and examination formats they are familiar with from their learning backgrounds. In order to benefit from blended learning events, they need more support in individualisings their learning compared to "regular" students. However, under certain conditions, the integration of digital tools has advantages and can support the learning process. The evaluation identified several positive factors, including didactically prepared study material for the independent development of course content, integration of face-to-face events, offering technical support and support for independent or research-based learning, and assistance from online mentors.

Study 6 by Evans et al. (25) used a mixed methods approach to investigate current conditions and change trends regarding operational digitalisation processes in both outpatient and inpatient geriatric care. The results are summarised in three areas of tension: "Digital innovations in care," "Need for digital competencies in geriatric care," and "Shaping change processes together. In the case of "Digital innovations in care," it is evident that not all technical possibilities have been fully utilised in the facilities thus far. Digital tools (employee files, roster management, etc.) are used comparatively frequently for organisationals and administrative tasks. In the context of nursing activities, digital systems (sensory systems, therapeutic robots, etc.) are used significantly less. The obstacles lie not only in financial aspects but also in the different framework conditions, which "lie outside the scope of action of the individual facilities" (ibid.). The field of tension "Need for digital competencies in geriatric care" is based on Becka et al. (36), who describe the competency areas and categorises them into 1. core competencies, 2. specialised competencies, and 3. reflexive and social-communicative competencies. In the context of the study, user competencies are most significant as core competencies, followed by reflexive and communicative competencies. According to the results, specialised competencies such as the operation of assistance systems play only a subordinate role. There is a desire for greater emphasis on teaching digital skills in vocational training, which is currently perceived as inadequate. At present, training in digital skills is mostly event-driven and focused on the specific use of a device or program. There is no systematic, target-group-specific identification of competence requirements that goes beyond user competence. In practice, little attention is paid to the last area of tension, "Shaping change processes together". The results show that "although participation is understood as a core element for the successful organisations of change processes, it is not yet sufficiently implemented in practice and nursing staff only report feeling involved in decision-making processes to a limited extent. It is also clear that there is a broad spectrum of participation concepts in practice, which do not necessarily go hand in hand with the involvement of company interest groups. A stronger awareness of co-determination can possibly lead to a stronger identification of care workers with the company and increase employee loyalty to the company" (25).

The seventh study is a theoretical reflection article by Meissners (26), which first describes the development of technical and digital care in Germany from the 1950s to the present day. It then describes "new technologies of care" using the example of robotics, age appropriate assistance systems and information and communication technology. The consequences of the technical changes on the interactive relationship structure in care is not only accompanied by financial questions, but also by ethical questions. To address these concerns, a model for the ethical evaluation of socio-technical arrangements was developed in 2013 [MEESTAR, cf (37)], which "is intended as an analytical tool to guide reflection on the use of technology" (ibid., p. 17). The evaluation is carried out by combining seven ethical dimensions (care, self-determination, safety, justice, privacy, participation, self-image) with four levels of sensitivity. The model is to be applied in an interdisciplinary manner, involving all those involved in technology, from research to development

and deployment. The model is differentiated into 15 guidelines, which are intended to support ethically oriented judgment, decision-making and action through questions (e.g., "Can care be delegated to technology?") (ibid., p. 18). It is critically discussed to what extent technology, through its *per se* fixed parameters, opposes the negotiation process of care and how this creates limits in nursing studies. In the long term, the use of technology in nursing science can only succeed if it is more strongly anchored in education, receives greater relevance in research, a "systematic integration in theory building" takes place, and a "society-wide debate about the notion of nursing dependency and the use of technology" is initiated (ibid., p. 25).

Study 8 by Koch (27) uses a literature analysis and qualitative survey of four exemplary interviews to examine the question of how age management should be designed in outpatient care in order to support older caregivers as digitalisation continues to increase. The existing discussion on the effects of digitalisation on care activities and organisations is expanded with the perspective of age management, which has received relatively little attention. Through literature analysis and qualitative survey, the possible uses and applications of digital technology were investigated. Electronic care documentation, electronic tour planning, digital duty scheduling and service recording proved to be suitable for the field of outpatient care. The prerequisite for the use of the technologies is, of course, the corresponding competences of the care workers. Some measures of age management proved to be helpful to support older care workers in outpatient care in countering the effects of digitalisations in the area of care planning and care process organisation. Especially actions related to the dimensions of "awareness/sensitisations", "(age) diversity" and "changed/changing attitudes" can have a positive impact on the inclusion of (older) employees in the introduction and use of digital technologies. Lifelong and shared learning, regardless of age, can contribute to increasing age diversity, employee motivation and knowledge transfer. According to the author, supervisors and managers play a central role, as the measures of age management must come from them.

Longhini et al. (28) identified four areas of research from the literature included in a systematic review analysing the health literacy of health professionals in Study 9: 1. studies on self-assessed competencies, i.e., studies on digital literacy, eHealth competency, patient-centered competencies and the process of care-oriented competencies. 2. studies on psychological and emotional aspects towards the use of digital technologies, i.e., attitudes and beliefs, trust, awareness. 3. studies on the use of digital technologies, i.e., digital literacy, eHealth competence, patient-centered competencies and the process of care-oriented competences. 3. use of digital technologies, i.e., general use of digital technologies, use of digital technologies for specific functions, and 4. knowledge about digital technologies. In summary, the authors noted an increase in the number of studies over the last five years, with most studies having a cross-sectional design or examining frequencies. Only two studies had an experimental design. About half of the studies focused on the hospital setting, making the community level less prominent. All professional groups were covered in the studies. At the same time, the authors identified a need for a stronger conceptualisations of the studies. A lack of validated instruments to measure digital literacy was also noted. It is assumed that the already existing instruments in the respective studies can be used to a limited extent and the rapid evolution of digital technologies requires continuous updates of competencies and, consequently, the corresponding measuring instruments. Furthermore, self-assessments were made in all studies, thus lacking objective measurements. The authors, therefore, call for the increased use of objective measurements by third parties, which, however, have yet to be developed in the research field.

In Study 10, Mohr et al. (29) describe a desideratum with regard to basic and applied research on the topic of digitalisation in nursing. However, it is not only academia that pays little attention to the topic. Digital technologies also play a rather minor role in nursing practice and vocational training. In the Nursing Professions Act, the teaching of digital skills has so far only been mentioned in connection with university education, but this is clearly not enough for everyday nursing practice. Beyond the Nursing Professions Act, some concrete forms of application can be found in various framework curricula. However, which concrete competences are required for application-related use in practice have so far been mentioned neither in the law nor in the curricular training. "In the course of a further profiling of the professional profile, it would be necessary to grasp digitalisations as an integral component: Not merely as a further (possibly annoying) content add-on in an already extensive content catalogue, but as a cross-sectional competence to the nursing core and contextual competence under the condition that the professional nurses define and control the use of digitalised technology" (ibid., p. 178). The implementation should accordingly take place with the involvement of the stakeholders; here, clear parallels emerge in the articles by Mohr et al. (29) and Evans et al. (25), which also call for a more participatory approach to the recording and definition of digital competences from practice. Accordingly, the development would take place less from the subject-specific and technically possible point of view but could rather be developed and implemented individually from the professional logic. The prerequisite here is to define and systematically clarify the concepts of digitalisations/digital technologies in order to develop a common basic understanding from practice for practice.

Gonçalves Nes et al. (30) conducted a scoping review on technology competence in nursing education in Study 11. They grouped the 28 included studies according to their thematic focus. Eight publications focused on the acquisition of technical knowledge and skills. The second thematic focus of the remaining 21 publications was the measurement of technical knowledge and skills (ibid.). Here, the authors distinguished between sub-topics, with some of the publications addressing several sub-topics (ibid.): 10 publications addressed digital/computer literacy/competence, 9 publications examined nursing informatics literacy, 2 examined technology acceptance, and 4 examined students' technology-related interests and preferences. A single publication related to the thematic focus of maintaining technical knowledge and skills (ibid.). Thus, the scoping review

aimed to map and explore the topic of technical literacy in nursing education. The measurement instruments used in the included studies showed a high degree of heterogeneity, which underlines the need for a universally applicable instrument to achieve comparable results (ibid.). Gonçalves Nes et al. (30) derive several implications from their scoping review: First, nurses need to take a more active role in technology development and implementation, including claiming a leadership role. Relevant to building strategies for acquiring technical literacy is the availability of information about nursing students' technology acceptance and interests, as well as their preferences. It is essential to implement strategies that increase technical literacy among teaching staff, enabling them to successfully impart this literacy to students. The findings suggest the need for more knowledge to maintain technical literacy. This in turn requires an increase in IT competences and skills among teachers, based on which appropriate strategies as well as methods can be defined.

As part of Study 12, Tacke (31) deals with the risks and opportunities associated with computer-aided nursing diagnostics in her theoretical reflection contribution. The advantages of digital technologies, such as standardisation of processes through nursing documentation systems and ensuring quality, are obvious. However, if these systems are to be used across the board for nursing diagnostics, extensive training and further education of the nursing staff is required in order to perform the translation from pure documentation to validated diagnostics. Various other studies (38–40) show that nurses have so far been insufficiently prepared for this process leading to diagnostics and have problems "observing specifically, interpreting what is perceived and taking the patient's perspective" [(31), p. 212]. Further training in the use of digital technologies should therefore not only refer to the purely technical teaching, but also sensitises for the practical use and stimulate and promote the critical reflection ability of the nursing staff (ibid.).

The Study 13 "ePflege" was commissioned by the Federal Ministry of Health (BMG) and was conducted as a mixed methods study to analyse the current status quo and the resulting identification of needs and the development of recommendations for action. The results indicate that while digitalisations is of great importance, the focus on networked care and the inclusion of users has not been in the foreground so far. Associated expectations of care using digital solutions are above all quality improvement, increased efficiency, the reduction of bureaucracy and the networking of actors. The lack of technical skills on the part of the users and the exchange of information among each other are usually obstacles to the use of digital solutions. If existing digital solutions exist, they are not considered very user-friendly, and the securing of long-term financing for these solutions is also often unclear (ibid., p. 7). In order to promote the reputation, the effects of digital techniques on the care process and their implementation and benefit assessment from an application perspective would be of interest. However, there is a clear need for research in this area as well. The respondents, differentiated according to various stakeholder groups, highlighted different focal points of need. Beneficiaries seek greater involvement in technology development and better information exchange. Careers expect greater involvement in implementation and better networking among themselves, while developers of digital technology solutions would like to see an improvement in the technical infrastructure and greater involvement of users in the development and implementation process (ibid., p. 8). "To promote the anchoring of care ICT in the health care system, the study recommends the establishment of a "Network ICT in Care", the creation of incentives for the widespread use of electronic care documentation and the strengthening of transparency about the benefits of ICT solutions for anchoring in the initial care market" (ibid., p. 8).

In order to provide a more differentiated insight into the findings of the studies in relation to the research question, they have been summarised in a table (Table 4).

Discussion

From the overall view of the literature included, it becomes clear that the sustainable integration of digitalisation in nursing education is a topic of discussion in the nursing science discourse. A differentiation can be made between different key areas. One key area is concept development. This includes the orientation towards pragmatic concepts (20) as well as the consideration of the heterogeneity of the demand constellations [with reference to (32) and the previously existing competences in the sense of a reflexive refocusing (21)]. Instead of looking at existing competences and skills in isolation and trying to circumscribe them, these must be viewed holistically as interconnected aspects (21).

Another key area relates to the initiation of digital competences in training. Brown et al. (22), Buhtz et al. (23) and Meissnerss (26) emphasises the importance of laying the foundations for digital (technical) competences in basic nursing training. However, Brown et al. argue in the context of fully academicised nursing training, which has not yet been established in Germany, for example. In order to classify the results of Buhtz et al., the fallacy can be raised here that the structured acquisition of digital competences could become obsolete in the future due to the generation of so-called digital natives. Just because a person has grown up surrounded by computers, cell phones, and other digital devices does not automatically make them digitally competent. Their informally acquired skills to use technology safely and effectively are likely to be incomplete (41). This leads to a new digital divergence between digital lifestyle skills and digital workplace skills. It means that young people are not automatically excluded from digital skills education (41). Implications for the long-term use of technology in nursing education include a stronger integration of technology into nursing education, greater relevance in research, systematic integration into theory development and a societal debate on the concept of the need for care and the use of technology (26).

Other key areas in the discourse are vocational training (24, 31) and participatory technology development (25, 29). Further training to acquire digital competence currently takes place mostly on an *ad hoc* basis and with a view to the specific

TABLE 4 Overview of the findings in relation to the research question.

Study (year of publication)	Topic	Method	Findings in relation to the research question
Study 1—Bleijenbergh et al. (20)	Digital adaptability competency for healthcare professionals	Explorative e-Delphi study	The 29 identified themes of digital adaptive competence provide a comprehensive insight into the diverse requirements and challenges associated with the use of digital technologies in nursing education. Consideration of these topics is crucial to ensure that the integration of digitalisation is sustainable and that both individual needs and ethical standards in nursing education are taken into account.
Study 2—Brice and Almond (21)	Health Professional Digital Capabilities Frameworks	Scoping Review	Based on the identified subject areas and categories and the conclusion of Brice and Almond (21), it can be stated that it is not sufficient to adapt or redefine individual skills or competences for a sustainable integration of digitalisation into nursing education. Rather, a holistic approach should be pursued that links the various subject areas such as change management, user applications, technological skills and innovative practice. Professional digital competence frameworks must therefore not only map the current skills and competences, but also focus on the identified subject areas in order to ensure a holistic and sustainable integration of digitalisation into nursing education.
Study 3—Brown et al. (22)	Issues affecting nurses' capability to use digital technology at work	Integrative review	The authors emphasise the importance of a holistic view that takes into account personal, interpersonal and ethical issues in addition to technical aspects. Their conclusions suggest that the discussion on the sustainable integration of digitalisation should include not only technical, but also practical, political and educational aspects. Implications for practice include the provision of time and support for nurses and patient-centred access to evidence-based information. At a policy level, the involvement of various stakeholders in the development of digital platforms and privacy policies is emphasised. In education, the integration of digital competences into curricula and continuing professional development is emphasised.
Study 4- Buhtz et al. (23)	Affinity for technology and interest in continuing education among nursing trainees	Onlinesurvey	The authors emphasise the need to integrate training courses on digital and assistive technologies into nursing education in order to meet the needs of practitioners and strengthen confidence in the use of technology in the long term.
Study 5—Eiben etal. (24)	Digitalisation in Continuing Academic Education in Health and Care—Special consideration of the blended learning format	Interviews	Overall, the results show that the discussion about the sustainable integration of digitalisation into nursing training encompasses both challenges and opportunities and requires careful adaptation of teaching and learning methods to effectively support the learning process.
Study 6 -Evans et al. (25)	Design paths and design practice of digitalisation in geriatric care in NRW	Mixed-Methods-Design	The study highlights the complex areas of tension associated with the sustainable integration of digitalisation into nursing education. Firstly, it is found that digital innovations in care are not yet widely used, especially in nursing activities, partly due to financial barriers and external conditions. Secondly, a high need for digital competences in nursing is identified, with user competences in particular being considered crucial. However, the teaching of these competences is considered insufficient and is mostly event-driven. Thirdly, the need to jointly shape change processes in practice and promote the participation of care staff is emphasised in order to strengthen their identification with the company.
Study 7—Meissner (26)	Technicisation of professional nursing	Theoretical reflection	For the sustainable integration of digitalisation in nursing education, Meissner (26) emphasises the importance of ethical considerations in the integration of digital technologies in nursing, in addition to the comprehensive integration of technologies in nursing education.
Study 8—Koch (27)	Age Management in Outpatient Care: Supporting Older Caregivers in Digitalisation Processes	Literature analysis and qualitative interviews	In connection with the sustainable integration of digitalisation in nursing training, it can be concluded from the study that the recognition of age diversity and the teaching of age management measures can represent considerable added value in training.
Study 9—Longhini et al. (28)	Digital Health Competencies Among Health Care Professionals	Systematic review	Longhini et al. (28) note that the discussion about the integration of digital technologies into nursing education is increasing. There is a need for better conceptualised studies and validated measurement tools for digital competences.

(*Continued*)

TABLE 4 Continued

Study (year of publication)	Topic	Method	Findings in relation to the research question
Study 10—Mohr et al. (29)	The importance of digitalisation in the reorientation of nursing training—challenges for professional nursing in the context of securing skilled workers	Delphi survey	The study by Mohr et al. (29) emphasises a deficit in research and practice with regard to the integration of digital technologies into nursing training. It is noted that digital competences are insufficiently taken into account in the Nursing Professions Act and are not sufficiently defined in the curricula. It is recommended that digitalisation be considered an integral element of the nursing profession and that the development of digital competences be driven forward in a participatory manner with the involvement of those affected.
Study 11—Gonçalves Nes et al. (30)	Technological literacy in nursing education	Scoping Review	The study by Gonçalves Nes et al. (30) shows that nurses should take a more active role in technology development. Teachers need to improve their IT competences in order to teach technical skills effectively.
Study 12—Tacke (31)	Opportunities and risks of computer-assisted nursing diagnostics	Theoretical reflection	For the sustainable integration of digitalisation into nursing education, Tacke (31) emphasises the importance of the training and further education of nursing staff for the use of computer-aided nursing diagnostics. It becomes recommended to focus further training not only on technical use, but also on practical application and critical reflection.
Study 13—Zelt et al. (32)	Information and communication technology for nursing	Mixed-Methods-Design	For the sustainable integration of digitalisation into nursing education, it is crucial to focus on networked care and the involvement of users. Nursing training must therefore concentrate more on teaching digital competences and also take into account the needs and perspectives of different stakeholder groups.

application of a device or program. There is no systematic and target group-specific identification of competence needs beyond user competence (25). For the further profiling of the professional profile, digital competences should not be a content-related add-on in a complex education, training and continuing education catalogue, but should be regarded as an integral component of a core or cross-sectional competence of professional nurses (29). In line with the emphasis on participatory technology development, Gonçalves Nes et al. (30) call for nurses to take an active role in technology development and implementation, and recommend that leaders actively support this process. Participatory technology development can thus make a decisive contribution to the sustainable implementation of digitalisation in nursing.

Other publications refer to the topics of maintaining the working ability of older nursing professionals (27), the adaptation of competence development to the evolution of digital technologies (28) as well as the technology literacy of teaching staff (30). Action-oriented age management measures can therefore positively impact the inclusion of (older) employees in the introduction and use of digital technologies. Supervisors and managers play a central role in such age management orientation (27). Building strategies for acquiring technical literacy goes hand in hand with information about students' technology acceptance, interests and preferences (30). The development of corresponding strategies could be done by teachers, although this requires a certain level of technical expertise. Early incorporation of this age management orientation during nursing education can therefore result in a sustainable strategy for the integration of digitalisation into nursing care. In doing so, trainees should become familiar with the concept of age management in order to subsequently achieve effective empowerment of older staff in practice by promoting the acceptance of technology.

Based on the literature, it is evident that digitalisations is a topic under discussion. Sustainable implementation appears more likely in an international context than in Germany. The following sustainability desiderata can be derived from the aforementioned key points in a broad sense: a high need for (basic) research activities, the conceptual design of competence attributions, the integration of nursing science expertise in the drafting of curricula and, above all, the integration of nursing professionals in the development, testing and implementation of digital technologies. In the context of the high demand for research activities, Longhini et al. (28) call for the development and subsequent inclusion of objective measurement tools related to the use of digital technologies and associated digital competences. A first starting point is the DigComp Framework of the European Union (42). The DigComp framework identifies the key components of digital literacy in the following 5 areas: information and data literacy, communication and collaboration, digital content creation, safety, problem solving (42).

The discussion about the sustainable integration of digitalisation into nursing education raises a number of open research questions. These include the development of teaching concepts, the measurement and teaching of digital competences, participatory technology development, age management in the context of technology acceptance and long-term strategies for the use of technology. These questions reflect the complexity and the various dimensions that need to be considered when integrating digital technologies into nursing education and offer important starting points for future research activities and the development of educational concepts in this area.

In the context of this scoping review, it is important to note that the work does not claim to cover the topic in its entirety. This is explained by the underlying research question on one hand, and by the search operators and search filters on the other. A further limitation arises from the literature itself, as it mainly provides findings at a meta-level. In this sense, this review already relies on third party interpretations. Nevertheless, the work offers added value by addressing the discourse on the sustainable integration of digitalisation in nursing education in the context of nursing science.

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

TT: Visualization, Writing – original draft. AH-M: Formal Analysis, Investigation, Writing – review & editing. S-NR: Writing – review & editing. MM: Conceptualization, Writing – review & editing. SS: Formal Analysis, Investigation, Writing – review & editing. TS: Conceptualization, Writing – review & editing. MH: Conceptualization, Project administration, Writing – original draft.

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Conflict of interest

The Reviewer [SG] declared a past co-authorship with the authors [TT and TS] to the Handling Editor.

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.

Publisher's note

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Quality assessment of mHealth apps: a scoping review

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Introduction: The number of mHealth apps has increased rapidly during recent years. Literature suggests a number of problems and barriers to the adoption of mHealth apps, including issues such as validity, usability, as well as data privacy and security. Continuous quality assessment and assurance systems might help to overcome these barriers. Aim of this scoping review was to collate literature on quality assessment tools and quality assurance systems for mHealth apps, compile the components of the tools, and derive overarching quality dimensions, which are potentially relevant for the continuous quality assessment of mHealth apps.
Methods: Literature searches were performed in Medline, EMBASE and PsycInfo. Articles in English or German language were included if they contained information on development, application, or validation of generic concepts of quality assessment or quality assurance of mHealth apps. Screening and extraction were carried out by two researchers independently. Identified quality criteria and aspects were extracted and clustered into quality dimensions.
Results: A total of 70 publications met inclusion criteria. Included publications contain information on five quality assurance systems and further 24 quality assessment tools for mHealth apps. Of these 29 systems/tools, 8 were developed for the assessment of mHealth apps for specific diseases, 16 for assessing mHealth apps for all fields of health and another five are not restricted to health apps. Identified quality criteria and aspects were extracted and grouped into a total of 14 quality dimensions, namely "information and transparency", "validity and (added) value", "(medical) safety", "interoperability and compatibility", "actuality", "engagement", "data privacy and data security", "usability and design", "technology", "organizational aspects", "social aspects", "legal aspects", "equity and equality", and "cost(-effectiveness)".
Discussion: This scoping review provides a broad overview of existing quality assessment and assurance systems. Many of the tools included cover only a few dimensions and aspects and therefore do not allow for a comprehensive quality assessment or quality assurance. Our findings can contribute to the development of continuous quality assessment and assurance systems for mHealth apps.

Systematic Review Registration: https://www.researchprotocols.org/2022/7/e36974/, International Registered Report Identifier, IRRID (DERR1-10.2196/36974).

KEYWORDS

mHealth, quality, apps, scoping review, assessment, Digital Health Application

1 Introduction

The number of mobile phone users in 2023 was estimated at 7.3 billion worldwide, representing over 90% of the world's population (1, 2). The intensive use of mobile devices has affected many industries, including the proliferation of mobile healthcare (mHealth) apps (3). While a universally accepted definition is lacking (4), the term mHealth is broadly defined as using "portable devices with the capability to create, store, retrieve, and transmit data in real time between end users for the purpose of improving patient safety and quality of care" (5). As an integral part of eHealth, mHealth apps aim to improve access to evidence-based information and engage patients directly in treatments by enabling providers (e.g., doctors, healthcare facilities) to connect with patients (6, 7). As such, mHealth apps have the potential to improve healthcare through accessible, effective and cost-effective interventions (8). In times of demographic change and healthcare workforce shortages, high-quality apps might contribute to sustainable healthcare (9). Especially with the rise of chronic diseases, mHealth apps can be an opportunity for prevention and improved treatment, as these diseases require constant self-care and monitoring (10). Despite this potential, literature suggests a scarcity of high-quality mHealth apps (11). In line with this, a scoping review identified several problems and barriers to the utilization of mHealth apps, including issues related to validity, usability, as well as data privacy and security, among others (12). Particularly with the widespread use of mHealth apps, it is important to avoid quality issues such as misinformation, which can limit effectiveness or potentially harm the user. As in other areas of health care, high standards are needed for evidence-based and high-quality mHealth apps (12). Appropriate quality assessment and assurance is therefore needed both during the development and ongoing use of mHealth apps.

According to a World Health Organization's definition, quality of care is "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes" (13). While in general, health care quality is a multidimensional construct (14), quality dimensions in mHealth differ from those in other existing healthcare services (15). With its fast-track procedure, Germany was the first country in the world to create a system that makes selected, tested mHealth apps [called "Digital Health Applications" (DiGA)] an integral part of healthcare (16). The Federal Institute for Drugs and Medical Devices (BfArM) has set certain requirements the app must meet in order to be included in the so called "DiGA directory". These apps have to demonstrate scientifically proven evidence of a benefit, either in the form of medical benefits or patient-relevant structure and process improvements for the patient (16). Furthermore, they must meet requirements for product safety and functionality, privacy and information security, interoperability, robustness, consumer protection, usability, provider support, medical content quality and patient safety. Once listed in the directory, patients can request these mHealth apps from their health insurance company, or the apps can be prescribed directly (16).

Currently there is a need for further adjustments to the fast-track procedure on the part of providers, health insurers and manufacturers (9). For example, the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) requires, among other things, that quality specifications must be met for user-friendly and target group-oriented design, data protection and data security (17).

Quality assessment tools: In addition to country-specific approaches, a number of simple assessment tools have been developed, such as the Mobile App Rating Scale (MARS) (18), ENLIGHT (19) or the System Usability Scale (SUS) (20). These approaches (in the following called *quality assessment tools*) typically assess the quality of apps with a number of items and provide the user with a score. For example, as one of the most widely used evaluation tools, MARS was developed on the basis of a literature review of existing criteria for evaluating the quality of apps and subsequent categorization by a panel of experts. The resulting multidimensional rating scale covers the areas of engagement, functionality, aesthetics, information and subjective quality of apps. Resulting scores are intended to be used by researchers, guide app developers, or to inform health professionals and policymakers (18, 19).

Quality assurance systems: In addition, approaches have been developed (hereinafter referred to as *quality assurance systems*) which go beyond traditional scoring instruments, e.g., by providing a framework for assessing the mHealth apps along their product lifecycle. For example, Sadegh et al. (21) propose an mHealth evaluation framework through three different stages of the app's lifecycle. Similarly, Mathews et al. (22) detail a framework assessing technical, clinical, usability, and cost aspects pre- and post-market entry. To date, there is no overview in the literature that differentiates between quality assessment tools and quality assurance systems.

Therefore, and in view of the situation in Germany described above, this work pursues two objectives: (1) to collate literature on quality assessment tools and quality assurance systems for mHealth apps, compile the components of the tools, and group them into overarching quality dimensions, which are potentially relevant for the continuous quality assessment of mHealth apps; (2) to identify and characterize quality assurance systems with a view to continuous quality assurance.

Relevant information can be extracted from publications in which the tools are developed or validated. Studies in which the tools are used for the evaluation of apps are also potentially relevant, as they provide evidence that the respective tools have been applied for the assessment of an mHealth app by researchers. The method of scoping review was found feasible, as no single precise question regarding feasibility, appropriateness, meaningfulness or effectiveness had to be answered (23). While specific questions of effectiveness are traditionally answered by collating quantitative literature in a systematic review, scoping reviews are used to map literature and address a broader research question (e.g., identify gaps in research, clarify concepts, or report on types of evidence that inform clinical practice) (24).

This work is part of a larger research project (QuaSiApps—Ongoing Quality Assurance of Health Apps Used in Statutory Health Insurance Care), which is funded by the Innovation Fund of the Federal Joint Committee and aims to create a concept for continuous quality assurance of mHealth apps.

2 Methods

A scoping review was conducted to answer the following questions: Which quality assessment tools and quality assurance systems have been developed and/or used in the field of mHealth apps? Which items do they consist of? Which quality dimensions can be derived from the quality assessment tools and quality assurance systems? To answer these questions, we followed the key phases outlined by Levac et al. (25), including identifying relevant studies, study selection, charting the data, and collating, summarizing, and reporting the results. Reporting followed the PRISMA extension for scoping reviews (26). A review protocol was written and published prior to screening (27). The protocol contains detailed information on the databases searched, the search terms used, and the inclusion and exclusion criteria applied during the screening process.

2.1 Literature search

The electronic indexed databases Medline, EMBASE and PsycInfo were searched for primary literature on the topic. Studies containing description of a literature review were included, if the review served to develop the items of the assessment tool presented. However, the focus had to be on the development and description of a specific tool. Search strategies were developed through discussion (GG, NS, CS) and with aid of the working group leader (SN). The strategies were pilot tested and refined. The search strategies comprise of keywords and synonyms for assessment tools and mHealth. All bibliographic searches were adapted to the databases' requirements. Full search strategies and number of hits per keyword can be found in the review protocol. Searches were executed on July 26th, 2021. Reference lists of included articles were screened for further eligible literature. Further information such as the search string can be found in the corresponding research protocol (27).

2.2 Inclusion and exclusion criteria

Studies were eligible for inclusion if they fulfilled the following criteria: (1) included either development, or description, or further information on disease-independent concepts of quality assessment or quality assurance of mHealth apps, (2) were in English or German language, and (3) were published between January 1st, 2016 and July 26th, 2021. This means that studies were included if quality assessment tools and quality assurance systems were applied (application studies), developed (development studies) or validated (validation studies). In order to incorporate approaches currently in use, the quality assessment tools and quality assurance systems used in application and validation studies were identified and included, even if they were published before January 1st, 2016. For application studies, the investigated mHealth apps had to be used by patients in outpatient treatment and needed to have more functions than improvement of adherence, text-messaging, reminder or screening for primary prevention or (video) consultation or disease education or reading out and controlling of devices.

Applied exclusion criteria were: (1) articles that did not include information on quality assessment tools or quality assurance systems, (2) the investigated quality assessment or quality assurance system was not disease-independent, (3) the assessed mHealth app had not more functions than the following: improvement of adherence, text-messaging, reminder or screening for primary prevention or (video) consultation or disease education or reading out and controlling of devices, (4) The mHealth app evaluated was not primarily for patient use, (5) the assessed mHealth app is not used in outpatient treatment, (6) articles that included only research protocols, conference abstracts, letters to the editor, or expression of opinions. Apart from the publication date, the inclusion and exclusion criteria were all set manually and not using the filter function of the databases. Further information on the inclusion and exclusion criteria, including the search timeframe, can be found in the review protocol (27).

2.3 Selection of relevant studies

Identified results were loaded into the EndNote reference management program (Clarivate Analytics, Philadelphia, US; version X9). Duplicates were removed automatically and manually during the screening process. All unique references were screened in terms of their potential relevance based on title and abstract. Documents considered potentially relevant were reviewed in full-text and retained if the study met inclusion criteria. Two researchers (GG, NS) performed all screening steps independently. Any disagreements were resolved by consulting a senior researcher (SN).

2.4 Extraction and analysis of data

Included studies were extracted in tables by two persons independently (GG, CS). Relevant data of included articles was marked and extracted using MAXQDA 2022 (Verbi Software GmbH, Berlin). In a first step, articles were categorized into application studies, validation studies, and development studies and were then extracted into pre-specified tables. The extraction table for application studies comprised author(s), year, country, the used quality assessment tool(s), investigated disease(s) or the field(s) of application, the number of investigated apps, the study type and the source of the tool used in the application study. Data extraction from validation studies included author(s), year, country, the validate quality assessment tool(s), investigated disease(s)/field(s) of application and the origin of the validated

tool. The extraction table for development studies included author (s), year, country, quality assessment tool, disease(s)/field(s) of application, the quality dimensions described and named by the author of the respective studies and the attribution to the quality dimensions developed in this scoping review.

Identified items were extracted and grouped into clusters in Microsoft Excel by one researcher (GG) and quality-checked by two researchers (FP, CA). Results were compared and discussed in case of disagreement. If necessary, a senior researcher was involved (SN). In case a criterion or aspect did not match into an existing cluster, a new cluster was created. Based on the information from the literature analyzed, the clusters were labeled. The labeled clusters were described and constituted the quality dimensions. The results were summarized, systemized and presented in tables.

3 Results

The selection process is shown in Figure 1. A total of 2,871 articles were identified in the three databases. Of these, 2,235 articles remained after duplicate removal and were screened according to title and abstract. One hundred and twenty-four articles were included in full-text screening and subsequently, 59 studies met inclusion criteria. See Supplementary Appendix A for a table of studies excluded in full-text screening. A further 11 articles were identified via citation searching. This refers to the studies in which the tools mentioned in the application studies were developed. In total, 70 articles were included.

In 15 of the included articles, a quality assurance system or a quality assessment tool was developed (10, 21, 28–40). Five of the included articles were validation studies (8, 41–44). In addition to development and validation studies, a number of studies ($n = 39$) were identified in which quality assessment tools were applied. Of these, 19 studies employed the Mobile App Rating Scale (MARS) which was developed by Stoyanov et al. (18) or a modified version of it (33, 38, 45–61), and one study (62) used the user version of the MARS (uMARS) proposed by Stoyanov et al. (63). Another ten studies (39, 64–72) employed the System Usability Scale (SUS) developed by Brooke et al. (20). Two studies (73–75) used the (modified) Silberg scale. Further seven studies were identified in which additional quality assessment tools and quality assurance systems were applied (76–82). In total, 14 quality assurance systems and quality assessment tools were found in application or validation studies (18–20, 22, 63, 73, 83–90). Of note, the articles by Liu et al. (33), Tan et al. (38) and Wood et al. (39) report on both development and application and were therefore classified in both categories. An overview of all included articles is given in Supplementary Appendix B. In the 74 included articles, a total of 29 distinct approaches to quality assurance or quality assessment were identified. Five of these have been identified as quality assurance systems (21, 22, 30, 35, 90), while the remaining 24 tools are considered quality assessment tools. Figure 2 gives an overview of the different types of studies included.

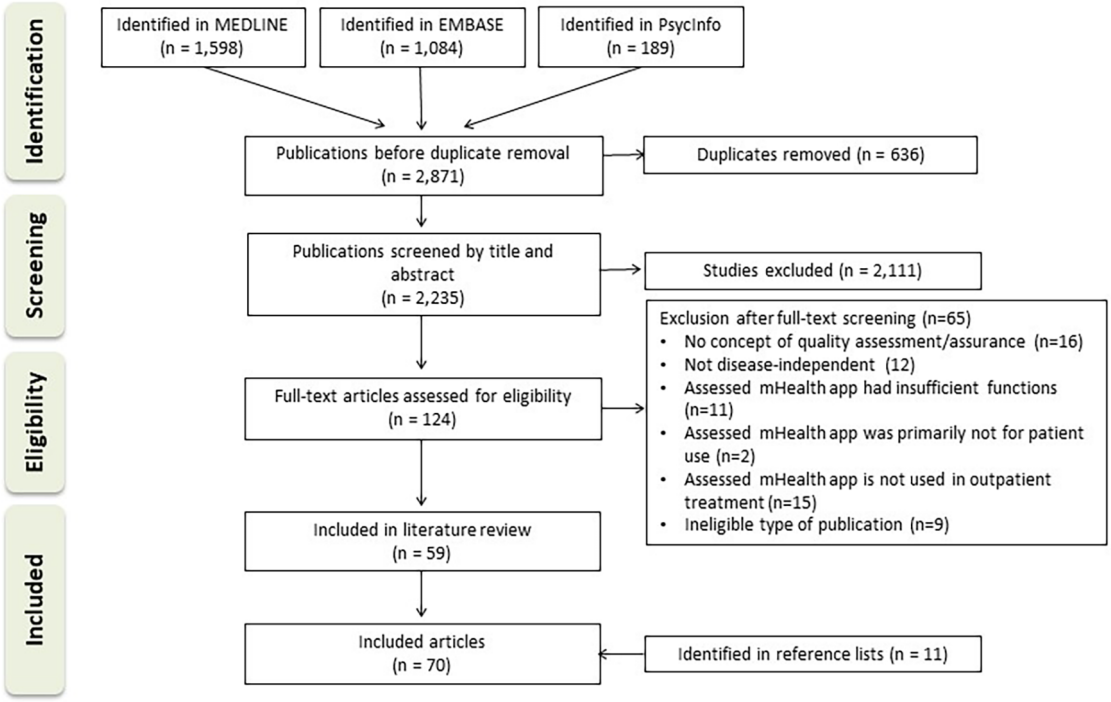

FIGURE 1
Flow diagram depicting the selection of sources of evidence.

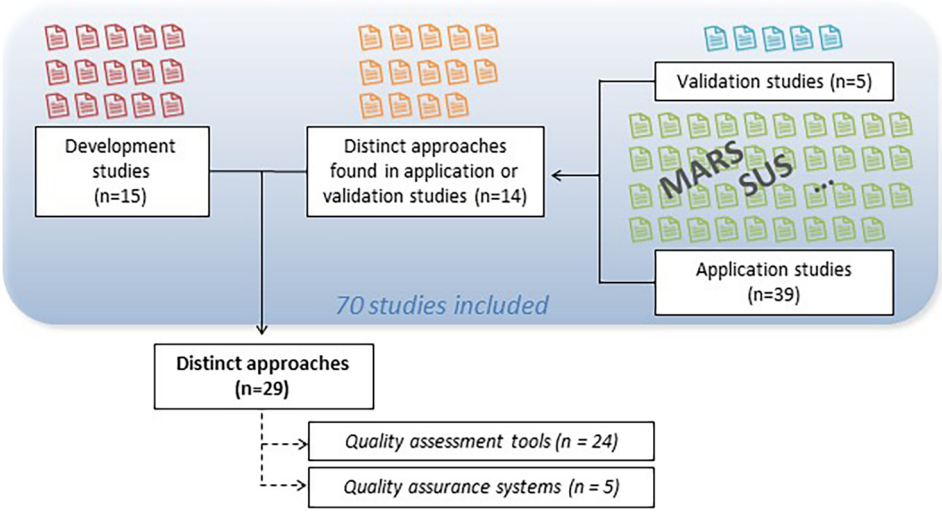

FIGURE 2
Included studies and approaches.

3.1 Characteristics of included quality assessment tools

An overview of the identified 24 quality assessment tools is presented in Table 1. Of these, 8 were developed for the assessment of mHealth apps for specific diseases or disease areas and 11 for assessing mHealth apps for all fields of health. Another five are not restricted to health apps, but have been included as they have been used for the assessment of health apps in application studies. Included articles dealing with quality

TABLE 1 Characteristics of the included quality assessment tools.

Author (year)	Country	Tool name	Field of application
Baumel et al. (2017) (19)	US	ENLIGHT	All fields of health
Berry et al. (2018) (28)	UK	Mobile Agnew Relationship Measure (mARM) Questionnaire	Mental health
Brooke et al. (1996) (20)	UK	System Usability Scale (SUS)	Not restricted to health
Brown et al. (2013) (29)	US	Health-ITUEM	All fields of health
Doak et al. (1996) (83)	US	Suitability Assessment of Materials (SAM)	All fields of health
Glattacker et al. (2020) (31)	Germany	Usability questionnaire	Allergic Rhinitis
Huang et al. (2020) (32)	Singapore	App-HONcode	Medication Management in Diabetes
Huckvale et al. (2015) (84)	UK	Untitled	All fields of health
Jusob et al. (2022) (10)	UK	Untitled	Chronic diseases
Lewis et al. (1995) (85)	US	After-Scenario Questionnaire (ASQ), Post-Study System Usability Questionnaire (PSSUQ), Computer System Usability Questionnaire (CSUQ)	Not restricted to health
Liu et al. (2021) (33)	China	Untitled	Traditional Chinese Medicine and Modern Medicine
Llorens-Vernet and Miro (2020) (40)	Spain	Mobile App Development and Assessment Guide (MAG)	All fields of health
Minge and Riedel (2013) (34)	Germany	meCUE	Not restricted to health
O'Rourke et al. (2020) (36)	Austria	App Quality Assessment Tool for Health-Related Apps (AQUA)	All fields of health
Pifarre et al. (2017) (37)	Spain	Untitled	Tobacco-quitting
Reichheld (2004) (86)	US	Net Promoter Score (NPS)	Not restricted to health
Ryu and Smith-Jackson (2006) (87)	US	Mobile Phone Usability Questionnaire (MPUQ)	Not restricted to health
Schnall et al. (2018) (88)	US	Health Information Technology Usability Evaluation Scale (Health-ITUES)	All fields of health
Shoemaker et al. (2014) (89)	US	Patient Education Materials Assessment Tool (PEMAT)	All fields of health
Silberg et al. (1997) (73)	Sweden	Silberg Scale	All fields of health
Stoyanov et al. (2015) (18)	Australia	Mobile App Rating Scale (MARS)	All fields of health
Stoyanov et al. (2016) (63)	Australia	User Version of the Mobile Application Rating Scale (uMARS)	All fields of health
Tan et al. (2020) (38)	Australia	Untitled	Allergic Rhinitis and/or asthma
Wood et al. (2018) (37)	Australia	Untitled	Cystic fibrosis

assessment tools predominantly stem from the USA ($n = 8$), Australia ($n = 4$), and the UK ($n = 4$). The identified quality assessment tools were developed in different ways, e.g., by adapting existing measures, based on findings from literature and guideline review, by conducting focus groups or by mixed-methods approaches. The quality assessment tools were developed for utilization developers, academics, healthcare providers, government officials and users.

None of the 24 articles includes a definition of a concept for quality. Of note, Brooke et al. (20) define the concept of usability in the context of the SUS. The tools are diverse with regard to their extent. Some tools consider single aspects, such as engagement (28, 86). For example, the net promoter score (86), which was used by de Batlle et al. (64), consists of only one question. In contrast, other tools cover a wider range of aspects (19, 40).

3.2 Characteristics of included quality assurance systems

The identified approaches were assigned to quality assurance systems if they assessed the apps over time. An overview of the included quality assurance systems is presented in Table 2.

The five included quality assurance systems stem from the US ($n = 2$), Australia ($n = 1$), Iran ($n = 1$), and France ($n = 1$). Similar to the quality assessment tools identified, none of the five articles includes a definition of a concept for quality. The quality assurance systems were developed to be used by developers, health practitioners, government officials, and users. Camacho et al. (30) tailored an existing implementation framework and developed a process to assist stakeholders, clinicians, and users with the implementation of mobile health technology. The Technology Evaluation and Assessment Criteria for Health apps (TEACH-apps) consists of the four parts (1) preconditions, (2) preimplementation, (3) implementation, and (4) maintenance and evolution. The authors recommend to repeat the process at least biannually, in order to adapt for changing consumer preferences over time (30). Mathews et al. (22) propose a digital health scorecard consisting of four domains (technical, clinical, usability, cost), which aims to serve as framework guiding the evolution and successful delivery of validated mHealth apps over the product's lifecycle. Moshi et al. (35) have developed criteria for evaluation of mHealth apps within health technology assessment (HTA) frameworks. The multidimensional module also contains items allowing for post-market surveillance. Sadegh et al. (21) have conducted an mHealth evaluation framework throughout the lifecycle in three stages, namely (1) service requirement analysis, (2) service development, and (3) service delivery. Finally, Yasini et al. (90) have developed a multidimensional scale for quality assessment of mHealth apps.

3.3 Derived quality dimensions

In total, 584 items were extracted from the identified quality assessment tools and quality assurance systems and were categorized into clusters, respectively the quality dimensions. The number of quality dimensions derived from each of the 29 articles ranged from one to 13 dimensions, with an average of 4.9 dimensions. These were grouped to a total of 14 distinct quality dimensions. Figure 3 gives an overview of the identified quality dimensions and quality aspects.

Items pertaining to the quality dimension "validity and (added) value" were contained in 21 of the included quality assessment tools and quality assurance systems. Items addressing the clear, complete and accurate presentation of relevant and useful content based on evidence-based information were included here. In addition, items concerned with the provision of information about the (scientific) sources used, the involvement of experts in the development and evaluation process and the patient-specific benefits were considered relevant for this quality dimension. Twenty-one articles contained items which were grouped to "usability and design". Usability provides information on how difficult / complex it is to operate and use the app. Usability can be indicated by ease of use. Both direct and long-term use should be taken into account. The design includes the presentation and associated clarity. The application itself, but also the results provided, should be clear and concise. Integrated functions should always be fit for purpose. The usability should be tested by usage tests before publication.

Eighteen of the 32 articles included information which was grouped to the quality dimension "engagement". Engagement describes the user's involvement and can be indicated by the extent of use or the intention to use the app long term. It can be strengthened by calls to action, the setting of goals and human attributes such as friendliness, trust, and acceptance. Users can be motivated by interactions, personalization, interesting content and resulting fun during use. In contrast to the intention to use, the subjective benefit is not part of this dimension but belongs to Validity & (Added) Value.

Fifteen of the included articles describing quality assessment tools and quality assurance systems contained dimensions which were sorted into "information and transparency". The dimension "data privacy and data security" was contained in 11 articles. Further dimensions are "technology" ($n = 9$), "equity and equality" ($n = 8$), "interoperability and compatibility" ($n = 7$), "(medical) safety" ($n = 7$), "actuality" ($n = 7$), "legal aspects" ($n = 5$), "(cost-) effectiveness" ($n = 5$), "social aspects" ($n = 4$), and "organizational aspects" ($n = 4$). An overview of the quality dimensions derived from the included studies can be found in Supplementary Appendix C. The full descriptions of these dimensions, which

TABLE 2 Characteristics of included quality assurance systems.

Author (year)	Country	Tool name	Field of application
Camacho et al. (2020) (30)	US	Technology Evaluation and Assessment Criteria for Health Apps (TEACH-Apps)	All fields of health
Mathews et al. (2019) (22)	US	Digital Health Scorecard	All fields of health
Moshi et al. (2020) (35)	Australia	Health technology assessment module	All fields of health
Sadegh et al. (2018) (21)	Iran	Untitled	All fields of health
Yasini et al. (2016) (90)	France	Multidimensional assessment program	All fields of health

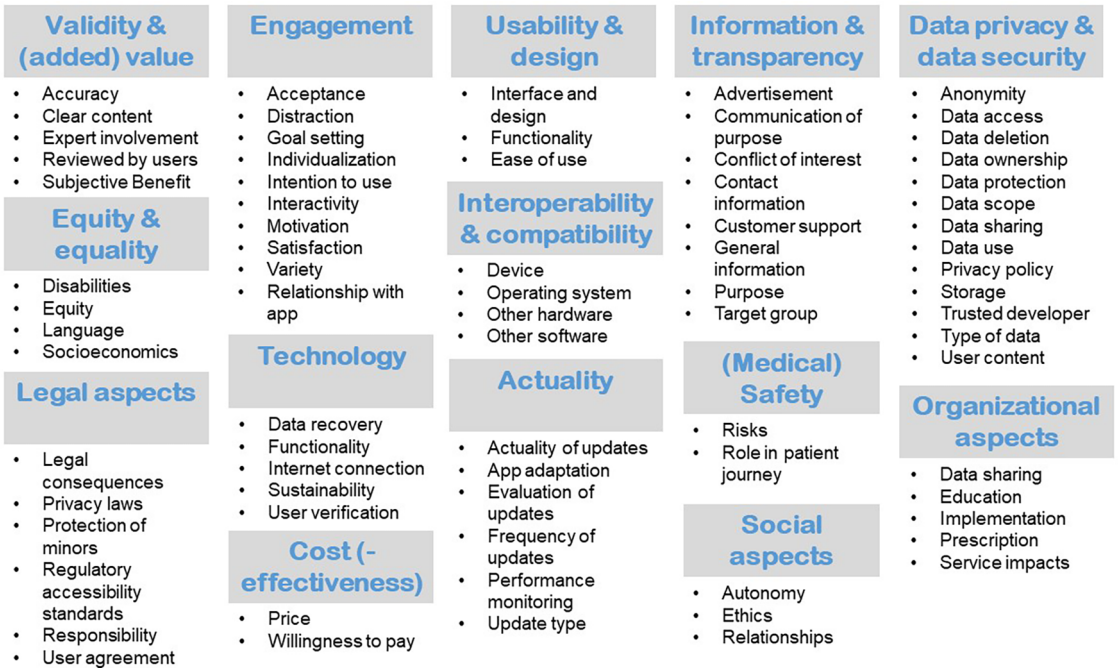

FIGURE 3
Quality dimensions with corresponding criteria.

were developed based on the extracted criteria from the quality assessment tools and quality assurance systems, can be found in Supplementary Appendix D. The frequency of the individual quality dimensions in the 33 quality assessment tools and quality assurance systems included is illustrated in Figure 4.

4 Discussion

The aim of this scoping review was to identify relevant quality dimensions by searching and analyzing quality assessment tools and quality assurance systems. Thereby, the aim was not to obtain a complete survey of all available quality assessment tools. Such a list was meanwhile provided by Hajesmaeel-Gohari et al. (91). A total of 70 articles were included in the review, of which 29 articles contained distinct approaches of quality assessment tools and quality assurance systems.

FIGURE 4
Word cloud including the quality dimensions.

Of the identified approaches, some include one or two aspects, while others allow a more comprehensive assessment. For example, the Net Promoter Score (86), which de Batlle et al. (64) used alongside the SUS to evaluate an mHealth-enabled integrated care model, consists of just one item. The NPS is based on the question „How likely is it that you would recommend [name of company/product/website/services] to a friend or colleague?". In their study, de Batlle et al. (64) used the NPS to measure acceptability and thus, the score was assorted to the quality dimension "engagement" in our scoping review.

A large number of approaches from application studies were identified. In these studies, the MARS or a modified version of the MARS ($n = 19$) and the SUS ($n = 10$) were used most frequently. The MARS is a 23-item questionnaire with questions on engagement, functionality, aesthetics, the quality of the information contained and general questions for the subjective assessment of the app (18). The MARS was developed to enable a multidimensional assessment of app quality by researchers, developers, and health-professionals. The items contained in the MARS were assigned to six quality dimensions in this review, namely "information and transparency", "validity and (added) value", "engagement", "usability and design", "technology", and "equity and equality". The SUS, which is also frequently used, was developed by Brooke et al. in 1996 (20) with the intention of providing a "quick and dirty" tool for measuring the usability in industrial systems evaluation. It consists of ten elements, which were grouped into the dimensions "engagement" and "usability and design" in this review.

Many quality assessment tools contain questions that are easy to answer, but which reflect opinions rather than facts. For example, the items "I feel critical or disappointed in the app." (28) or "Visual appeal: How good does the app look?" (18) can be answered in subjective ways by different people. The tools therefore consist of parameters that are used to approximate the quality of the app. In this context, it is questionable how the quality of an app can be fully measured. This may also include the consideration of problems with the app.

Many of the approaches identified focus on usability. Presumably because usability is quite easy to measure and provides app developers with important insights. For example, patient safety is rarely addressed in the identified studies. Thus, the frequency of items in different questionnaires does not necessarily indicate their relevance to the healthcare system. This could be due to the target group of the approach and the complexity of the survey. However, in the next step, it is necessary to determine which aspects are relevant to the quality of apps from the perspective of the healthcare system.

Besides the quality assessment tools and given the objective of QuaSiApps (to develop a continuous quality assurance system), a particular focus of this scoping review was to identify approaches which consider mHealth apps over time. Interestingly, only five quality assurance systems could be identified. Compared to quality assessment tools, these quality assurance systems were somewhat more extensive overall and their items contributed to between five and 13 quality dimensions. For example, the items of the health technology assessment module presented by Moshi et al. (35) contributed to a total of 13 of the 14 quality dimensions in our review.

The descriptions of the 14 dimensions were derived based on the extracted criteria from the quality assessment tools and quality assurance systems. The main aim of this work was to identify relevant quality dimensions in the context of mHealth apps in order to conduct focus groups with patients and expert interviews with other stakeholders. This was done to gain further insights into each dimension and to investigate their relevance. Based on this, a set of criteria for evaluating the provision of mHealth apps will be developed.

In addition to the use within the research project, our findings can also be used as an orientation in the development of an mHealth app or related assessment instruments such as checklists. The dimensions should not be seen as a simple rating tool. Developers and researchers should critically reflect on each quality dimension.

In the following, the application of the quality dimensions "Information and Transparency" as well as "Validity & (Added) Value" will be briefly presented using the example of an mHealth app for diabetes management. In the context of "Information and Transparency", it should be ensured that the information is presented transparently and that the relevant target group is clearly defined. For example, information should be provided on the responsible manufacturer, the costs involved and how to deal with problems during the use, or what forms of support are generally available. More indication-specific, the quality dimension "Validity & (Added) Value" should ask whether the content and functions are evidence-based and in-line with published guidelines. Recorded vital signs such as blood glucose must be clear, complete, accurate, relevant and useful. The information provided should be supported by (scientific) sources. Endocrinologists and other stakeholders should be involved in the development and evaluation process. The final application should be subject to clinical trials to demonstrate the patient benefit.

In a next step in the QuaSiApps project, these quality assurance systems will be analyzed and checked for their transferability to the German context. Interestingly, some quality assurance systems in particular show a certain degree of flexibility, thereby taking into account the dynamic developments in the mHealth sector. For example, Yasini et al. (90) developed a multidimensional scale that is completed in a web-based, self-administered questionnaire. The resulting report is both app-specific and applicable to all types of mHealth apps.

The appropriateness of the identified 14 dimensions has to be examined from a bottom-up patients' perspective as well as from a top-down healthcare system perspective to develop a quality assurance system feasible for the German health care system. As described, there are common dimensions for the quality assessment of mHealth apps that are included in many of the approaches analyzed, such as usability, data privacy and validity. Concerning the additional dimensions that we found, the question arises as to how they relate to these classic dimensions. The International Organization for Standardization (ISO) defines quality as the "degree to which a set of inherent characteristics […] of an object […] fulfils requirements" (92). It is to be discussed whether quality dimensions such as "cost (-effectiveness)" represent inherent quality characteristics of an object and thus, their suitability needs to be discussed.

As mentioned above, the approaches included in this review differ from traditional quality assurance concepts. A variety of framework concepts for quality assurance in the healthcare sector exist. They are similar to each other, but have different focuses depending on their objectives (e.g., whether they were designed for quality improvement in the healthcare system, to compare the quality of healthcare internationally, as a template for the accreditation of healthcare services, etc.). In Germany, the Institute for Quality Assurance and Transparency in Healthcare (IQTIG) acts as the central scientific institute for quality assurance in the healthcare sector. The framework concept, whose requirements are based on the principles of patient-centeredness, contains the quality dimensions "effectiveness", "safety", "responsiveness", "timeliness", "appropriateness", and "coordination and continuity" (93).

The BfArM's fast-track procedure includes requirements in its checklists relating to "product safety and functionality", "privacy and information security", "interoperability", "robustness", "consumer protection", "usability", "provider support", "medical content quality" and "patient safety". Thereby, the fast-track procedure ensures pre-selection by including criteria which are also included in many of the quality assessment tools and quality assurance systems identified in this review. The next step in the QuaSiApps project will be to analyze the transferability of results obtained in this scoping review into a concept for continuous quality assurance of DiGAs, also against the criteria already used in the fast-track procedure. QuaSiApps includes literature reviews, focus groups with users and patients, and interviews

with health care stakeholders. Based on the results, proposals for procedural purposes and quality dimensions will be formulated. These will be agreed and refined in expert workshops. The project aims to develop a set of quality aspects and corresponding quality characteristics, quality requirements, quality indicators and measurement tools.

While we are not aware of a literature review specifically on quality assurance systems, at the time of our search several literature reviews on the quality assessment of mHealth apps had already been published (91, 94–99). The most recent review of these included literature published up to December 2022 (99). The authors identified a set of 216 evaluation criteria and 6 relevant dimensions ("context", "stakeholder involvement", "development process", "evaluation", "implementation", and "features and requirements"). Although the systemization of the dimensions differs from ours, the content is comparable. This could be indicative for the relevance of the findings.

For example, Azad-Khaneghah et al. (94) conducted a systematic review to identify rating scales used to evaluate usability and quality of mHealth apps. They note that the identified scales ask about different criteria and it is therefore unclear whether the scales actually measure the same construct. Similar to our review, a theoretical basis for the construct of app quality could only be identified to a very limited extent, which is also reflected by the lack of definition of the term "quality" in the included literature. Similarly, McKay et al. (96), who conducted a systematic review of evaluation approaches for apps in the area of health behavior change, criticize the incompleteness of the evaluation criteria, resulting in the authors being unable to propose a uniform best-practice approach to the evaluation of mHealth apps.

Transferring one of the identified systems without adapting to the German healthcare system would not be appropriate. Therefore, further steps are necessary to develop a quality assurance system operating on the system level. The 14 dimensions identified need to be further explored to determine whether they address the potential risks to the quality of health care, and they need to be reflected by stakeholders in the German health care system. Our review has a number of limitations. We searched three databases and also included literature from the field of psychology by searching PsycInfo, but it cannot be ruled out that a more extensive search might have led to additional results. In addition, the exclusive use of bibliometric databases and the omission of secondary literature are limitations in this context. With regard to the search strategy, there is currently disagreement on terminology (27). Therefore, different strategies were tested beforehand and the results were compared to ensure an optimal search strategy. A further potential limitation arises from the inclusion of literature published between January 1st, 2016 and July 26th, 2021. Since we also included older quality assessment tools and quality assurance systems via application studies published during this period, relevant instruments developed before 2016, such as the SUS (20), the NPS (86), or the Silberg Scale (73) were also covered. Our review only included articles up to mid-2021. However, a current review pointed out older assessment tools such as the SUS (1996) (20), the MARS (2015) (18), the PSSUQ (1995) (85), and the uMARS (2016) (63) are still among the most commonly used in mHealth assessment (99). Therefore, we are confident that our search strategy has enabled us to include a large proportion of quality assessment tools and quality assurance systems currently in use.

In addition, we only included articles in German and English language. It is notable that the majority of the quality assessment tools and quality assurance systems included are from English-speaking countries, which may indicate that some tools published in other languages may not have been identified. Nevertheless, we limited our search to articles in bibliographic databases, most of which are published in English. Further, descriptions for quality dimensions were formulated based on the information contained in the quality assessment tools and quality assurance systems. Thus, these descriptions are based on the subjective perception of the researchers and are not based on existing definitions. One reason for choosing this approach was the lack of international agreement on the underlying concepts. As described by Nouri et al. (97), there are major differences in the classification and definition of the individual criteria, so that usability, for example, has very different subcategories depending on the scale or is even seen as a subcategory of functionality, as in Stoyanov et al. (18). The ISO defines usability as the "extent to which a system can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" (100). While this definition identifies the fundamentals of usability and makes clear that effectiveness, efficiency and satisfaction are key criteria (101), ISO 9241-11:2018 is not intended to describe usability evaluation methods (100). Finally, the study protocol (27) announced the assessment of the suitability of the criteria and derived dimensions for the continuous quality assurance of mHealth apps in Germany as part of this review. In the light of our results, this seems unattainable without taking further steps (e.g., focus groups with patients). Results will be published elsewhere.

Concluding, this review serves as a building block of a continuous quality assurance system for mHealth apps in Germany. Based on our findings, we agree with Nouri et al. (97) that it is challenging to define suitable evaluation criteria for the wide range of functionalities and application areas of apps. In addition, apps are constantly evolving, which means that quality assessment tools and quality assurance systems will also need to constantly adapt.

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

GG: Investigation, Writing – review & editing, Writing – original draft, Visualization, Methodology, Formal Analysis, Data curation.

CS: Data curation, Formal Analysis, Methodology, Visualization, Writing – original draft, Writing – review & editing, Conceptualization, Funding acquisition, Validation. NS: Writing – review & editing, Investigation. CA: Conceptualization, Funding acquisition, Methodology, Validation, Writing – review & editing. FP: Writing – review & editing, Validation, Formal Analysis. VH: Writing – review & editing, Investigation. DW: Investigation, Writing – review & editing. KB: Writing – review & editing, Supervision, Methodology, Conceptualization. JW: Writing – review & editing, Supervision, Methodology, Conceptualization. NB: Writing – review & editing, Supervision, Methodology. SN: Conceptualization, Writing – review & editing, Supervision, Methodology, Funding acquisition.

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Conflict of interest

KB is managing director of the company QM BÖRCHERS CONSULTING+.

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.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2024.1372871/full#supplementary-material

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Implementation of the electronic health record in the German healthcare system: an assessment of the current status and future development perspectives considering the potentials of health data utilisation by representatives of different stakeholder groups

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Introduction: The digitalisation of the German healthcare system enables a wide range of opportunities to utilize healthcare data. The implementation of the EHR in January 2021 was a significant step, but compared to other European countries, the implementation of the EHR in the German healthcare system is still at an early stage. The aim of this paper is to characterise the structural factors relating to the adoption of the EHR in more detail from the perspective of representatives of stakeholders working in the German healthcare system and to identify existing barriers to implementation and the need for change.
Methods: Qualitative expert interviews were conducted with one representative from each of the stakeholder groups health insurance, pharmacies, healthcare research, EHR development and panel doctors.
Results: The interviews with the various stakeholders revealed that the implementation process of the EHR is being delayed by a lack of a viable basis for decision-making, existing conflicts of interest and insufficient consideration of the needs of patients and service providers, among other things.
Discussion: The current status of EHR implementation is due to deficiency in legal regulations as well as structural problems and the timing of the introduction. For instance, the access rights of various stakeholders to the EHR data and the procedure in the event of a technical failure of the telematics infrastructure are remain unclear. In addition, insufficient information and communication measures have not led to the desired acceptance of EHR use among patients and service providers.

KEYWORDS

digital health, electronic health record (EHR), personal health records, health data use, digitalisation

Abbreviations

BDSG, Bundesdatenschutzgesetz [Federal Data Protection Act]; BfDI, Bundesbeauftragter für den Datenschutz und die Informationsfreiheit [Federal Commissioner for Data Protection and Information Security]; e-prescription, electronic prescription; EHR, electronic health record, GDPR, Datenschutz-Grundverordnung [General Data Protection Regulation].

Introduction

In order to achieve comprehensive digitalisation of the German healthcare system, all stakeholders must agree to implement this change together. In addition to hospitals, doctors' surgeries and health insurance companies, patients and politicians are also involved. This change includes the creation of digital infrastructures on the one hand and the digitalisation of procedures and processes in healthcare on the other (1). The digitalisation of the healthcare system offers a multitude of opportunities. In the German healthcare system alone, there is an economic potential of 42 billion euros per year (2). Other potentials include opportunities to develop new diagnostic and treatment options, improve communication between individual players in the healthcare system and between patients and service providers. The quality of care can also become better (3). One basis for realising the aforementioned potential is the use of healthcare data generated in everyday care. To effectively use this data, a platform is required where it can be digitally collated and then made accessible to selected groups of people. In this context, the electronic health record is a central and promising application. The contents of the record include data on diagnostics and medical treatment in the doctor's surgery and in hospitals, as well as data on the supply of medicines or from providers of remedies and aids.

With regard to the current status of digitalisation in various healthcare systems, it is clear that Germany still much ground to cover compared to other countries. This is reflected, among other things, in the fact that the implementation of electronic health records in everyday care in the German healthcare system has not yet been realised to the desired extent. In Europe, Estonia and Denmark in particular have comprehensively digitalised their healthcare systems (4). In Denmark, for example, the EHR was introduced as early as 2012 and in Estonia as early as 2008. In addition, almost the entire population in both countries currently has an EHR (3). They use the digital data of the healthcare system and provide patients and authorised service providers with additional information from the consolidation and analysis of a wide variety of data, in particular through the use of data from electronic health records.

In order to promote the further development of the German healthcare system with regard to electronic health records, it is necessary to identify the causal factors that have caused the delay this process thus far. Consequently, these factors should be analysed in a way that allows adjustment of these factors with the aim of achieving the objectives.

Definition of an electronic health record

The health record is a document to be kept by the service providers involved in the treatment of a patient. All essential medical data that arises during treatment must be documented in the record. This includes information from the medical history, the measures applied and their results, as well as diagnoses made by the service provider during the patient's treatment. The patient's explanations and consent are also recorded. A patient's entire medical history thus becomes part of the record (5).

In the context of this work, the term electronic health record refers to the integrative electronic health record for an electronic documentation system that can be viewed and edited by doctors and other service providers involved in the treatment across disciplines, institutions and sectors [(3), p. 70].

In the EHR consent procedure, a basic distinction is made between the opt-out and opt-in procedure. While in the opt-out procedure, an EHR is set up for each patient or insured person as long as they do not expressly object, in an opt-in procedure, patients or insured persons must actively contact a corresponding authority in order to open a file.

Development and current status of implementation in the German healthcare system

The German healthcare system can be divided into three levels: the legal framework, self-administration and the individual players. The legal framework becomes the responsibility of the federal, state and local governments. The Federal Ministry of Health is in charge of health policy within the federal government. However, the organisation of healthcare is carried out by the self-administration. This means that the individual institutions organise themselves independently and thus guarantee the provision of medical care [(6), p. 18]. The individual stakeholders who are ultimately directly involved in patient care include the medical profession and various healthcare professionals, hospitals and pharmacies. To enable them to represent their interests at the health policy level, the stakeholders are organised in professional organisations, as well as professional and business associations (6). Around 84.3 million citizens need to be cared for within the German healthcare system (7). The healthcare system is primarily financed by statutory and private health insurance. These in turn are financed by the contributions of their members.

gematik is one of the central institutions involved in the digitalisation of the healthcare system. The Federal Ministry of Health holds the largest share in gematik with 51%. gematik's tasks primarily include the introduction, operation and further development of the telematics infrastructure, the electronic health card and associated specialised applications, as well as the creation of an interoperability directory. It also assumes responsibilities in the area of data security (8). With regard to health data protection, the Bundesbeauftragter für den Datenschutz und die Informationsfreiheit [Federal Commissioner for Data Protection and Information Security] (BfDI) is a key authority. This is the public supervisory authority for all public bodies of the federal government as well as for certain social security organisations. Issues relating to data protection and data security must be coordinated with the BfDI (9). Each of the 16 federal states in Germany also has its own state data protection officer and corresponding supervisory authorities.

Several laws form the legal framework for the development and design of digitalisation in the German healthcare system, particulary for the implementation of the EHR and use of healthcare data. In addition, the requirements of the Datenschutz-Grundverordnung [General Data Protection Regulation] (GDPR) and the Bundesdatenschutzgesetz [Federal Data Protection Act] (BDSG) apply in Germany. The basis for digitalisation in the German healthcare system became law with the Act for Secure Digital Communication and Applications in Healthcare (E-Health Act), which came into force on 29 December 2015.

The EHR was introduced as a patient-moderated record in the German healthcare system in January 2021. From this point onwards, anyone with statutory health insurance can obtain an EHR on request from their health insurance provider. Private health insurers can offer an EHR on a voluntary basis; therefore, there is no legal obligation. The term patient-moderated means that the patient alone decides whether and to what extent they use the record and to whom they make which data available. Data that can be entered into the EHRs includes care and service data. Patients can also enter their own health data, such as that collected by wearable devices, into the record (10–12). Access becomes possible via an app provided by the respective health insurance company using a smartphone, tablet or computer. The prerequisite for using the EHR is prior registration with the respective health insurance company. EHR registration currently takes place either via the new electronic health card with NFC interface and a PIN applied for the card or alternatively via two-factor authentication. As of April 2023, around 667,449 people with statutory health insurance, which corresponds to around 1% of people with statutory health insurance, have an EHR (13). In addition, the records that currently exist are hardly filled with data. Due to the low number of existing records, utilisation by service providers is also at a very low level. Finally, data is exchanged between service providers via the telematics infrastructure. Access to the telematics infrastructure is via a connector (14). The use of EHR data, for example, for research projects, should be possible from 2023 for a selected group of authorised applicants. In this context, patients should be given the opportunity to voluntarily make their data available for research projects as part of a data donation through an opt-in procedure. Until now, using the data contained in EHRs for research purposes or merging data collected at different locations in the healthcare system has not been possible.

Most recently, in March 2023, the Federal Ministry of Health presented its digitalisation strategy for the healthcare and nursing sectors up to 2030. In this context, gematik is to become a digital health agency and will be tasked with defining comprehensive binding requirements for interoperability. The further development of the lead data protection supervisory authority is also planned. The aim is to become a standardised data protection supervisory practice in the health and care sector. One of the objectives of the strategy is to facilitate access to pseudonymised health data for researchers. The decisive interface in this context is the research data centre, through which the data is to be made available after an application has been submitted. In addition, around 80% of people with statutory health insurance should have an EHR by 2025. These goals are to be achieved, among other things, with the legislative proposals presented in this context for a Health Data Utilisation Act and a Digital Act. As part of a digital law, the consent procedure for the EHR is to become an opt-out procedure (15).

The aim of this study is to scrutinise the structural factors in the context of EHR implementation from the perspective of stakeholders working in the German healthcare system and, based on this, to identify existing barriers to implementation and the need for change. The aim is to answer the question of how relevant actors in the German healthcare system assess the current structural conditions regarding the implementation of her. Additionally, the study aims to explore existing implementation hurdles or areas that require change related to this topic and examine the causes contributing to the current status of EHR implementation, particularly regarding the potential use of health data in the German healthcare system. The focus here will be on the current legal regulations and the framework conditions of the healthcare system.

Methodological approach

The methodological approach was based on a qualitative research design. In view of the defined objectives of the work, the investigation using a qualitative method is suitable, as it offers the possibility of describing an object of investigation in detail and developing hypotheses and theories. The approach taken in the study is exploratory in character and is intended to provide initial insights into the research topic (16). In order to ensure the quality of this scientific work, the catalogue of criteria from Lincoln et al. (17) was used. Firstly, it is necessary to define individual specific subject areas in relation to the general survey topic. The specific interview topics were selected on the basis of expert opinions on the one hand and a selective literature review on the other. In addition to the access authorisations of various stakeholders to the data contained in the EHR, the topics also include the existence or expansion of corresponding infrastructures and technical requirements, data protection and information security as well as the needs of patients with regard to the design of the EHR. The development of the EHR since its introduction and the resulting potential are also discussed. With regard to the field of investigation, the decision was made to take a multi-perspective view of the various representatives of stakeholder groups in the German healthcare system (16). With regard to the existing structures in the German healthcare system, the central stakeholder groups can be identified as service providers, patients, health insurers, academic and other public research, developers and manufacturers as well as healthcare policy and authorities [(18), p. 30]. However, the analysis should be limited exclusively to the perspectives of healthcare providers, patients, health insurers, developers and researchers. The views of health policy makers and authorities will deliberately not be included in the study, as both actors have a controlling or monitoring function regarding the implementation of the EHR and the use of health

data. Consequently, they are not directly involved in the utilisation. However, the focus should be on these actors who are directly involved in the utilisation. The selection of these stakeholders can be justified by the fact that they formulate stakeholder-specific requirements and needs for the use of the EHR in everyday care and work as well as for the design of the record itself. These requirements and needs play a crucial role in the design of the legal framework and the EHR itself, so that it can be integrated seamlessly into care provision. The sample was then compiled from the previously defined field of investigation. This should be as heterogeneous a group of people as possible, with maximum contrast in the relevant characteristics and therefore informative for the study (19). With regard to representative of the health insurance stakeholder group, the analysis should focus on the level of statutory health insurance. Statutory health insurers cover around 90% of the German population (20). In addition, they have become legally obliged to provide an EHR for their policyholders with corresponding requirements. Private health insurers, on the other hand, cover a comparatively smaller proportion of the population. In addition, there are no precisely defined requirements for the provision of EHRs. In order to comprehensively reflect the perspective of the statutory health insurance funds, it is necessary for them to be represented by a high-ranking representative from the management level of a nationally active statutory health insurance fund. In addition, the representative must have extensive professional experience and appropriate specialist knowledge in the context of the EHR and its development. The service provider perspective is to be illuminated by doctors on the one hand and pharmacies on the other. The selection of pharmacies is justified by the fact that they have the role of supplying medicines within the healthcare system. By utilising the health data contained in the EHR, they would become empowered to actively improve the quality of the supply of medicines to patients. Both the representative of the medical profession and the representative of the pharmacy profession must be a person who acts within the framework of one of the corresponding nationwide interest groups. Only on this basis can the results be generalised beyond the specific case. In addition, it is necessary for the physician and pharmacy representative to have extensive professional experience and expertise in the context of the EHR and its development. For the area of research, the analysis should be carried out from the perspective of health services research, as EHR data in particular forms a central basis for their activities (11). The developer and manufacturer perspective is to be presented by a member of an EHR development team from the statutory health insurance funds and the patient perspective by a patient representative from a nationwide patient organisation. These representatives of the relevant stakeholder group must also hold a high-ranking position in their professional activities, have extensive professional experience and appropriate knowledge of the EHR and its development. Recruitment was carried out through the relevant contact persons of a nationwide association of pharmacies, patients and statutory health insurance physicians. The contact details of two other people were obtained from the contact database available as part of the work. The identified potential interviewees were then contacted by email and the subject of the research and the preliminary interview guidelines were briefly described. Finally, the interviewees were selected on the basis of predefined criteria such as length of professional experience, existing knowledge of the EHR and its development, and professional position. The result was a sample of five male interviewees (Table 1). This is therefore a convenience sampling [(16), p. 306]. The interviewees were selected for the study because they were easy to reach and met the predefined inclusion criteria. In accordance with the aforementioned requirements for the participants, this is not a random sample.

The semi-structured interview method in the form of guided interviews was chosen to illustrate the structural conditions of EHR implementation from the perspective of the actors working in the German healthcare system. The reason for choosing this method is that the interviewees, who represent one of the previously defined actors, have a certain proximity to both the topic and the corresponding actor due to the nature of their work. They can describe their view of the situation subjectively. This variant of the guided interview is also referred to as an expert interview, as the interviewees are technical experts on a specific topic whose structural expertise is to be developed with the help of the interview [(16), p. 375]. The semi-structured interview is based on an interview guideline, which roughly specifies and structures the questions to be answered by the interviewee. The guideline itself is considered flexible. Accordingly, additional or in-depth questions that arise during

TABLE 1 Composition of the sample.

ID	Professional field of activity	Professional experience	Duration of the interview
B1	Head of a business unit in a large statutory health insurance company in Germany; The responsibilities of the division include representing the interests of the health insurance fund at federal level	30 years in the healthcare sector; Head of division since 2015	17 min
B2	Pharmacist who works in the telematics department of a nationwide pharmacy association	24 years in the healthcare sector	31 min
B3	Researcher in the field of health services research; team leader of a research team of a large statutory health insurance company in Germany	20 years in the field of health services research	35 min
B4	Team leader of an EHR development team on behalf of a large statutory health insurance company in Germany	28 years with a large statutory health insurance company; Since 2016 with the topic of developing an EHR	33 min
B5	Economist who works in the telematics and digitalisation department of a nationwide association of statutory health insurance physicians	25 years in the healthcare sector With a nationwide association of statutory health insurance physicians since 2019	36 min

ID, identifier; Min, minutes.

the interview can be asked [(16), p. 358]. The data collection took place in the period from 1 March 2023 to 20 March 2023. The appointments were arranged in advance by email or in person. While one interview took place face-to-face, the other interviews were conducted as hybrid interviews. Before the interviews were conducted, all interviewees were informed about the use of the data and a verbal declaration of consent was obtained. In addition, all interviews were recorded. All interviews were based on the same interview guide.

The material obtained from the guided interviews was initially available in the form of audio recordings. These were then transcribed into a document with the help of AI-supported transcription software. Then the documents were then compared with the audio recordings and any content that was not correctly transferred by the software was corrected with the help of the audio recordings. The transcription became complete and was carried out without adapting the wording. Only dialect was not taken into account in this context and was translated into standardised German. Punctuation marks were used when revising the transcripts according to sound and not grammatical correctness. In addition, personal and company-related data became unrecognisable by replacing them with synonyms. Finally, the transcripts in Word documents were imported into the computer-aided analysis programme MAXQDA (version 2020). The data collected in the context of the interviews, which were subsequently transcribed, were available in qualitative form. This paper therefore uses the method of qualitative content analysis with the help of the computer-assisted analysis programme MAXQDA (Version 2020) [(16), p. 602]. With regard to the content analysis process model, the material was first analysed comprehensively based on the research question and text passages that deemed relevant were then marked. This was followed by the development of thematic main categories, which should roughly structure the material. These became deductively derived from the research question and the thematic complexes of the individual questions of the interview guide. Finally, the entire material became coded with the help of the main categories. In the next step, the text passages that were coded with the same main category were compiled. Subcategories were then inductively derived from the material within the individual main categories and the entire material was coded using the differentiated category system [(16), p. 557]. The final evaluation was carried out along the main categories. Only those categories that were classified as relevant to answering the research question were analysed. In addition, it was analysed whether there were correlations within a main category between the subcategories and between the main thematic categories. In addition, the statements of the interviewees were compared as part of the multi-perspective analysis.

Results

In the following, the results of the evaluation of the qualitative interviews are presented along the main categories.

Development of the EHR

The development of the EHR became predominantly negative for all respondents. In this context, four interviewees refer to the fact that only a very small number of people with statutory health insurance have an EHR. The representative of the statutory health insurance physicians cites the fact that it has never been defined what is meant by a patient-moderated record and how the use of the EHR is intended for service providers and in which architectures.

However, the EHR developer states that he considers the development of the EHR to be positive in terms of the functionality of the record.

Access authorisations

The representative of the SHI-accredited physicians stated that a basis for the discussion on access authorisation must be created at the outset. This means that it must be determined for which group of people which information should be made accessible and for what reason.

In the context of access authorisations, three interviewees refer to the role of the record owners. The care researcher criticises the fact that the will of the record owners regarding the use of the data has not been sufficiently taken into account in the discussions on access authorisations to date. The representative of the SHI-accredited physicians emphasises the need to provide comprehensive information to record users on how the system works. Building on this basis, the record owners can ultimately become empowered to make informed decisions regarding access authorisations. The representative of the pharmacies is in favour of an opt-out procedure in order to give people who do not trust anonymisation the freedom to make their own decisions.

The EHR developer is in favour of access by all service providers involved in the treatment and justifies this with the fact that medicine depends on a holistic view of the state of health.

The representative of the health insurance company is in favour of health insurance companies having access and emphasises that they would thus become able to use the EHR data to support the insured person in their care. The representative of the pharmacies, on the other hand, emphasises that, in his view, the statutory health insurance funds should not be given access to the EHR data. The EHR developer states that if the health insurance funds are to be granted access, this must be regulated via an opt-in procedure, as in this case it is a matter of private interests. The EHR developer states that the release of data for research purposes should also be regulated via an opt-out objection procedure, as the data is used to further develop and improve medical care for the entire German population.

In this context, the representative of the health insurance company emphasised that research must be able to access the overall data of the healthcare system in anonymised form.

Infrastructure and technical requirements

With regard to infrastructures and technical requirements, various problems were mentioned by the interviewees. The

representative of the SHI-accredited physicians criticised the fact that the current discussion is mainly about fictitious usage scenarios. The processes and their process steps and how the relevant players are involved in these are not currently defined in relation to the infrastructures. However, these would become the basis for formulating requirements for corresponding architectures. The representative of the health insurance company points out that the different structures of the data from the outpatient and inpatient areas are seen as problematic from the health insurance company's perspective. This means that the data from the outpatient sector is transmitted quarterly and is therefore available to the health insurance funds with a considerable delay, which makes it difficult to react promptly to acute events. In this context, the pharmacy representative cites time pressure when introducing new applications as a problem. In the past, this mistake had already been made with e-prescriptions and applications had been introduced that were not yet fully developed for use in practice. The EHR developer emphasises that there would be an implementation problem in Germany. In his view, the providers of practice management systems or hospital information systems must become active and implement the specifications published by gematik in 2019. A functioning system would already exist and therefore no new concepts would be necessary.

All interviewees emphasised the necessity for technical requirements and infrastructures to ensure that data is input into the EHR in a structured manner. The representative of the SHI-accredited physicians emphasised that the various EHR usage scenarios must be defined at the outset. In addition, priorities must be set as to which clinical pictures and scenarios are currently most important in order to plan the further procedure for expanding the corresponding infrastructures on this basis. The representative of the health insurance company states that the system needs to be converted to the use of cloud applications. The representative of the pharmacies also stated that appropriate lead times must be guaranteed regarding to the technical requirements. In addition, future users would have to be trained in advance.

Data protection and information security

In terms of data protection and information security, the EHR developer and the representative of the health insurance company consider the current design of the registration process for insured persons to be problematic. This is very complex, and it becomes an access barrier for users.

Two interviewees named specific requirements that they place on EHR use related to data protection and information security.

The representative of the statutory health insurance physicians points out that data protection and information security are a fundamental prerequisite for entry and should not be seen as a hurdle. The representative of the pharmacies highlights a further requirement that the possibility for patients to exercise their right to self-determination must be retained in the context of EHR use. In addition, the establishment of such a system should become possible in agreement with the BfDI.

Patient requirements for the EHR

The representative of the pharmacies emphasises that the EHR must become simple and user-friendly. There must also be options for using a proxy, for example for people who do not have their own end device or those who cannot use the functions of the record themselves due to other restrictions.

The representatives of statutory health insurance physicians and pharmacies emphasise the need for comprehensive information and communication measures aimed at patients in order to create a basic understanding among them of what the aim of the record is and the aim of its use. All stakeholders involved in the record as well as the Federal Ministry of Health must become involved in information and communication.

The supply researcher stated that a basis of trust must be created among users. They must be able to trust that it is a functioning and secure application in terms of data protection, information security and user-orientation.

Needs from the service provider perspective

The representative of the pharmacies addresses the needs from the perspective of the service providers and emphasises that additional costs incurred by the service providers through the use of the EHR should be remunerated. In this context, it must also be clarified which group of people checks that the records are up to date. In addition, the issue of liability for service providers must be clarified in advance. In particular, it must be clarified whether service providers are obliged to read all the data contained in the EHR. In addition, a regulation must be found on how to deal with technical problems or failures in day-to-day care.

The challenges

Two interviewees commented on the challenges that they believe the German healthcare system will have to overcome in the context of the introduction. The representative of the health insurance company and the healthcare researcher point out that it will be challenging to bring together the various data sets and formats of health data to subsequently use them in the direct context of healthcare or to further develop healthcare from a scientific perspective. The healthcare researcher emphasises that a regulation must be found on how to deal with data that can be set by the patient themselves, such as vital signs data collected by smart watches. The health insurance company representative also sees a challenge in the mandatory filling of EHRs by service providers. With the introduction of a writing obligation, it would also be necessary to discuss corresponding sanctions for service providers in the event of non-compliance with the requirements

The health insurance company representative sees a further challenge in dealing with the current structure of data protection regulations. He emphasises that an assessment must be made of

how important data protection is to the system and its stakeholders compared to the benefits of health data. This requires committees to carry out this assessment.

Potential

The healthcare researcher, the health insurance company and pharmacy representatives emphasise the resulting benefits from an economic perspective for the entire German healthcare system. Due to the data situation, an optimisation of patient flows could be achieved. This would give practitioners the opportunity to deal with patients who actually fall within their area of specialisation. The pharmacy and health insurance company representatives emphasise that financial resources could be saved by avoiding incorrect treatment and duplicate examinations.

Respondents also mentioned improvements in the area of research and care. The EHR developer emphasises that improvements for research would be achieved through the availability of mass data on the health status of the entire German population. The German healthcare system would ultimately have to rely less on data from other countries. In this context, the representative of the statutory health insurance physicians criticised the fact that the focus is currently more on improving research opportunities. However, such improvements would become of little use to those who are currently ill. In his view, care must first become better and then improvements in the area of research can be considered. From the healthcare researcher's point of view, tangible added value would be available to patients if they were able to find their optimal level of care promptly and consequently receive targeted treatment in a timely manner. The representative of the health insurance company and the healthcare researcher highlight the aspect that patients can receive more quality-oriented support and guidance within the healthcare system, thanks to the improved possibilities of cross-sector treatment. Moreover, doctors would be able to incorporate the expertise of another doctor into their own decisions. In the context of follow-up treatment, health data would also be directly available and promptly accessible to doctors in private practice. The pharmacy representative emphasised that pharmacies could improve medication management using the available data.

The healthcare researcher states that, considering the enhancement in care, there would likely be an increase in satisfaction among service providers and patients with the German healthcare system.

Discussion

Discussion of results

Development of the EHR

All respondents rated the development of the EHR as predominantly negative since its introduction in January 2021. One of the reasons for this is that only a very small number of people with statutory health insurance have an EHR and existing records are hardly ever used by them. In turn, the low use of the records also shows that patients do not recognise any added value in this functionality. On the one hand, the cause of this can be the fact that patients were not sufficiently involved in the type and scope of the information measures and the design of the EHR. On the other hand, the cause could also be on the patient side, them being closed to digital innovations or their insufficient individual resources for developing digital skills to cope with this change.

From the perspective of the service provider, the pharmacy representative points out that the EHR is currently not being used in pharmacies. There is also a conceptual problem with the introduction of new applications such as the e-prescription or the EHR. As an example of this, he brings up the fact that in the past, various applications were introduced at the same time. Both service providers and patients did not receive sufficient support and training. The EHR developer assesses the record itself as a functional product, which was simply unable to achieve the desired effect in the area with the objectives formulated for the record. According to this, the current status of target achievement is not because of the EHR itself, but because of a lack of communicative and informative measures. As a result, the experience gained so far and the causes identified as to why the objectives formulated for the record could not be achieved should be taken into account and be included in the future design of the further implementation procedure.

The low user numbers for the EHR in the German healthcare system and the poorly rated development of the EHR against this backdrop are due, among other things, to the choice of consent procedure. In comparison, Estonia and Denmark have at least relied on an opt-out procedure when implementing the EHR, which means that almost the entire population is provided with an EHR (3, 4). In the German healthcare system, on the other hand, an opt-in procedure was used. The patient must therefore make a conscious decision in favour of an EHR and apply for it independently. The choice of consent procedure for the EHR is therefore a relevant factor in terms of successful implementation. The low availability of EHRs and their low utilisation in the German healthcare system can therefore be explained, among other things, by the choice of consent procedure. In order to achieve the widespread availability of EHRs in the German healthcare system, it is therefore necessary to rely on an opt-out procedure.

Furthermore, with regard to the process of implementing the EHR in Denmark and Estonia, it can be seen that both countries are pursuing a stand-alone digital health strategy (4, 21). This forms the framework of a structured, holistic concept according to which the EHR was implemented. There was no digitalisation strategy for the German healthcare system until March 2023. Although the various laws enacted contained requirements and objectives for the introduction of an EHR and were intended to promote the use of the health data it contains, there was no holistic framework in the form of a strategy. The pursuit of a digitalisation strategy with its individual goals and measures serves as orientation for all representatives of stakeholders involved in a complex and lengthy process. For the

implementation of an EHR in the German healthcare system, it is therefore crucial in future to be guided by the strategy defined by the Federal Ministry of Health (15). The strategy's goals and measures must be actively and gradually implemented. However, it is necessary to regularly evaluate the current status of target achievement during the course of the process. If, for example, it turns out that individual goals cannot be achieved by the specified date, they must therefore also be updated and adjusted as part of the digitalisation strategy.

Access authorisations

The interviewees express various opinions regarding the access authorisations of different stakeholders. In particular, the interests behind the required access play a role here. Accordingly, it is decisive whether there are economic interests or interests in the public. According to the representative of the SHI-accredited physicians, the fundamental question that must be clarified is which interests exist for each actor regarding access to EHR data and what justifies the type and scope of access. Only with this understanding can the discussion about corresponding access options be conducted.

Both the representatives of statutory health insurance physicians and pharmacies and the healthcare researchers emphasise that the role of record owners has not yet been sufficiently taken into account in the discussions on access authorisations thus far. In this context, comprehensive communication and information measures towards patients would have to be implemented at the outset. As part of these measures, it should be demonstrated in a simple and understandable way how this system works and where the potential of file utilisation lies in terms of improving medical care. The aim should be to create a basis of trust and enable patients to make informed decisions based on the information provided. The representative of pharmacies is also in favour of the planned opt-out procedure, as this will allow patients who do not trust the system or do not wish to use it to retain their freedom of choice. The latter aspect in particular plays a decisive role in creating a basis of trust.

Access options for all service providers involved in the treatment are a crucial prerequisite, as only on this basis can be possible the simplified interdisciplinary and cross-sectoral exchange of data be made possible.

The opinions of the interviewees differed when it came to health insurance companies' access authorisations to EHR data. While the health insurance company representative is in favour of access options and argues that the health insurance companies can better support the insured persons in their care based on the data, the pharmacy representative rejects access options for statutory health insurance companies. From the EHR developer's point of view, the access options for health insurance companies should be regulated via an opt-in procedure, as there are no public interests involved here. As already explained, this also raises the question of the interests of the respective actor behind the corresponding demand. On the one hand, the statutory health insurance funds are pursuing the goal of improving the provision of customised care services. On the other hand, however, they also have economic interests, as the services provided can in turn be billed. The choice of an opt-in procedure for the access options of health insurance funds would therefore be a conceivable solution that would preserve the freedom of choice of the insured person. With the implementation of the EHR, its use became mandatory for all healthcare institutions in Estonia and Denmark. A debate on access authorisations comparable to that in the German healthcare system has therefore not been held in these countries. In Estonia, for example, patients are allowed to decide for themselves which service providers are authorised to view their data. The reason for the extensive discussion of access authorisations in the German healthcare system is partly due to the number of structures and players involved. Compared to Estonia and Denmark, the German healthcare system has many structures and actors that need to be taken into account when making political decisions. Bertram et al. (22) describes this aspect as an inhibiting factor with regard to the digitalisation of the healthcare system. The large number of actors in self-government significantly slows down the decision-making process in connection with existing conflicts of interest.

With regard to the release of data for research purposes, it is crucial that research institutes can access the overall data of the healthcare system in anonymised form to serve as a foundation for advancing healthcare from a scientific perspective. In this context, the EHR developer also proposes the release of data via an opt-out procedure. This regulation is one approach to generating the largest possible amount of data. However, it is questionable to what extent such regulations will be approved by patients. In both Estonia and Denmark, the release of data from the EHR for research purposes is permitted (4). However, the laws applicable in the respective countries specify that the data may only be made available for research purposes in anonymised form.

Infrastructure and technical requirements

From the point of view of the representative of the SHI-accredited physicians, a corresponding basis for decision-making, which provides for the definition of usage scenarios for the EHR, would be missing—similar to the sub-item access authorisations. Here too, the political authorities had not fulfilled their tasks in a timely manner and to a sufficient extent. As a result, the various utilisation scenarios must first be defined. This includes the individual processes and process steps as well as the involvement of the various stakeholders. Based on this, there are requirements for the further development of the infrastructure and the associated technical requirements. In addition, all interviewees see a need to define specifications for the structure of the data. In particular, the aim is to ensure that relevant data can be retrieved by various service providers in a targeted manner and processed by the systems in a partially automated manner.

From a health insurance perspective, it is crucial that data from the outpatient sector is available promptly. In fact, this aspect is also essential for the exchange of data between the outpatient and inpatient sectors. As long as the data is not available on the same day, it becomes more difficult to react quickly to acute events. The gradual approach to the ideal of real-time availability of health and care data is one of the goals of the digitalisation strategy [(15), p. 27]. The health insurance company representative suggests switching to cloud-based systems for this purpose. However, this requires an adjustment to the regulatory framework, as the use of such systems is currently only possible to a very limited extent in the German healthcare system. This changeover would facilitate the exchange of data across disciplines and sectors and would significantly increase the speed of the system. Cloud-based systems are already in use in Denmark and Estonia. In Denmark, for example, data from the individual databases of hospitals and general practitioners is transmitted to the national health portal sundhed.dk and can then be accessed by the various service providers and patients (3). Estonia also has a national health information exchange network called the Estonian National Health Information Service. Similar to Denmark, data is passed on to the health information portal by the service providers (4). The use of these systems is associated with a number of advantages. Among other things, they offer a high degree of flexibility and nationwide access options, as the data can be accessed by authorised persons at any time and from any location as long as there is an internet connection (3). The use of cloud-based systems in the German healthcare system could improve the timely availability of health data in the future.

From a service provider perspective, appropriate lead times and training for future users must be guaranteed when introducing new applications. This is a task for the health policy authorities and, according to the pharmacy representative, has not been sufficiently taken into account in the past. The latter point also highlights the conceptual problems in the German healthcare system when introducing new applications. From the healthcare researcher's point of view, it is crucial, especially when it comes to infrastructures, to involve the user stakeholders and to organise the further development in such a way that they experience added value as a result.

Data protection and information security

The EHR developer and the representative of the health insurance fund emphasise that the current design of the registration process would represent a barrier to access for insured persons and that a more user-friendly solution must be found here. In contrast, the representative of the statutory health insurance physicians emphasised that data protection requirements should not be put on the back burner. Compliance with data protection requirements is a prerequisite for handling of health data. Similar to the issue of access authorisations, a conflict of interest between various stakeholders can be identified here. The design of the registration process is particularly crucial for the statutory health insurance funds, as this has a significant influence on the number of users of the corresponding EHR checkout app. For the care itself, the design of the registration process plays a less decisive role, as the EPR, if the patient does not object as part of an opt-out procedure, is in the system as a pure service provider file and can be used by the service providers in the context of treatment. For the representative of the statutory health insurance fund, the focus is on increasing the number of users of the health insurance app on the part of the insured. In contrast, the representative of the statutory health insurance physicians prioritises the protection of doctor-patient confidentiality.

The pharmacies' representative mentiones the requirement that patients must be able to exercise their right to self-determination when using the EHR. According to the BfDI, the current design of the EHR for access management violates the GDPR, especially for people who do not have their own device or do not want to use one. These people would become restricted in their patient sovereignty and would not be able to exercise their rights to self-determination (23). It is important to establish regulations for this group of people that enable the uncomplicated use of a representative. In addition, from the perspective of pharmacists and statutory health insurance physicians, data protection and information security must become a matter of agreement with the BfDI. As announced when the Federal Ministry of Health published its digitalisation strategy, the BfDI's right of co-determination is to be changed from agreement to consultation.

With regard to data protection and information security, the requirements of the GDPR apply in Germany, Estonia and Denmark. However, it is up to each individual country to organise the corresponding measures to ensure that the requirements of the GDPR are met. With regard to the number of existing laws and the requirements formulated therein, the German healthcare system has a comparatively strict framework in terms of data protection and information security requirements. In addition, the requirements and interests of various stakeholders must be taken into account in Germany with regard to this topic. According to former Federal Data Protection Commissioner Peter Schaar, this federal system would secure nationwide healthcare provision, but at the same time make it more difficult to implement nationwide digital information structures (24). By comparison, in Estonia and Denmark, only individual institutions are entrusted with ensuring data protection requirements are met (25, 26). This makes the decision-making process much simpler. At the same time, compliance with the requirements of the GDPR ensures that the handling of health data becomes more secure.

Patient requirements for the EHR

The healthcare researcher and the representatives of statutory health insurance physicians and pharmacies name specific requirements for the EHR that must be met from the patient's perspective. As already mentioned in the access authorisations

sub-item, comprehensive information and communication measures for patients and the creation of a basis of trust are emphasised once again. Verifiable value propositions should form the basis of a foundation of trust and corresponding information and communication measures. Formulating these is a task for the political authorities. The EHR must also become user-friendly. Particularly, it should be determined how the patient side defines the criterion of user-friendliness. In this context, it must be taken into account that Germany is strongly affected by the effects of demographic change and that the population therefore has an increasing proportion of older people (27). The consequences of demographic change must be taken into account in corresponding communication and information measures by integrating the channels that older people prefer to use. As already shown in the subsection on data protection and information security, people become excluded from EHR use due to restrictions of any kind. This aspect must be viewed critically from an ethical perspective. In order to make the EHR user-friendly, the different needs of patients must be recorded and then implemented in the design of the EHR. This could be done as part of further research, as the needs of the different user groups are complex and also depend on the age group. In addition, a test phase in which a heterogeneous group of people goes through the registration process up to the actual use of the various EHR applications would be recommended.

Needs from the service provider perspective

Only the representative of pharmacies commented on needs that exist from the perspective of service providers. Here, he mentions, among other things, the remuneration of additional time expenditure incurred by service providers through the use of the EHR. This measure could increase the acceptance of service providers to use the EHR, as it would provide financial compensation for the increased workload. In addition, the issue of liability must become regulated before the introduction to create a secure basis for action and information for the service provider. The use of e-prescriptions and electronic certificates of incapacity for work in day-to-day care has recently led to an increase in technical faults in connection with the telematics infrastructure (28). As the use of digital applications is to be further expanded in the future, it is imperative to find a regulation for dealing with technical problems or failures. The representative of the statutory health insurance physicians does not comment on needs that exist from the point of view of service providers. This could be due to the fact that, unlike the representative of the pharmacies, he did not work in healthcare himself.

Challenges

The healthcare researcher and the representative of the health insurance company see a challenge in bringing together the various data sets and formats so that they can be analysed together. A legal basis must first be created for this, as already explained in advance. Currently, data collected at different points in the healthcare system may neither be merged nor analysed together. The basis for this is expected to become part of the announced Health Data Utilisation Act.

In addition, a regulation must be found on how to deal with such data that was not collected in the context of medical treatment and can, for example, be set by the patient themselves. The problem here is that no clear statements can be made about how valid this data is. One possible approach would be to include data collected on a patient's exercise behaviour using appropriate wearables in the treatment of diabetes or obesity. However, this data should only be used to supplement the data collected by doctors.

The representative of the health insurance company identifies another challenge in the need to discuss corresponding sanctions alongside the introduction of a reporting obligation for service providers. The concern is that this might reduce the acceptance of using the EHR among service providers. Additionally, it entails increased bureaucratic effort, and relevant authorities must take responsibility for checking compliance with the obligations outlined in this context.

Potential

The care researcher, the representatives of health insurance company and the pharmacies emphasise the economic benefits that arise in relation to the successful implementation of the EHR. These include, in particular, cost and time savings resulting from the avoidance of incorrect treatment and duplicate examinations. These freed-up financial and time resources can ultimately be used for more effective and targeted patient care. In addition, the avoidance of incorrect treatment and duplicate examinations is also in the interests of patients.

Improvements in the areas of care and research are also mentioned. In this context, however, the representative of the SHI-accredited physicians points out that the priority should initially be on improving care. This includes ways to improve interdisciplinary and cross-sector treatment, as the data is available more quickly. During the COVID-19 pandemic, it became particularly clear how the rapid and structured exchange of health data can contribute to the early detection and thus containment of infections and improve care (29). In addition, patients can be guided through the healthcare system in a more targeted manner in order to find the optimal level of care for them in a timely manner.

At the research level, improvements can be achieved by making a very large amount of data on the health status of the German population accessible as soon as the corresponding access rights for research projects have been clarified. The findings gained here can then in turn be used to improve care. This process is also referred to by the German Advisory Council on Health and Care as a learning healthcare system (3). This opens up possibilities for developing new forms of care. In light of the

expected improvements, satisfaction among service providers and patients can be expected to increase.

Discussion of methods and limitations

As part of the discussion of methods, we would first like to emphasise that the results, particularly due to the small sample size, are to be understood as a first step towards a deeper understanding of the introduction of the EHR and cannot cover the topic in its entirety.

A qualitative study design was consciously chosen for this study, as it allows for an in-depth exploration of the different perspectives and experiences of the actors involved in the EHR implementation process. Given the complexity of the topic and the need to develop a comprehensive understanding of the challenges and opportunities associated with the implementation of the EHR, a qualitative design provided the scope for a multi-perspective investigation. Building on the more exploratory findings of this thesis, a political science model that provides an appropriate framework in terms of decision-making, conflicts of interest and lobbying influence could now be applied to gain further insights in this area. The outcomes of our paper can provide a starting point for this. To ensure the quality of this work, the study became subject to the quality criteria proposed by Lincoln et al. (17). Trustworthiness was ensured by collecting data comprehensively and over a longer period of approximately two months in the field of investigation. The quality criterion of transferability was achieved through the dense description of the people and contextual conditions studied. In this context, personal data and information on professional development in the German healthcare system became part of the interviews. According to Lincoln et al. (17), the quality criteria of reliability and confirmability should be ensured with the help of a research audit. In the context of this work, a reviewer was used as an alternative. During data evaluation using qualitative content analysis, the data was coded in several passes and the finalised category system was discussed with the reviewer in order to avoid distortion of the results by the researcher's feelings, values, interests and motives.

As the selected sample is a convenience sample and therefore not a random sample, the sample is not fully representative of the population under investigation (16). Distortions in the study results could also be due to the composition of the sample, as three of the interviewees come from the working environment of a large statutory health insurance fund in Germany. In addition, one interviewee, who was to be interviewed as a representative of the patient side, cancelled at short notice. Therefore the patient perspective can not be analysed in this study. With regard to the survey instrument used, it must be mentioned that the guidelines contain some very large and complex subject areas. When analysing the data, it must be taken into account that the respondents' answers are subjective and depend on their professional activity and thus their proximity to one of the previously defined actors. The strengths of qualitative content analysis lie in the systematic and rule-based approach, which ensures a high level of transparency in the research process (16).

Conclusion

The current status of EHR implementation and the low utilisation of health data in the German healthcare system in this context can be attributed to a lack of legal regulations, structural problems and the timing of implementation. In order to catch up, it is essential to implement the measures and objectives set out in the digitalisation strategy promptly and with the involvement of all stakeholders. With regard to the implementation process, Germany can orientate itself on Estonia and Denmark, for example, as the EHR is implemented nationwide there and is used extensively within the healthcare systems.

With regard to the political authorities in the German healthcare system, they did not fulfil their tasks to a sufficient extent, as the basis for decision-making was lacking and the set time frame was not adhered to.

In the context of implementation, the focus must be on ensuring that the added value of the application becomes tangible for all those involved. Only with this foundation can acceptance of the introduction of new digital applications be increased. Attention should be paid to a user-friendly design for both patients and all other stakeholders.

From the perspective of the German healthcare sector, there are various changes and challenges that need to be addressed as part of the implementation process. With regard to the service provider perspective, for example, appropriate lead times should be guaranteed and liability issues clarified in advance. When it comes to the issue of access authorisations for various stakeholders to EHR data, there is still no viable basis for decision-making. The decision-making process becomes significantly more difficult in this context, as the needs of the various stakeholders must be taken into account and the interests behind the request for data access differ greatly. In order to improve the exchange of data across disciplines and sectors, a solution is needed to ensure that data becomes available in near real time. How the use of data for research purposes will develop against the background of a successful implementation depends largely on the design of the legal framework and consequently the choice of the consent procedure for data release as well as the will of the patients. The findings obtained in this thesis can be used as a basis for further investigations in order to take a more differentiated look at the individual problems that have been identified.

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 West Saxon University of Applied Sciences Zwickau Ethics Committee. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent to participate in this study was not required from the

participants in accordance with the national legislation and the institutional requirements.

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Digital competence using the example of executives in residential care facilities in Germany—a comparison

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Background: Change and progress through digitalisation is also becoming increasingly important in the field of professional care and the associated increasing demands on the skills of nursing staff. The European Union considers digital skills to be one of the eight key competences for lifelong learning. At present, few reliable statements can be made about the status of digital skills in professional nursing care in Germany. The aim of this study was to map the current status of digital competences of executives in full inpatient care facilities in Germany and to identify possible differences to reference values of academics.
Methodology: This survey is based on a Germany-wide cross-sectional survey in full inpatient care facilities ($N = 8{,}727$). The survey instrument Digital Competences Framework (DigComp 2.2) according to the European Union's reference framework was used as the basis for recording the digital competence characteristics. The statistical analysis was descriptive and inferential (t-test, two-sided, $p < 0.05$).
Results: Out of 15 items across five dimensions, significant differences for nine items can be determined. The competence levels of the participating managers from the full inpatient care facilities were lower compared to the reference sample.
Discussion: In order to be able to counter the skills discrepancy shown by the study in the future, it is of central importance to deepen knowledge and skills in the area of digitalisation in the care context.

KEYWORDS

digital competence, inpatient care facilities, DigComp, online survey, cross-sectional survey

Introduction

Technology and technologisation are reflected in almost every area of everyday life. The number of Internet users worldwide is rising continuously. In 2022, the number of users, also known as "onliners", was around 5.3 billion, an increase of 2.9 billion in the last ten years (1). In this context, the question arises as to how digitalisation is defined. Generally speaking, it is the change in the electronic storage, networking and processing of information and, in particular, the integration of technologies into work processes (2). Digital skills are one of the eight key competences of lifelong learning defined by

Abbreviations
BIBB, Federal Institute for Vocational Education and Training; DigComp 2.2, Digital Competences Framework; DigiK-Part, Digital competences through participation; EU, European Union.

the European Union (EU) (3). Digital literacy encompasses the safe and critical use of digital technologies, which are used for information, communication and problem-solving strategies in all areas of life (4). In this context, however, a study by the EDCL Foundation (2014) draws attention to a fallacy regarding the so-called "digital natives". Simply growing up with the technological progress of computers, mobile phones and other technologies is no indication of a person's digital competence. There is the possibility of the incompletely acquired ability to use these technologies safely and efficiently (5). Contrary to the assumption that young people are automatically exempt from acquiring digital skills, there is a new digital divergence between the actual skills of the digital lifestyle and the skills for a digital workplace, which should not be disregarded.

The constant change and progress of digitalisation, particularly in the nursing context and the associated growing demands on the skills of nursing staff, are becoming increasingly important (6). In recent decades, a dynamic process of lifelong learning has emerged, which is reflected in the general lengthening of educational pathways and the often changing occupational fields within a profession (7). In addition to the numerous opportunities for society and, in particular, the professional care sector, the use of technology also contains risks. Digitalisation still raises many unanswered questions in this field of operation. When it comes to digitalisation in the healthcare sector, there are various associations that are linked to different elements of modern healthcare. These include algorithms, the processing of large amounts of data for complex medical conditions, state-of-the-art medical devices and surgical robots. These associations are undoubtedly correct, as these aspects play an increasingly important role in modern healthcare, as does their differentiation (8). Digital transformation refers to the conversion of data, documents and processes from analogue to digital. Digitalisation is the transformation of business processes (9).

The aim of this study was to map the current status of digital competences of executives in full inpatient care facilities in Germany and to identify possible differences to reference values of academics. At present, few reliable statements can be made about the level of digital skills in professional care. This is primarily due to a lack of meaningful data. The studies available indicate that the sector is lagging behind others in this area (6). Compared to the leading Scandinavian countries Finland and Denmark in the European ranking of the digital economy and society in 2022, Germany is in 13th place (10). Only a few assistance technologies are currently being used in German hospitals and care facilities (11). The efficient processing of health data and the establishment of comprehensive data-based medicine are essential elements of a modern healthcare system. However, Germany is still a developing country in this context. This is confirmed by a recent study by the Organisation for Economic cooperation and Development (OECD). In an international comparison, Germany only ranks third to last in terms of accessibility and linking of health data. The Scandinavian countries in particular are leading the way (12). On December 2023, the German Bundestag passed the Digitalisation Act (DigiG) and the Health Data Usage Act (GDNG) to drive forward digitalisation in the healthcare sector. The latter aims to improve the use of healthcare data.

McKinsey & Company tracked the progress of the healthcare industry using around 30 indicators, including the degree of digitalisation of doctors' practices and hospitals as well as the acceptance of e-health tools for patients. The expansion of the telematics infrastructure (TI), to which almost 99 per cent of all pharmacies and doctors' surgeries are now connected, is also having a positive impact. Nevertheless, two thirds of connected practices cite technical problems that occur weekly or even daily in everyday practice as the reason for the digitalisation of the healthcare system. The activation of electronic patient records is also progressing slowly. Only one per cent of those with statutory health insurance currently have an activated electronic patient file (13). The reason for this is the seemingly less lucrative cost-benefit ratio (11). In the coming years, however, an upswing in the field of information and communication systems, as well as robotics and technical assistance systems is predicted due to an improvement in the cost-benefit ratio and an increase in suitability for everyday use (11). It can be assumed that continuing technological progress and the increased use of assistive technologies will have an impact on the everyday work of caregivers, which requires the training of digital skills (11).

In a survey conducted by the ifo Institute (Leibniz Institute for Economic Research) in May and June 2021, 56% of respondents across Germany stated that digital and media skills are very important for the future of society. A further 36% rated them as somewhat important. The global megatrends of globalisation, artificial intelligence, health and digitalisation should not be ignored to illustrate the ever-increasing relevance of digital skills for Germany's participation in international competition (14). In view of the ever-increasing demands placed on nursing staff in the areas of digital documentation, data management and the use of diagnostic and decision-making tools, further research in this area is urgently required (15).

The present study focuses on the digital competence of executives in residential care facilities in Germany with regard to data processing and evaluation, communication and cooperation, content creation, security and problem solving. A manager in a care facility is understood as a person who holds a managerial position within the organisation. As a minimum, they are entrusted with personnel management in a defined area of this organisation and usually also have budget and material responsibility. As executives in care facilities also have access to personal data and have to deal with complex management tasks, it can be assumed that they must also have digital competences in accordance with the EU Framework.The DigComp 2.2 questionnaire forms the basis for this survey regarding digital competence.

Methodology

The nationwide cross-sectional survey in full inpatient care facilities was realised with the help of the online platform

SoSci-Survey (16). Email addresses from 8,727 inpatient care facilities were included, which were provided as a data set by the AOK-Bundesverband for scientific purposes (17). No phone calls were Made, only a reminder about the survey was sent. The management of the care facility was able to distribute the survey to the relevant employees. The AOK Care Navigator contained gaps, meaning that 8,727 of the 11,358 fully inpatient care facilities in Germany in 2021 could be taken into account. Nationwide, North Rhine-Westphalia has the most fully inpatient care facilities in Germany with 2,244, followed by Baden-Württemberg with 1,536 and Bavaria with 1,504. Bremen has the lowest number of facilities nationwide with 97 fully inpatient care homes (18).

Invitations to participate in the online survey were sent via the mail merge function of SoSci-Survey. On the landing page of the online survey, consent to participate had to be actively given by clicking on it before accessing the actual questionnaire. If this was not given, participants were redirected to the end of the questionnaire. The survey was conducted in compliance with the applicable data protection regulations, with a comprehensive data protection concept available on the landing page. The survey period was from March 23rd to April 30th 2023 and a reminder email was sent on April 18th. Descriptive and inferential statistical analyses were carried out using IBM SPSS Statistics 29 (t-test, $p < 0.05$, two-sided).

The DigComp 2.2 questionnaire according to the EU reference framework was used as the basis for recording the digital competence characteristics. It is constructed according to Krempkow (2022) is a theoretically and empirically based survey instrument for recording digital competences in accordance with the DigComp 2.1 reference framework of the EU (19), which was used in the KaWuM-Survey 2 trough out Germany in 2022 (20). As part of this survey, reference data was collected from over 1,200 science managers and around 7,000 students from several large universities in Germany across all subject groups. Science managers organise, control and design the relevant processes at universities. These include, for example, research funding, personnel development, organisational development and controlling.

The DigComp 2.2 was also used in the survey of the digital competences of executives from inpatient care facilities in order to ensure appropriate comparability of the data on the basis of a standardised measurement instrument. A comparison of the executives of the inpatient care facilities with the sample of the KaWuM survey is appropriate, as it can be assumed that the executives of the inpatient care facilities have a comparable level of academic competence and are qualified in terms of leadership in a similar way to the scientific managers.

With 15 items, the DigComp 2.2 questionnaire construct covers all five dimensions (subscales) of digital competences according to DigComp 2.1. The subscales include (1) data processing/evaluation, (2) communication/cooperation, (3) content creation, (4) security and (5) problem solving. They are answered on a five-point response scale (1 = to a very great extent to 5 = not at all) (10). In addition, an open knowledge test question was asked in order to determine the extent of some suspected tendencies to overestimate oneself in relation to the self-assessment of search strategies within the subscale of data processing/analysis. A possible overestimation with regard to reliable research strategies on the internet does not exist if the research results are systematically analysed from various sources in order to ensure a broad perspective and a comprehensive assessment. This includes the consideration of specialised literature, research studies and expert opinions in order to arrive at a well-founded conclusion that adequately reflects the complexity of the topic. A suitable approach would be, for example, the creation and application of search strings using Boolean operators, truncation, synonyms and the definition of inclusion and exclusion criteria (19).

The 15 items surveyed on digital skills were not normally distributed (Shapiro-Wilk test). Only mean values were available for the reference values of the KaWuM-Survey 2, which is why the t-test based on medium-values was used in this study. Simulation studies have shown that the t-test is largely robust to violations of the normal distribution assumption and has proven to be suitable for the following analysis (21).

Results

Of 8,727 emails, 830 could not be delivered shown by an error message. The link to the survey was clicked 830 times (click rate of 9.5%). 290 people took part in the survey, 184 of whom completed the questionnaire. The net response rate was 2.1%.

One hundred seventy-five out of 290 participants provided information on their function in the care facility. Most of the responses in terms of age were in the 40–49 age range and 50–59 age range (Table 1).

The management is responsible for the strategic direction, financial planning and legal affairs of the facility. It bears overall responsibility for the economic success and long-term development of the care home. The care home management is responsible for the operational management of the care home. They coordinate day-to-day operations, monitor the quality of care and support, are the point of contact for residents and relatives and take care of organisational matters such as personnel management and compliance with standards. The nursing service manager is responsible for the nursing area within the care home. They are responsible for the professional management of the nursing staff, the planning and implementation of care measures, ensuring the quality of care and compliance with legal requirements and guidelines.The “other” category included, for example, social services or occupational therapy. The average work experience (n = 184) was 11.4 years (SD ± 9.7). 84.2% (n = 154) of the participants who answered the question on gender (n = 183) were female, 15.8% (n = 29) were male. The facilities in which the participants worked (n = 163) mostly had 50–99 (38%; n = 62) or 1–49 (27.6%; n = 45) care places. 61.7% (n = 108) of the participants classified their facility as non-profit, 29.7% (n = 52) as private and 8.6% (n = 15) as public (n = 175). The federal states with the highest response rate (n = 182) were Bavaria (n = 40), Saxony (n = 40) and North Rhine-Westphalia (n = 39). Of the total

TABLE 1 Current role in the organisation by age group.

		Function					Total
		Management	Facility management	Nursing service management	Quality management	Other	
Age	18–29 years	0	2	1	1	7	11
	30–39 years	2	8	14	1	12	37
	40–49 years	1	17	19	3	16	56
	50–59 years	5	17	9	4	15	50
	60–69 years	2	10	5	0	4	21
Total		10	54	48	9	54	**175**

of 15 items of the five subscales of the DigComp 2.2 construct, significant differences were found in nine items (Figure 1).

No significant differences were found with regard to the first dimension of data processing/evaluation. In addition, an open knowledge question was asked as free text in connection with the first dimension of data processing/evaluation. This included the question of which search strategies the respondents use to search for reliable information on the Internet. Of the 234 respondents, a total of 73 answered this question. The most frequently given answer was Google ($n = 29$). In addition, keyword searches ($n = 19$), strategies customised to the question or problem ($n = 5$) and Boolean operators ($n = 3$) were cited as search strategies. A total of 17 answers could not be categorised. These include "no answer" ($n = 2$) and "secure websites" ($n = 1$) or "no internet on site" ($n = 1$).

In the communication/cooperation and security subscales, on the other hand, there were significant deviations from the DigComp 2.2 reference values in all items. With regard to the content creation subscale, significant differences were found in the statements on knowing how to apply licenses, copyrights and determining appropriate (operating) instructions for a specific task. In the fifth dimension, problem solving, significant differences became apparent in the ability to select the right application for themselves and others to solve a problem and to determine the need for further development of digital skills for themselves and others.

The mean deviations were above the reference values in 13 of the total of 15 items among the respondents from the care facility managers, which indicates lower digital skills among the participants compared to the KaWuM survey sample. Due to

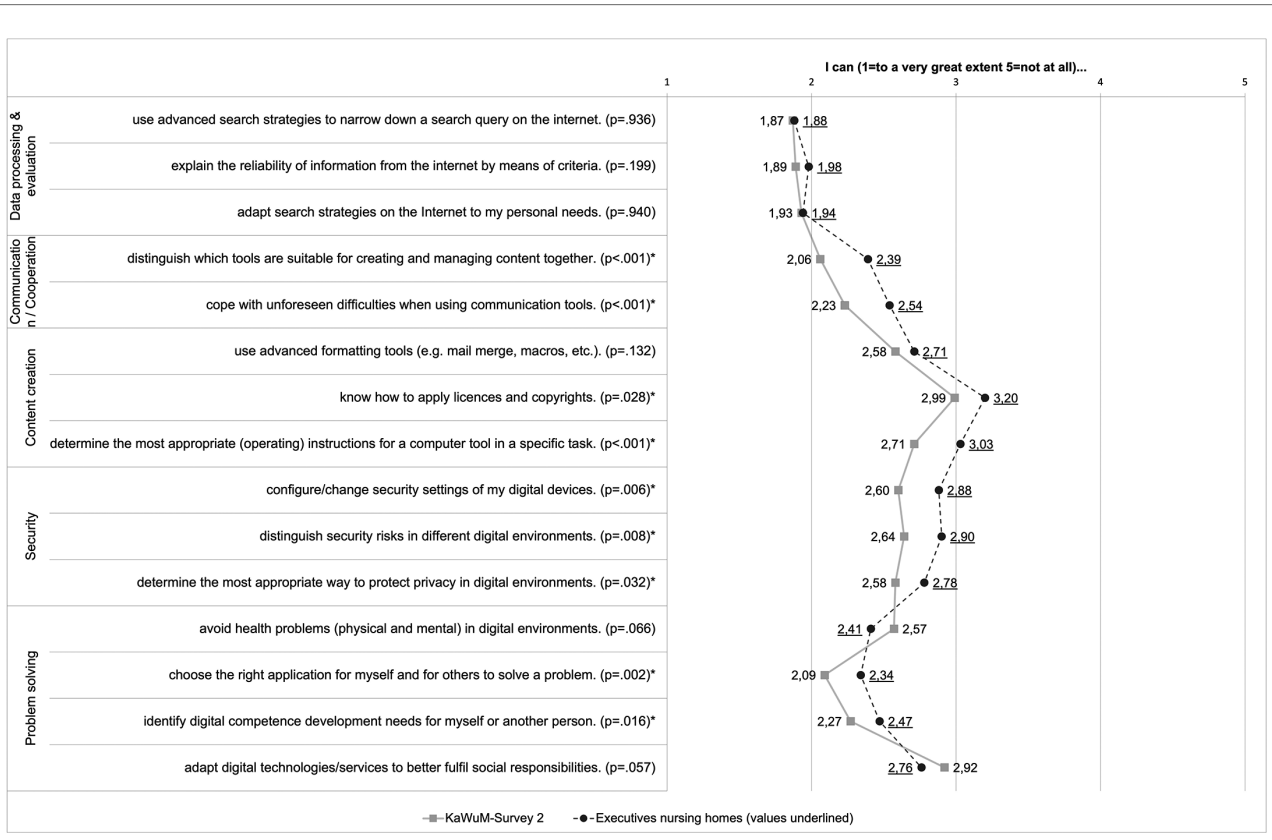

FIGURE 1
Mean values of the digital competences recorded (*difference statistically significant).

the non-parametric properties of the variables, the Kruskal-Wallis test was statistically calculated for differences between the items of DigKomp 2.2 according to Krempkow in relation to the stated activity of the executives of inpatient care facilities participating in our survey. No significant differences were found between the individual activity statements in relation to the DigKomp 2.2 items.

Discussion

In relation to the five dimensions of DigComp 2.2, the communication/cooperation and safety subscales show the greatest differences to the reference values of this study. In both dimensions, the reference values for digital competence in the reference sample of the KaWuM survey were significantly better than for participants in care facilities in this survey. With regard to the communication/cooperation dimension, early involvement and the ability to engage with digital team tools during (academic) training can make a decisive contribution. Related to this, the study by the EDCL Foundation (2014), among others, makes it clear that a differentiated distinction should be made between "digital lifestyle" and "digital workplace skills" (5). These "digital lifestyle skills" are not the skills required, for example, to get a job, negotiate with authorities or manage healthcare. The latter skills require formal and structured training (5).

Safe, critical and responsible use of and engagement with digital technologies requires a profound level of security competence within digital skills (3). Particular attention should therefore be paid to the significantly lower competence estimates of respondents from nursing care facilities in the security dimension. Medical data, for example, is particularly worthy of protection in the healthcare sector. The competence area of security can be divided into four individual competences, which should be considered in curricular developments of training and further education programs. These include the protection of devices, personal data and privacy, the environment as well as health and wellbeing (3).

Based on the open knowledge question in the data processing/evaluation dimension on search strategies and the free text answers provided, there is a potential overestimation of the digital skills of care staff, which is confirmed by the most frequently specified response to the use of the search engine "Google". In this context, the work of Krempkow et al. 2022 can be used to categorize the results of the knowledge question. In his study, the students surveyed were found to overestimate the search strategies they use on the Internet to customise their personal searches (22). These outcomes emphasise the importance of targeted promotion of digital competencies in the healthcare sector to ensure that nursing staff can access digital resources effectively and efficiently. The promotion should therefore not be limited to basic, advanced and further training, but should already be an integral part of nursing training.

Measured by the mean values, the reference values for the two items "I know how to apply licenses and copyrights" and "I determine the most appropriate (operating) instructions for a computer tool in a specific task" in the content creation dimension were statistically significantly better than for the participants in the care facilities. The individual skills in the content creation dimension include developing digital content, using and editing third-party digital content, knowledge of copyright as well as free licenses and programming. This suggests that those outside the care sector may have more advanced digital competences in terms of content creation, which has important implications for digital training and support for nurses. There may be a need to provide targeted training programmes or resources to ensure that nurses have the necessary skills to create, use and manage digital content effectively, which could ultimately improve the quality of nursing care and meet the demands of an increasingly digitalised healthcare landscape (14).

In the fifth and last dimension of the digital competencies survey, statistically significant differences were found, particularly for the items "I can choose the right application for myself and for others to solve a problem" and "I can identify digital competence development needs for myself or another person". Digital competences for problem solving represent an end point of digital competences that builds on previous basic competences (3). This is another crucial aspect that should be taken into account in the systematic development of digital skills in the healthcare sector. If basic skills in dealing with digital technologies are insufficiently developed, this leads to further competence deficits in the search for solutions to problems. Care service managers should receive targeted training on individual skills with regard to the careful use of time resources. Specific skills, such as data management, should be passed on to internal experts such as data protection officers or IT officers. They can also act as multipliers within the institution to ensure knowledge management within the institution. It might also be possible to offer individual courses or workshops for nursing staff who have already been working in nursing for several years, which could be offered in addition to the basics of nursing training. The introduction of digital innovations in care facilities can be analysed through the NASSS framework, taking into account factors such as the acceptance of the technology by care staff, the availability of resources for training and support, and the integration of digital systems into existing workflows. The initiation of digital competences among care professionals therefore requires targeted training and support to ensure the successful use and integration of digital tools into care practice and thus promote sustainable implementation.

Becka et al. make it clear that with the increasing importance of digital technology in the nursing context, the work processes specific to the profession will change fundamentally. As a result, more training should be provided on the competences relevant to the respective changing work processes. For example, digital skills are becoming increasingly important for more highly qualified and managerial nursing staff, whereas communication and cooperation should be prioritised for nursing staff in non-managerial positions (15).

In the context of Becka et al., it can be summarised that the digital competence of full inpatient care facilities in Germany is an important factor in improving the quality of care and meeting the increasing demands of the ongoing structural change in Germany (15). The results of the study indicate that the respondents of the facilities in question have lower digital skills than the reference values from the KaWuM survey. This emphasises the importance of promoting digital competencies both during the further training of care professionals as well as during the education of these professionals. It is crucial that all stakeholders in the healthcare sector work together to drive forward digitalisation and use their respective potential to actively shape progress together. The education sector in particular should focus on promoting digital skills development in the training of specialists at vocational medical schools. In addition to the education sector, politicians also have a duty to revise the Nursing Professions Act regarding the lack of digital skills. This relevant problem is already becoming the subject of various projects by the Federal Institute for Vocational Education and Training (BIBB) in an attempt to develop the skills of teachers and future nurses. The Digital Competences through Participation (DigiK-Part) project has the goal of establishing the digital competences of teachers and future teachers at nursing schools and universities. In addition to deepening knowledge in the field of digitalisation in the nursing context and the latest technologies, special attention should be paid to the consequences of digital technologies in the continuing education program, focusing not only on nursing processes, but also on the consequences for the work of nurses (14). The topics should focus in particular on acceptance, satisfaction and stress on both a psychological and physical level (14). In an internet and literature search by Nüßlein and Schmidt (3), it was found that, compared to its European neighbors, there are few to no offers in the sense of a 3-stage learning model in the area of DigComp 2.1 in Germany. There is an urgent need to expand the programs and increase their presence (3). A suitable political framework and the anchoring of digital skills in the EU key competences, which support companies in refinancing measures in the course of digitalisation, should be further promoted in order to make it more attractive for employers to make use of them.

Limitation

The online survey was a cross-sectional survey, which is why it is not possible to map developments over time. The sample of inpatient care facilities in Germany was based on data from the AOK Care Navigator (16). Depending on the federal state, there were gaps in the contact data records. On the one hand, e-mail addresses of the facilities were missing. On the other hand, contact details were not up to date. As a result, only 8,727 of the existing 11,400 facilities could be contacted which leads to an incomplete data collection.

Personalised links were not used, as these would have lost their validity if forwarded internally within the facilities. This meant that multiple participation could not be excluded technically. As the functional email addresses from the AOK Care Navigator were used for recruitment, it can be assumed that the executives accepted the email and that multi-level forwarding to nursing staff was not favoured. As a result, however, the Other notification as an activity showed that third parties also had access to the questionnaire. However, a further review showed that this had no influence on the mean values or the significance.

The questionnaire category of digital competences was based on the theoretically and empirically based survey instrument DigComp 2.2 construct according to Krempkow (2022). It should be noted here that the competence assessments may be subject to limitations from the outset due to self-assessment bias (20). The uncertainties identified in this context in the area of digital skills can be used as thematic focal points in the further work and should be investigated more in-depth. With regard to the dropout rate of the questionnaire, social desirability and survey fatigue can be assumed as possible factors.

Taking into account the response rate of 2.1% the high drop-out rate can be attributed to the complexity of the question or a lack of interest. Social norms and survey fatigue were also discussed as possible factors that contributed to the cancellation of participation. For a better understanding, an overview of the drop-out rate of the study has been included in the appendix.

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 Kommission für Ethik der Westsächsischen Hochschule Zwickau. 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

SL: Writing – original draft, Writing – review & editing, Conceptualization, Data curation, Investigation, Methodology. TT: Conceptualization, Data curation, Formal Analysis, Methodology, Visualization, Writing – original draft, Writing – review & editing. MH: Data curation, Formal Analysis, Investigation, Writing – review & editing. LG: Investigation, Writing – review & editing. TS: Funding acquisition, Project administration, Resources, Supervision, 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/frhs.2024.1372335/full#supplementary-material

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Assessing the accessibility and quality of mobile health applications for the treatment of obesity in the German healthcare market

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Introduction: Overweight and obesity are among the most prevalent health problems worldwide leading to various diseases and having a significant impact on the healthcare system. In Germany, the prevalence of obesity among adults is 19%. Mobile health applications offer a new approach to treatment and prevention and have been proven effective in previous studies. However, it is essential to investigate the availability and quality of these digital applications. The aim of this systematic assessment is to evaluate the accessibility and quality of digital health applications in German language designed to treat obesity.

Methods: In January 2024, a systematic search for mobile health applications was conducted on both the Google Play Store and Apple App Store. Just those apps available in German for both iOS and Android were considered acceptable. The German Mobile Application Rating Scale (MARS-G) was used to assess the quality of the apps. The content of mobile health applications was evaluated using the guideline from the German Obesity Society for the treatment of obesity. The characteristics of the apps were summarized and presented, and the results were analyzed using descriptive statistics and presented in tables.

Results: After screening, ten apps were included in the review. The apps varied in terms of calorie tracking, individual workout plans, educational aspects, nutritional plans, and exercises for behavioral change. On average, 6.4 out of 12 items of the German Obesity guideline recommendations were fulfilled. The MARS score (possible range from 1–5) reached a mean of 3.39 (SD = 0.39). The section "Engagement" had the lowest quality score with a mean of 3.14 (SD = 0.57), while the section "Aesthetics" achieved the highest mean of 3.57 (SD = 0.52).

Discussion: Most German mobile health applications for managing obesity meet some guideline recommendations. They demonstrate adequate to good quality according to the MARS score. Assessing the quality of mobile health applications can be challenging for patients, despite being easily accessible and low-threshold. However, such digital health applications, reimbursed by the German SHI, offer evidence-based information, even if access can be associated with higher hurdles.

KEYWORDS

smartphone, mobile apps, mobile health, obesity, weight management, behavior change techniques

1 Introduction

The World Health Organization (WHO) defines obesity in the ICD-11 (International Classification of Diseases 11th revision) as a chronic, complex disease caused by a variety of factors, such as psychosocial or genetic causes. Obesity is mostly measured by the body mass index (BMI), which is calculated from height and weight. A BMI of ≥30.0 kg/m^2 is classified as obesity and can be further categorized as class I (30.0–34.9 kg/m^2), class II (35.0–39.9 kg/m^2), or class III (≥40.0 kg/m^2) to determine appropriate treatment options (1).

Based on data from the Global Burden of Disease (GBD) study, obesity had a global prevalence of 14% in 2019 (2). Furthermore, approximately five million deaths in 2019 were attributed to obesity (3). This indicates that obesity is a growing global problem, affecting healthcare systems in different countries (4). The GBD study also assumed that the number of Disability-adjusted Life Years (DALYs) due to obesity will increase by 3.4% annually worldwide by 2030, resulting in an overall increase in obesity-related DALYs of 39.8% within one decade (3).

Germany is no exception in these developments regarding obesity. Based on a national, representative study using self-completed questionnaires of the German population to collect information on body height and weight, a total of 53.5% of German adults were overweight or obese in 2019 and 2020 (5). Over the last ten years, the prevalence of obesity has increased. Based on this study from 2019–2020, 13 million German adults, equivalent to 19% of adults in Germany, were affected by obesity (5).

The increasing number of patients affected by obesity also amplifies the economic burden. An international study has analyzed the economic impact of overweight and obesity in 161 countries based on direct and indirect costs from a societal perspective and calculated a loss in global Gross Domestic Product (GDP) of around 2.19% in 2019 (6). In addition, the loss of GDP due to the effects of obesity and overweight is estimated at 3.29% globally by 2060 (6).

In Germany, obesity-related medical costs increased by 193 million euros in five years, leading to more than one billion euros spent on obesity in 2020 (7). A study examining the costs associated with obesity in Germany, using a prevalence and life-cycle perspective, found that healthcare costs per quarter increase with BMI class. For BMI class I, there are quarterly additional costs of € 314.96 per patient, rising to € 631.64 for BMI class III (8).

Obesity is associated with several non-communicable diseases and comorbidities. Therefore, obese people have a higher risk of developing diabetes mellitus, hypertension, coronary heart diseases, a stroke, Alzheimer's disease, or certain types of cancer (9, 10), resulting in various diseases in different organ systems associated with obesity. People affected by obesity are five times more likely to develop a simple multimorbidity and 12 times more likely to develop a complex multimorbidity (10).

In addition to the increased risk of multimorbidity, affected individuals must also cope with various psychosocial impacts. While mental illness is a risk factor for developing obesity (11), there is a reciprocal link found for depression and obesity (12). Various adverse interacting aspects are discussed, such as possible metabolic changes due to medication, reduced exercise due to a lack of drive (11, 13), but also emotional eating (13, 14). Regardless of the development of pathologies, obese people often experience stigmatization in different parts of their lives. These issues include marginalization, teasing and prejudice in society and the healthcare sector, leading to professional disadvantages (13, 15). Thus, our society is centered on the average individual, people with obesity must deal with various difficulties, including small chairs in public spaces, narrow changing rooms, and limited clothing options (16). All these aspects result in psychological strain. This has to be taken into account when choosing a treatment and, if necessary, combine it with additional psychotherapy (17).

Several guidelines for effective preventive measures and evidence-based, optimal treatment of obesity have been developed as recommendations for healthcare professionals and patients. They are intended to support decision-making on the adequate treatment of obesity. Both the German Obesity Society guideline *(Deutsche Gesellschaft für Adipositas)* and the National Institute for Health and Care Excellence (NICE) guideline recommend several approaches for a successful management of the disease (13, 18). These include dietary therapy, exercise therapy, behavioral therapy (13, 18), and lifestyle interventions (18). Besides treatment options, the German guideline specifies various preventive actions, which mostly concentrate on dietary recommendations, as well as suggestions for sufficient physical activity (13). The guideline from the German Obesity Society also mentions the potential use of weight loss programs, mostly containing self-management aspects that should fulfill quality requirements (13).

In April 2024, a disease management program (DMP) for the treatment of obesity in Germany came into force. A DMP is a special structured treatment program for selected chronic diseases which is based on the findings of evidence-based medicine and involves expertise from General Practitioners (GPs) as well as specialists. The obesity DMP will probably consist of multimodal training, focusing on individual fitness and nutritional recommendations as well as suggestions for behavioral changes (19). Access is given to patients by enrolling in a DMP at their statutory health insurance (SHI) company, coordinated by their general practitioner (GP) (20).

In the era of digitalization, more and more programs for the most important lifestyle changes such as smoking cessation, healthy diet, weight reduction, and adherence to the regular practice of physical exercises are being offered and used as mobile health applications (21, 22, 23). Smartphones and wearables, such as smartwatches or activity tracker, can be used to measure and record vital parameters and other health-related data using a variety of sensors. Interested users can download the mobile health applications from the app store, either free of charge or as a self-payment option. These apps, which are mostly used for a self-management, are accessible to anyone with a mobile device.

The Digital Healthcare Act *(Digitale-Versorgungs-Gesetz* or *DVG),* which came into force in 2020, represents a change in the German healthcare system. Since then, physicians have the

option of prescribing digital health applications (*Digitale Gesundheitsanwendungen* or *DiGA*) for the treatment of various diseases (24). A DiGA is a medical device whose main functions are based on digital technologies. Thereby, the DiGA is only used by the patient or together by the patient and the healthcare professional. In contrast to mobile health applications downloaded for free from the app store, the DiGA is not solely a digital application used for data collection from a device or for device control. Instead, the DiGA is aimed at recognizing, monitoring, treating or alleviating diseases, injuries, or disabilities. Insured persons of the SHI have the possibility to receive a DiGA, which is financed by their health insurance. Therefore, the DiGA must demonstrate a positive care effect, either as a medical benefit or an improvement of the procedure, by conducting a comparative study. If the DiGA can demonstrate a positive proof of effectiveness, the DiGA will be permanently included in the DiGA directory. It is also possible to become a provisional listed DiGA for one year, even if the evidence has not yet been proven. In this case, an ongoing study is carried out, to demonstrate a positive care effect during the one-year period (25). Currently 57 DiGA are listed or provisional listed (status: 23 May 2024) in the DiGA directory (26). The listed DiGA address various diseases, also showing two digital health applications for the treatment of obesity: "Oviva Direkt" and "zanadio" (26, 27).

The aim of this review is to identify mobile health applications for self-treatment of obesity. The mobile health applications will be evaluated in terms of content, quality, and accessibility. In particular, the use of the mobile health apps from the perspective of the patients is essential.

2 Methods

2.1 Search and screening

A systematic search for smartphone apps for Apple iOS and Google Android was carried out. For this purpose, the Apple App Store was searched for iOS apps and the Google Play Store was searched for Android apps. The final search was carried out in January 2024. Relevant German synonyms for obesity and overweight were used as search terms. Each term was searched individually in the two app stores by one reviewer (PMS). The following search terms were used: "*Adipositas*" (obesity), "*Übergewicht*" [overweight (as a noun)], "*übergewichtig*" [overweight (as an adjective)], "*adipös*" (obese), "*Gewichtsreduktion*" (weight reduction), "*Gewichtsverlust*" (weight loss), "*abnehmen*" (lose weight), "*Gewichtsabnahme*" (weight loss), "*Diät*" (diet). No other search filters were used.

The relevant app data were collected in a table by this reviewer (PMS). This included the app name, age recommendation, developer, the latest update, the average rating in the store, the number of ratings given, and the description associated with the app. Any duplicates found during the search were excluded.

Afterwards, the screening process began. The first step was to check the list to see whether the apps were available in both the Apple App Store and the Google Play Store. If not, the app was excluded. In the next step, the names of the apps and the descriptions from the App Store were screened and examined for the inclusion criteria. This step is like the abstract screening in a systematic review, in which non-matching hits are excluded. The previously defined inclusion criteria related to the app being in German, being available free of charge (for at least 14 days as a trial version), being available in both the Apple App Store and Google Play Store and functioning independently (no need for external additional devices or a membership). These criteria aim to make the apps easily accessible and ensure that all patients—regardless of their smartphone—can use them. The app should also cover at least two of the following topics according to the guideline: nutritional therapy, diet programs, exercise therapy or behavioral therapy. As a final screening step, the remaining apps were downloaded, tested, and examined for at least ten minutes by two reviewers (PMS and LK). After the examination, these apps were checked again regarding the inclusion criteria. The two reviewers (PMS and LK) discussed uncertainties regarding the reviewed applications, and if they could not agree, the third reviewer (SAMM) was consulted to reach a consensus. The assessment was methodically adapted from similar studies (28, 29, 30).

2.2 Outcomes

The apps included in this review were assessed for their quality using the MARS-G, the German version of the mobile app rating scale (31, 32), and for their evidence using a checklist based on the German guideline for the prevention and treatment of obesity (13).

The MARS-G scale initially records descriptive information about the application, such as the manufacturer, name of the app or when the last update was conducted. Afterwards, the items of the MARS-G tool are divided into six quality categories. Each item can be answered using a Likert scale with five answer options (1 = inadequate to 5 = excellent). With these answers, it is possible to calculate the mean score of each category and finally the overall mean score of the app. The first section A focuses on the engagement including the entertainment, customization, interactivity, target group, and interest. After checking the first quality dimension, the second section B concentrates on the functionality of the mobile application. The subjects of performance, usability, navigation, and gestural design are highlighted. The third section C, which concentrates on the aesthetics, evaluates the layout, graphics, and visual appeal. Then, fourth section D assesses the information quality, including the accuracy of the app description presented in the store, goals, quality of information, quantity of information, visual information, credibility, and if the information is evidence-based (31, 32). The German version of the MARS tool additionally focuses on the therapeutic gain of the application (31). This additional dimension as well as the subjective quality of the app are not included in the overall mean score (31, 32). The MARS-G tool showed similar interrater reliability (ICC = 0.83)

as the MARS tool (ICC = 0.84) and proved a good internal consistency ($\omega = 0.82$) (28). The raters (PMS and LK) trained using the MARS-G tool according to a training video (33).

To ensure both the quality and content of mobile health applications are evaluated, the German guideline for the prevention and treatment of obesity (13) is used to assess the evidence. To check whether the content of the applications agree with the guideline, a checklist was developed. Therefore, the guideline was checked for recommendations regarding the treatment of obesity and those suggestions were formed into items which could be answered with "yes", "no" or "unclear". The checklist contains items based on the main topics nutritional therapy, diet programs, as well as exercise and behavioral therapy. Items contained, whether individual nutritional recommendations were given, the patient was educated about dietary changes, the patient's preferences were taken into account, diets were recommended, and different nutritional strategies were presented. It was also checked, if a step-by-step approach to weight-reduction was explained, if the user was encouraged for physical activity, and whether the physical activity is safe to execute. The last four items contained, whether the user was educated on the health benefits of physical activity apart from weight loss, the app helped to set relatable goals, a stabilization of the weight after the weight loss was encouraged, and whether behavioral therapy interventions, containing different elements, were included. These elements for example include self-monitoring of the behavior, cognitive restructuring, problem-solving training, reinforcement strategies or strategies for dealing with weight gain (13).

3 Results

In total, the search in both app stores identified 731 mobile apps, after excluding duplicates from each app store and checking if each app was available in both the Google Play Store and the Apple App Store. During the first screening process, checking the title and description of the apps, 690 applications were excluded based on the defined inclusion criteria, leaving 41 apps for the final, second screening after the apps were downloaded. Testing the apps after the download excluded 31 apps. As a result, ten mobile applications were included in the assessment, two of them are DiGA ("Oviva Direkt", "zanadio") and therefore the costs are reimbursed by the SHI. The identification process and details about the exclusions can be seen in a flow chart diagram based on the PRISMA statement (34) (Figure 1).

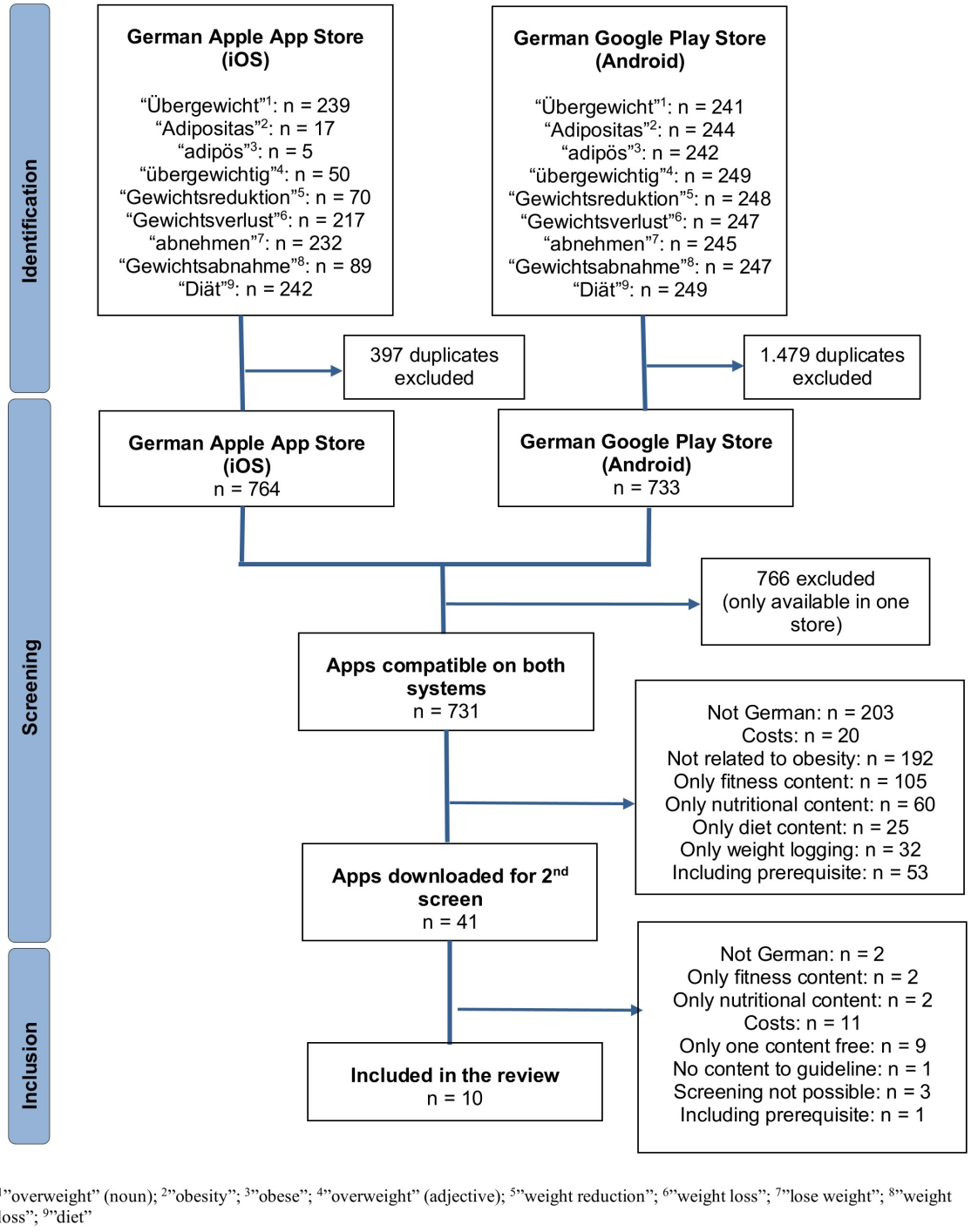
The main attributes of the ten apps were collected in Table 1, including the app name as displayed in the Apple App Store and Google Play Store, the developer, the last update, the app characteristics, the MARS-G mean score, and the content based on the German obesity guideline. The content could therefore be divided into nutritional therapy, diet programs, exercise therapy, and behavioral therapy (13). The item characteristics refer to the elements commonly found in the mobile health applications.

The most common elements, included in six of ten apps, were a calorie tracking tool as well as individual workout plans. Five applications included some type of educational content, of which three also focused on behavioral changes. Some sort of nutritional plan was delivered in five apps. The inclusion of challenges (three apps), a coaching chat (one app), and the opportunity of a personal nutritional coaching (one app) were much less common in the identified apps. The apps each showed different combinations of those characteristic elements.

Looking at the latest updates for each of the included apps, nine out of ten apps have been updated within the last two months (status: 25 January 2024). Only one app was last updated in October 2021. Moreover, each of the apps included content based on nutritional therapy, and nine applications had elements from the field of exercise therapy. However, two apps addressed diet programs, and five apps contained behavioral therapy elements. In one of those apps the behavioral aspects were only accessible in English, whereas the remaining content was in German.

To evaluate whether the apps fulfilled the items listed in the German obesity guideline, each app was individually checked for including the recommended content. Overall, the mean of items answered with "yes" was higher than the mean of "no" (6.4 vs. 4.6). The mean of items answered with "unclear" was 1.0. Table 2 shows that item 7, "Encouragement of physical activity", was mostly answered with "yes" and was found in nine out of ten applications (90%). Item 4 "Recommendations for diets" was least often answered with "yes" (10%), but three apps (30%) were classified "unclear" in this regard. The highest number of "no"'s was found in item 8 "Safety of physical activity", which was not included in eight apps (80%). Item 1 "Individual nutritional recommendations" (70%), item 3 "Patient preferences" (80%), item 6 "Approach to weight reduction" (70%) and item 10 "Setting relatable goals" (70%) were also mostly answered with "yes". Hence, item 11 "Encouraging weight stabilization" and item 4 "Recommendations for diets" was each answered with "no" in six times (60%). The answer "unclear" was not once given in six items: "Individual nutritional recommendations", "Education on change of diet", "Patient preferences", "Approach to weight-reduction", "Safety of physical activity", "Behavioral therapy interventions".

After analyzing the overall outcomes for each item on the checklist, Table 3 displays the compliance of each app with the German obesity guideline. The ratio between "yes" (green), "no" (red), and "unclear" (transparent) answers is visible as a color profile. For the DiGA "Oviva Direkt" no item was answered negatively. "zanadio" did not meet item 4 ("Recommendations for diets"). Consequently, two items ("Recommendations for diets", "Present different nutritional strategies") at "Oviva Direkt" and one item ("Encouraging weight stabilization") at "zanadio" were answered with "unclear". In the remaining eight apps, there were always at least two items marked as "no". For example, "Foodvisor—Ernährung und Diät" did not show "Safety of physical activity" (item 8) and "Setting relatable goals" (item 10). The mobile health application "Fizz Up: Training und Ernährung" showed the most "no"'s, with nine negations. In this case, only item 3 ("Patient preferences") and item 7 ("Encouragement of physical activity") were answered with "yes",



[1]"overweight" (noun); [2]"obesity"; [3]"obese"; [4]"overweight" (adjective); [5]"weight reduction"; [6]"weight loss"; [7]"lose weight"; [8]"weight loss"; [9]"diet"

FIGURE 1
Identification process of the included apps.

while "Setting relatable goals" (item 10) was classified as "unclear". Three apps ("DWP Fitness—Diät & Sport", "FIT-UP: Fitness & Ernährung", "wikifit—Kalorienzähler") showed six negations each, resulting in 50% of the items not being met.

The quality of the mobile health applications, represented via MARS-G mean score, varied between 2.93 and 3.89 (see Table 4). The mean overall MARS-G score for all apps included in the rating was 3.39 (SD = 0.39). The median was 3.24. The first section A focusing on the engagement received an overall mean score of 3.14 (SD = 0.57), with the apps differing between a score of 2.4 and 4.0. The engagement score therefore was the lowest overall mean score. Section B, targeting the functionality, showed scores between 2.75 and 4.0 and resulted in an overall mean score of 3.5 (SD = 0.43). The highest overall mean score

TABLE 1 Attributes of the assessed apps.

App name iOS (Version)	App name Android	Developer	Last update	Characteristics	MARS-G mean score	Content based on guideline
DWP Fitness—Diät & Sport (2.8)	DWP Fitness—Diät- und Sport	DWP Creation	05.01.2024	- Calorie tracking - Individual workout plan - Educational content	3.15	NT, ET
Fabulous—Gewohnheitstracker (1.49.1)	Fabulous—Gewohnheitstracker	Fabulous	08.01.2024	- Individual workout plan - Exercises for behavioral change	3.78	NT, ET, BT
FIT-UP: Fitness & Ernährung (368)	FIT-UP: Fitness & Ernährung	Shahab Daban	31.12.2023	- Individual workout plan (live workouts) - Nutritional plan	3.15	NT, ET
FizzUp: Training und Ernährung (4.6.6)	FizzUp: Training und Ernährung	FizzUp	22.01.2024	- Individual workout plan - Nutritional plan	2.93	NT, ET
Foodvisor—Ernährung und Diät (6.8.0)	Foodvisor—Ernährung & Diät	Foodvisor	22.01.2024	- Calorie tracking - Educational content - Daily courses with behavioral and educational aspects[a]	3.82	NT, DP, BT[a]
GlücksFigur—Abnehmen & Diät (1.7.18)	GlücksFigur—Abnehmen & Diät	Lukas Mausebrink	10.01.2024	- Fitness challenges - Calorie tracking - Educational content	3.0	NT, ET, BT
wikifit—Kalorienzähler (1.15.5)	wikifit—Kalorienzähler	Paul Thomae	22.12.2023	- Calorie tracking - Individual workout plan - Diet/nutritional plan	3.32	NT, ET, DP
Workouts Zuhause—Training (19.6.3)	Spartan Home Workouts	Tech 387 LLC	01.10.2021	- Calorie tracking - Individual workout plan - Nutritional plan	3.07	NT, ET
Oviva Direkt (1.47.0)[b]	Oviva Direkt	Oviva AG	22.01.2024	- Nutritional plan - Educational content via lections with educational and behavioral aspects - Personal nutritional counseling - Fitness challenges	3.89	NT, ET, BT
zanadio (1.1.46)[b]	zanadio	Sidekick Health Germany GmbH	11.01.2024	- Educational content via lections with educational, behavioral, fitness aspects - Calorie tracking - Challenges (fitness, nutrition, behavior) - Coaching chats	3.85	NT, ET, BT

NT, nutritional therapy; DP, diet program; ET, exercise therapy; BT, behavioral therapy.
[a]A part of the app is in English.
[b]Official "Digitale Gesundheitsanwendungen" (DiGA) (accessed via test access).

with 3.57 (SD = 0.52) was achieved in section C, targeting the aesthetics. The values of the apps varied between 2.67 and 4.33. The last section D, focusing on the information, reached an overall mean score of 3.35 (SD = 0.45), with scores from the apps varying between 2.6 and 4.0.

4 Discussion

The systematic search identified ten mobile health applications, while two of them ("Oviva Direkt" and "zanadio") are DiGA for the treatment of obesity in Germany. Each app included content based on at least two of the following topics: nutritional therapy, diet programs, exercise therapy, or behavioral therapy.

All apps assessed met some recommendations based on the German obesity guideline, but the range between the apps in terms of fulfillment of these recommendations is quite wide, between two and eleven items. In most cases, it was possible to decide on whether the content was included or not. One exception was the item "Recommendations for diets", which remained "unclear" in four apps. This was due to the fact that although diets were mentioned in these apps, no further explanations or recommendations were provided for the diets.

The items mostly fulfilled in the apps were items 1, 3, 7, and 10.

Item 1 and 7, focusing on "Individual nutritional recommendations" and "Encouragement of physical activity" reflect two of the essential components of holistic treatment of

TABLE 2 Compliance of the apps with the German obesity guideline.

Item	Yes		No		Unclear	
1. Individual nutritional recommendations	7	70%	3	30%	0	0%
2. Education on change of diet	6	60%	4	40%	0	0%
3. Patient preferences	8	80%	2	20%	0	0%
4. Recommendations for diets	1	10%	6	60%	3	30%
5. Present different nutritional strategies	6	60%	3	30%	1	10%
6. Approach to weight-reduction	7	70%	3	30%	0	0%
7. Encouragement of physical activity	9	90%	0	0%	1	10%
8. Safety of physical activity	2	20%	8	80%	0	0%
9. Education of benefits from phys. activity	4	40%	5	50%	1	10%
10. Setting relatable goals	7	70%	1	10%	2	20%
11. Encouraging weight stabilization	2	20%	6	60%	2	20%
12. Behavioral therapy interventions	5	50%	5	50%	0	0%
Mean	6.4		4.6		1.0	

obesity (13). A recent qualitative study investigated the personal motivation for weight loss in people with obesity. The majority of participants expressed their intention to eat healthily or increase their physical activity, but eventually lacked motivation and self-regulation to success. The participants reported a need for motivation boosters, such as reminders, to continue with healthy habits (35). A review about mobile apps for weight management also concluded that one of the biggest challenges regarding the use of apps targeting the treatment of obesity is to increase the motivation of the participants, especially in populations with lower adherence (36). Because longer treatment duration leads to positive effects (37), the motivation to continue using the app might be essential for an effective treatment. According to the German guideline for the treatment of obesity, motivation is an important aspect of long-term weight loss and weight maintenance (13). Similar results were discovered in a randomized controlled trial examining a personalized web-based weight loss program. The trial has shown that adherence is a key to success. Each additional session accomplished by participants led to an increased chance of a significant weight loss after 24 weeks by 2% (38).

Item 3, "Patient preferences", requires the treatment to be patient-centered and consider individual preferences (13). Individual preferences were carried out differently in the apps. In most of the apps, it was possible to choose between different nutritional strategies and to exclude individual foods. Furthermore, fitness content most often showed various exercises from whom to choose and allowed patients to choose a workout-

TABLE 3 Compliance with the German obesity guideline of each app.

App \ Item	1	2	3	4	5	6	7	8	9	10	11	12
DWP Fitness—Diät & Sport	yes	yes	no		no	yes	yes	no	no	yes	no	no
Fabulous—Gewohnheitstracker	no	yes	yes		no	no	yes	no	yes	yes		yes
FIT-UP: Fitness & Ernährung	yes	no	yes	no	yes	yes	yes	no	no	yes	no	no
Fizz Up: Training und Ernährung	no	no	yes	no	no	no	yes	no	no		no	no
Foodvisor—Ernährung und Diät	yes	yes	yes	yes	yes	yes		no		no	yes	yes
GlücksFigur—Abnehmen & Diät	no	yes	no	no	yes	yes	yes	no	yes		no	yes
wikifit—Kalorienzähler	yes	no	yes	no	yes	yes	yes	no	no	yes	no	no
Workouts Zuhause—Training	yes	no	yes	no	yes	no	yes	no	no	yes	no	no
Oviva Direkt[a]	yes	yes	yes			yes	yes	yes	yes	yes	yes	yes
zanadio[a]	yes	yes	yes	no	yes	yes	yes	yes	yes	yes		yes

1–12 marks the checklist items showed in Table 2.
Colors representing the answer options yes, no or unclear.
[a]Official "Digitale Gesundheitsanwendungen" (DiGA).

TABLE 4 MARS-G quality scores.

App	Overall mean	Section A "Engagement"	Section B "Functionality"	Section C "Aesthetics"	Section D "Information quality"
DWP Fitness—Diät & Sport	3.15	2.6	3.5	3.33	3.17
Fabulous—Gewohnheitstracker	3.78	3.8	3.5	4.0	3.83
FIT-UP: Fitness & Ernährung	3.15	3.0	3.5	3.33	2.8
Fizz Up: Training und Ernährung	2.93	2.8	2.75	2.67	3.5
Foodvisor—Ernährung und Diät	3.82	3.8	3.75	4.33	3.4
GlücksFigur—Abnehmen & Diät	3.0	2.4	3.25	3.33	3.0
wikifit—Kalorienzähler	3.32	2.6	4.0	3.0	3.67
Workouts Zuhause—Training	3.07	3.0	3.0	3.67	2.6
Oviva Direkt[a]	3.89	4.0	4.0	4.0	3.57
zanadio[a]	3.85	3.4	4.0	4.0	4.0
Mean values	3.39	3.14	3.5	3.57	3.35
(SD)	(0.39)	(0.57)	(0.43)	(0.52)	(0.45)

[a]Official "Digitale Gesundheitsanwendungen" (DiGA).

plan, which would most likely suit them. A systematic review and meta-analysis of personalized eHealth interventions for obese and overweight adults found that a combination of personalized content and customized human feedback can lead to the greatest treatment effects. The intervention may have a positive effect if personalization elements such as reminders, self-monitoring, and goal setting are included. The meta-analysis also showed a personalized digital treatment strategy significantly reduced participants' weight (39). Another systematic review of tailored eHealth interventions for weight reduction concluded that personalized content in eHealth weight loss programs is perceived by patients as more relevant, helpful, and understandable and at the same time may have a small effect on weight reduction (40). A study examining a personalized web-based weight loss program concluded personalized feedback given by a human led to a longer use of the program and a higher engagement rate, which could be especially beneficial for participants who would otherwise abandon the program quickly (38). The inclusion of personalized elements in mobile health applications may improve adherence and motivation, potentially enhancing the effectiveness of the treatment.

Item 10 "Setting relatable goals" was fulfilled by seven apps. The objectives ranged from a fixed date on which the weight was to be achieved, to weekly weight targets and individual motivational targets relating to specific life events. In a recent study examining the association between goal setting and weight reduction in a community weight loss program, participants were more willing to continue the program and lose weight if they set themselves reachable goals. Findings also revealed a medium weight loss goal had better effects than goals which were set below 10% weight loss (41). It can be assumed that it is important for a successful app to assist patients in setting manageable goals based on their individual measures to avoid demotivation.

While item 5 "Behavioral therapy interventions" was only fulfilled by 50% of the assessed apps, literature highlights these behavioral components can be the key element of any obesity treatment, both in face-to-face treatment and in digital solutions, leading to an overall increased effectiveness of the apps (36). A systematic review targeting cognitive behavioral therapy for obesity, concluded that behavioral therapy is an effective treatment of obesity leading to weight reduction. In combination with other methods, such as physical activity the treatment of obesity can become multi-dimensional and most effective (42).

Overall, it can be noted that using mobile health apps can achieve clinically relevant weight loss, help patients improve their self-regulation and therefore be overall effective (43). However, a systematic review and meta-analysis examining the effectiveness of smartphone apps for weight loss reported mobile apps achieved significant overall weight loss, but even greater when the mobile health app was used in combination with human behavior coaching or feedback. The highest weight loss was reached when the mobile health app was combined with a tracker and a behavioral intervention given by a human coach (44). This raises the question of whether blended care interventions, combining digital support with professional health coaching, might be an effective approach to treating obesity. Results of another recent systematic review on the effects of combined face-to-face and eHealth interventions for weight reduction showed how blended care approaches can lead to significant weight loss, an increase of physical activity and an improvement in quality regarding nutrition (45). Nevertheless, it is still a lack of research about what the blended care approach should look like in terms of the optimal design and frequency of personal contact.

The overall MARS-G mean score, assessing the quality of the apps, is 3.39 and therefore shows an overall acceptable quality. Compared to the other apps, the two DiGA have the highest MARS-G score. Both DiGA have proved their effectiveness in randomized controlled trials. "Oviva Direkt" demonstrated a significant weight reduction of 3.2% after 12 weeks and a weight maintenance after 24 weeks in the intervention group (46). The randomized controlled trial on the efficacy of "zanadio" showed an average significant weight loss of 7.75% in the intervention group within 12 months and a significantly improvement of the well-being, quality of life and waist to height ratio compared to the control group (47). In contrast, patients who can download the other mobile health apps free of charge cannot assess the effectiveness of these apps, because no evaluation was conducted. Nevertheless, especially section C regarding the aesthetics, showed the highest mean score. The section on engagement received the lowest mean score. Based on the already named need for personalized structures within the app to increase the motivation and adherence of the participants, the features leading to engagement are among the most important ones.

Trying to assess the acceptance of patients using the included mobile health apps, an important consideration is the access to these treatment options. The access for the eight assessed apps, which are no DiGA, can be described as low-threshold. This can be assumed, as the apps can be downloaded and used free of charge. Hence, these are treatment options for patients to test and use self-determined and without being prescribed by healthcare professionals. However, the DiGA are also free of charge if the patient consults a healthcare professional (physician or psychotherapist), and the DiGA is reimbursed by the SHI. Maybe the threshold is higher here because the patient first needs to contact the physician or the SHI to have a free access to these DiGA. According to a survey of insured and routine data from one German SHI, the majority of DiGA users became aware of this option because their physicians recommended it, and other information channels were rarely used (48). Although access may be more cumbersome, the DiGA offer a high quality with evidence for the content displayed, whereas the freely accessible mobile health apps do not provide evidence, making it difficult to assess quality from the patient's perspective.

The number of patients using DiGA increased over the last few years, leading to 374 thousand prescribed DiGA since 2020 (49). If the number of prescribed DiGA is compared to the total number of insured adults in the German SHI, which is around 61 million (50), it becomes apparent that a rather small proportion of the insured people utilize DiGA up to now. The survey conducted by a German SHI yielded similar results, with only 0.29% of all

insured individuals taking advantage of digital health applications. These numbers suggest DiGA are not yet fully implemented in the treatment of diseases in Germany (48).

An online survey study analyzing the acceptance of mHealth apps in Germany in 2022 discovered 76% of the participants would use mHealth apps or DiGA. A younger age and higher digital competences (self-assessed) were indicators for the intention to use. For 53% of participants, a governmental quality control would be a prerequisite for the use of health apps. Additionally, for 67% of participants, it does not matter whether a health app is prescribed by a physician, which indicates they would be willing to use non-prescribed, freely available health apps. In total, only 27% of those surveyed indicated they would be willing to pay for a mobile health application on their own. Comparing the acceptance of mHealth apps and DiGA, 31% of the participants would only consider DiGA as an effective treatment addition, while 53% of the participants viewed health apps in general as a positive addition to the therapy. DiGA are mainly distinguished from other health apps by acceptance of the physician, medical performance, and data security. The study showed an overall high level of acceptance for mHealth interventions in Germany (51).

While the acceptance may be rather high from the patient perspective, it is just as relevant to perceive the acceptance of the healthcare professionals to increase the use of DiGA. A representative, national survey of healthcare professionals in 2022 explored the insights of DiGA in day-to-day care. A third of the respondents already gained experience in testing or prescribing a DiGA, but just 6.3% of them assigned DiGA more than fifteen times. 49.2% of the surveyed physicians would not prescribe a DiGA and even 77.8% of the respondents recognized obstacles in the deployment of DiGA. These included doubt about the effectiveness, concerns about the data safety as well as the excessive price. The survey demonstrated an increase in acceptance among healthcare professionals in 2022 compared to 2021, but about half of the respondents were not fully convinced about the benefits of the DiGA. The survey also pointed out how often healthcare professionals criticized the relation between DiGA costs and the reimbursement of their own services. Particular attention is given to the difference between a higher cost expenditure for the digital application and lower reimbursement for the medical service associated with additional time resources required to prescribe, explain and educate the patient (52). A recent qualitative study, where 38 GPs in Germany were asked about their experience with DiGA, also indicated a need for high-quality information and comprehensive training programs on DiGA. They would also like the SHI to educate patients about DiGA and to promote them to ensure they are not left alone with this task (53).

4.1 Limitations

A few limitations should be pointed out in this work.

First, this review was based on the methodology for systematic reviews according to the PRISMA statement (34). Nevertheless, the assessment of apps differs significantly from the assessment of scientific literature. Because of this, the search terms used in the assessment were single terms, trying to display what affected persons would search, including the disease itself but also highly associated terms, mostly applied in the linguistic usage. The possibility of an important search term not being used, is nevertheless existing. In addition, the previously defined aspect that the apps included must be available in both the Apple App Store and the Google Play Store can also be seen as a restriction.

Secondly, the systematic search only includes apps that are free of charge for patients: on the one hand, eight apps that can be downloaded free of charge from the App Store and, on the other hand, two DiGA. Additional apps that have to be paid for by the patients themselves (one-off or subscription) may also be available in the app stores. Literature suggests a correlation between higher app quality and higher prices (54, 55). For instance, the two DiGA, which cost the SHI € 220.90 ("Oviva Direkt") and € 218.00 ("zanadio") for three months each (26), already show a higher rating in the MARS-G score than the other eight available apps from the App Store. Perhaps some mobile health apps not listed as DiGA and only available behind a paywall are of better quality than free downloadable apps. However, it is still difficult for patients to assess the quality of these applications.

And third, the checklist used in analogy to the guideline is not a validated instrument. In addition, no criteria were formulated for determining when a recommendation was or was not fulfilled by an app. Moreover, no weighting was given to the points whose fulfilment is particularly important. In this context, it is important to mention that the German guideline for the treatment of obesity based on the last update from 2014 (13) may be outdated. Therefore, it should be considered here a change in the requirements for a successful treatment of obesity. As a result, the content displayed in the apps must be adapted. This can also be surmised with reference to the DMP for obesity, in which aspects such as sleep, psychosocial factors etc. are already addressed (19). Nevertheless, the problem of obesity not being a mental and behavioral disorder according to the ICD classification still exists, making accompanying psychotherapeutic treatment neither justified nor financed by SHI.

5 Conclusion

All mobile health applications assessed in this work, included at least two of the recommended topics, such as nutritional therapy, diet programs, exercise therapy, or behavioral therapy. In addition, all of them met some recommendations for the treatment of obesity from the German obesity guideline but varied rather widely in the number of recommendations met. The two DiGA included in this assessment fulfilled most of the recommendations and therefore stood out both in terms of content and the quality as assessed by MARS-G.

In principle, acceptance of mHealth seems to be quite high among the German population, whereas healthcare professionals still have concerns regarding safety and effectiveness aspects. To increase the effectiveness of mobile health applications, a personalized approach considering participants' preferences as well as engaging structures enhancing adherence and motivation are important. Overall, the use of an app may be an effective approach with an increased access to care for some obese patients. The use of a blended care treatment, for example the combination of the DMP and a mobile health app, may increase the effectiveness for patients with low adherence. Further research to find out if different patient groups may prefer and benefit from various treatment options for obesity, such as mobile apps, blended care, personal face-to-face contact or group settings, is necessary. In the future, it should also be researched if mobile applications and DiGA can reduce barriers and simplify the access to a holistic obesity treatment.

Author contributions

PS: Writing – review & editing, Writing – original draft, Formal Analysis, Methodology, Visualization. SM: Writing – original draft, Writing – review & editing, Validation. LK: Writing – review & editing, Writing – original draft, Conceptualization, Supervision, Validation.

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Conflict of interest

LK is the director of LiKe Healthcare Research GmbH. PS and SM are employees of LiKe Healthcare Research GmbH.

Publisher's note

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Exploring patient perspectives on Iran's Electronic Prescription System: a Qualitative Inquiry

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Background: Electronic prescriptions represent a fundamental shift in service delivery, healthcare management, and associated costs, offering numerous advantages. However, akin to other electronic systems, they also present challenges. This study aimed to investigate patients' understanding of the challenges associated with electronic prescriptions in Iran.

Methods: This study used a qualitative research design, utilizing individual and semi-structured interviews with patients referred to selected pharmacies across all 11 districts of Shiraz City. The data were analyzed using MAXQDA software (version 10), and descriptive statistics for demographic data were calculated using SPSS version 19.

Results: The study revealed that the participants generally demonstrated a certain level of familiarity with electronic prescribing systems. However, it was evident that many were unaware of the potential implications of such technology for their relationships with healthcare providers. This underscores the urgent need for patient understanding in the context of the electronic prescription system. While patients were relatively familiar with the functionality of electronic prescribing systems, they lacked a comprehensive understanding of how using these systems could affect their interactions with healthcare providers.

Conclusion: Patients are significant beneficiaries of the electronic prescribing system. By addressing their needs and concerns, they can develop a positive attitude toward this system. Their active engagement can pave the way for the system's ease of use, increase its acceptance, and ultimately enhance the quality of healthcare services.

KEYWORDS

electronic prescription, health information technology, doctor, pharmacist, qualitative analysis

Introduction

Electronic prescription, typically defined as the transition from paper prescriptions to electronic systems facilitating the creation, transmission, and processing of prescriptions by healthcare providers and pharmacies, represents a pivotal transformation in healthcare management. This includes a range of activities, from patient registration to information retrieval and service provision, all within the context of electronic systems. Many countries

are transitioning toward electronic systems to improve safety, efficiency, and cost-effectiveness in healthcare delivery, with electronic prescriptions being a key component of this transformation (1–3). Electronic prescribing is intended to alleviate the burden on patients with chronic conditions, reducing the necessity for frequent consultations with their physician, as electronic prescriptions can be issued through online consultations. This approach saves both time and money for the therapist and patient, and so far, it has reduced up to 60% of chronic patients' visits to the doctor (4, 5).

There has been a significant increase in the adoption of electronic outpatient treatment services, which is indicative of a global trend toward digitizing healthcare delivery. This shift from manual to electronic systems underscores the crucial role of digital transformation in healthcare services worldwide (6–8). In most European Union member states, healthcare services are progressively provided electronically. This trend is expected to accelerate, with initiatives to integrate these systems into an international electronic health service framework. This integrated network will enable citizens to have seamless access to medications and medical services across member countries, primarily facilitated by electronic prescribing initiatives (9–11).

Electronic prescriptions offer numerous advantages, including reducing revisits for chronic patients, ensuring accurate insurance information, minimizing prescription errors during pharmacy delivery, enabling patients to purchase items from different pharmacies with a single prescription, and providing access to prescription histories. Moreover, it eliminates paper documentation, reduces production costs, assists treatment decisions through decision support systems, and enhances service quality for patients (10, 12). Research indicates a preference for electronic prescribing among primary care practitioners, citing benefits such as enhanced legibility, reduced medication errors, and streamlined workflows (4, 8, 9, 13). Conversely, the inherent challenges of manual prescription systems, such as illegible handwriting leading to medication errors, underscore the pressing need for electronic prescribing solutions to enhance patient safety and elevate the standard of care (4, 9, 13).

However, electronic prescribing systems are not without their challenges. These include high setup, maintenance, and training costs for medical staff, bandwidth limitations leading to system outages, security and privacy concerns among users, an increase in physician errors in electronic prescriptions, and communication barriers between patients and healthcare providers (5, 11). In Iran, the Ministry of Health is mandated by the fifth and sixth development plans to implement electronic prescriptions. The initial implementation occurred in 2016 in private physician offices in collaboration with the Tamin-E-Ejtemaei organization. Following this, health insurance agencies such as Salamat and Tamin-E-Ejtemaei expanded the program across provinces as a pilot project until January 2021, when it became mandatory for all outpatients nationwide (13, 14).

Until now, in Iran, there has been limited investigation into the complex aspects of electronic prescriptions from the patient's perspective. This study investigates patients' attitudes toward electronic prescription and its impact on their satisfaction levels, the quality of healthcare delivery, and their interactions with healthcare professionals, including doctors and pharmacists. The primary objective of this research is to shed light on patients' understanding of electronic prescribing and its influence on the quality of care, their interactions with prescribers and pharmacists, as well as their perceptions of the benefits and drawbacks of electronic prescribing within the city of Shiraz.

Materials and methods

This qualitative study is based on one-on-one interviews. Semi-structured and individual interviews were conducted with patients referred to selected pharmacies across all 11 districts of Shiraz city. This approach was chosen to provide the necessary flexibility to explore patients' attitudes. An initial list of pharmacies in Shiraz city was selected as a stratified sample based on the 11 regions to collect patients' views on electronic prescribing. Announcements were placed in the selected pharmacies, and invitation letters were included in patients' medicine packages. This allowed patients willing to participate in the study to call the contact number on the invitation letter and arrange the interview time. Patients aged 18 years or older who had at least three visits to a doctor in the past year and were prescribed an electronic prescription were included in this study.

A semi-structured interview was conducted to collect the necessary data to assess patients' attitudes, ensuring maximum flexibility in capturing patients' perspectives. The interview evaluated three areas: patients' understanding of electronic prescriptions, their relationship with the doctor and pharmacist, and their viewpoint on the advantages and disadvantages of electronic prescribing.

Following data collection, rigorous analysis procedures were implemented. All interviews were transcribed verbatim immediately after recording, with researchers concurrently taking detailed notes during the interviews to ensure the accuracy and completeness of the data.

Thematic analysis, a well-established qualitative research method, was conducted for data analysis. The analysis process adhered to a structured six-step approach:

Familiarization with the Data: Researchers immersed themselves in the collected data, gaining a profound understanding of the content and identifying underlying concepts.

Generation of Initial Codes: Each concept, including its primary and sub-elements, was systematically assigned a code, facilitating data organization.

Category Exploration: Through iterative examination, categories were developed to group related codes, allowing for the identification of overarching themes within the dataset.

Review of Main and Subcategories: This critical step involved revisiting codes, categories, and subcategories to ensure they accurately reflected the dataset's nuances.

Definition and Naming of Categories and Subcategories: Distinct definitions and appropriate labels were assigned to each category and subcategory, ensuring clarity and consistency in the analysis.

Report Preparation: The final phase involved summarizing and presenting the findings coherently and comprehensively.

The researcher conducted the interviews in a room within the pharmacies. The interviews were recorded, and verbatim transcription was performed after obtaining consent from the interviewees. The transcripts were then cross-verified against the audio recordings. Limited demographic data were also collected as part of the interview process.

Two researchers read and coded transcripts separately. They then discussed the transcripts to identify inconsistencies and reach a consensus on coding decisions.

In the initial stage, both researchers shared common opinions on approximately 76% of the codes. Subsequently, the two researchers re-coded the transcripts, and in the second phase of the review, the

TABLE 1 Demographic information of interviewed patients.

The average age of the participants	Male	37 ± 10
	Female	33 ± 10
	Total average	35 ± 10
	Diploma and below (*n*) percent	33% (7)
	Master's degree and bachelor's degree (*n*) percent	52% (11)
Level of education	Master's degree and doctorate (*n*) percent	10% (2)
	PhD (*n*) percent	5% (1)
The number of visits to the doctor in the past year	Minimum	3
	Maximum	8
	Average	5 ± 1

agreement on codes reached 99%. The remaining 1% was discussed in a second session, and ultimately, both researchers reached a consensus.

The interviews yielded three main categories and 28 sub-categories. Qualitative analysis was performed using MAXQDA software (version 10), and descriptive statistics for demographic data were calculated using SPSS version 19.

The interview questions were selected from the article titled "Patient perceptions of e-prescribing and its impact on their relationships with providers: A qualitative analysis" (7).

To ensure the validity and accuracy of the qualitative data, the research adhered to Guba and Lincoln's criteria, which encompass reliability, variability, dependability, and confirmability (15). The interview analysis was conducted iteratively, and the text was shared with participants to rectify potential errors. Various coding methods were also utilized, and an expert in qualitative studies assisted in the analysis.

The present study received approval from the Ethics Committee of Shiraz University of Medical Sciences, Shiraz, Iran (IR.SUMS.REC.1401.361). After securing the necessary permits from the Research Vice-Chancellor of the Faculty of Medical Information and Management and a letter of approval from Shiraz University of Medical Sciences, the researchers explained the research objectives to the participants and introduced themselves. They assured the participants that all recorded information would remain confidential. After that, participants willing to participate in the study were selected, and they were also assured that they could withdraw at any stage of the interview process. Other ethical considerations included: (1) obtaining written consent from the participants, (2) assuring the participants that the study results would be made available to them if they wished, (3) observing ethical considerations in terms of data confidentiality, (4) expressing gratitude to all the people who cooperated in the research, and (5) obtaining approval from the ethics committee.

Results

Between December and February 2021, we conducted 21 interviews, each lasting approximately 15 to 60 min. The participants comprised of 48% men and 52% women. Table 1 shows the demographic information of the participants.

Subjects regarding patients' attitudes toward electronic prescribing were organized into 3 main categories and 11 sub-categories. Some of these sub-categories were further divided into sub-sub-categories. In total, 42 main codes were extracted. Table 2 reveals the detailed breakdown of these categories, sub-categories, and codes.

The key findings from the analysis are outlined below. It is worth noting that the number of participants may not always be 21 in certain instances, as responses were not mutually exclusive. In certain cases, participants expressed more than one opinion on a specific topic, resulting in a frequency count exceeding 21 for some measures.

A: patients' awareness of electronic prescribing

Most participants were not entirely familiar with electronic prescribing, and when asked to provide a detailed explanation, they could not explain what it meant to them. Most explained that the prescriber uses a computer, and the prescription is sent directly to the pharmacy, bypassing manual delivery ($n = 16$).

One of the patients perceived electronic prescriptions as the use of Internet platforms such as WhatsApp for doctor consultations:

> "Yes, I know that it is online instead of in person. We call the doctor, and the doctor consults us through WhatsApp, explains what to do, prescribes our medicine, and then we go to the pharmacy to get our medicine." (P4-ph.A-D1)[1]

Another participant equated it with a person's authentication system:

> "I will provide a national code so that they can identify us. This is referred to as electronic prescription." (P6-ph.B-D3)

Patients with very limited knowledge of the electronic prescribing system were provided with explanations about these services. Interviews were conducted only after patients had gained a clear understanding of the electronic prescribing system.

These interviews occurred approximately a year after the electronic prescription project was launched in Iran. Over half of the participants ($n = 13$) were unaware of the exact start time of electronic prescriptions. Regarding their awareness of this project, participants learned about it during a doctor's appointment ($n = 9$), through social media ($n = 6$), and via online platforms ($n = 3$). Additionally, three participants were informed about the project through other means, such as acquaintances and friends.

Regarding the time and method of becoming acquainted with the system, one participant mentioned:

> "I believe I learned about it about two years ago or less…through my colleagues." (P10-ph.C-D9)

1 P: Patricipant/ph: pharmacy/D: district.

TABLE 2 Main category, sub-category, sub-sub-category, and main codes extracted from the study.

The main category	Subcategory	Sub subcategory	Original code
Patients' awareness of the plan	Design definition	——	Correct and accurate definition
			General and imprecise definition
	How to find out when the plan starts	——	Knowing the exact start time of the project
			Knowledge of the starting time of the project with a difference of 3 months
			Knowledge of the starting time of the project with a difference of 6 months
			Knowing the start time of the plan with more than 6 months' difference
	How to know about the start of the project	——	Through social media
			By visiting a doctor's office or pharmacy
			Through virtual space
			Other ways (hearing from friends and acquaintances)
Attitude toward prescription and electronic prescription	Knowledge of prescribed services (number and type of medicinal items or diagnostic and therapeutic service) by the doctor	——	Full knowledge and information
			Knowledge and relative information
			Lack of information on the type of prescription
	Information about the prescribed prescription and how to follow up to receive the prescription	Yes (how to find out)	Receive SMS after registration
			Receive the tracking code of the registered prescription from the doctor or his secretary
		does not have	——
	Doctor–patient communication	——	It is better than before
			It has not changed
			It is worse than before
	Duration of service in the pharmacy	——	Earlier than before
			It has not changed
			Later than before
	(pharmacy technical officer) communication with the patient	——	It is better than before
			It has not changed
			It is worse than before

(Continued)

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TABLE 2 (Continued)

The main category	Subcategory	Sub subcategory	Original code
Advantages and disadvantages of electronic prescribing	General view of the plan	——	Positive
			Indifferent
			Negative
	Positive attitude and experiences	Quality and safety	No mistakes in reading version and screw version
			Removal of pen corrosion and bad handwriting
			Not losing the copy
		Reduce costs	Saving paper
		Ease of use	No need to renew the notebook
			Reducing the time of providing some services
			No need to carry paper and notebooks
			Virtual visit and drug registration
			The possibility of receiving from several pharmacies
	Negative attitudes and experiences	Poor infrastructure	Network problems
			Hardware and software problems
			Slow or frequent system crashes
		Time-consuming	Prescription error and returning the prescription to the doctor
		Reduced communication	Less communication between the doctor and the patient
			Failure of doctor and pharmacist to pay attention to the patient
		Reducing the amount of information about the prescription	Not knowing the type of medicine prescribed
			Not knowing the brand of prescribed drugs

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Other participants mentioned that they became aware of this program approximately 3 months ago through visiting a pharmacy or a physician:

> "I guess it was around two or three months ago that I went to a pharmacy and found out about this." (P14-ph.D-D5)

> "It has been three or four months now… I found out through the media and after visiting the doctor." (P12-ph. E-D8)

Another participant had detailed information about the beginning of the project:

> "It has been electronic for about a year … they announced it on TV." (P16-ph. F-D6)

B. attitudes toward electronic prescribing

B-1: attitude toward electronic prescribing (in the physician's office)

Most participants were unaware of the type of services provided by the doctor and the type and number of prescribed medicinal items ($n = 18$). On the other hand, almost half of the participants ($n = 9$) did not perceive any difference in the doctor's behavior during their visit compared to the previous visits. The second phase of this issue pertained to the group that had experienced negative feelings about their doctor ($n = 7$). Only three participants mentioned that the conditions were better than in the past.

In this regard, one participant mentioned:

> "No; They do not disclose the number and type of medicine unless the doctor has the ethics to do so, and they also do not explain." (P5-ph. G-D11)

Another participant expressed dissatisfaction with the change in doctor–patient communication due to electronic prescribing:

> "The relationship has worsened. Doctors used to communicate, but now most doctors are more connected to the system, trying to find the medicine and write the prescription. They used to communicate more than now".(P7-ph. F-D6)

One participant expressed concerns regarding the electronic prescription being managed by the doctor's secretary and noted the absence of noticeable changes in the doctor's behavior compared to the manual prescription writing:

> "I've visited a doctor several times since electronic prescriptions were introduced. This doctor did not directly enter medicine details into the system. Instead, he prescribed paper and instructed me to take it to his secretary for typing. It feels like he's still prescribing it as if it were a paper prescription."(P1-ph. H-D4)

On the other hand, another participant felt satisfied about the type of prescriptions and improved communication with the doctor.

> "Every time I visit the doctor, who is familiar with me, he always inquires whether I have certain medicines at home to avoid prescribing them again. When he writes the prescription, he consults us, and since the doctor knows us, he asks about the medicines we already have. The doctor's clear explanation of my prescription alleviates my concerns." (P19-ph. I-D2)

B-2: attitude toward the electronic prescription (in the pharmacy)

The participants were asked two questions during a visit to the pharmacy to receive their medicine. The first question was about the waiting time to receive the medicine, and the second was about communicating with the pharmacist regarding the necessary explanations of prescribed medicines.

Regarding the waiting time to receive medicine, a total of 17 individuals responded. Nine individuals reported a delay in the delivery services, five reported no difference, and three reported quicker delivery services in the pharmacy.

One patient expressed dissatisfaction with the delayed delivery of the medicine:

> "Now there is more of a delay. We used to wait less, but now we have to wait longer. They have sent letters everywhere about the electronic system; we have to wait longer because of the electronic system"(P8-ph.C-D9)

One participant attributed the longer waiting time in the pharmacy to the perceived dishonesty of the pharmacy staff and a lack of patient information:

> "The duration of receiving medicine has increased. Sometimes pharmacists lie that the system is not working in order to rest for a while."(P17-ph. G-D111)

On the other hand, some patients evaluated the delivery time as favorable:

> "Now it is faster than the paper prescription."(P1-ph. H-D4)

Regarding the pharmacy technician's explanations of the drugs and the pharmacist's interaction with the patient, seven individuals rated the conditions as worse than before, nine rated them as unchanged from before, and five rated them as improved compared to before. One participant shared their experience with the pharmaceutical manufacturer as follows:

> "Yes, The pharmacists inform patients, for instance, that out of this prescription, we do not have two of the medications, or that we offer the Iranian brand or the foreign brand."(P21-ph. J-D7)

Another participant said:

> "Yes. In the pharmacy, they explain the medication, how to take each one, or whether it is a foreign or Iranian brand."(P8-ph.C-D9)

Yet another patient evaluated the situation as worse than before:

> "No, they do not say how many medicines are there. If they do not have a medicine, sometimes they mention that they do not and refer us to check other pharmacies, but sometimes they do not say anything."(P20-ph.B-D3)

C: advantages and disadvantages of electronic prescription

C-1: positive attitudes and experiences

Patients' positive attitudes and experiences with electronic prescribing were primarily related to ease of use ($n = 17$), safety and quality ($n = 9$), and cost ($n = 4$). Some individuals reported more than one positive experience, the frequency of which was mentioned in both sections.

The ease of electronic prescription refers to the elimination of the need to renew health insurance booklets, reducing the time spent providing some services, no need to carry a health insurance booklet, and the possibility of receiving single-prescription drugs from several different pharmacies without removing the paper from the insurance booklet.

One of the patients stated:

> "The pharmacies used to say that we have one of the drugs, we do not have the other one, and you have to buy the one we do not have without insurance coverage. Previously, there were mistakes in the doctor's handwriting, or the doctor had stamped only one medicine, and the other was not stamped. Now these problems have been solved." (P5-ph. G-D11)

Issues regarding safety and quality include reducing medication errors, increasing access to information for prescribers, and avoiding losing prescriptions.

A participant mentioned in this regard that:

> "The most important advantage, in my opinion, is that the mistakes that pharmacies and lab technicians used to make because of doctors' bad handwriting will not be repeated. Secondly, patients used to lose prescriptions. Before, if the doctor wrote the prescription incorrectly or it was in poor handwriting, we had to go back to the doctor to correct it. But now, we no longer have to return to the doctor because they write prescriptions with a computer. It is always written correctly and is no longer a problem."(P5-ph. G-D11)

Positive experiences have been reported in terms of both overall cost reduction for the healthcare system and environmental protection.

A 23-year-old woman made the following positive observations:

> "For example, I believe that less paper should be used. I am one of those who believe that life should be green. The less paper we use, the less environmental damage there is. I think this is a very positive thing."(P19-ph. I-D2)

C-2: attitude and negative experiences

Patients' negative perceptions and experiences of electronic prescribing predominantly point to the infrastructural problems, the slowness and uncertainty of the system ($n = 18$), a feeling of less control over their prescriptions ($n = 18$), communication problems with prescribers ($n = 13$), and errors in the timing of prescriptions by their doctor ($n = 10$).

Several patients reported that the doctor incorrectly prescribed their electronic prescription.

Communication challenges with prescribers include worsening interpersonal communication, as the prescriber seemed to be more focused on the computer than interacting with the patient. Communication challenges with pharmacists included missing the opportunity to interact at the prescription delivery stage.

In general, patients associate electronic prescribing with a loss of control over their prescriptions. On the other hand, delays in sending prescriptions lead to delays in receiving drugs.

Patients also reported that previous written prescriptions provided them with personal access to information about what was being prescribed, even if it was just the name of the drug.

Two patient statements presented below are examples of negative perceptions/experiences of electronic prescription:

> "A 35-year-old woman said: My uncle's daughter once went to the pharmacy. She was allergic to a certain medicine, and the doctor mistakenly prescribed that medicine. Luckily, the pharmacist, who knew my cousin well, realized she was allergic to the prescribed medicine. The pharmacist asked her, "Don't you have an allergy? Why do you want to take this medicine? Her physician had already changed that medicine for her. If she had taken the wrong medicine that the doctor had prescribed for her, it would have been very dangerous."(P8-ph.C-D9)

Another patient said:

> "I asked several times and from different pharmacies about the medicine and why it was given to me. I realized that it had nothing to do with my medicine and nothing to do with my disease. When I went back to the doctor and questioned it, he said that he had typed the drug code wrongly. He then rewrote the prescription, and I had to leave and come back again. It is true that there were mistakes in reading the prescription, and now those mistakes are not happening. Still, there could be a problem with the medicine code due to doctors' lack of familiarity with this new system. Some doctors do not have complete information about the new system, so they cannot work with it properly and prescribe the wrong medicine. The relationship has unfortunately deteriorated. Previously, doctors would communicate, but now it seems that most doctors primarily concentrate on navigating the system to locate the medication and write the prescription. The level of communication was notably higher in the past than the present."(P7-ph. F-D6)

Another participant stated:

> "The disadvantages that I would say are internet and website outages, and patient delays. It means that there is internet, but the site might have a problem. More time is being spent."(P14-ph.D-D5)

Despite participants identifying both advantages and disadvantages of electronic prescription, some patients reported no

personal impact from the technology or expressed neutral opinions about its use. Specifically, patients did not report any changes in communication with the doctor ($n = 9$), communication with the pharmacist ($n = 5$), or the duration of service in the pharmacy ($n = 5$).

Discussion

This study aimed to explore patients' attitudes toward electronic prescription systems in Shiraz. Interviews were conducted with 21 patients who sought medical services and visited pharmacies across 11 city districts for medication. The findings revealed a range of positive and negative attitudes and experiences among patients.

Patients in our study reported positive attitudes and experiences regarding electronic prescribing. They emphasized the ease of use, enhanced safety, improved healthcare quality, and cost reduction associated with this system. Seventeen patients mentioned a positive experience, and one only mentioned positive points. These findings align with a study conducted in Poland in 2021, which also highlighted the convenience of electronic prescribing, the reduced risk of prescription loss, and the elimination of the need for in-person doctor visits (14). On the other hand, patients in our survey spoke negatively about their experiences and views related to infrastructural difficulties, system hiccups, slowness, electronic prescription mistakes, feeling like they have less control over their prescriptions, and poor contact with their prescribers. Eighteen patients mentioned at least one negative point, and three people mentioned only negative points. These findings correspond with those of a previous article (9). Interestingly, our research suggests that patients generally held a more favorable opinion of electronic prescribing compared to the perspectives of doctors and pharmacists, as noted in a study conducted by Amlashi et al. in 1401 (equivalent to 2022–2023 in the Persian calendar) (16).

In general, patients were unfamiliar with electronic prescribing, and they felt that using this technology had little impact on their care. However, patients reported positive attitudes and experiences regarding ease of use, safety, quality, and cost. The participants in this study were unaware of the capabilities of electronic prescribing, such as checking the records of previous prescriptions and utilizing machine learning methods to help the doctor improve the quality of care and reduce the incidence of errors. This issue is addressed by a study named "Patient perceptions of e-prescribing and its impact on their relationships with providers: a qualitative analysis" (7). On the other hand, the results of this study differed from the results of a study titled "Patient perception and satisfaction with the electronic prescription system: results of the PERSA-RE questionnaire" (4).

The study highlighted the challenges stemming from the limitations of the e-prescribing system, which resulted in an increased workload and time consumption for patients. These limitations reduced the effectiveness of e-prescribing, ultimately forcing patients to obtain only a portion of their prescribed medications. Consequently, patients were compelled to cover the costs of medications not covered by their insurance plans, contributing to a financial burden. These findings align with the results of a study titled "A Pilot Study to Evaluate Prescription Transfer and Drug Collection through a New Electronic Prescription Service: A Cross-Sectional Survey" conducted in Saudi Arabia (12). This correspondence underscores the universal nature of the challenges associated with e-prescribing system limitations and their impacts on patient care and financial well-being.

There is still hope that the passage of time and the usage of electronic prescriptions will enhance patient's experiences and knowledge about all of their features. Despite the disadvantages of electronic prescribing, some patients have provided valuable suggestions to improve their conditions. In a study evaluating prescription transfer and drug collection through a new electronic prescription service (12), the participants were not interested in making suggestions. However, most participants in this study were satisfied with the plan's encouragement and presented significant suggestions. Their suggestions included using a printer to print prescriptions if requested by the patient, sending the contents of registered prescriptions to the patient's mobile number, creating a proper hardware infrastructure, adapting the doctor–patient interaction in response to the changes in the platform of interactions, and providing 24-h support from the technical team to remove existing obstacles. These were some of the proposals mentioned by patients to resolve problems and improve the existing situation. This study's results were inconsistent with the study conducted in Saudi Arabia (12).

In addition to the common concerns that patients express about losing opportunities to interact with the doctor, the non-compliance of the pharmacy and the pharmacist during the prescription delivery phase was also a point of worry. Some patients were concerned that because they did not know the content of the prescribed medication, they may be delivered more or less medicine, or without their knowledge, a specific type and brand of medicine that the doctor intended may not be delivered to them. Participants suggested that information at the time of prescription, such as printed patient information and post-visit summaries, could be made available to these people to address such concerns. In their study, Jabraeili et al. suggested that system developers should improve their capabilities by properly communicating with users and fully understanding their real needs, which is consistent with the suggestions made by the participants in this study (17).

Most global studies have examined the technical advantages and disadvantages of electronic prescribing systems. These studies have focused on the attitudes of doctors, pharmacists, and other personnel related to electronic prescribing, with few studies conducted on patients' attitudes toward electronic prescribing (5, 11, 13). Like other countries, following the introduction of electronic prescriptions in Iran, studies have been conducted to assess their advantages, disadvantages, and problems, particularly from the technical perspectives of doctors and pharmacists. However, no research has been conducted regarding the patients' attitudes toward this issue (2, 3). Patients and those who refer to health and treatment centers for medical services can be important beneficiaries of the electronic prescribing system. Patient satisfaction with the electronic prescribing system will help patients adhere to treatment with better and more effective communication with the doctor. It is very important to know the strengths and weaknesses from the perspective of patients, who are the significant beneficiaries of this plan (2, 5). However, physicians and pharmacists should also be aware of the potential problems that can arise from miscommunication related to electronic prescribing. More research is needed to determine how clinicians can use these existing tools to improve patient education and prescription decisions.

This study had several limitations. One of these limitations was the small sample size. Another limitation was the generalizability of the results. Although qualitative studies inherently have limited generalizability, an effort was made to increase the generalizability of the results by including women with different characteristics. Another limitation was the relative youth of the interviewed population compared to other studies. This issue is due to the better understanding of this group of interviewees regarding the use of emerging technologies, including electronic prescriptions. This group of patients was also more willing to

answer our questions. Despite these limitations, the study provides valuable insights into patients' attitudes toward electronic prescriptions. Further research with a larger and more diverse sample size could help to address these limitations.

Given the importance of patient–therapist communication in healthcare, it is essential to explore the changing dynamics of doctor–patient interactions in the context of electronic prescribing. Future research can delve into the nature of these evolving communication patterns and aim to develop strategies to mitigate potential harm. Such research would illuminate ways to optimize the doctor–patient relationship within the framework of electronic prescribing. Moreover, addressing patients' concerns about privacy violations is a pressing issue. Future studies should focus on implementing measures to alleviate patient apprehension regarding the security and confidentiality of their health information in electronic prescribing systems. By enhancing data security and privacy safeguards, healthcare providers can foster greater patient trust and confidence, ultimately improving the adoption and acceptance of electronic prescribing technologies. Given that the mean age of the statistical sample in our study was 35 ± 10, extrapolating the findings of this study to communities with a different mean age requires careful consideration.

Conclusion

Patients reported positive attitudes and experiences regarding the ease of use, safety, quality, and cost of electronic prescribing. However, they also reported negative attitudes and experiences related to infrastructural problems, system delays and interruptions, errors in electronic prescribing, a perceived loss of control over their prescriptions, and communication problems with their prescribers. Many patients' concerns stemmed from a lack of knowledge about the program and its advantages. Therefore, educating medical staff, especially doctors and pharmacists, is necessary to adapt their interactions to the electronic prescribing system. This includes familiarizing them with more features of electronic prescription to improve their use. By doing so, we can address patients' concerns and enhance their experience with electronic prescribing.

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 Ethics committee of Shiraz University of Medical Sciences, Shiraz, Iran (IR.SUMS.REC.1401.361). 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

SA: Data curation, Conceptualization, Methodology, Formal analysis, validation, Writing – original draft. SZ: Conceptualization, Methodology, validation, supervision, Project administration, Writing – original draft, Writing – review & editing. MR: Conceptualization, Methodology, Investigation, Writing – original draft.

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Acceptance of electronic referrals across the Kingdom of Saudi Arabia: results from a national e-health database

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Introduction: An effective referral system is necessary to ensure quality and an optimum continuum of care. In the Kingdom of Saudi Arabia, an e-referral system known as the Saudi Medical Appointments and Referrals Centre (SMARC), has been fully functioning since 2019. This study aims to explore the rate of medical e-referral request acceptance in the KSA, and to study the factors associated with acceptance.

Methods: This period cross-sectional study utilised secondary collected data from the SMARC e-referral system. The data spans both 2020 and 2021 and covers the entirety of the KSA. Bivariate analyses and binary logistic regression analyses were performed to compute adjusted Odds Ratios (aORs) and 95% confidence intervals.

Results: Of the total 632,763 referral requests across the 2 years, 469,073 requests (74.13%) were accepted. Absence of available machinery was a significant predictor for referral acceptance compared to other reasons. Acceptance was highest for children under 14 with 28,956 (75.48%) and 63,979 (75.48%) accepted referrals, respectively. Patients requiring critical care from all age groups also had the highest acceptance including 6,237 referrals for paediatric intensive care unit (83.54%) and 34,126 referrals for intensive care unit (79.65%). All lifesaving referrals, 42,087 referrals, were accepted (100.00%). Psychiatric patients were observed to have the highest proportion for accepted referrals with 8,170 requests (82.50%) followed by organ transplantations with 1,005 requests (80.92%). Sex was seen to be a significant predictor for referrals, where the odds of acceptances for females increased by 2% compared to their male counterparts (95% CI = 1.01–1.04). Also, proportion of acceptance was highest for the Eastern business unit compared to all other units. External referrals were 32% less likely to be accepted than internal referrals (95% CI = 0.67–0.69).

Conclusion: The current findings indicate that the e-referral system is mostly able to cater to the health services of the most vulnerable of patients. However,

there remains areas for health policy improvement, especially in terms of resource allocation.

KEYWORDS

tele-health, digital health transformation, e-referrals, public health policy, the Saudi Medical Appointments and Referrals Centre, the Kingdom of Saudi Arabia

Introduction

Healthcare systems face different challenges that influence the provision of access to health services for patients (1). These may include geographical challenges such as access in rural areas, lack of medical equipment and unavailable specialists (1). Linking between healthcare facilities to ensure patients have access to their needed services and to fulfil the gap in health infrastructure is therefore vital (2, 3). A referral system is an integrated system that links different healthcare facilities and regional hospitals together (4). It provides patients with access to specific and needed healthcare resources that are not available at patients' original sites (5).

The literature indicates a significant variation in referral rates amongst physicians, with some primary care providers issuing referrals at a rate more than five times higher per patient or per visit compared to others (6). The variation is due to several factors including the scope of training and length of experience of physicians, and the healthcare settings (urban vs. rural) (6). These referral requests have also been remarkably increased over the past few years (5, 7). These increases may be attributed to increasing complexity of the required care which subsequently requires more specialised physicians as well as the increasing demands of health care services which is likely due to the growing number of people (5, 8, 9). Subsequently, meeting the increasing number of referral requests is therefore challenging. However, it is critical to provide the required care to these requests as failure to do so may lead to delay in disease diagnosis and proper management.

Despite the overarching intention of a referral system to optimise patient care, not all referrals are accepted. The reasons for rejection can be multifaceted, such as low severity of the case therefore a low priority for referral, multiple referrals for the same person, and limitations in hospital capacity (10, 11). On the other hand, acceptance of referrals implies that the patients' medical needs align with the receiving hospital's specialists and available resources. Hence, it is essential to understand the dynamics between acceptance and rejection as it plays an important role in enhancing the quality of healthcare services. It helps to identify areas for improvement to facilitate better coordination of referral processes and to ensure receiving timely and appropriate care.

The Kingdom of Saudi Arabia (KSA) uses a national level electronic referral system known as the Saudi Medical Appointments and Referrals Centre (SMARC). This centre was firstly launched in 2012 and previously known as 'Ehalati' (12). However, during the healthcare transformation within the national initiatives for Saudi vision 2030, this centre was expanded to its current formation. The SMARC currently manages and operates all e-referral requests from the 13 administrative regions across the country (5). It provides all registered physicians in the KSA access to the referral system to request referrals when there is a need. The requested referrals are processed in the e-referral system and sent to potential receiving healthcare facilities providing the requested healthcare resources. It also provides a 24-h hotline service where registered physicians can directly call and request lifesaving referrals for critically ill patients, to save time and expedite the referral process. The presence of the system provides an opportunity to epidemiologically explore the patterns of e-referral acceptance across the KSA using the secondary collected data collected by this system. Therefore, this paper aims to examine the level of e-referral request acceptance, and the predictors of these acceptances which will in turn shed light on the effectiveness of the system as well as highlight potential weaknesses and drawbacks worthy of policy changes.

Materials and methods

Study design and settings

This period cross-sectional epidemiological study analysed data retrospectively from the Saudi e-referral system known as SMARC. The SMARC system manages all referrals from all 13 administrative regions of the KSA whether internally or externally, i.e., a referral from an institution to another within the same administrative region, or a referral from an institution to another outside of that specific administrative region. This system is unique in that it operates in secondary healthcare systems and above. Therefore, there is no primary care involvement. All data of patients with a referral request initiated between January 2020 and December 2021 have been included in this study.

Ethical considerations

The institutional review board of the MoH as well as the institutional review board of Imam Abdulrahman Bin Faisal University both approved the study (23-77 E) and (IRB-2023-01-357). The data was completely anonymised with no patient identifying information. Also, the data was properly secured and was used for the purposes of this research.

Measurements

The data provided by the SMARC e-referral system included basic sociodemographic variables such as age, sex, nationality, and the administrative region from which the patient was referred. These regions were then collated to form the five business units (BUs) that

form the basis for the Saudi New Model of Care, namely, the Central BU, Eastern BU, Northern BU, Western BU, and the Southern BU. Also included in the dataset were referral characteristics which included the data of the referral, referral bed type, the type of the referral itself, reason for the referrals, speciality for which the referral is requested, internal vs. external referral, and finally the status of the referral request (accepted vs. rejected). The accepted referral indicates the acceptance of the receiving facility to receive the referred patient whilst the rejected ones indicate the rejection of the receiving facility. The referral status, either accepted or rejected, does not indicate whether the patient attended the referral appointment or not.

Statistical analyses

The main outcome of this study was whether the referral was accepted or rejected. Descriptive statistics were analysed through frequencies and proportions. Cross tabulations were performed by means of a series of Chi-squared tests. A binary logistic regression analysis was performed to obtain adjusted Odds Ratios (aORs) and their accompanying 95% confidence intervals (CIs). The level of significance was set to 0.05 and the Stata Statistical software version 16 was used for the analyses.

Results

Sociodemographic characteristics according to e-referral status

A total of 632,763 referral requests were included in the analyses. Of those, 74.13% were accepted and 25.87% were rejected. Acceptance was highest for children under 14 in general (75.48%), followed by the adult population aged between 25 and 65 years followed by the older people aged above 65 years of age (73.98 and 73.65% respectively). Acceptance was slightly higher for non-Saudis. For seasons, the highest acceptance was during winter and the lowest was during autumn (74.55 and 73.83% respectively). With regards to BUs, the Eastern BU had the highest proportion of acceptance reaching 83.70% whereas the Central BU had the lowest at 69.23%. Internal referral requests were more accepted than external ones (75.54% vs. 68.51%; Table 1).

E-referral characteristics according to the e-referral status

Table 2 shows the bivariate associations between e-referral characteristics and the status of referral requests. Patients who require paediatric intensive care unit (PICU) beds had the highest acceptance, followed by patients who required intensive care unit beds (ICU) (83.54% and 79.65% respectively). Patients who required a regular ward bed had the lowest acceptance (72.13%). According to referral types, life-saving requests were all accepted (100.00%). As for the reason for referral, health crisis had the highest referral acceptance, followed by the unavailability of a specialised physician (75.86% and 75.17%). Patients with social reasons had the lowest acceptance (69.80%).

Distribution of medical specialities according to referral status

According to the distribution of specialties in Table 3 and Figure 1, general surgery had initiated the highest proportion of referral requests followed by medicine (25.77% and 22.18% respectively). With regards to referral status, psychiatry had the highest acceptance reaching 82.50% followed by organ transplantation (80.92%). Dentistry had the lowest acceptance at 69.96%. Differences were significant at the <0.001 level.

Distribution of BUs and administrative regions of the KSA according to referral status

The distribution of BUs and administrative regions in the KSA showed variations in terms of initiating referral requests and their acceptance rates, as illustrated in Table 4. The Western BU initiated the highest proportion of referral requests (35.11%), followed by the Southern BU (20.60%). Regarding referral acceptance, the Eastern BU had the highest rate at 83.70%, followed by the Western BU at 75.10% (Figure 2). Amongst the 13 administrative regions, Makkah initiated the highest proportion of referral requests (22.12%). The Eastern region had the highest acceptance rate (83.70%), whilst Riyadh had the lowest (68.01%; Figure 3). The differences in referral acceptance rates across BUs and administrative regions were statistically significant ($p < 0.001$).

Multivariable associations of predictors for referral acceptance

Table 5 shows the adjusted multivariable associations of predictors with referral acceptance. Children under 14 years of age have exhibited a statistically significant increased likelihood of referral acceptance when compared to adults aged 25 to 65 years old (aOR = 1.05, 95% CI = 1.02–1.08 and aOR = 1.09, 95% CI = 1.07–1.12). Conversely, the older people aged above 65 years of age had decreased likelihood of acceptance (aOR = 0.96, 95% CI = 0.94–0.97). Females were 2% more likely to have their requests accepted compared to males (95% CI = 1.01–1.04). Also, the data shows that there is a 6% increase in referral acceptance in 2021 compared to 2021 (95% CI = 1.05–1.08). The winter season had a significantly higher likelihood of referral acceptance when compared to spring (aOR = 1.06, 95% CI = 1.04–1.08). With regards to the BUs, the Eastern BU had more than double the likelihood of referral acceptance (aOR = 2.39, 95% CI = 2.33–2.45). Higher acceptance was also more likely in all other BUs compared to the Central BUs, although less extremely. When comparing bed types to ward beds, requests involving PICU were 93% more likely to be accepted (95% CI = 1.80–2.06). followed by ICU requests (aOR = 1.59, 95% CI = 1.55–1.64). All other bed types were also more likely to be accepted compared to regular ward beds except for burn beds. Upon examination of reasons for referral, requests with a reason of an unavailability of speciality or specialised physicians, unavailability of a bed, and social reasons were statistically significantly less likely to be accepted compared to requests with a reason of an unavailability of machine. Also, external referrals were 32% less likely to be accepted compared to internal referrals (95% CI = 0.67–0.69).

TABLE 1 Sociodemographic characteristics of patients according to e-referral status between 2020 and 2021 across the Kingdom of Saudi Arabia.

Characteristics	Total	Rejected	Accepted	*p-value*
	N (%)	*N* (%)	*N* (%)	
	632,763(100)	163,690 (25.87)	469,073(74.13)	
Age (years)				*<0.001***
<1	38,361 (6.06)	9,405 (24.52)	28,956 (75.48)	
1–<14	84,762 (13.40)	20,783 (24.52)	63,979 (75.48)	
14–< 18	20,678 (3.27)	5,484 (26.52)	15,194 (73.48)	
18–< 25	48,631 (7.69)	13,160 (27.06)	35,471 (72.94)	
25–65	353,684 (55.90)	92,029 (26.02)	261,655 (73.98)	
>65	86,647 (13.69)	22,829 (26.35)	63,818 (73.65)	
Sex				*0.129*
Males	341,059 (53.90)	89,493 (26.24)	251,565 (73.76)	
Females	291,703 (46.10)	76,017 (26.06)	215,685 (73.94)	
Nationality				*0.006***
Non-Saudi	88,215 (13.94)	22,493 (25.50)	65,722 (74.50)	
Saudi	544,548 (86.06)	141,197 (25.93)	403,351 (74.07)	
Year				*<0.001****
2020	275,956 (43.61)	73,453 (26.62)	202,503 (73.38)	
2021	356,807 (56.39)	90,237 (25.29)	266,570 (74.71)	
Seasons				*<0.001****
Winter	173,751 (27.46)	44,224 (25.45)	129,527 (74.55)	
Spring	127,968 (20.22)	33,427 (26.12)	94,541 (73.88)	
Summer	153,950 (24.33)	39,685 (25.78)	114,265 (74.22)	
Autumn	177,094 (27.99)	46,354 (26.17)	130,740 (73.83)	
Business units				*<0.001****
Central	96,778 (15.29)	29,778 (30.77)	67,000 (69.23)	
Eastern	70,461 (11.14)	11,487 (16.30)	58,974 (83.70)	
Western	222,151 (35.11)	55,314 (24.90)	166,837 (75.10)	
Northern	113,011 (17.86)	29,799 (26.37)	83,212 (73.63)	
Southern	130,362 (20.60)	37,312 (28.62)	93,050 (71.38)	
External vs. internal				*<0.001****
Internal	505,650 (79.91)	123,660 (24.46)	381,990 (75.54)	
External	127,113 (20.09)	40,030 (31.49)	87,083 (68.51)	

Results were presented as frequency [number (*N*) and percent (%)]. The relationship between variables was assessed using the chi-square test. *Significant difference at $p \leq 0.05$, **significant difference at $p \leq 0.01$, and ***significant difference at $p \leq 0.001$.

Discussion

This study aimed to explore the proportion of accepted e-referral requests and identify their predictors using national-level secondary data of over 600,000 requests across the KSA. No prior research has examined e-referral acceptance on such a large, nationwide scale. The study found that the overall acceptance rate for referral requests was 74.13%. Key predictors that increased the likelihood of acceptance included children under 14, the absence of available machinery, patients requiring critical care, psychiatric patients and those needing organ transplants, being female, and referrals between facilities within the same region (internal referrals). On the other hand, lower acceptance was associated with older adults, males, regular ward bed requests, requests with reasons like unavailability of a specialty/physician or social reasons, and external referrals. The findings provide comprehensive insights into e-referral acceptance and rejection patterns across various key factors, offering valuable information to optimise healthcare delivery and resource allocation.

E-referral acceptance according to sociodemographic characteristics

Around three-fourths of all referrals were accepted. This proportion of acceptance highlights the critical need to provide the necessary care for these cases. It suggests the healthcare system was

TABLE 2 E-referral characteristics according to the status of e-referral requests between 2020 and 2021 across the Kingdom of Saudi Arabia.

Referral characteristics	Total	Rejected	Accepted	*p*-value
	N (%)	*N* (%)	*N* (%)	
	632,763(100)	163,690 (25.87)	469,073(74.13)	
Bed types				*<0.001***
OPD no bed	302,815 (47.86)	78,256 (25.84)	224,559 (74.16)	
Ward	225,600 (35.65)	62,885 (27.87)	162,715 (72.13)	
Burn bed	552 (0.09)	131 (23.73)	421 (76.27)	
Isolation	25,423 (4.02)	6,156 (24.21)	19,267 (75.79)	
CCU Bed	17,560 (2.78)	3,978 (22.65)	13,582 (77.35)	
NICU	10,501 (1.66)	2,335 (22.24)	8,166 (77.76)	
ICU	42,846 (6.77)	8,720 (20.35)	34,126 (79.65)	
PICU	7,466 (1.18)	1,229 (16.46)	6,237 (83.54)	
Referral types				*<0.001***
Life saving	42,087 (6.65)	0(0.00)	42,087 (100.00)	
Routine OPD	304,188 (48.07)	78,641(25.85)	225,547 (74.15)	
Routine admission	81,899 (12.94)	20,751(25.34)	61,148 (74.66)	
ER	204,589 (32.33)	64,298(31.43)	140,291 (68.57)	
Reason for referral				*<0.001***
Unavailable subspecialty	390,054 (61.64)	101,509 (26.02)	288,545 (73.98)	
Unavailable physician	108,012 (17.07)	26,815 (24.83)	81,197 (75.17)	
Unavailable machine	84,931 (13.42)	22,162 (26.09)	62,769 (73.91)	
Unavailable Bed	22,465 (3.55)	6,519 (29.02)	15,946 (70.98)	
Social	1,573 (0.25)	475 (30.20)	1,098 (69.80)	
Health crisis	25,728 (4.07)	6,210 (24.14)	19,518 (75.86)	

Results were presented as frequency [number (*N*) and percent (%)]. The relationship between variables was assessed using the chi-square test. ***Significant difference at $p \leq 0.001$. OPD, Outpatient Department; CCU, Coronary Care Unit Bed; NICU, Neonatal Intensive Care Unit; ICU, Intensive Care Unit; PICU, paediatric Intensive Care Unit; ER, Emergency Room.

generally able to accommodate the majority of referred patients. The analysis also showed that acceptance proportions were quite similar across the different age groups. However, compared to the 25–65-year-old age group, children under 14 years old, including neonates and infants, were more likely to have their referrals accepted. This may reflect the special healthcare needs that are time-sensitive due to the critical nature of their paediatric condition, especially since that for neonates and infants, fragility and rapid deterioration due to the low immunity may render their medical situation unpredictable (13, 14). Also, it may be due to the availability of highly specialised maternal and children hospitals in large referral regions which in turn facilitates a higher proportion of acceptance compared to other age groups (15).

Referrals by sex showed an overall higher referral request for males but a higher proportion of acceptance for females. Sex-specific health conditions, such as prenatal care, gynaecological conditions, and breast health could provide an explanation to the increased accepted referrals amongst females compared to males. For example, obstetric complications preceding delivery could be life-threatening and necessitate specialised care services that may be lacking in the same region which consequently would make it more probable that such a referral by accepted (16). Additionally, specialised maternity and children hospitals in the different regions in the KSA might expedite the process of acceptance for females (15).

Similarly, referrals by nationality exhibited higher referrals for Saudis but slightly less rejected requests for expatriates. Though non-Saudis are medically covered by private insurance, initiated referrals could be due to the need for specialist care that is not available in the private sector or not covered by their insurance (17, 18).

E-referral acceptance according to e-referral characteristics

The current analysis shows that PICU referrals were fewer in number but had the highest proportion of acceptance. All other critical care bed types including NICU, ICU and CCU were also amongst the highest for acceptance, which shows a higher prioritisation for the critically ill. Critically ill patients are in need for close monitoring and management of these patients are time sensitive (19). Several studies have showed that delay in treating critically ill patients can contribute to increasing complications and mortality (19–23). The fact that these cases are usually accepted may also indicate the lack of specialised services or specialised staff to deal with these cases in the places of referral request initiation.

With regards to the type of referrals, it is of importance to note that all referrals that were tagged or entered as 'lifesaving' were accepted (100.00%). This shows that the system is functioning

TABLE 3 Distribution of medical and clinical specialties according to referral status between 2020 and 2021 across the Kingdom of Saudi Arabia.

Medical and clinical specialties[¥]	Total	Rejected	Accepted
	N (%)	*N* (%)	*N* (%)
	632,763(100)	163,690 (25.87)	469,073(74.13)
General surgery	163,052 (25.77)	47,172(28.93)	115,880(71.07)
Medicine	140,334 (22.18)	37,187(26.50)	103,147(73.50)
Cardiac Surgery	61,836 (9.77)	14,876(24.06)	46,960(75.94)
Ophthalmology	50,218 (7.94)	10,739(21.38)	39,479(78.62)
Paediatrics	43,168 (6.82)	10,863(25.16)	32,305(74.84)
Radiology	41,673 (6.59)	10,103(24.24)	31,570(75.76)
Obstetrics and gynaecology	35,831(5.66)	8,668(24.19)	27,163(75.81)
Ear, nose, and throat	28,919 (4.57)	7,416(25.64)	21,503(74.36)
Dentist	20,799 (3.29)	6,247(30.04)	14,552(69.96)
Oncology	14,847 (2.35)	3,882(26.15)	10,965(73.85)
Psychiatry	9,903(1.57)	1733(17.50)	8,170(82.50)
Medical rehabilitation	6,534(1.03)	1,498(22.93)	5,036(77.07)
Dermatology	5,598 (0.88)	1,176(21.01)	4,422(78.99)
Clinical laboratory	4,960 (0.78)	1,044(21.05)	3,916(78.95)
Organ transplantation	1,242(0.20)	237(19.08)	1,005(80.92)
Others	3,849(0.61)	849(22.06)	3,000(77.94)
P-value < 0.001***			

Results were presented as frequency [number (*N*) and percent (%)]. The relationship between variables was assessed using the chi-square test. ***Significant difference at $p \leq 0.001$.

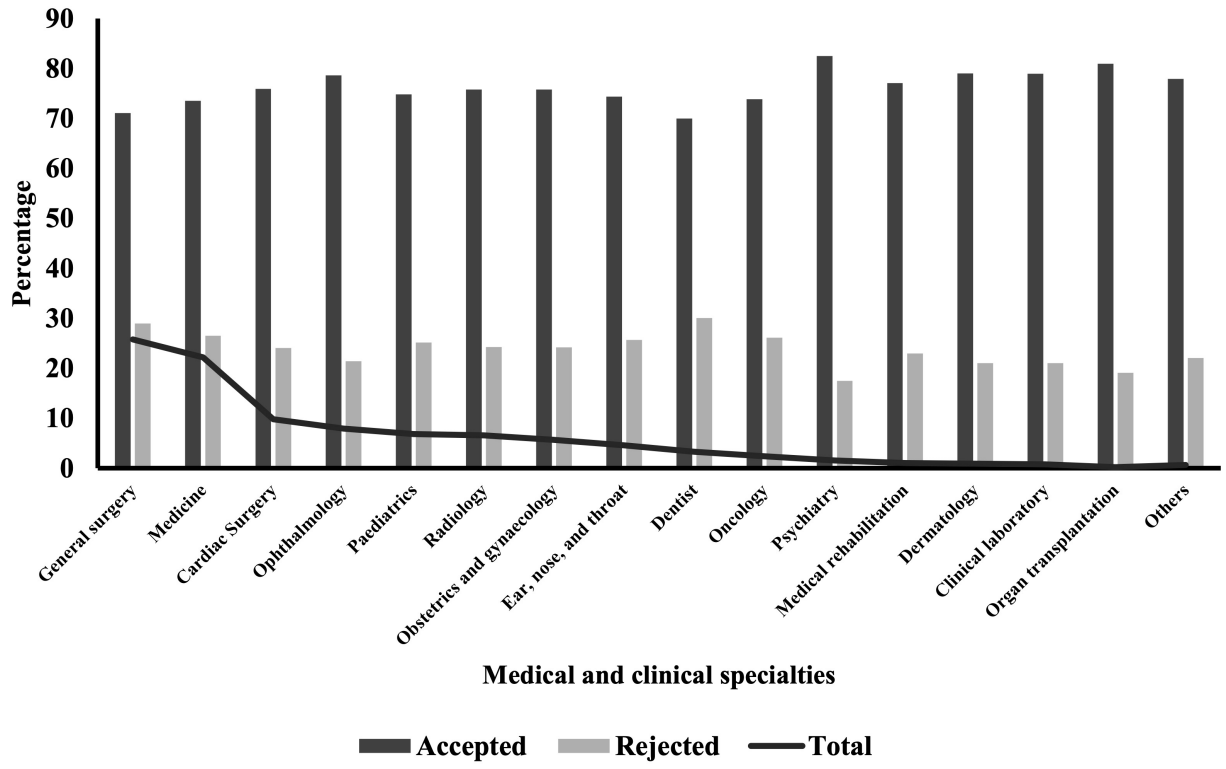

FIGURE 1
Distribution of medical specialities according to referral status.

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TABLE 4 Referrals according to referral status across the five business units and 13 administrative regions of the Kingdom of Saudi Arabia.

Business units		Total	Rejected	Accepted
		N (%)	*N* (%)	*N* (%)
		632,763(100)	163,690 (25.87)	469,073(74.13)
Central		96,778(15.29)	29,778(30.77)	67,000(69.23)
Eastern		70,461(11.14)	11,487(16.30)	58,974(83.70)
Western		222,151(35.11)	55,314(24.90)	166,837(75.10)
Northern		113,011(17.86)	29,799(26.37)	83,212(73.63)
Southern		130,362(20.60)	37,312(28.62)	93,050(71.38)
P-value < *0.001***				
Business units	**Administrative regions**	**Total**	**Rejected**	**Accepted**
		N (%)	**N (%)**	**N (%)**
		632,763(100)	163,690(25.87)	469,073(74.13)
Central	Riyadh	67,203(10.62)	21,499(31.99)	45,704(68.01)
	AL Qassim	29,575(4.67)	8,279(27.99)	21,296(72.01)
Western	Makkah	139,986(22.12)	33,569(23.98)	106,417(76.02)
	Madinah	49,300(7.79)	11,826(23.99)	37,474(76.01)
	Albaha	32,865(5.19)	9,919(30.18)	22,946(69.82)
Eastern	Eastern	70,461(11.14)	11,487(16.30)	58,974(83.70)
Northern	Al-jouf	34,512 (5.45)	9,891(28.66)	24,621(71.34)
	Northern Border	36,707(5.80)	8,221(22.40)	28,486(77.60)
	Tabuk	25,604(4.05)	7,547(29.48)	18,057(70.52)
	Hail	16,188(2.56)	4,140(25.57)	12,048(74.43)
Southern	Aseer	66,458(10.50)	19,752(29.72)	46,706(70.28)
	Jazan	42,953(6.79)	12,704(29.58)	30,249(70.42)
	Najran	20,951(3.31)	4,856(23.18)	16,095(76.82)
P-value < *0.001***				

Results were presented as frequency [number (*N*) and percent (%)]. The relationship between variables was assessed using the chi-square test. ***Significant difference at $p \leq 0.001$.

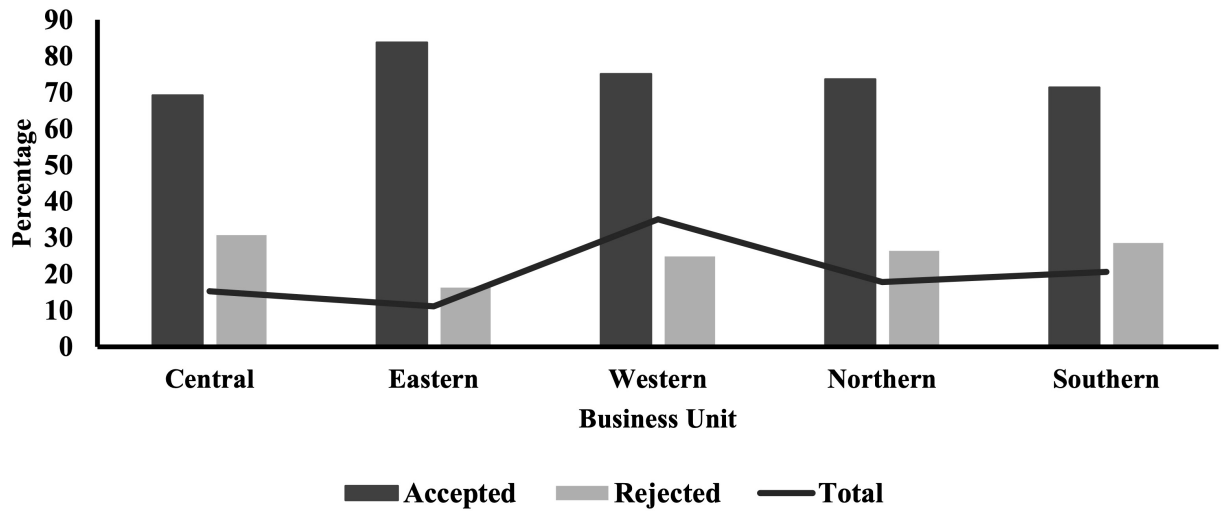

FIGURE 2
Referral status across the five business units of the Kingdom of Saudi Arabia.

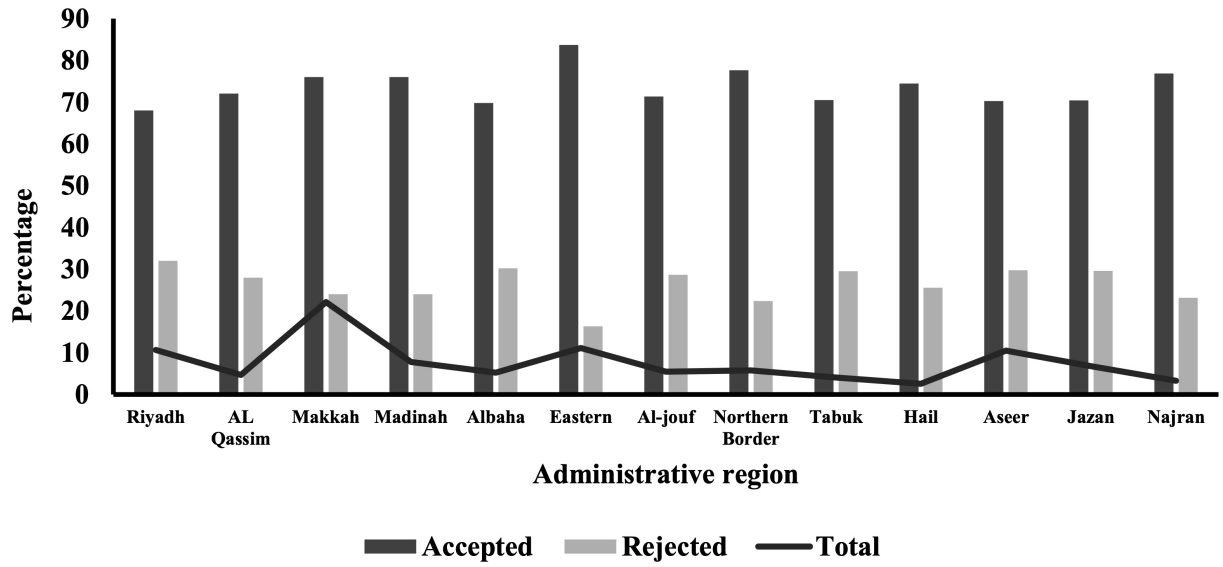

FIGURE 3
Referral status across 13 administrative regions of the Kingdom of Saudi Arabia.

according to its objectives in terms of catering for the most needed and more vulnerable of cases. Whereas for emergency referrals, around two-third of them were accepted. This lower acceptance of emergency cases raises the questions as to whether they were genuinely emergency cases or were in fact not emergent and were simply due to a lack of resources and capabilities. It also raises the question of how those patients will receive the necessary treatment in the event of a refusal.

Upon examination of the reasons for referrals as a predictor for acceptance, a major predictor was the lack of machine or equipment. Equipment availability is a global issue, and such complex equipment requires maintenance, training of qualified users, then replacement (24–26). Consequently, some advanced medical technologies might not be feasible to be available in every healthcare institution thereby naturally requiring a referral of patients. However, medical equipment is a key in healthcare services as it is routinely used for diagnosis, treatment, and rehabilitation (27, 28). Thus, they are significant in providing the care needed for patients to improve and recover (29). In some cases, lack of access to medical equipment can result in poor prognosis and mortality (30, 31).

The current analyses show that psychiatry was the speciality with the highest proportion of acceptance. The KSA currently has 19 specialised psychiatric complexes and hospitals distributed across the 13 administrative regions (32). The high availability of resources needed to treat psychiatric patients may have contributed towards the high proportion of acceptance. Similarly, there are 11 centres for organ transplantations across the KSA (33). These centres are distributed in the five BUs with the Western and Central units as the highest, which could be explained by the high population density at these two units (34). A further explanation could be that organ transplantation is a successful method to improve morbidity and mortality, but only if managed swiftly (35, 36). The time sensitivity in organ transplantation might explain the existence of a special pathway for it in the KSA to expedite the process (37). All these factors may have allowed for the high proportion of acceptance for organ transplantations. On the other hand, dental services were found to be amongst the lowest in terms of referral request initiation, but also is the speciality with the lowest proportion of acceptance. This may be due to the low utilisation of dental services in the country, where literature shows that only 11.5% of Saudi adults visit dentists for routine checkups but may also be due to the low prioritisation of dental care services provided (38).

Variation between BUs was noticed in terms of the total referrals and the proportion of acceptance (Table 4). All BUs demonstrated a higher odd of acceptance than the Central BU. Despite the fact that the lowest referral requests originated from the Eastern BU, they were the highest accepted amongst all BUs. The Eastern BU was able to successfully implement the New Model of Care that yielded positive results including care provision and disease prevention (39). In contrary, referrals originating from the Central BU had the highest proportion of rejections. Hence, there is a need to explore the reasons of referrals in the central BUs that could explain the proportion of rejection. It is worth mentioning that the higher density of the population in the Central region, along with the easy access to private healthcare services, might add explain the higher rejections. The high socioeconomic status amongst people living in Riyadh might opt for out-of-pocket payments to access private care services instead of awaiting approval within governmental hospitals or after their referral requests have been rejected (40).

Finally, the trend of referrals had noticeably increased in 2021 in comparison to the preceding year which could be attributable to different factors. First, the expansion of healthcare providers within the network may have led to more referrals being initiated. Second, governmental support to strengthen the SMARC e-referral system could have positively influenced the referral process. This support has the potential to improve the efficiency and adoption of the SMARC system. Third, software improvement and enhancement could have streamlined and facilitated the referral process. Finally, increased

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TABLE 5 Multivariable logistic regression analysis of predictors for referral acceptance between 2020 and 2021 across the Kingdom of Saudi Arabia.

Predictors	Adjusted OR	*p*-value	95% CI
Age			
<1	1.05	*0.001***	1.02–1.08
1–<14	1.09	*<0.001****	1.07–1.12
14–< 18	0.99	*0.78*	0.96–1.03
18–< 25	0.98	*0.16*	0.96–1.01
25–65	*Ref*		
>65	0.96	*0.001****	0.94–0.97
Sex			
Males	*Ref*		
Females	1.02	*<0.001****	1.01–1.04
Nationality			
Non-Saudi	*Ref*		
Saudi	0.99	*0.789*	0.979–1.017
Year			
2020	*Ref*		
2021	1.06	<0.001***	1.05–1.08
Season			
Spring	*Ref*		
Winter	1.06	*<0.001****	1.04–1.08
Summer	1.01	*0.13*	0.99–1.03
Autumn	1.01	*0.15*	0.99–1.03
Business units			
Central	*Ref*		
Eastern	2.39	*<0.001****	2.33–2.45
Western	1.43	*<0.001****	1.40–1.45
Northern	1.45	*<0.001****	1.42–1.48
Southern	1.17	*<0.001****	1.15–1.19
Bed types			
Ward beds	*Ref*		
OPD	1.10	*<0.001****	1.08–1.11
Burn beds	1.27	*0.02**	1.03–1.57
Isolation beds	1.18	*<0.001****	1.14–1.22
CCU	1.40	*<0.001****	1.34–1.45
NICU	1.44	*<0.001****	1.36–1.51
ICU	1.59	*<0.001****	1.55–1.64
PICU	1.93	*<0.001****	1.80–2.06
Reason for referral			
Unavailable machine	*Ref*		
Unavailable subspecialty	0.93	*<0.001****	0.91–0.95
Unavailable physician	0.98	*0.089*	0.96–1.00
Unavailable bed	0.73	*<0.001****	0.70–0.76
Social reasons	0.61	*<0.001****	0.55–0.69
Health crisis	0.96	*0.067*	0.93–1.00
Referral direction			
Internal	*Ref*		
External	0.68	*<0.001****	0.67–0.69

*Significant difference at $p \leq 0.05$, **Significant difference at $p \leq 0.01$, and ***significant difference at $p \leq 0.00$.

awareness and trust on the SMARC system amongst healthcare providers from different specialties could have played an important role in the higher utilisation in 2021. It is worth mentioning that despite the challenges posed by the COVID-19 pandemic, the proportion of accepted referrals in 2021 was higher than the previous year. This could be due to the measures taken to adapt to the pandemic and to improve the delivery of healthcare system accordingly.

Nevertheless, the COVID-19 pandemic had a significant impact on healthcare services worldwide, and the KSA was no exception, particularly in managing chronic diseases and maintaining essential healthcare services (41). The sudden and global spread of COVID-19 led to unprecedented changes in healthcare systems and shifted the focus of healthcare providers to manage the pandemic (42). Whilst COVID-19 may have influenced the volume of healthcare referrals in the KSA, it is not possible to make a direct comparison as referral patterns prior to the pandemic were not investigated. Despite this, many studies have shown that the pandemic had a significant impact on healthcare delivery worldwide, including referral rates (43–46). The prevalence of COVID-19 has significantly affected the referral and admission rates for non-COVID-19 patients due to health measures like self-isolation, quarantine, and stay-at-home recommendations, as well as the fear of infection in medical centres (46). Our data have shown that the number of healthcare referrals decreased in 2020 compared to 2021, but the acceptance rate was higher in 2021. This trend could be attributed to the severity of the pandemic during the early months of 2020. In the future, longitudinal studies should focus on the impact of the pandemic specifically on the referral system during and after the pandemic to investigate its real effect. This will help to improve preparedness for critical periods in healthcare delivery.

Recommendations

According to the findings of this study, several key recommendations can be proposed to address identified disparities and improve the efficiency of e-referrals in the KSA. Given the variation in e-referrals by age, targeted interventions can be designed and tailored specifically for people at high risk. This can include proactive management of the prevailing conditions and preventive care strategies, which in return can reduce the need for referrals. Regional variation highlights the need for region-specific interventions to enhance healthcare infrastructure and streamline referrals. This can include increasing the availability of outpatient department, ward beds and medical technologies to meet the high demand and ensure timely

and appropriate care. In addition, the effective prioritisation system for critical care referrals, including life-saving and ICU, necessitates ensuring the continuous availability of resources to maintain the high acceptance rate. It is also recommended to address the gap in human resources given the top reason for referrals due to unavailable subspecialties by investing in training and recruitment.

Further research should also investigate the impact of COVID-19 during various pandemic peaks and across different seasons on the efficiency of the ICU referral system. This study would provide valuable insights into how the referral system adapted and responded under the pressures of fluctuating patient volumes and changing healthcare needs during the pandemic. Additional research is needed to assess the effect on general healthcare services provided by the Saudi Medical Referral Centre (SMARC) during these periods. Understanding the broader implications of the pandemic on general healthcare services will help in identifying strengths and potential areas for improvement in the healthcare system's response to public health emergencies.

Strength and limitations

This study is the first to investigate the e-referral status in terms of acceptance vs. rejection and its potential predictors on a national level. This novel study highlights the significance of having such a national level system to monitor patients' access to healthcare services, and subsequently plan for improvement. This study specifically provides a comprehensive insight on the allocation of healthcare resources in all regions across the KSA, which supports policy makers to make well-studied decisions. It also analysed data for two consecutive years which allows measuring the overall trend of referral requests. However, this study has some limitations that need to be acknowledged. First, the retrospective design used in this study limits the ability to establish a relationship about the predictors/factors of referral request acceptance. Second, due to the uniqueness of the data and the system itself, there are limitations for comparison with existing literature. Third, the effects of COVID-19 on the e-referral system and the kind of referral demands, especially during 2020 and 2021, should not be minimised.

Conclusion

Acceptance of referral requests was predominant in the current practice of e-referrals across the KSA. This study analysed all e-referral requests initiated from secondary healthcare systems and above over 2 years. The findings indicate that the majority of the requests were accepted, with all lifesaving referrals being accepted. Acceptance rates were highest for children under 14, female patients, critical care patients, including those in the PICU, ICU, and CCU, psychiatric patients, organ transplant recipients, and those referred from the Eastern BUs. These results illustrate the importance of prioritising patient care and health patient populations, especially those with life-saving and critical conditions. The study highlights the need for resource allocation assessment to reduce referral requests and improve acceptance and access to care.

Data availability statement

The datasets presented in this article belong to the Saudi Medical Appointments and Referrals Centre (SMARC) and are not publicly available. Researchers interested in accessing the data should direct their requests to the first author of this article, [AAlh, aalharbi@jazanu.edu.sa], who will facilitate obtaining permission from SMARC. Access will only be granted after SMARC reviews and approves each request.

Author contributions

AAlh: Conceptualization, Data curation, Formal analysis, Investigation, Software, Writing – original draft, Writing – review & editing. NA: Conceptualization, Project administration, Resources, Supervision, Writing – review & editing. MB: Data curation, Investigation, Methodology, Software, Writing – original draft. HA: Data curation, Investigation, Methodology, Software, Writing – original draft. RA: Formal analysis, Investigation, Methodology, Software, Writing – original draft. AAls: Conceptualization, Resources, Supervision, Validation, Writing – review & editing. MAr: Conceptualization, Formal analysis, Methodology, Resources, Writing – review & editing. AAld: Conceptualization, Project administration, Supervision, Writing – review & editing. AAlo: Investigation, Project administration, Software, Writing – review & editing. EA: Data curation, Project administration, Resources, Supervision, Writing – review & editing. MAl: Methodology, Resources, Supervision, 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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NGOs' initiatives and grassroots approach for accessing to health care services for the slum people in Dhaka

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Objective: This study holds significant importance as it aims to delve into the impactful NGOs' initiatives and grassroots approaches instrumental in providing healthcare services to Dhaka's underserved slum people. It focuses on understanding how these factors influence the use and access to health services, which is a crucial aspect for researchers, policymakers, and healthcare professionals.

Study design: This study was meticulously designed, utilizing a comprehensive cross-sectional mixed-methods design. By incorporating qualitative and quantitative data collection methods, we ensured a thorough understanding of NGOs' initiatives and grassroots approaches to providing healthcare services to slum dwellers in Dhaka, thereby instilling confidence in the validity of our research for the audience.

Methods: A face-to-face interview was used to survey the participants ($n = 722$) using semi-structured questionnaires, following a systematic sampling technique. Four focus group discussions (FGDs) were also conducted with the slum people. Binary logistic regression was performed to know NGOs' initiatives, roles, and grassroots approach as predictors or independent variables and healthcare services as an outcome or dependent variable. The quantitative data were analyzed using SPSS version 23.0. At the same time, thematic analysis was conducted following Philip Adu's Qualitative data analysis process and Braun and Clarke's six steps of the thematic analysis system, integrating the 11 subthemes with the quantitative findings to highlight the interpretative findings of the qualitative data.

Findings: Major findings revealed that NGOs' initiative roles and grassroots approach had a significant impact on slum dwellers' use and access to healthcare services. The initiatives included affordable health services (OR = 22.86, 95% CI = 3.87, 35.00, $P = 0.01$), special health services (OR = 5.63, 95% CI = 3.36, 9.42, $P = 0.00$), engagement of responsible community leaders (OR = 1.72, 95% CI = 1.14, 2.59, $P = 0.01$), distribution of health and medicine items (OR = 1.92, 95% 2 CI = 1.40, 2.63, $P = 0.01$), provision of updated information to slum dwellers (OR = 1.37, 95% CI = .99, 1.90, $P = 0.05$), telehealth and telemedicine (OR = 1.82, 95% CI = 1.55, 2.13, $P = 0.01$), BCC strategy (OR = 1.26, 95% CI = 1.00, 1.57, $P = 0.05$), and doorstep services as NGOs' grassroots approach (OR = 1.84, 95% CI = 1.00, 3.38, $P = 0.05$). Qualitative findings supported the quantitative findings through 2 main themes and 11 sub-themes, which were integrated with quantitative findings to highlight the interpretative findings of qualitative data.

Conclusions: Health services and other facilities for urban slum people through NGOs' initiatives and grassroots approaches are highly affordable and practical, special health services with the involvement of special exceptional health professionals, community supportive services, BCC strategies, and doorstep health services may trigger the use and access to health services for slum dwellers. Results suggest and recommend capitalizing and investing in such initiatives and grassroots approaches from the government, policymakers, and donors with NGOs to find accessible, affordable health services for the unprivileged slum people.

KEYWORDS

NGOs, initiatives, grassroots approach, access to healthcare services, slum people

Introduction

Non-government organizations (NGOs) play a crucial role in development and are long-trusted partners with the government in implementing various social development activities in Bangladesh (1). They provide multiple services to reach disadvantaged populations through collaborative and participatory efforts, including primary education and healthcare (2, 3). NGOs have emerged as a vital alternative for making health services accessible to low-income populations (4, 5). Since their inception, NGOs have been providing health services to the underserved and disadvantaged rural and urban slum people in our country. They have undertaken various innovative and initiative efforts by working in slums, including projects to provide water, sanitation, and housing and to improve child survival, early childhood development, nutrition, and health (5, 6). NGOs are vital in extending primary healthcare or essential health services to underserved, remote rural, and urban periphery slum areas (7). They established clinics, operated satellite clinics or mobile health units, and employed community health workers or community service providers to bridge gaps in healthcare access (8, 9). They were the core implementing partner of the second Urban Primary Health Care Services Delivery Project (UPHCSDP) (10). Behavior change communication, outreach, counseling, and marketing activities were undertaken to improve maternal and child health, nutrition, and family planning, including primary healthcare services for the urban poor (11). As a health promotion strategy, NGOs started training to produce community health workers (CHWs) (12, 13). The NGO Gonoshasthaya Kendra (GSK) trained para-professionals to provide primary healthcare. Similarly, the Bangladesh Rural Advancement Committee (BRAC) has taken the initiative to train almost 10,000 female CHWs in caring for selected common illnesses (14).

Bangladesh's urban population is increasing rapidly. The average annual growth rate was 3.19% from 2018 to 2022. The urban population was 52.07 million in 2022, which is expected to reach 92.0 million by 2050 (15–17). With the expansion of urbanization and urban population, the number of slum people also increases (17.58 million in 2022) (15). Bangladesh is committed to achieving set health indicators of the Sustainable Development Goals (SDGs) (18). Urban areas, specifically urban slums, present health conditions that are challenging for the government. Thus, the government is collaborating with hundreds of national and international NGOs to provide health services in Bangladesh (19, 20). The NGO Health Service Delivery Project (NHSDP) of the United States Agency for International Development (USAID) is a flagship program in Bangladesh implemented from 1990 to 2018 to provide essential health services (ESP), maternal child health, and family planning services in partnership with 26 local NGOs (21). In Bangladesh, the mandate for providing primary healthcare in urban areas is the responsibility of the Ministry of Local Government, Rural Development, and Cooperatives within their administrative jurisdiction. It has urban primary healthcare programs to support essential health packages, free health services, red cards for ultra-poor, reduced-cost medicine, and outreach services for slum and floating people for slum people in partnership with 36 NGOs (22). The World Health Organization (WHO) provides medical aid such as vaccination, research support, and other advanced medical technologies for Bangladesh to improve health in urban slums (23). Tuberculosis, malaria, HIV, and AIDS are also taken care of with the financial and technical assistance of the Global Fund. NGOs primarily deliver maternal child health and family planning (MCH-FP) services in urban slums with paramedics and community health workers (CHWs) (24). Functional collaboration was strengthened with city corporations' urban primary healthcare (UPHC) program for reproductive health: MCH-FP services in the city slums and outside (25).

NGOs emphasized that community-based health workers or volunteers should go door to door in every urban slum and village, providing doorstep services to citizens (6, 26). Satellite clinics were established to provide maternal and child health (MCH) services to the slum dwellers (27–29). Mobile (mHealth) services were also introduced by NGOs in the urban slum context, where people have limited access to health services (30, 31). In case of doorstep service initiatives are unavailable due to health workforce shortage, time constraints, and moving from community to community, then NGOs initiated mobile health (mHealth) services (32). This mHealth service has widened access to healthcare for the slum people (26, 32). Using mobile phones can enhance efficiency and continuity of care during the antenatal and postnatal period, thereby improving the accessibility and delivery of maternal and child healthcare among women (26). Since 2007, BRAC has been implementing some approaches to promote

positive Maternal, Neonatal, and Child Health (MNCH) behaviors and practices (33). Manoshi developed key messages for behavior change and applied different means of communication using different BRAC health staff, including the community health volunteers (*Shasthya Sebika*) and community health workers (*Shasthya Karmi*, program organizer) (34). At the community level, the NGOs take the initiative to employ female Family Health Visitors (FHVs) who conduct visits to an allocated number of households. They are responsible for essential health and family planning counseling, doorstep delivery of contraceptives (oral pills and condoms) and oral rehydration salts, and mobilization of women to use satellite clinics and higher-level facilities (35–38). At the Mohammadpur slum area of Dhaka city, under public and private partnership (PPP), a maternity clinic initiated and launched affordable and accessible healthcare services for low-income people. This health project also provided health education, became a referral point for poor patients, and sent complicated cases to specialized hospitals (6, 39).

Grassroots approaches lead to greater participation of members or beneficiaries with more significant support and cooperation from professionals and service providers (40). The grassroots approach to healthcare services mainly focuses on the people who confronted and experienced homelessness or social exclusion, especially low-income urban people or migrant slum people (41, 42). The full realization of grassroots healthcare services to improve people's access to healthcare services and ensure adequate resources for disease prevention is significant. Hence, it is essential to optimize the services of grassroots health facilities (including NGOs) and guide the masses to seek, utilize, and receive medical or healthcare and services reasonably (43). Several studies in developing countries also showed that the grassroots approach of NGOs made healthcare services more effective for low-income people than public and private providers because they are locally based and are more accountable to their communities (44–46). Very little is known from previous research on NGOs' initiatives and grassroots approaches to healthcare for slum people in Bangladesh. Most of the prior research studied a partial or single aspect of NGOs' initiatives such as affordability or subsidizing services, BCC strategy, telehealth and telemedicine services, and doorstep services. Therefore, the current study addresses the knowledge gap and covers NGOs' multifarious initiatives and grassroots approaches to accessing healthcare services for the slum people.

NGOs' initiative roles and grassroots approach for accessing healthcare services for slum people: a point of view from South Asian stance

The roots of NGOs can be traced back to various social and political movements that emerged in the 19th century. During this period, rapid industrialization and urbanization led to widespread poverty, labor exploitation, and the marginalization of vulnerable populations. In response to these issues, groups of concerned individuals began organizing themselves to advocate for social reforms and humanitarian initiatives, giving birth to the early form of NGOs (14, 47). Over the past few decades, citizens in low-income countries have established increasing numbers of NGOs to serve unmet local needs. Poverty, disasters, war, health, and other misfortunes provided grounds and reasons for NGOs to flourish in low-income countries. Most NGOs in developing countries have their bases in rural areas and urban slums, often not served at all or minimally served by the existing government service structure (26). An estimated 41.8% of Mumbai's population lives in urban slums (48). The health condition of the slums in both Mumbai and Delhi is worsened by a high degree of poverty and low access to resources combined with low living conditions (48, 49), which leads to a greater degree of infections, disease, and health conditions. The country (India) has a mixed healthcare system, with approximately 10.0% of hospitals being government-run and the rest operated by private for-profit sectors or charitable organizations as well as NGOs (49–51). In the Panjrapole slum of Mumbai, 31.0% of respondents consulted private/NGO doctors due to dissatisfaction with the quality of care at government/public hospitals (49, 50). In 2022, 48.0% of the total urban population of 10 big cities in Pakistan live in slum areas (52), and NGOs are the significant contributors to the choice of healthcare services (53). The government of Indonesia launched the National Health Insurance (NHI) in 2014 to cover people with low financial status, including slum dwellers (54). NGOs in Indonesia have played a crucial role in mobilizing the resources of the urban people in low-income communities (55). In developing countries such as the Philippines, up to one-third of healthcare services are provided by non-profit organizations (NPOs) and NGOs. NGOs, being small-scale and flexible, help poor communities provide services where government assistance is usually minimal and ineffective (56, 57).

The above literature and their discussion and illustrations denote and uphold NGOs' presence and rigorous functions in the urban slum areas of India, Pakistan, Indonesia, and the Philippines, where government services are minimal, inadequate, and unavailable. Bangladeshi NGOs administer a network with static and satellite clinics, covering 20 million Bangladeshi areas where government services are largely inaccessible. In addition to clinic-based services, many NGOs support female community workers, called depot-holders, who provide health commodities, BCC strategy, and referral services to NGO clinics (44). NGOs generally work with disadvantaged and unprivileged people at the grassroots level. Their service provider is more concentrated and attached to the urban slum disadvantaged people than the government employees and healthcare providers (8).

The current study seeks imperative empirical data on NGOs' initiatives and grassroots approaches toward accessing healthcare services for the slum people in Dhaka. To answer the research question or achieve the research objective, some metatheories, especially Andersen's Behavioral Model of Health Services Use, were used as the most appropriate model for understanding and predicting the use and access to health services for the slums in Dhaka city. The manuscript has several parts. The introductory part consists of contextual discussion, a statement of problems, and a scenario of healthcare services for NGOs in South Asian slums, highlighted with relevant literature. The next part contains

the methodology section, which includes study design, study settings, study population and sampling, variables and measurement of the study, and data collection and analysis process. The subsequent section comprises the results (findings) of the study, which represent the answer to the research questions/objective. The next chapter is part of the discussion section, where significant findings reveal similarities and dissimilarities of existing literature and limitations, as well as the scope of the study and significant implications suggested in this section. Finally, the conclusion implies the study's significant findings and recommendations for further initiatives or steps from the government and policymakers.

Access to health services: a theoretical overview

Theories attempt to explain phenomena logically and meaningfully, often following narrative structures (58). The theoretical and conceptual framework describes the research avenue and grounds it firmly in theoretical constructs. Andersen's Behavioral Model (59, 60) for Health Services Use provides a theoretical structure to understand access to and utilization of health services and recognize the factors that impact an individual's and community's decision to use or not use existing health services. According to the model, access to and use of health services is determined by three dynamic factors: predisposing, enabling, and need factors. Predisposing factors can be social and demographic characteristics such as sex, age, marital status, education, income, occupation, community or ethnicity/race, attitude, and belief, indicating and increasing one's need for health services. For example, an individual or community who believes health service is an effective treatment or health services are needed to cure or prevent diseases he/she/they are more likely to seek care. Andersen's enabling factors are the main factors that facilitate or assist people to use or access health services (e.g., resource availability or service affordability) (59, 60). The enabling factors are, for instance, household income and support, initiatives to use services, access to free services or insurance or subsidizing services, spatial or geographical nearest, and availability and affordability of those services. Enabling factors facilitate and impede one's or community's access to and use of health services. Need factors represent self-perceived and actual need for healthcare services. Therefore, need factors denote or push individuals/communities (patients) to what type of health services they do or do need for their ailments or diseases. The predisposing factors of this study indicate the sociodemographic characteristics of participants, who comprise the study population of the study settings (Figure 1).

Methods

Study design

This study used a cross-sectional mixed methods design to collect both quantitative and qualitative data. A face-to-face interview was conducted using a semi-structured questionnaire to obtain quantitative data from 722 respondents, of whom 329 were males and 393 were females. Qualitative data were administered through focus group discussions (FGDs) with the

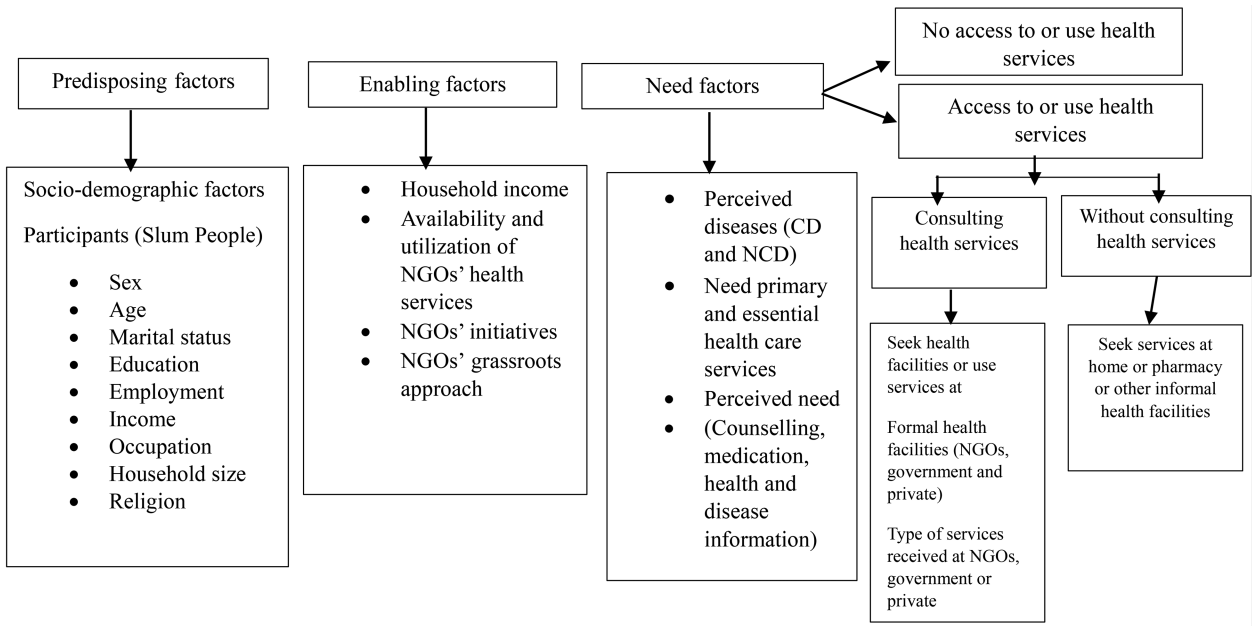

FIGURE 1
The conceptual framework of this study adopted from Andersen's Behavioral Model of Health Services Use (59, 60).

help of Adu's (61) qualitative data analysis process and Braun and Clarke's (62) six principles of thematic analysis system and following phenomenological study.

Study setting

The slums of three Thanas Pallabi, Rupnagar, and Vashantek Thanas from the Dhaka North City Corporation were selected for this study (Map 1). Thana is the second level of the administrative unit from below in Bangladesh. The Dhaka division and district were selected purposively as Dhaka, the capital of Bangladesh, was considered to have more slums than the country's other cities. Then, the Dhaka North City Corporation was chosen randomly, and the three Thanas were considered based on the location of the larger slums (63).

MAP 1
Study area map, including both Dhaka North and Dhaka South City Corporation (map source: Internet).

Study population and sampling

This study used a sampling formula where $z = 1.96$ set at 95% confidence level; $p = 0.5$, proportion of slum people used NGO's health services; $q = 0.5$; margin of error = 0.05; and design effect = 2.0. Using the formula, the sample size was 768 ($384 \times 2 = 768$). The sample was distributed among the selected three slums using probability proportionate sampling. Several males and females were taken into consideration. The sample frame was prepared, and the required number (768 households) of sample households was selected from the sample frame using systematic sample techniques. Finally, 722 respondents (322 males and 393 females) successfully attended the interview with a response rate of 94.0% (Table 1). Reasons for exclusion or non-responses to the interviews were deaths, divorce, mobility to other places, separation, and absence from home. Respondents were between the ages of 15 and 74 years, and they were able to provide information and were included in the study. Four focus group discussions (FGDs) were conducted to collect qualitative data. This study followed the door-to-door recruitment process, considering the nature of the study and its respondents. Variables included in the study are presented in Table 2.

Data collection and analysis process

A total of four (two males and two females) masters-level students with experience in field-level data collection were recruited as research assistants and were engaged and trained by the researcher. The researcher engaged and trained research assistants before the pretest and final survey. The questionnaire was pretested with different slum people and slum settings. Some critical issues, such as health service-related questions, wording of the questions, and time management, were learned from the pretest. After adjustment of the data collection instruments, a face-to-face interview was conducted at the households or a convenient place of the respondent's household from August 2021 to September 2021. Almost 25–30 min was required to complete each interview. A total of four FGDs were conducted, each consisting of 9–11 participants. The researcher conducted each session as a moderator, while research assistants performed as the notetakers. Descriptive statistics was used to present the socioeconomic characteristics of the respondents. Pearson's chi-square test was used to know the factors associated with NGO's initiatives and access to healthcare. Finally, a binary logistics regression model was used to determine the factors associated with NGO's initiatives using Statistical Package for the Social Sciences (SPSS) version 23.0 and Microsoft Excel 2019. The results were presented as odds ratio (OR) with a 95% confidence interval (95% CI). We used *P*-values to show the probability of error while rejecting the test and presented the odds ratio to express the effect size. Qualitative data were transcribed, and thematic analysis was conducted with the help of Adu's (61) qualitative data coding and analysis and Braun and Clarke's six-step thematic analysis (62) related to the research question/objectives (Figure 2).

TABLE 1 Distribution of study population and respondents.

Study Thana	Estimated population in each Thana	Estimated sample size	Collected sample size
Pallabi	4,238	228	216
Rupnagor	2,818	164	158
Vashantek	7,390	376	348
Total	14,446	768	722

Qualitative: focus group discussion (FGDs) $4 \times 10 = 40$ people.

Ethical issues

This study seriously followed and addressed ethical matters. Before starting and conducting the data collection process, an approval letter was asked by the corresponding author and obtained from the chairman of the department of the university. Throughout the study, the researcher and his team always

TABLE 2 Variables, operational definitions, and their level of measurement.

Variables	Indicators	Operational definitions of the variables	Level of Measurements
NGOs' role-related variables/enabling resources (based on Andersen's model)	Initiative roles or step	Quick and high priority-based services for quality and rapid services	Nominal
	Affordable services	The capability of bearing the expenses of services, medicines, and products	Nominal
	Special services	Special health services focus on priority and distinctive basic services	Nominal
	Community supportive services	Slum community leaders perform and provide health services to the community through concerted efforts on behalf of NGOs	Nominal
	BCC strategy	Communication strategies to promote positive health behavior through interaction and intervention	Nominal
	e-technology	Health services are provided and brought to the community through mobile and social media.	Nominal
	Counselling	Trained and professional people provide health services for Essential MCH, reproductive, and adolescent health.	Nominal
	Updated information	Alert people with new and regular information	Nominal
	Grassroots approach	Meticulous, thorough, and wide-ranging services are provided with the involvement of CSP/CHW or community peer group for each individual and household of the slum	Nominal
	Doorstep services	Health service delivered at home	Nominal
	Provided 24 h services by CSP	Deliver services round the clock	Nominal
	Access to health services	The ability to use health services when and where they are needed	Nominal

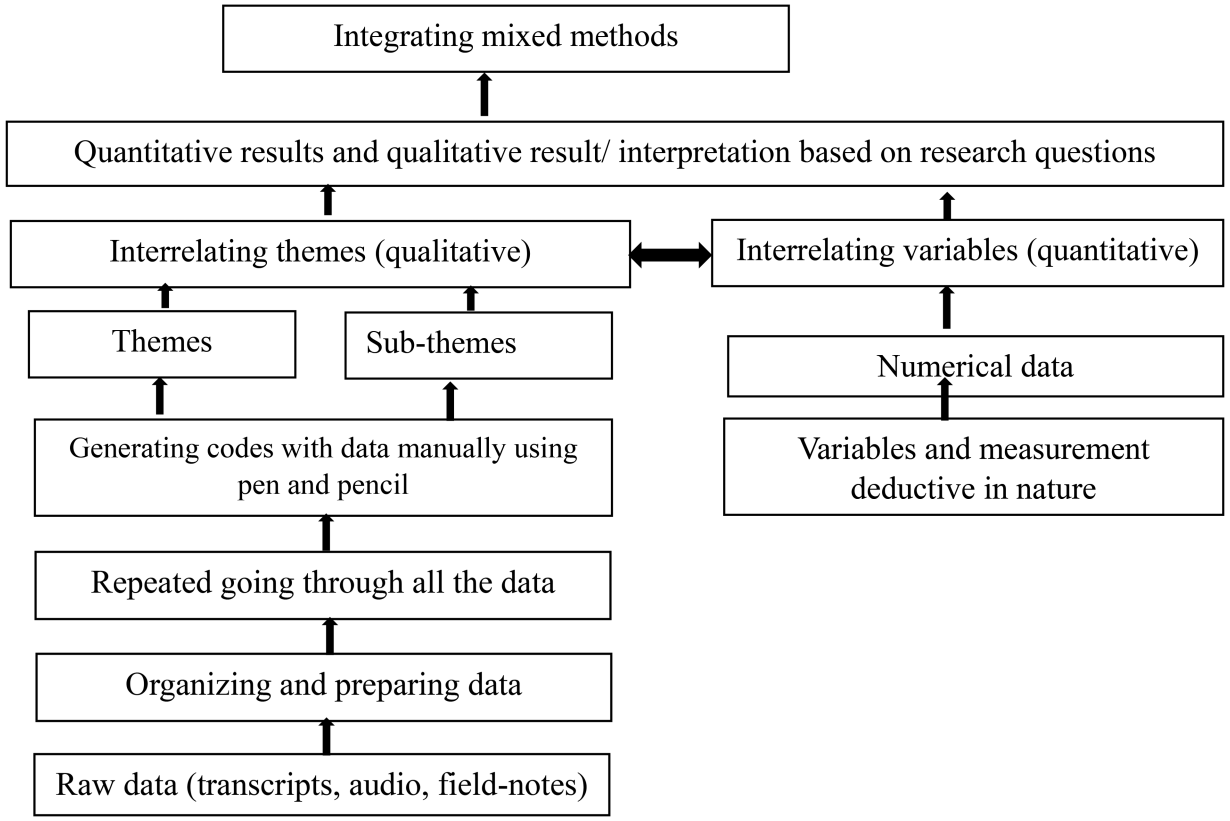

FIGURE 2
Processes or stages of mixed methods data analysis and stages of processing qualitative data analysis.

considered ethical principles established for human participants under the Helsinki Declaration. Verbal consents were also taken from the participants and informed them about the purpose of the study before starting the interview. Participants were assured about the anonymity of their names and identities and informed about using their data only for academic purposes. Participants' identities were encoded with specific numbers for the betterment of both data collectors and participants. As the data collection process of this study was conducted during COVID-19, some specific precautions and safety measures such as using masks, keeping sanitizer with both data collectors and study participants, and physical distancing were implemented. Social gatherings are also avoided during the data collection process.

Results

Sociodemographic characteristics of the respondents

Table 3 demonstrates the sociodemographic characteristics of the respondents. The study population included 722 respondents from the three Thanas of seven slums, where most participants were female (54.4%), and the minority was identified as male respondents (45.6%). Age ranges (25–44) covered most respondents (57.1%). Most of the participants (92.4%) were married, and the majority (39.1%) of the respondents were part of "no education," which meant illiterate. A greater portion of the respondents (34.6%) were housewives involved in household chores, and a vital proportion of participants (39.2%) were dependent on the income of their husbands, sons, and wives of the households.

Figure 3 illustrates the study's respondents' visits to the healthcare centers. Here, the figure is shown through the usage of multiple responses. One patient/respondent said that she/he might use or go to government, private, and NGO healthcare centers simultaneously for her/his necessary healthcare services. Participants (30.9%) stated that they would go to government hospitals. A small number of respondents (6.7%) shared that they went to private hospitals or healthcare centers to receive healthcare services. Most participants (31.7%) of this study said they used or went to NGO healthcare centers/clinics for health services. A significant number of respondents (29.6%) reported that they experienced and experimented with healthcare services from their nearby pharmacies.

Table 4 presents the NGO's initiatives and grassroots approach to accessing healthcare services for the slum people using a multivariate logistic regression model. Initiatives and grassroots approach were the two main predictor variables, and these two variables had 11 sub-variables, which demonstrated the association with the outcome variable (visiting or access to NGO healthcare

TABLE 3 Sociodemographic or background characteristics of the respondents ($n = 722$).

Variables	Frequencies	Percentage (%)
Sex		
Male	329	45.6
Female	393	54.4
Age		
15–24	118	16.3
25–34	223	30.9
35–44	189	26.2
45–54	104	14.4
55–64	65	9.0
65–74	23	3.2
Marital status		
Married	672	93.1
Unmarried	4	0.6
Separated	12	1.7
Widow/widower	34	4.7
Educational qualification		
No education	282	39.1
Primary	242	33.5
Secondary incomplete	139	19.3
Secondary school certificate (SSC)	24	3.3
Higher secondary certificate (HSC)	27	3.7
HSC +	8	1.1
Employment status		
Employed	188	26.0
Unemployed	40	5.5
Self-employed	184	25.5
Day labourer	60	8.4
Housewife	250	34.6
Income (BDT)		
Dependent	283	39.2
<5,000	78	10.8
5,000	24	3.3
5,001–10,000	189	26.2
10,000+	148	20.5
Total	722	100.0

services). The study showed that the NGOs' initiatives (seven initiatives) and grassroots approach (doorstep services) were significantly associated with access to healthcare services. The study found NGOs' initiatives and grassroots approach to affordable services (OR = 22.86, 95% CI: 3.87–35.00, $P = 0.01$), special health services (OR = 5.63, 95% CI: 3.36–9.42, $P = 0.000$), doorstep services (OR = 1.84, 95% CI: 1.00–3.38, $P = 0.05$), engaging responsible community leaders (OR = 1.72, 95% CI: 1.14–2.59, $P = 0.01$), distribution of medical and medicine items (OR = 1.92, 95% CI: 1.40–2.63, $P = 0.01$), update slum dwellers with updated information (OR = 1.37, 95% CI: 0.99–1.90, $P = 0.05$), e-health technology (OR = 1.56, 95% CI: 1.28–1.99, $P = 0.00$), and BCC strategy (OR = 1.26, 95% CI: 1.00–1.57, $P = 0.05$) were significantly associated with dependent variable access to healthcare services.

Table 5 describes the special incentive healthcare packages of NGOs. Special incentive healthcare packages are part of the NGOs' initiative roles. Incentive packages of healthcare services of NGOs ensured better access to healthcare services for slum dwellers. The majority (27.1%) confessed that FP services were the most proposed incentive package of healthcare services NGOs offer for their slum people. Both service providers of NGOs and respondents of slum people shared their experiences that these FP services continue to operate upon the capable or eligible reproductive age group (15–49). The second most crucial incentive package of health services NGOs provide is various blood tests (22.7%). Delivery care, both normal and caesurae (19.1%), became the third most incentive package of healthcare services offered by NGOs for the participants. Respondents (14.0%) reported that they would receive antenatal care as the most initiative package of their healthcare services from an NGO. Additionally, 8.9% of respondents mentioned they would enjoy discounts on their required health services.

Qualitative part

A thematic analysis was used to present the qualitative data. Two main themes and 11 sub-themes emerged from the collected data. These themes and subthemes were coded and analyzed using Adu's and Braun and Clarke's thematic analysis process and principles, as shown in Figure 4.

Theme 1: initiatives

Respondents shared their experiences and opinions about the initiatives of NGOs in providing healthcare services. According to their opinions, such initiatives of NGOs brought about drastic changes in the arena of health and the usage of health services for their slums and slum people. These initiatives have nine subthemes: affordable and reasonable health services, special health services with the involvement of health professionals, counseling and consultation services, engaging supportive community team/leaders, providing updated health information, e-mobile (telehealth and telemedicine), BCC strategy/techniques, distributing health and medicine materials, and providing emergency services either with their own health professionals or referral system.

Affordable and reasonable health services

Respondents expressed that the NGOs sometimes undertook initiatives to ensure affordable and reasonable health services for our slum dwellers. They provided some affordable and reasonable health services for our people. Most participants described that expanded programs on immunization (EPI) services, FP services, and some tests such as blood tests and pregnancy tests became affordable for them. The researcher and others concerned with this study observed various personal and non-personal communication, such as campaigns with

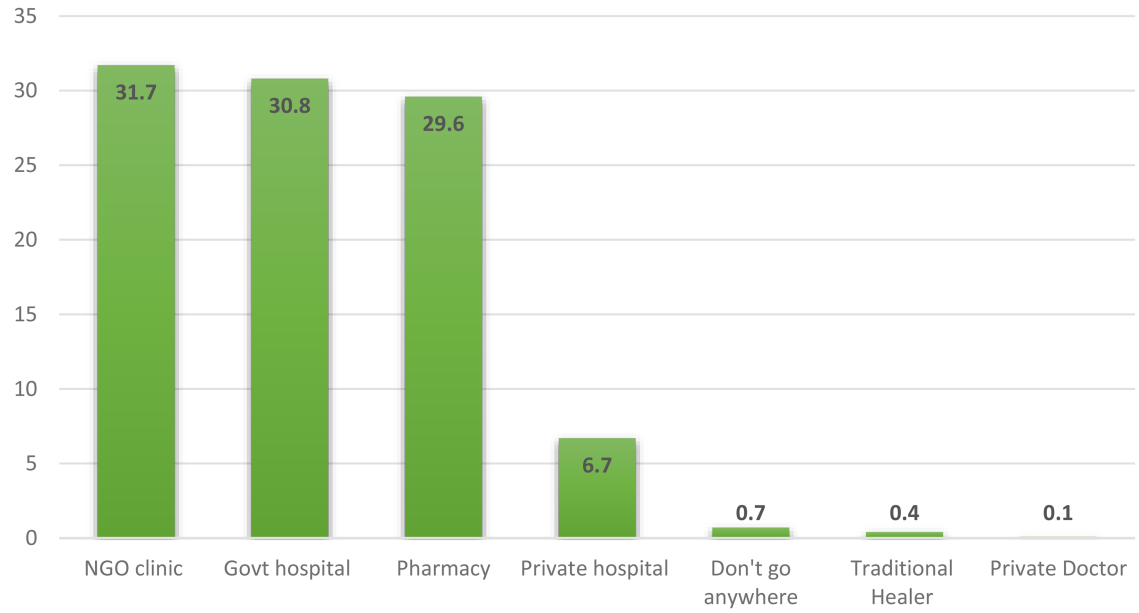

FIGURE 3
Visiting healthcare centers by seeking health services.

TABLE 4 NGOs' initiatives and grassroots approach for accessing healthcare services for slum people.

Independent variables	B[a]	S. E	*P*- value	Exp (B)	95% CI for Exp (B)
Affordable health packages: Yes (Ref Category: No)	3.13	0.906	0.01	22.86	3.87–35.00
Special health services: Yes (Ref Category: No)	1.73	0.263	0.00	5.63	3.36–9.42
Regular site visiting: Yes (Ref Category: No)	4.47	1,799.3	0.99	87.1	0.00-
Doorstep services: Yes (Ref Category: No)	0.61	0.311	0.05	1.84	1.00–3.38
Counseling services: Yes (Ref Category: No)	0.39	0.273	0.15	1.48	0.87–2.53
Engaging responsible community leaders: Yes (Ref Category: No)	0.54	0.210	0.01	1.72	1.14–2.59
Distributing leaflets, brochures, etc.: Yes (Ref Category: No)	0.65	0.160	0.01	1.92	1.40–2.63
Updating slum people with updated health information: Yes (Ref Category: No)	0.32	0.165	0.05	1.37	0.99–1.90
Free services for red card holders: Yes (Ref Category: No)	1.86	337.9	0.99	6.39	0.00–2.98
Telehealth and telemedicine: Yes (Ref Category: No)	0.46	0.108	0.00	1.56	1.28–1.99
BCC strategy: Yes (Ref Category: No)	0.23	0.113	0.05	1.26	1.00–1.57

B[a], regression coefficient slope (β), ($P < 0.000$; $P < 0.01$; $P < 0.1$; $P < 0.05$), Exp (B) = OR, 95% CI for odds ratio (exp B[b]).

TABLE 5 Special incentive healthcare packages provided by NGOs.

Healthcare services	Number of respondents (%)
Delivery services[a]	152 (19.1)
Family Planning services	215 (27.1)
Ultrasonogram	65 (8.2)
Blood test	180 (22.7)
Antenatal care services	111 (14.0)
Discount offered	71 (8.9)

[a]Multiple responses.

community supportive teams, hanging banners, and *miking* conducted around the slum areas for free and reasonable health services.

> Responsible persons of NGOs or community service providers (CSP) in our locality or area sometimes inform us about NGOs' initiatives on low and affordable service packages. They provide our services at low or reasonable prices. (A veteran service beneficiary)

Special health services with the involvement of health professionals such as doctors, paramedics, and CSP

NGOs have been providing a range of specialized healthcare services in the slum areas. These include Maternal and

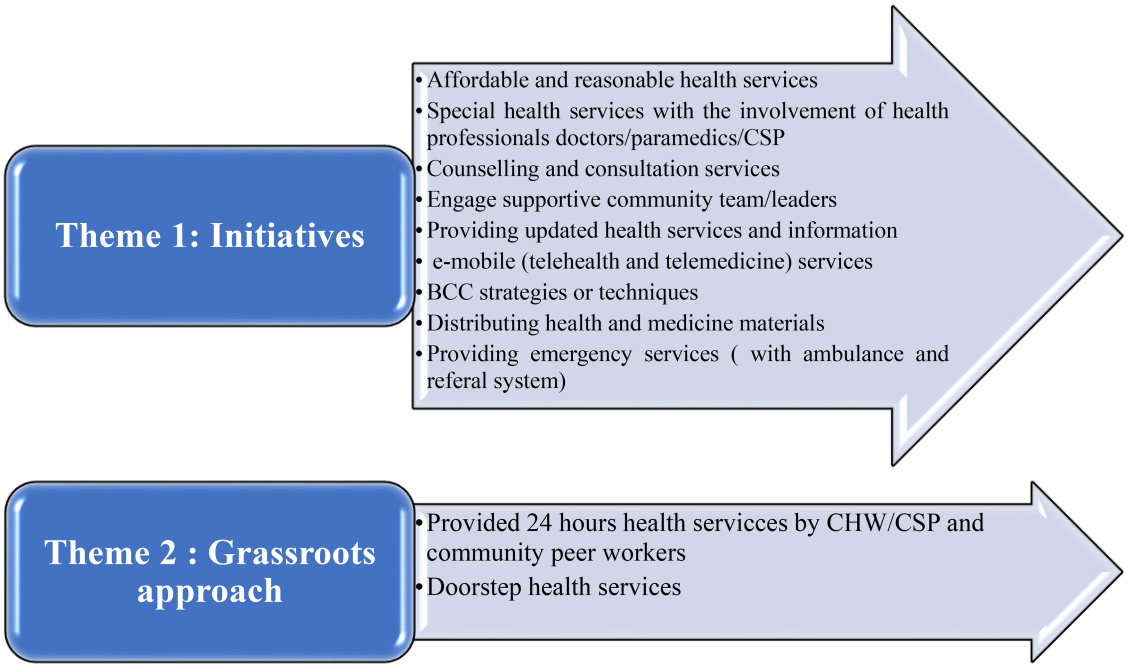

FIGURE 4
The themes and subthemes of the qualitative study.

Child Health (MCH) services, hepatitis B programs, special eye care services, vitamin A capsule campaigns, and sanitary and hygienic services. The involvement of special health professionals, such as doctors and paramedics, in these services has been crucial in addressing the unique healthcare needs of the slum population.

> When any health services or program decided to launch or conduct our slums, we immediately got informed by our CSP or community supportive team or leaders over the phone or in meetings. Those who were considered patients and suffered from related diseases or morbidity received services from the ongoing program or campaign of NGO. (An MCH patient)

Counseling and consultation services by nurses, paramedics, and CSP/CHW

Respondents of this study expressed that NGOs' counseling services took place through NGOs' static clinics, satellite clinics, and CSP. Sometimes, counselors visited slum areas to advise and instruct on different health services. The study found and observed that MCH, FP services, and adolescent and reproductive services were conducted through counseling.

> Once or twice a week, a female counselor, a female counselor visited our slum area from the respective NGO, and a female counselor from the respective NGO visited our slum area. We also gained counseling facilities from our paramedics and CSP. However, the counselor who visited us was good at counseling our health services. We found many guidelines like FP services, EPI services, ANC and PNC services, health and nutrition services, and reproductive and adolescent services from the counselor. (A young mother and health beneficiary)

Engage supportive community team/leaders

NGOs engaged responsible community teams/leaders in respective slum areas. Most of these leaders were female, and they provided us with early information about healthcare services. It was observed that every slum has an NGO's community-supportive team, which was employed with different lucrative offers and logistic support from NGOs. Slum people derived constant and updated information from their community-supportive team.

> We immediately got information about health services, other services, or news from our community leaders. During COVID-19 or before the onset of COVID-19, our community leaders always played a pioneering role in doing our best. Most of the NGOs entered and welcomed to the slums with the aegis of our slum community leaders. (A middle-aged MCH and an FP beneficiary of the NGO)

Providing updated health services and information

Participants described that NGOs initiated to provide them with regularly updated information through CSP and community supportive leaders. For this, NGOs provided mobile phones to CSPs to convey updated health information to their respective slum dwellers.

> We receive all updated information from our community leaders or CSP. If any information or new health services or

> packages are offered, soon we get this information from our leaders or CSP and such message is publicized among the people in our slum. During COVID-19, we frequently got health-related information from NGOs to protect us from COVID-19. (A maternal and FP patient)

e-Mobile (telehealth and telemedicine) services

Respondents discussed the revolution of health services through e-Mobile and e-Health. Before COVID-19, telehealth and telemedicine health services were meagerly served, but during COVID-19, when all direct healthcare services were hindered and stopped, telehealth and telemedicine became a vital and popular way of receiving persistent health services from NGOs. Especially telemedicine has become a very inevitable service for slum dwellers. The study finds any emergency and critical conditions of a pregnant mother, elderly people, and neonatal complications are immediately resolved through telehealth and telemedicine.

> When COVID-19 began to spread, all direct health services through static and satellite clinics almost decided to stop serving in our slums. Authority and persons from NGOs assured us of continuing health services through mobile. Hence, they provided our CSPs with mobiles and continued for 24 h during COVID-19. Specifically, NGOs emphasize providing MCH, TB, and COVID-19 services through telehealth and telemedicine. (A delivery and mother of the neonatal patient)

BCC strategies/techniques

Participants vastly shared and discussed their experiences with BCC strategies of NGOs. They were happy with the BCC strategies, which helped them change their attitude and adjust to their healthcare behavior. They learned about BCC strategies from messages CSP or CHW, such as pregnancy care/taking rest and cleanliness, birth preparedness, safe delivery, and postpartum care with neonatal health. Moreover, posters and stickers about the danger signs of pregnancy, the eight newborn danger signs, post-delivery period, the danger signs of high fever, severe headache and blurring of vision, and hemorrhage or excessive bleeding gave them profuse knowledge and made them cautious about health and illness.

> It was surprisingly a new experience for me when I came to know and observe the pictures of dangerous signs of a pregnant mother, marriage of a young/adolescent girl, a skinny infant with a young married girl, convulsion and hemorrhage picture of a pregnant mother, and NGOs. I gradually became familiar with BCC strategies and learned many things from the paramedics and NGO CSPs about caring for a maternal mother and her newborn baby. I also learned about the devices of FP services. (A maternal and FP patient)

Distributing health and medicine materials

Respondents of this study spontaneously discussed NGOs' initiative steps for distributing health and medicine materials. Initiatives to distribute health materials encouraged them to use health services. Researchers and research assistants also noticed that NGOs provided slum dwellers with hand sanitizers, masks during and after COVID-19, brochures, pills, vitamins, and paracetamol tablets and syrup.

> Receiving health and medicine materials like leaflets, brochures, pregnancy strips, FP devices, hand wash, and hygienic materials made us more vibrant and curious towards NGOs' health services. Sometimes, training arrangements, meetings with us, and distributed materials and gifts attracted us greatly to their services. (A community leader and service beneficiary)

Providing emergency and referral services

Participants confessed that the NGOs' people are always linked with their community service providers (CSPs) and community leaders to provide them with updated information and emergency health services. Patients with essential healthcare services, communicable diseases, or non-communicable diseases get direct services or referral services from the NGOs' people.

> Getting or finding emergency or immediate health services from NGOs was beyond our imagination and thoughts. One day, my daughter-in-law felt severe pain in her abdomen during her first pregnancy. I was alone at my house and didn't think about what I should do with her right now. Then I rushed to our community services provider (CSP), but I could not find her in her room, so I informed community support leaders about my daughter-in-law's condition. They at once communicated with NGO people over the phone and told them about the severity of the pain. NGO people told us to bring my daughter-in-law to their hospital, which was not far away from our slum. We instantly took her to this small NGO hospital and got a new baby after two hours of attempts of all concerned health professionals. (An experienced slum dweller and mother-in-law of a young delivery patient)

Theme 2: grassroots approach

Provided 24 h services by CHW/CSP and community peer workers

NGOs engage community health workers (CHWs), community service providers (CSPs), and community peer health workers to provide 24 h health services for slum dwellers. These CHWs/CSPs and community peer workers were chosen and appointed from the respective slum areas to ensure the grassroots-level health services of the slums.

> Our community service providers, health workers, and peer workers became our constant and remedial fellows and friends for providing 24-hour health services for us. During COVID-19, when government health services were insufficient, and most NGOs at service abstained from visiting our slums and

> stopped providing health services, NGO authorities decided to offer our services within 24 h through our local CHW and peer workers (An MCH health service beneficiary)

Doorstep/knocking at the door services

Participants said the doorstep healthcare services were a remarkable and beneficial step for NGOs. NGOs' paramedics, community service providers (CSPs), and community health workers (CHWs) provided doorstep health services. CSP and CHW are providing constant health services for the slum people because they live in slum areas. Paramedics provided services through satellite clinics and visited slum households for doorstep services. The study observed that service providers of satellite clinics and CSP/CHW were very influential in grassroots-level services because both service providers have strong and close links with the slum dwellers.

> We got much benefit from doorstep health services. Our women and pregnant women received many instructions from paramedics and CSP/CHW before and during their pregnancies. Paramedics and CSP advised and instructed our adolescent girls and young and newly married couples about using senora/pads and condoms during intercourse. Both have advised the new couple to use contraceptive devices to avoid or prevent unwanted pregnancy. (Patient of NGOs' multi-health services).

Discussion

Health is a fundamental and constitutional right and one of the crucial priority sectors of the government. There has been increasing recognition that a healthy population is essential to economic growth and prosperity. To attain universal health coverage, equitable access to healthcare services must be ensured irrespective of gender, including disability and marginalized populations (64, 65). However, most slum dwellers are not served well by all the layers of health facilities from the top entities of the state except a few national and foreign NGOs (25, 66, 67). Many barriers slum dwellers face in accessing quality health services because of a lack of availing initiatives (68). Existing literature from the scenario of Bangladesh's slums and South Asian and Asian countries' slums demonstrated and indicated the common barriers, limitations, and deprivations of getting healthcare services from both the public and private ends. Previous studies also plainly presented the challenges in coordinating two ministries of Bangladesh, which deprived urban poor people (e.g., slum dwellers) of finding, availing, and reaching health services (6). Since Bangladesh is committed to providing essential healthcare services to its entire population, many public healthcare facilities are officially free or available at a minimum fee (69). Unfortunately, these services are still unreachable, unavailable, and underutilized in Bangladesh for various reasons, especially for urban poor people (e.g., slum people), some of which are already mentioned. Some facilities, along with initiative steps and grassroots level services from the large and small number of NGOs and GO- NGOs/PPP health projects, ensured better use and access to healthcare services for the urban areas, particularly in slums and squatters settled in Dhaka (70). The significant findings and themes from integrating mixed method study are discussed below.

NGOs' initiatives and grassroots approach worked and helped like a super aid and super benediction services for the slum people

The urban slum dwellers have been categorized as "hardcore" and "absolute" poor based on their household incomes and vulnerability. Their purchasing capacity, level of expenditure, living standard, lifestyle, and health condition are deplorable (71). Urban slum people are heavily pushed by migrant people in Bangladesh (72, 73). Hence, such destitute, impoverished, homeless, and socially excluded people always look for and depend on financial assistance and other initiative roles and grassroots-level services of government, donors, and NGOs. Most slum dwellers are informal workers who desperately need urban services while living in horrible conditions (74–76). NGOs and people of these NGOs cordially, cooperatively, and desperately engaged in initiatives and grassroots-level services for slum people. They could be significant in organizing slum dwellers to enjoy and utilize amenities (77). Participants (both quantitative and qualitative) of this study stated and mentioned some initiative roles (affordable and reasonable services, providing special health services with the involvement of health professionals, Engaging responsibly community leaders/community supportive services, e-mobile/telehealth and telemedicine services, distribution health and medicine items, BCC strategy/techniques) and grassroots approach (providing 24 h health services with CHW, doorstep services) of NGOs greatly influenced slum dwellers to use and access to healthcare services. Fair and feasible prices of services ensured better use and access to healthcare services for the slum-poor dwellers (78). Launching special health services such as maternal and child health (MCH), health and nutrition services, sanitation and hygiene, special eye care, and adolescent and reproductive healthcare with special health professionals among the slum dwellers can enhance access to health services. Counseling and consultation and BCC strategies and techniques can inspire and motivate slum people to use health services. Using mobile technology (e-Mobile/telehealth and telemedicine) in health services increases the popularity, usage, and access to service volume on a large scale (79). All participants unanimously believed and insisted that such initiatives and grassroots-level services should also come from the government. Big private hospitals and domestic donors align with NGOs and ensure these initiatives are implemented in all slums of Dhaka.

Participants claimed and the research team also observed that only a few big NGOs such as ICDDR, B, BRAC, Radda, Shakti Foundation, and Gonoshasthaya Kendra (GSK) provided healthcare services with their static and satellite clinics to slums. Some small slums enjoy and find health facilities from big NGOs, which are relatively located in the vicinity of and at geographical disadvantage points of urban areas. FGD respondents from the Vashantek and Pallabi slums shared that they got better healthcare facilities from the NGOs than the respondents of the Rupnagar slums. A few small NGOs provided scanty health services to the slum dwellers of Rupnagar. As a result, outreached and backward slums such as Rupnagar were extremely deprived of access to these services. BRAC, Radda, GSK, and Shakti Foundation undertake initiatives and provide five days of static or satellite/outreach clinic services, affordable health packages, special health packages, referral health services for emergency or critical patients, doorstep health services, ambulance services, and 24 h CSP and CHW services through e-technology/mobile services for their slums (Vashantek and Pallabi). However, these. Still, these health services and facilities are not available in Rupnagar slums. Although some NGOs were found to be actively providing urban services to the slum communities, others were found to be preoccupied with extending their projects rather than addressing improvised people's actual needs (74–76). Most NGOs in the slums provide services on a project basis and with the support of donors as well as government registration and restrictions, so NGOs have faced challenges and drawbacks and discontinue their projects and services and tend to diminish their role due to donor's declining funds and growing government restrictions (2). NGOs emphasize counseling services in the slums rather than medication services.

Limitations and scope of the study

The researcher and his team faced some barriers and problems while conducting the study. More or less, every slum was influenced and controlled by the local political leaders. Hence, the participants were initially disinclined and afraid of participating in interviews, but later, the researcher convinced community-supportive leaders of each slum for this study. The data collection process of this study was conducted during COVID-19, so participants did not stay in their slums, and few moved to their rural areas. As the data collection process was going on during COVID-19, most of the slum dwellers thought we visited their slum to distribute relief and donations.

Implications

Although this study has limitations, it demonstrates an inclusive and diversified aspect of NGOs' initiative roles and grassroots approach to healthcare services for the government, donors, and private health organizations who aspire to organize and provide health services for the urban poor slum people. Government and policymakers can undertake and launch new initiatives and grassroots approaches apart from the NGOs' existing initiatives and grassroots level services or collaborate with existing and grassroots level services to expand and enhance healthcare services for the underserved slum dwellers.

Conclusion

The study found that NGOs' initiatives and grassroots approaches had a significant association and impact on using and accessing healthcare services. Initiatives including affordable or reasonable services, special health services by health professionals, BCC strategy, grassroots approaches such as doorstep services, and providing constant or 24 h services by CSPs/CHWs are mentionable for accessing health services for the slum people. Addressing these initiatives and the grassroots-level approach of NGOs is necessary to draw serious attention to other concerned policymakers for launching and triggering the same or innovative initiatives and grassroots approach for the unprivileged slum people. The study bears an inclusive scenario and insight into NGOs' initiatives and grassroots approach for accessing health services for the slum people, and this paper paves the way for government, donors, and other concerns materializing their new projects about the disadvantaged slum people. This study also recommends and suggests that government, donors, and policymakers synchronize their initiatives and grassroots-level services with the NGOs so that such initiatives and approaches, along with their services, may easily trace, reach slum people, and help them use and access health services. Further and future studies are necessary to evaluate NGOs' initiatives and grassroots approaches to access to health services. More novel or innovative initiatives and grassroots approaches may be explored and enhanced through this further and future works.

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 research evaluation committee of the Department of Population Sciences, University of Dhaka. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent to participate in this study was not required from the participants in accordance with the national legislation and the institutional requirements. The participants provided their verbal informed consent to participate in this study prior to commencing the interview.

Author contributions

MIB: Conceptualization, Formal Analysis, Investigation, Methodology, Software, Writing – original draft. MAH: Conceptualization, Data curation, Methodology, Resources, Supervision, Validation, Visualization, 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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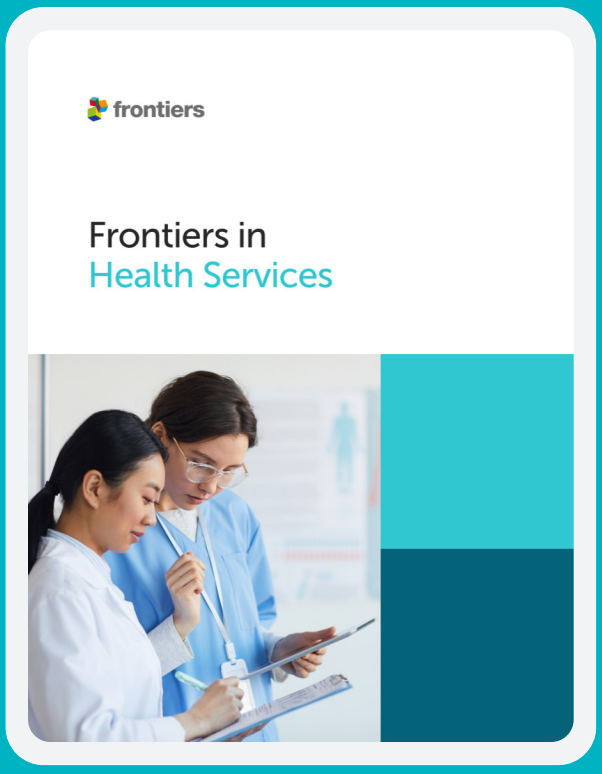

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