Systematic Review

SAGE Open Medicine

SAGE Open Medicine
Volume 9: 1–10

DOI: 10.1177/20503121211016179
journals.sagepub.com/home/smo
SAGE

Pros and cons of eHealth: A systematic review of the literature and observations in Denmark

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Abstract

Objectives: The main objectives of this article are to systematically review the recent literature on patient safety in relation to the use of eHealth and to investigate how the Danish authorities supervise private eHealth clinics with regard to patient safety.

Methods: Original studies reporting the association between patient safety and the use of eHealth as a means of communication between patients and healthcare providers were included. Four literature databases were searched for English-language articles reporting results from cohort studies and clinical trials, published from 2015 until March 2021. Moreover, registered private eHealth clinics in Denmark were evaluated with reference to a recent national audit of patient safety issues in eHealth.

Results: The literature search retrieved four intervention studies. The studies did not identify any particular patient safety risks associated with the use of eHealth. Many different authorized healthcare providers (preferably, doctors) apply eHealth in various contexts. eHealth is being used as the only form of contact between the healthcare provider and the patient, as a supplement to patient visitations in an outpatient clinic, or as a tool for communicating between two or more healthcare providers. The regulation of eHealth involves patient safety issues but also has interfaces to marketing, IT systems, and infrastructure. Supervision of eHealth includes the organization of clinics, handling patient charts, prescription medicine, patient legal rights, and patient transition. However, there are many interfaces in the division of responsibilities among the various governmental players.

Conclusion: eHealth is being used increasingly and in many settings, although recently published intervention studies investigating patient safety issues by the use of eHealth are limited. A structured and continuous governmental control and regulation of patient safety in relation to the use of eHealth is warranted.

Keywords

eHealth, governmental regulation, indicators, patient safety

Date received: 2 December 2020; accepted: 16 April 2021

Introduction

In recent decades, there has been a rapid growth in the use of electronic health (eHealth), and recently, the growth has been accelerated by restrictions on in-person practice associated with the Coronavirus Disease 2019 (COVID-19) pandemic.[1,2] The increased use of eHealth has raised legal implications connected with the implementation of the technology and poses a challenge to patient safety.[3] According to the World Health Organization (WHO), patient safety includes the absence of preventable harm to a patient during the process of health care and the reduction of the risk of unnecessary harm associated with health care to an acceptable minimum.[4] Among the safety issues associated with the use of eHealth are a lack of proof of efficacy and reliability

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in clinical decision-making,[5] the protection of patient data with respect to privacy,[6] and its influence on the patient–healthcare provider relationship.[7–9] This may be due, in part, to the limited knowledge and supervision of eHealth providers.

eHealth is a broad concept that covers many types of information communication technology (ICT) tools used in the healthcare sector.[7] The WHO places eHealth into various categories including electronic health records (EHRs), health information systems, remote monitoring and consultation services, tools for self-management, and health data analytics. Mobile health (mHealth) is a subset of eHealth that is linked to cell phones and apps.[10] eHealth has the potential to transform health care and the practice of medicine by improving the quality of patient safety and care.[7]

Healthcare providers use eHealth for many purposes including administration, health records maintenance and access, communication and consulting, information gathering, and medical education.[7] Patient care management and treatment compliance are among the challenges faced by healthcare providers. Recently, an app in combination with an electronic monitoring system (EMS) has been shown to improve the treatment compliance of psoriasis patients and short-term outcomes.[11] Yet, systematic studies investigating the potential long-term improvement of treatment efficacy[12] and cost-effectiveness[1] of eHealth are limited. As more patients own electronic devices, new opportunities for direct digital communication with healthcare providers and improved self-monitoring and disease prevention have been introduced.[13] Furthermore, patient safety issues in regard to the increased use of eHealth need to be addressed.

In Denmark, the use of eHealth as a digital communication form (e.g. apps, websites, or mobile phone consultations) is expanding in the tax-financed public health sector at hospitals (where most hospitals have introduced eHealth services through which patients may get access to information about their treatment plans and video consultations with doctors or nurses) and with general practitioners (who are obliged to offer email appointments) as well as smaller private healthcare providers who offer their services to patients thorough digital communication. Since smaller private healthcare clinics operated by one or a few healthcare professionals may pose a greater potential risk to patient safety than eHealth used in a well-established public sector, the first Danish governmental supervision of patient safety in the use of eHealth was conducted among private eHealth clinics.[14]

This article has two objectives: to provide an overview of recently published literature reporting eHealth effects on patient safety and to discuss the findings in a context of the use of private eHealth clinics in Denmark and governmental supervision thereof. The assessment of the clinical value of eHealth and its economic effects is outside the scope of this study.

Materials and methods

Literature review

A systematic literature review was performed for English-language, peer-reviewed articles in four major databases. The search included studies from 2015 until March 2021.

A three-block search strategy was designed using a combination of search terms for eHealth, patient safety, and limitations in use (Supplementary Material 1.1). The search blocks may be found in Supplementary Material 1.2 specified for the respective databases PubMed, Embase, Web of Science, and the Cochrane Library. The design for the review was in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.[15]

Published English-language articles reporting results from cohort or intervention studies in which eHealth was used as a communication tool between the patient and healthcare provider were considered for inclusion. The primary outcomes extracted were any associations between the use of eHealth and patient safety.

Duplicate independent study selection was done by M.T.S. and S.N.T. The sorting process was performed with Covidence software (Melbourne, Australia).[16] The first sorting was done by reading the title and abstract. The remaining studies were selected after reading the full text by focusing on study data that specifically reported any verified or presumed association between the use of eHealth and patient safety. Inconsistencies were resolved by consensus. The authors independently extracted data from identified studies using a standardized data extraction form.

Independent quality assessments were done by M.T.S. and S.N.T. A study-specific quality assessment table was designed for the specific requirements for this review. The quality table was inspired by the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklist.[17] To address the internal validity, an overall quality assessment was given for each study. Each study was graded by assigning yes, no, or not applicable (NA) to every question. Questions assigned NA were excluded from the overall quality assessment grading. If yes answers comprised 67%–100%, the study was considered of high quality. If yes answers comprised 34%–66%, the study was considered of medium quality. If yes answers comprised 0%–33%, the study was considered of low quality. Inconsistencies were resolved by consensus.

Use and supervision of eHealth clinics in Denmark

In Denmark, there is no register providing an overview of eHealth clinics, whether they are public or private. However, private eHealth clinics advertise on the Internet and operating systems (OSs) and, therefore, can be identified. A search

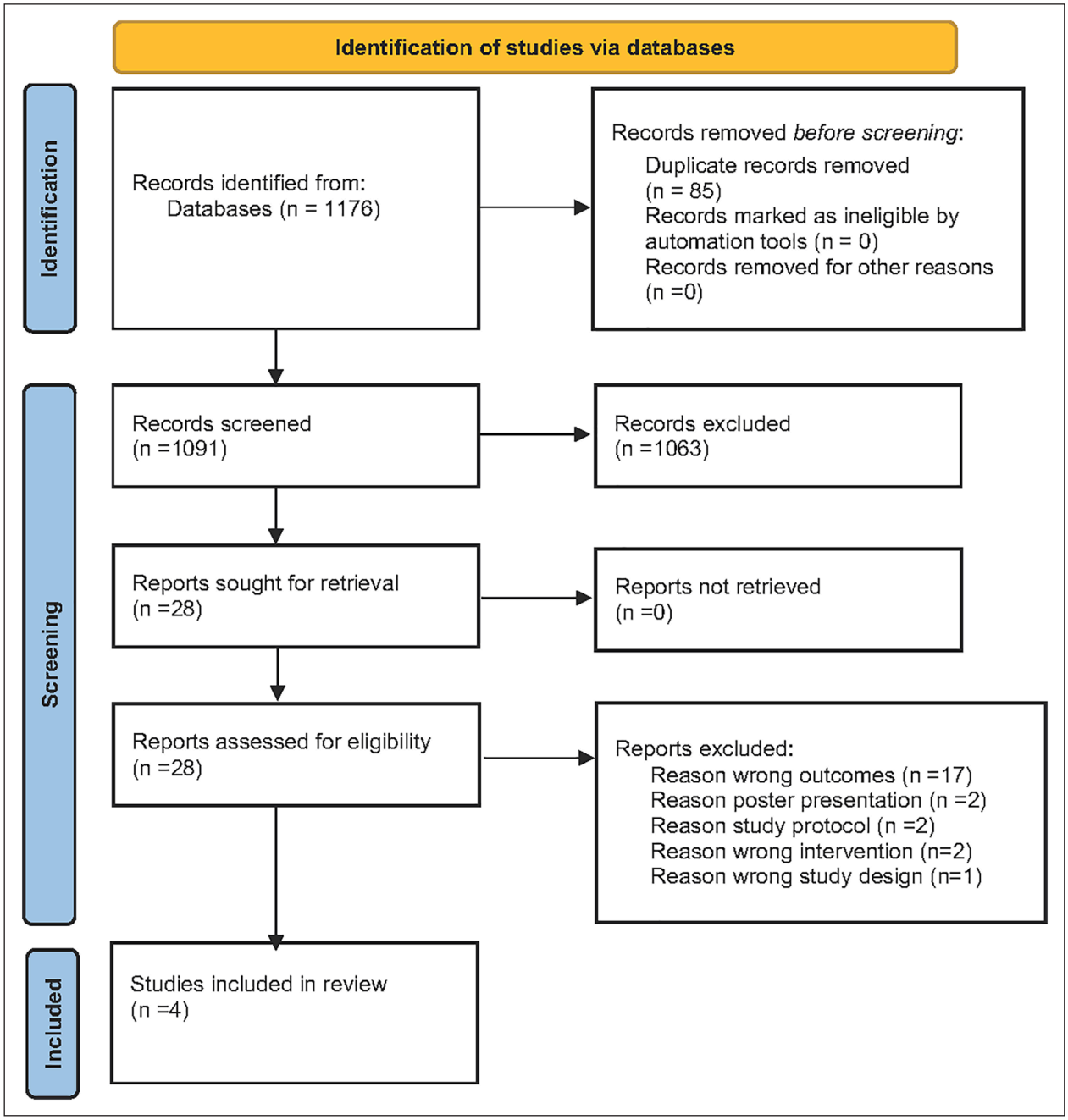

Figure 1. Trial flow depicting the selection of process of studies included in the literature review.

was conducted of private providers of eHealth advertising in Denmark on the Internet and OS. The findings were sorted according to the type of services offered and the form of contact between provider and patients.

Institutions with supervisory responsibility were identified in Danish patient safety legislation[14] and the institutions were grouped according to their respective supervisory area. Moreover, all recent indicators for the supervision of Danish eHealth providers were identified and summarized.[14]

Results

Scientific literature reporting how eHealth affects patient safety

Four studies addressing how the use of eHealth as communication between the patient and healthcare provider influences patient safety were identified (Figure 1). A summary of the evidence in the included studies is presented in Table 1. A list of excluded studies is available in Supplementary Material 1.3

Table 1. Summary of evidence from included studies.

Reference	Study design	Country	Aim of the study	Setting	Number of participants	Participants' age or years of experience using eHealth	Conclusion concerning patient safety in the use of eHealth
Prochaska et al.[18]	Multicenter cohort study	Germany	To compare the clinical outcomes for oral anticoagulation drugs in patients managed by eHealth-based intervention with patients receiving regular medical care	Healthcare professionals from university hospitals at 21 study centers	1558 patients receiving oral anticoagulation drugs for at least 3 months	>18 years of age and receiving anticoagulant therapy	Reduction of adverse events (thromboembolic events and bleeding) in patients receiving eHealth-based interventions
Liao et al.[19]	Randomized controlled trial	China	To investigate whether a 12-week mobile-based text-messaging system improves smoking cessation	Research assistants from psychiatric departments operating on smartphones in 30 Chinese regions	1369 patients who were daily smokers above 18 years of age from 30 different towns	>18 years of age and smokers	No reported adverse events from using the smartphone were reported
Schwalm et al.[20]	Cluster-randomized controlled trial	Colombia and Malaysia	To investigate whether an intervention consisting of support from non-physician health workers and an algorithm-based app improves reduction in blood pressure	Non-physician health workers in 30 different communities	1299 patients with hypertension	>50 years of age, prescribed antihypertensive drugs	No reported adverse events
Toro-Ramos et al.[21]	Randomized controlled trial	The United States	To investigate whether a coach-guided mobile-delivered diabetes prevention program reduces weight	Prediabetics aged >18 years	202 overweight patients	Mean intervention group (55.69 years of age) vs non-intervention group (57.54 years of age)	No serious adverse events were reported

while a list of included studies is available in Supplementary Material 1.4.

Quality assessment is presented in Supplementary Material 1.5. Two of the included studies[20,21] were deemed well-conducted and had a low risk of bias. However, two other included studies[18,19] had a medium risk of bias due to limited information regarding sampling[18] and lack of sufficient information regarding the outcome measures.[19]

Prochaska et al.[18] investigated the experience of an eHealth-based coagulation service and found the eHealth service to reduce adverse events (i.e. thromboembolic events and bleeding) in patients receiving anticoagulation therapy compared to standard care. Liao et al.[19] explored the use of a telephone-based text-messaging system to support smoking cessation and reported no adverse events from use of the intervention. Schwalm et al.[20] reported an intervention in which non-physician healthcare providers with the support of an algorithm-based app significantly reduced blood pressure and reported no adverse events from the use of the intervention. Finally, Toro-Ramos et al.[21] found that a coach-guided mobile-delivery system reduced weight in pre-diabetic patients while reporting no adverse events from using the intervention.

Types of eHealth clinics and their supervision

A total of 26 Danish clinics offering eHealth were found. The total number of patients seen by these clinics was not publicly available. In 21 clinics, contact was restricted to digital communications between the healthcare provider and patient; two clinics provided a combination of digital contact and physical attendance, while three clinics operated through digital contact between two or more healthcare providers. A broad spectrum of authorized healthcare providers offered their healthcare services through the eHealth clinics. The clinics hired healthcare providers within the following professions: 15 clinics

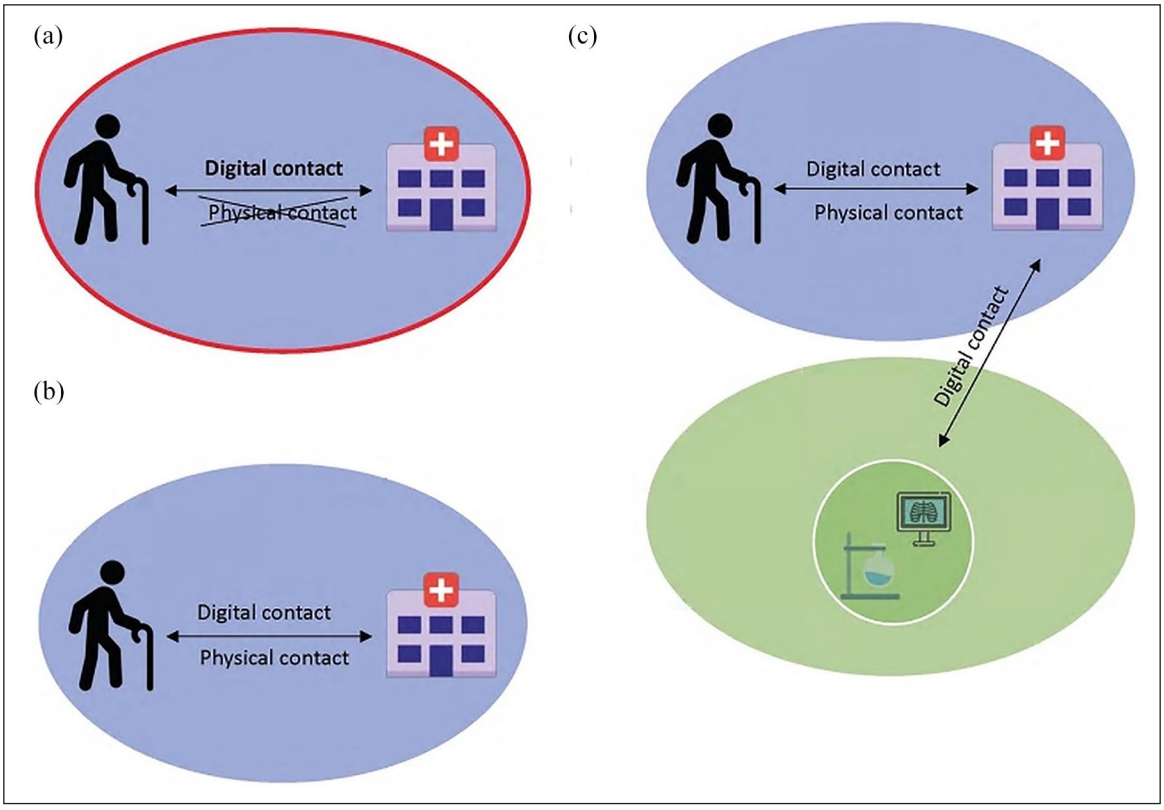

Figure 2. Constellations of digital healthcare contacts. Type (a): only digital contact. Type (b): mixed—digital and physical contact. Type (c): digital contact between providers. Type (a) (provided with a red circle) was the type of patient–healthcare provider contact supervised by the Danish Patient Safety Authority in the first supervision of private eHealth clinics in 2019.

were run by doctors, three by dieticians, two by physiotherapists, one by a nurse, and another by a midwife. Moreover, four clinics had mixed types of healthcare providers, that is, doctors, nurses, midwives, dentists, and physiotherapists (see Supplementary Materials 1.6–1.8 for a detailed description of the healthcare clinics and providers operating from the clinics).

Three main types of eHealth clinics were observed (see Figure 2):

1. All communication takes place via digitally based communication (e.g. app or Internet-based communication) between the patient and an authorized healthcare provider or staff member responsible for treatment.
2. Part of the healthcare treatment takes place by means of digital communication between the patient and the authorized healthcare provider or staff member responsible for treatment. In addition, the patient physically visits the clinic.
3. Exchange of patient data by digital communication between authorized healthcare providers or persons acting under their authority. The eHealth clinic may have no physical address. This means there is no direct patient–healthcare provider contact.

The Danish Patient Safety Authority is responsible for supervision with focus on areas such as the organization of the clinics, handling patient charts, medication prescriptions, patients' legal rights, and the individual patient's transition between clinics (for a detailed description, see Table 2). However, several national authorities are involved in different aspects of the regulation of eHealth, and many areas with interfaces to patient safety issues (see Figure 3). The supervision of healthcare activities that directly handle patient treatment is the responsibility of the Danish Patient Safety Authority. In addition, certain aspects of the supervision of marketing healthcare services are the shared responsibility of the Danish Patient Safety Authority, the Danish Consumer Ombudsman, and the Danish Medicines Agency. The supervision of the IT systems in eHealth clinics has interfaces to the Danish Patient Safety Authority (how the systems are used in the treatment of patients), the Danish Data Protection Agency (whether the system is safe in sharing and storing personal identifiable data) as well as the Danish Medicines Agency (in cases in which a medical device is being used). Finally, the supervision of the infrastructure is a responsibility for both the Danish Health Data Authority and the Danish Data Protection Agency. In order to ensure the safe handling of people's personal data, the European Union (EU) has introduced the General Data Protection Regulation (GDPR).

Table 2. Essential indicators.

Organization
Secure organization of leaders and instruction, delegation of responsibilities and supervision of employees
Sufficient written manuals for the employees
Patient charts
Correct handling of patient charts
Secure and safe patient identification
Correct indications for examination and prescribed treatments
Follow-up of prescribed treatments
Handling of medication
Prescription of medication
Handling of potential interactions between prescribed medications
Prescription of addictive medication
Patient legal rights
Informed consent
Transitions in patient treatment
Admissions and follow-up on admissions
Transfer of patient information to colleagues
Handling of paraclinical examinations

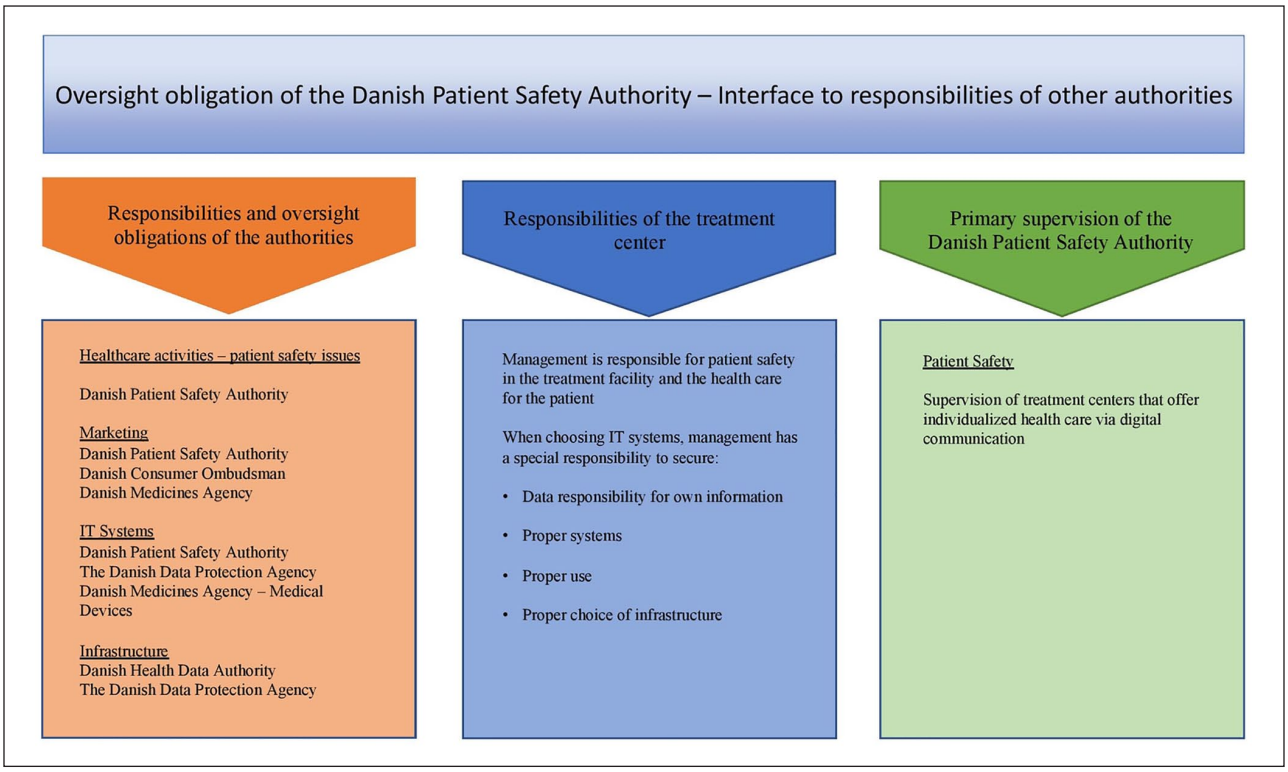

Figure 3. Governmental offices regulating safe use of eHealth.

All member states have standardized their treatment of citizens' personal data throughout the EU.[6]

There are many interfaces in the supervisory responsibilities of eHealth clinics. Nevertheless, with respect to the delivery of a healthcare service, the legislation on eHealth clinics does not differ from the legislation that all healthcare clinics are obliged to follow.

Discussion

Principal findings

Even though the use of eHealth is rapidly expanding, the literature search on eHealth safety in cohort and clinical trials investigating eHealth interventions in the last 5 years resulted in only four studies with low-to-medium risk of bias. In

general, the literature findings did not raise any particular patient safety concerns regarding the use of eHealth.

A mapping of Danish private eHealth clinics showed that 26 private clinics offered health care restricted to eHealth, and the majority of the providers were doctors. The eHealth clinics were divided into three groups: those with digital contact only between healthcare providers and the patient, those with an eHealth supplement to outpatient clinic visitation, or those that acted as a tool for communication between two healthcare providers.

The Danish Patient Safety Authority is responsible for the supervision of patient safety matters in private eHealth clinics. Yet, other governmental offices may be consulted with regard to aspects of marketing, the use of IT systems, and the organization of infrastructure. The indicators for the national supervision of eHealth are equivalent to the indicators used for the supervision of private health clinics, encompassing supervision of the organization, patient charts, handling medication, patients' legal rights, and the transition between clinics.

eHealth has potential but also pitfalls

The technologies are considered beneficial in the hospital sector for both patients and healthcare providers, who use it in diagnostics and follow-ups, in monitoring chronic diseases, in rehabilitation, and in residential management of patient medication. Nevertheless, broader experience with the use of eHealth is still needed, since it could be associated with potential risks that might put patient safety in jeopardy if not carefully monitored.

The use of private eHealth in Denmark is still limited—perhaps, because Danish patients predominately consult tax-financed public clinics and hospitals, where they are not charged for the healthcare services.[22] The studies included in the literature review found the use of eHealth efficacious compared to standard care with respect to anticoagulant therapy,[18] smoking cessation,[19] blood pressure reduction[20] and weight-loss.[20] However, eHealth has been widely introduced in spite of limited evidence of its efficacy.[12] In addition, physical contact between patients and doctors may be reduced without considering the value and understanding of this physical contact.[23] All studies had a medium-low risk of bias.

The included studies[18–21] did not investigate whether improved efficacy also had economic benefits compared to standard care. Modai et al.[24] studied hospital costs and treatment safety in telepsychiatry compared to physical consultations and concluded that patients and physicians are satisfied with the safety and effectiveness of video conference telepsychiatry (VCTP), although the operational costs of VCTP may be higher than face-to-face consultations. Using eHealth in daily clinical practice is assumed to save time and money, although published health economy analyses show mixed results. The findings from Modai et al.[24] are in agreement with Pak et al.,[25] who found that eHealth used in an asynchronous setting in dermatology was even more expensive than conventional dermatology when only direct costs were considered. In contrast, Zakaria et al.[26] reported that the implementation of a teledermatology triage system within the dermatology department was associated with cost savings compared to a conventional dermatology care model. Nonetheless, the study was limited by not including the revenue generated from billing and the exclusion of costs associated with rent, utilities, and non-personnel overhead. Armstrong et al.[1] concluded that the literature has shown mixed results on how the use of eHealth influences the health economy and advised conducting cost analyses of the use of eHealth from a societal perspective in which the total cost of eHealth is analyzed but also taking in account patients' reduced transportation costs and regained work productivity. While the benefit of the use of eHealth to the health economy is unknown, eHealth is still being used more frequently.[27]

The studies included in the literature search[18–21] did not find any patient safety concerns with the use of eHealth for communication between the patient and healthcare provider. However, van Poelgeest et al.[28] investigated the experience of healthcare providers with eHealth and found no improvement in the safety of hospital care through the use of advanced electronic medical records. Coletti et al.[29] explored the association between advanced electronic medical records and patient safety and concluded that tele-intensive care unit (tele-ICU) implementation is associated with perceived improvements in patient safety. Finally, Demiris et al.[30] investigated residents' perception of the influence tele-ICU implementation has on patient safety and concluded that eHealth providers need to be educated about security features related to the technology and recommended continuous quality improvement in order to increase quality and minimize errors. The residents reported that the use of eHealth was not associated with high risk for patient safety. Moreover, in order for eHealth to be safe, the residents recommended that they continuously update their education in the use of the technologies.

The literature included in the review raised[18–21] no particular concerns regarding the use of eHealth, which accords with a recent conclusion from governmental inspections of Swedish private eHealth clinics finding no serious patient safety issues in the use of eHealth.[31] However, the retrieved literature review had no hard data endpoints (e.g. severe unexpected adverse reactions such as mortality rates or hospitalization) as a measure of patient safety. The lack of similar outcome measures for patient safety among the studies limits a clear conclusion.

Even though the search did not find any warning signs in regard to the use of eHealth, it points out the importance of continuous education for healthcare providers in the use of eHealth and addressing situations in which it is not the best option to use. Rasmussen et al.[32] conducted a randomized controlled trial (RCT) and found that eHealth used in the

monitoring of diabetic foot ulcers was associated with an increased mortality in the group that received eHealth. The increased mortality rate might be explained by a reduced ability to detect serious complications through digital contact compared to seeing the patient in the outpatient clinic. Severe unexpected adverse events associated with the use of eHealth may only be detected in an RCT, which is why it is problematic if new and promising eHealth practices are introduced into clinics without being tested in a high-quality RCT. When new eHealth is introduced, there is no general agreement requiring that the technology to be introduced is superior to previous contact forms.

The supervision of eHealth clinics is equivalent to the supervision of healthcare clinics based on patients' physical presence and is subject to the same legislation. The potential risks are numerous and include unsafe patient identification and patient record-keeping, limitations in digital diagnosis and treatment without physical attendance, losing personal contact and continuity in patient care, lack of sufficient treatment plans and follow-ups, prescribing addictive medication, antibiotics misuse, and false or misleading online advertising. Furthermore, the quality of the technical equipment and use thereof is also of importance, for example, quality of sound, photo, or video.

eHealth supervision is focused on situations in which there is a potential risk in its use. For example, eHealth may be advantageous for giving patients the results of selected tests or scheduling outpatient visits and of doubtful value for diagnosing diseases and prescribing medications with potentially severe side-effects. The use of eHealth is expanding, and the development of eHealth may be a sound supplement to outpatient visits. Still, this expansion is often being implemented without an analysis of the potential benefits for patients, the health economy, patient safety, or the need for the education of healthcare providers and patients in the use.

Strengths and limitations of this study

This article is limited in that it does not analyze the efficacy and cost-effectiveness of the use of eHealth.

The literature review only included results from intervention studies published in the last 5 years and, thus, provided limited results. A further constraint on the search strategy might be that patient safety issues are rarely the main focus in reporting results from the use of new advanced technologies, and new technologies are rarely tested in systematic trials. A possible explanation is that the technology may often be outdated before a clinical trial is finished and results reported.

The systematic mapping of private eHealth clinics was limited by the lack of an updated central register of clinics offering eHealth, and no consensus was available on how to search for eHealth service.[33] Therefore, some private eHealth clinics may have been missed. Since there is no central register of eHealth clinics in Denmark, we do not know what percentage of private eHealth clinics was covered by our search. Health apps without direct patient–healthcare provider contact or without the use of medical devices are not supervised by the health authority, and many apps were outside the scope of this article. Furthermore, all general practitioners in Denmark are obliged to offer digital consultations, and many hospitals have different digital platforms for communicating with patients.

The division of different situations in which eHealth can be applied is a simplification. Future models may include other constellations for the use of eHealth.

The review of governmental offices involved with the supervision of Danish eHealth may not be illustrative for other countries, which may have different structures because responsibilities and governmental organizations differ between countries. The indicators mentioned for supervising eHealth were taken from the most recent Danish audit of eHealth, conducted in 2019 by the Danish Patient Safety Authority. Indicators are frequently revised, and the focus of supervisions differs, so the indicators are presented primarily as a guidance and inspiration for how the supervision of eHealth may be planned.

Conclusion

In order to ensure the safe use of eHealth, a number of safety measures must be thought through and put into the right context by clinicians, such as the management and organization of the eHealth clinic, written instructions, safe identification, informed consent, treatment follow-ups, and the retention of patient records by healthcare providers. Many new technologies may escape a thorough analyses in the context for which they are designed before they are implemented. A lack of evidence of the efficacy and safety of eHealth may be a barrier for policymakers' visions for a broader implementation of eHealth. A structured, effective, reliable and continuous governmental supervision is warranted to monitor the expanding use of eHealth.

Recommendations for future research

This study was limited by a lack of definition of outcomes for patient safety, which restricted the opportunity for comparative studies. Scientific associations and governmental offices regulating eHealth could collaborate and come up with simplified, comparable measures for patient safety, which could be applied in supervision as well as in research. In addition, a central registry of eHealth clinics would aid in the mapping of the field. This would help to identify eHealth clinics and allow a comparison of the efficacy and safety of eHealth across medical specialties and nations.

Acknowledgements

The Danish National Library in Copenhagen assisted in the literature search strategy.

Data availability

In Supplementary Materials 1.1–1.8, readers may access the relevant data underlying the findings of the study.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: M.T.S. and K.E.A. have received grants from LEO Pharma to conduct clinical trials testing interventions using eHealth patient-support solutions (ClinicalTrials.gov NCT04220554 and NCT02858713). In addition, M.T.S. was responsible for designing indicators and safety benchmark measures for eHealth for the Danish Patient Safety Authority and conducted the first national regulatory supervision of private eHealth providers. All of the data reported are publicly available. S.N.T. declares no conflicts of interest. No private companies or governmental regulatory institutions have been involved in the ideas behind or the writing of this article. All authors take full responsibility for the content of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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Supplemental material

Supplemental material for this article is available online.

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