Review

Patients Managing Their Medical Data in Personal Electronic Health Records: Scoping Review

Debby J Damen[1], PhD; Guus G Schoonman[1,2], MD, PhD; Barbara Maat[3], MD, PhD; Mirela Habibović[4], PhD; Emiel Krahmer[1], Prof Dr; Steffen Pauws[1,5], Prof Dr

[1]Department of Communication and Cognition, Tilburg School of Humanities and Digital Sciences, Tilburg University, Tilburg, Netherlands

[2]Department of Neurology, Elisabeth-TweeSteden Hospital, Tilburg, Netherlands

[3]Department of Pharmacy, Elisabeth-TweeSteden Hospital, Tilburg, Netherlands

[4]Department of Medical and Clinical Psychology, Tilburg School of Social and Behavioral Sciences, Tilburg University, Tilburg, Netherlands

[5]Department of Remote Patient Management & Connected Care, Philips Research, Eindhoven, Netherlands

Corresponding Author:
Debby J Damen, PhD
Department of Communication and Cognition
Tilburg School of Humanities and Digital Sciences
Tilburg University
Warandelaan 2
Tilburg, 5037 AB
Netherlands
Phone: 31 0630215926
Email: d.j.damen@tilburguniversity.edu

Abstract

Background: Personal electronic health records (PEHRs) allow patients to view, generate, and manage their personal and medical data that are relevant across illness episodes, such as their medications, allergies, immunizations, and their medical, social, and family health history. Thus, patients can actively participate in the management of their health care by ensuring that their health care providers have an updated and accurate overview of the patients' medical records. However, the uptake of PEHRs remains low, especially in terms of patients entering and managing their personal and medical data in their PEHR.

Objective: This scoping review aimed to explore the barriers and facilitators that patients face when deciding to review, enter, update, or modify their personal and medical data in their PEHR. This review also explores the extent to which patient-generated and -managed data affect the quality and safety of care, patient engagement, patient satisfaction, and patients' health and health care services.

Methods: We searched the MEDLINE, Embase, CINAHL, PsycINFO, Cochrane Library, Web of Science, and Google Scholar web-based databases, as well as reference lists of all primary and review articles using a predefined search query.

Results: Of the 182 eligible papers, 37 (20%) provided sufficient information about patients' data management activities. The results showed that patients tend to use their PEHRs passively rather than actively. Patients refrain from generating and managing their medical data in a PEHR, especially when these data are complex and sensitive. The reasons for patients' passive data management behavior were related to their concerns about the validity, applicability, and confidentiality of patient-generated data. Our synthesis also showed that patient-generated and -managed health data ensures that the medical record is complete and up to date and is positively associated with patient engagement and patient satisfaction.

Conclusions: The findings of this study suggest recommendations for implementing design features within the PEHR and the construal of a dedicated policy to inform both clinical staff and patients about the added value of patient-generated data. Moreover, clinicians should be involved as important ambassadors in informing, reminding, and encouraging patients to manage the data in their PEHR.

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KEYWORDS

patient-generated data; patient portal; personal electronic health record; patient activation; patient engagement

Introduction

Background

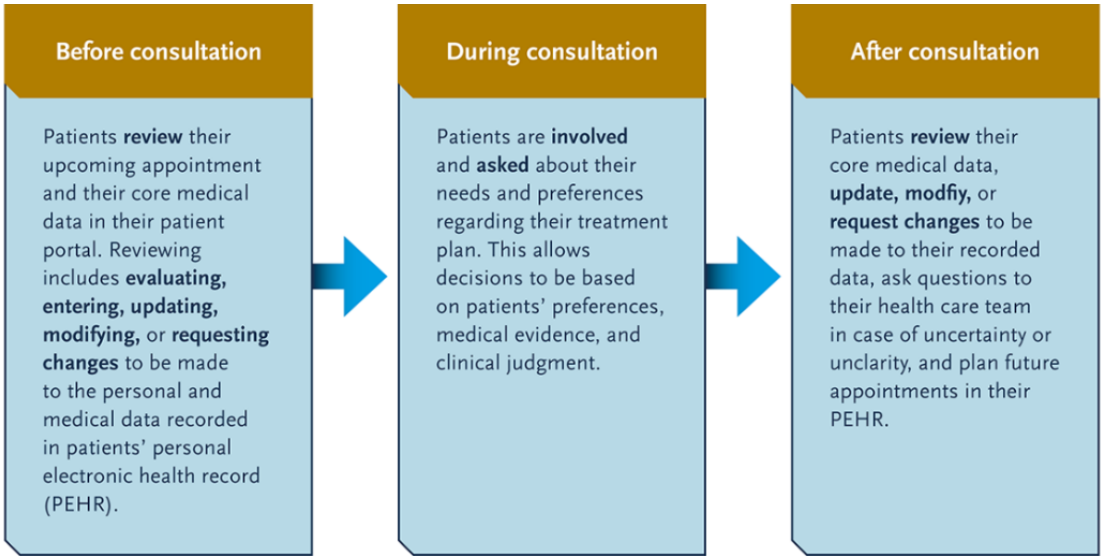
The beginning of most outpatient consultations is characterized by physicians going over the personal and medical information that is recorded in their patients' personal electronic health records (PEHRs). This includes information about their patients' current health problems and information about their vital signs, medication use, or known allergies. An up-to-date and accurate overview of this personal and medical information gives physicians a better sense of who is sitting in front of them and allows them to make appropriate and safe treatment-related decisions that correspond to their patients' needs. In most cases, clinicians are responsible for updating their patients' personal and medical data at the start of each consultation. However, this task can take up to 40% of the physicians' time, which would rather be spent on direct patient care [1,2]. Instead of only physicians managing their patients' personal and medical data (*core medical data*), patients can also play a role by entering, reviewing, and updating this information in their PEHR before or after each outpatient visit by themselves. Research shows that this active patient engagement is associated with various beneficial health-related outcomes, such as an increase in patients' self-care and medication adherence, improved patient-physician relations, shared decision-making, and even improved clinical outcomes for patients with chronic illnesses [3-5]. It is for this reason that health care services strive to engage patients in the self-entry and self-management of their health care data by using technology such as patients' PEHRs [6].

Over the past decade, identifying what determines whether patients are likely to engage with their PEHRs and how their engagement affects their clinical care has been a frequent topic of discussion [7-14]. The consensus is that less than half of the user population adopts a PEHR, and even less than one-third of the users actually use their PEHR records and manage their personal and medical data, with patients' data management declining as age increases, lower digital skills, and being unable to fully understand and use health information in treatment-related decisions [15-18]. Studies have also shown that patients are less likely to self-manage their medical data when they find it difficult or unpleasant to use the data management tools [11,19-23] or when the practice is not endorsed by their health care providers [21,24].

Although previous syntheses of the literature have been valuable in identifying the scope and potential causes of patients' disengagement [7-10,13,14,25], they have some limitations. First, the most recent review [10] synthesized knowledge from studies published till 2018 and retrieved them from a very limited set of 3 databases. Second, previous reviews have focused only on consumers' perceptions [7,10,13], patients aged ≥50 years [14], randomized controlled trials [8], or English publications [7,9,10,14], without providing an all-encompassing view on the patient-, care-, and system-related factors that drive or prevent patients' data management. Most importantly, previous literature refrains from providing sufficient information about patients' actual levels of engagement with their core medical data in their PEHR. The facilitators of and barriers to patients' personal data management have previously been considered in relation to patients' (future) portal adoption or access [25-27] or by basing patients' level of engagement on log-in frequencies or the number of times they view a certain page in their PEHR [7-10,12-14]. In these cases, we do not know the extent to which patients who access their PEHR feel coresponsible or "empowered" [28] to actually use their PEHR in a meaningful way. We define meaningful use as patients actively sharing, reviewing, updating, or modifying their personal and medical data in their PEHR throughout their entire care journey (Figure 1). Our definition does not include patients who only access their portal and passively view the recorded information, but it does include patients who evaluate the information recorded in their PEHR. Certainly, patients are meaningfully using their PEHR when they closely examine (evaluate) their core medical data and decide to leave the information as it is, because they believe it to be correct and complete (Figure 1). However, we know that PEHRs often lack sufficient or up-to-date core medical information [29]. Therefore, in this review, our aim is to synthesize the existing literature by focusing on instances in which patients take actual action to provide or update their core medical data in their PEHR. This focus on data generation (sharing) and management (updating and modifying) allows us (1) to determine what drives patients toward or prevents patients from maintaining an up-to-date record and (2) to examine the associated impact that this active data management has on patients' health and health care–related services.

To identify what may drive patients toward or prevent patients from taking on an active rather than a passive role when it comes to the management of their core medical data, we need to identify not only the type of data management activities patients perform within their portal but also the type of data that patients manage and how frequently they do so. Patients can engage differently with their PEHR depending on the personal and medical data they wish to share or update. Patients may be less inclined to share or update information about error-prone and sensitive data elements than to share or update personal and medical data that they are more confident or knowledgeable about. To date, it remains unknown whether the type of core medical information affects patients' personal data management.

Figure 1. Active patient engagement in terms of patients generating and managing their personal and medical data throughout their care journey. This figure was partially replicated and adapted from Carman et al [30]. PEHR: personal electronic health record.



Objectives

In this scoping review, we aimed to address the limitations of previous syntheses by exploring the barriers and facilitators that patients face when they decide to actively review, enter, update, or modify their core medical data in their PEHR throughout their care journey (Figure 1). We aimed to (1) identify the extent to which patients feel motivated or coresponsible for sharing, updating, and modifying their core medical data in their PEHR, and (2) examine the extent to which this engagement with a PEHR impacts the quality and safety of care and patients' satisfaction with the care delivered. Answers to these questions will result in clear recommendations on how to maximally stimulate active patient involvement with PEHRs.

Methods

Search Strategy and Eligibility Criteria

This scoping review was conducted and reported in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews [31]; Multimedia Appendix 1). The search protocol was preregistered with the Open Science Framework [32]. In April 2020, the MEDLINE (PubMed), Embase, CINAHL, PsycINFO, Cochrane Library, Web of Science, and Google Scholar web-based databases were searched to retrieve studies concerning patients' management of their core medical data in an electronic patient portal. In March 2022, the MEDLINE database was re-searched to retrieve records that were published between April 2020 and March 2022. The reference lists of all primary and review articles were hand searched. Literature reviews were excluded, but practice briefs, fact sheets, white papers, and peer-reviewed publications (including conference proceedings) that focused on any type of population or study design (eg, qualitative, quantitative, or mixed methods studies) were included. The databases were searched for English or Dutch articles published between January 2000 and February 2020. We chose January 2000 as the starting point of the search because the 3 known early adopters of a web-based patient portal, the Palo Alto Medical Foundation ("MyChart"), the Beth Israel Deaconess Medical Center ("PatientSite"), and the Boston Children's Hospital ("Indivo"), implemented their patient portals between the end of 1999 and the beginning of 2000 [33]. Our search strategy was developed in collaboration with an experienced research librarian (Multimedia Appendix 2) and targeted words related to electronic health records (eg, *patient portal* and *electronic health record*) combined with Medical Subject Headings terms related to patient engagement (eg, *patient participation*, *patient education*, *patient involvement*, and *patient engagement*) and the type of data being managed (eg, *medication reconciliation*, *medication verification*, *allergies*, and *intoxications*). To be included in the review, papers needed to focus on patients who actively handled their personal and medical data in a web-based patient portal (ie, entering, updating, or modifying; Figure 1) and identify either patient-, care-, or system-related determinants that influence this active patient involvement, or focus on the (perceived or examined) benefits or costs related to active patient involvement with a PEHR. Articles were excluded when they only included patients' management of their core medical data in a PEHR as a secondary concept. Table 1 provides an overview of the checklist for full articles.

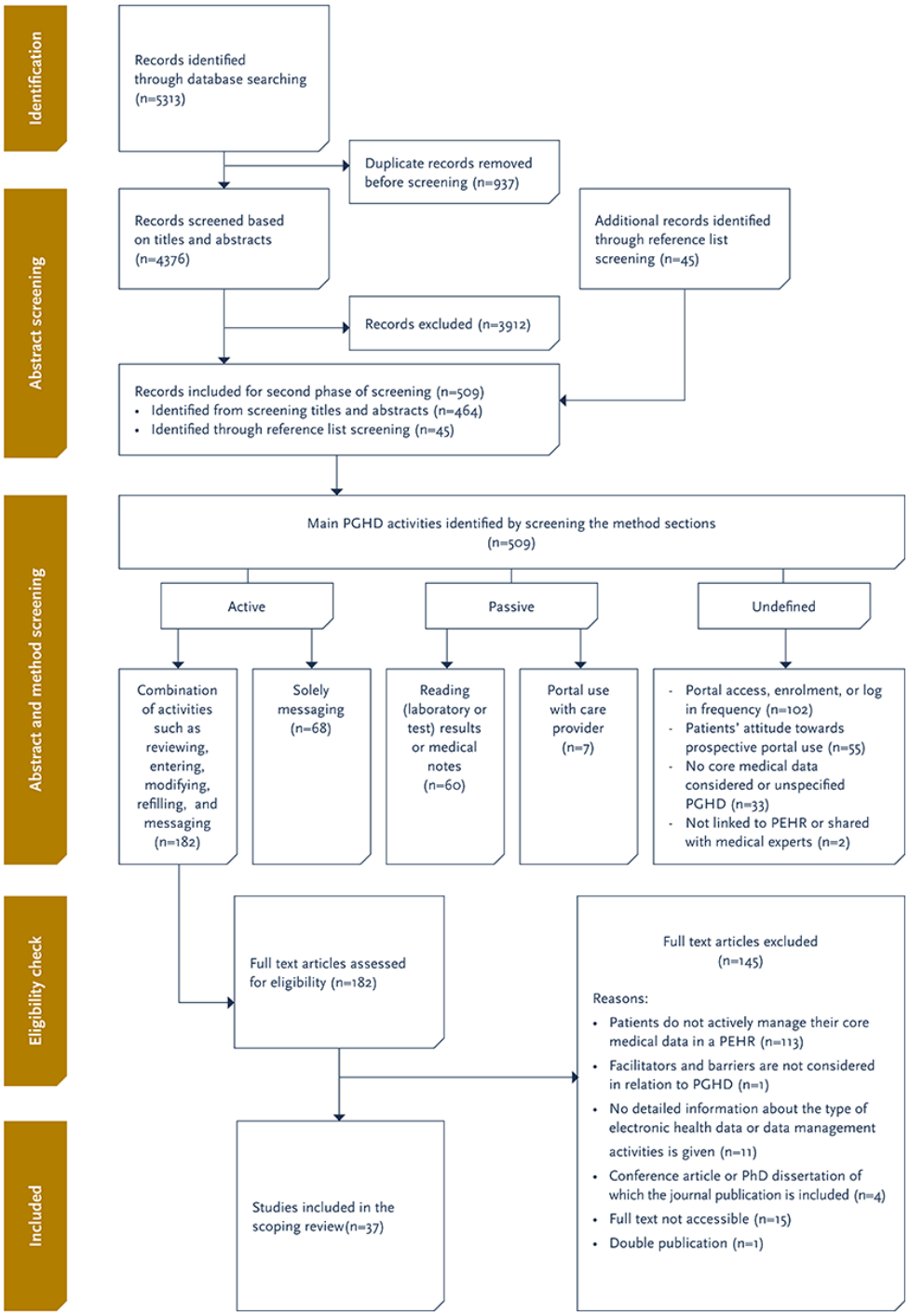
Table 1. Selection checklist for full articles.

Item	Inclusion
Report characteristics	
Type of publication	Practice briefs, fact sheets, white papers, and peer-reviewed publications and conference proceedings. Exclude when the articles are systematic or scoping reviews; meta-analyses
Date of publication	Between 2000 and February 2020; MEDLINE: re-searched in March 2022
Study details	
Type of study or intervention	All types of studies are allowed to be included in this review (eg, randomized controlled trial, non-randomized controlled trial, evaluation/usability, experimental, cohort/longitudinal, developmental, and pre-post design)
Type of health data being managed	Core medical data being managed in a personal electronic health record (eg, medication regimen, vaccinations, allergies, medical and family history, and intoxications)
Population	Both patients and clinicians

Screening Rounds and Data Extraction

The flowchart for the inclusion of articles in the scoping review is presented in Figure 2. The eligibility screening and data extraction form is presented in Multimedia Appendix 3. Searching the databases resulted in 5313 records that were imported into the reference manager, Mendeley (Elsevier). After duplicates were removed, 4376 (5313/4376, 82%) unique records were retained. The first author (DJD) used Mendeley to screen the identified records based on their titles and abstracts. A total of 45 (1%) additional records were identified through the screening of reference lists. This initial screening resulted in 509 records that were identified to be eligible for the review. However, after this initial screening, it remained unclear what kinds of activities patients performed within the PEHRs. Therefore, we diverged from our preregistered review protocol by administering an additional screening round. In this round, the first author (DJD) screened the Methods section of the 509 records to identify what kind of patient-generated medical data activities were included. This screening method identified 7 activities (Figure 2): active (ie, generating data, refilling, and messaging), passive (ie, viewing and portal use with health care provider), and undefined data management activities (ie, prospective use, portal access, log-in frequency, and portal enrollment). The first author (DJD) categorized the records into these 7 categories, and the second author (GGS) screened and reviewed a subset (51/509, 10%) of these records. Both authors discussed the screening method and the categorized subset until a consensus was reached. After the screening of the Method sections, 182 articles were found to be eligible for full-article screening. The full texts of these 182 records were subsequently screened by 4 authors (DJD, GGS, BM, and SP) in equally divided subsets. This resulted in 37 (20%) records that met the criteria for inclusion in this scoping review. The first (DJD) and second (GGS) authors then rated a subset of a mix of inclusions and exclusions, but no problematic cases were identified. The first author (DJD) then commenced with extracting the data from the 37 (20%) records according to the data extraction form (Multimedia Appendix 3).

Figure 2. Flowchart for the identification, screening, and inclusion of articles in this scoping review. PGHD: patient-generated health data; PEHR: personal electronic health record.



Results

Description of the Included Studies

The general characteristics of the 37 included records are presented in Table 2. We rejected articles that only addressed patients who passively reviewed their data without making actual changes to their records (eg, the studies by Apter et al [34] and Jhamb et al [35]). We categorized the included studies as reporting on one or more of the following three categories (Table 3) [33,36]: (1) information about patients' portal use, including the frequency of patients entering, updating, or modifying their core medical data; (2) patient and provider (perceived) facilitators of and barriers to the activities described in the first category, including usability, prototyping, and pilot studies in which portal features or tools were tested with specific end users; and (3) the impact of patients' active involvement in the management of their data on patient care, including studies that focused on the quality of the data entered and the (perceived or examined) effects of patient-generated or patient-managed data on the quality, safety, cost-effectiveness, and patient or health care provider satisfaction of health care services. In further sections, we will report the findings of the included studies based on these categories.

Table 2. Study characteristics of the records included in the scoping review.

Number	Study	Country	Study aim	Sample	Type of data	Data activity	Portal	Data entry tools
1	Ali et al [37], 2018	United States	Evaluating the usability of a portal	Patients or caretakers of patients (n=23) with chronic conditions (diabetes, cancer, ulcerative colitis, or thalassemia)	Medical history	Reviewing and entering data	myNYP	None
2	Ancker et al [38], 2019	United States	Describing portal adoption rates and characteristics of patients who enter health data and their association with clinical outcomes	Patients with diabetes (n=53), of which 23 were pregnant and 30 were nonpregnant, and their physicians in obstetrics-gynecology (n=12) or internal medicine (n=4)	Blood glucose values	Entering data	Weill Cornell Connect (EpiCare)	None
3	Arsoniadis et al [39], 2015	United States	Evaluating the quality of patient-generated health data with a health history tool accessible via the web or a tablet	Patients (n=146) with an appointment at a surgery clinic, of whom 50 completed the intervention	Medical history, surgical history, and social history (including questions related to tobacco use, alcohol consumption, illicit substance use, and sexual history)	Entering data	EpiCare	Questionnaires
4	Bajracharya et al [40], 2019	United States	Evaluation of the family history module implemented in a patient portal and patients' adoption of and experiences with the module	Patients (n=4223)	Family health history	Reviewing and entering and modifying data	PatientSite (electronic medical record of the Beth Israel Deaconess Medical Center)	Questionnaires
5	Bryce et al [41], 2008	United States	Exploring the usability of patient portal features and users' intentions to pay fees for portal use for a diabetes management portal	Patients (n=39) with diabetes, with 21 patients allocated to the preportal group and 18 to the portal users group	Vital signs (blood glucose values)	Entering data	HealthTrak	Calculator
6	Chrischilles et al [42], 2014	United States	Exploring how patient-generated health data affects medication use safety among older adults	Nonclinical population (n=1075) with variety in medical backgrounds; most participants were experiencing stomach-related problems; 802 participants were allocated to use a patient portal, and 273 were allocated to a control group	List of allergies, medication list, problem list, and medical history	Entering data	Iowa PHR[a] (stand-alone patient portal)	None
7	Cohn et al [43], 2010	United States	Evaluating the usability and analytic validity of the Health Heritage tool that helps patients to collect their family health history	Mixture of nonclinical and clinical participants (n=109), of which 54 were allocated to the intervention arm (Health Heritage) and 55 to the usual care arm	Family health history	Entering data	Health Heritage (stand-alone tool)	None

Number	Study	Country	Study aim	Sample	Type of data	Data activity	Portal	Data entry tools
8	Polubriaginof and Pastore [29], 2016	United States	Comparing the accuracy and completeness of a tablet-administered problem list questionnaire to a problem list that was self-reported by patients	Patients with variety in medical backgrounds (n=1472); details were given for patients with hypercholesterolemia and diabetes	Problem list, medical history, family health history, and risk factors	Entering data	LMR[b]	Tablet questionnaire administered via the Hughes RiskApps life cycle cost software
9	Dullabhet et al [44], 2014	United States	Exploring how patients can be engaged to provide feedback on electronic health record content and how this feedback affects the accuracy of medical records	Patients (n=457) with chronic conditions (obstructive pulmonary disease, asthma, hypertension, diabetes, or heart failure); the number of providers and pharmacists interviewed is not provided	Medication list	Reviewing and modifying data	MyGeisinger (Geisinger Health System)	Web-based feedback forms
10	Eschler et al [45], 2016	United States	Exploring the usability of a patient portal, whether and how it helps patients to remember important health tasks, and whether it enhances patient engagement and agency in managing a chronic illness	Patients with diabetes and parents managing asthma for child dependents (n=19)	Immunization record	Reviewing and entering data	Three paper prototypes that represented features of a regional health cooperative portal's interface were used	None
11	Hanauer et al [46], 2014	United States	Exploring the frequency, type, reasons, and outcomes of patient-initiated amendment requests	Patients (n=181) for whom amendment requests were made to various clinical departments and divisions but whose medical conditions were unspecified	Medical history, social history, intoxications, family health history, clinic notes, discharge summaries, and emergency department notes	Reviewing and modifying data	MyChart (Epic)	To initiate a chart amendment request, the patient had to contact the information management department by phone, by mail, fax or in person and obtain an amendment request form
12	Heyworth et al [47], 2013	United States	Testing a medication reconciliation tool to improve medication safety among patients who were recently discharged from the hospital	Patients (n=25) with chronic conditions (eg, diabetes, hypertension, prior myocardial infarction or stroke, hyperlipidemia, and heart disease)	Medication list	Reviewing and entering and modifying data	My HealtheVet (The Veterans Health Administration)	Secure Messaging for Medication Reconciliation Tool within the portal
13	Hill et al [48], 2018	United States	Exploring health care providers perceived advantages and disadvantages of PHR portal use	Health care providers (n=26) who treat patients with spinal cord injuries and disorders	Vital signs (blood pressure, pulse rate, and weight), medical history, immunization record, and medication list	Reviewing and entering data	My HealtheVet (The Veterans Health Administration)	None

Number	Study	Country	Study aim	Sample	Type of data	Data activity	Portal	Data entry tools
14	Laranjo et al [49], 2017	Portugal	Examining portal use, associated patient demographics, and clinical variables	Patients (n=109,619), of whom 18,504 were portal users	Vital signs (height, weight, blood pressure, glycemia, cholesterol, and triglycerides levels) and allergies	Entering data	Tethered PHR provided by the National Health Service	None
15	Lemke et al [50], 2020	United States	Exploring primary care physicians' experiences with the Genetic and Wellness Assessment tool for capturing patients' family health history	Health care providers (n=24) who specialized in internal medicine, family medicine, or obstetrics/gynecology	Family health history	Entering data	Epic	Genetic and Wellness Assessment tool
16	Lesselroth et al [51], 2009	United States	Exploring the extent to which kiosk technology improves the reporting of patients' medication history	Patients (n=17,868) visiting a chemotherapy facility	Medication list and list of allergies	Reviewing and entering and modifying data	See Data Entry Tools	Automated Patient History Intake Device accessed via computer terminal kiosk in the clinical waiting room
17	Murray et al [52], 2013	United States	To examine the capacity of 3 different electronic tools for collecting patients' family health history	Patients (n=959) scheduled for an annual examination visit, of which 663 were allocated to the intervention arms (interactive voice response technology, patient portal, and waiting room laptop computer)	Family health history	Reviewing and entering data	Patient Gateway, LMR	The Surgeon General: My Family Health Portrait
18	Nagykaldi et al [53], 2012	United States	Examining the behavior and experiences of patients and primary care clinicians with regard to the Wellness Portal	Patients in primary care (n=560) who were in the randomized controlled trial; 3 clinicians, 2 office staff, and 6 patients in the pilot testing of the portal	Vital signs (weight), preventive services (mammography, diabetes education, and smoking counseling), wellness plan, symptom diary, medical history, medication list, problem list, list of allergies, and immunization record	Reviewing and entering data	Wellness Portal linked to the Preventive Services Reminder System	None
19	Nazi et al [54], 2013	United States	Exploring Veterans' perspectives on receiving access to their personal medical information, which of its data elements they find most valuable, and how it affects their satisfaction, self-management, communication, and health care quality	Military service Veterans in the United States (n=688)	Medication list, list of allergies, and vital signs (eg, blood pressure, blood sugar, and cholesterol)	Entering data	My*HealtheVet* and Veterans Information System Technology Architecture	None

Number	Study	Country	Study aim	Sample	Type of data	Data activity	Portal	Data entry tools
20	Park et al [55], 2018	Korea	Evaluating how and which users are generating and managing their personal and medical data	Patients with diabetes (n=16,729) and general users of the app (n=1536)	Vital signs (blood pressure, blood glucose levels, and weight); the functions list of allergies, medical history, and medication list were excluded because the number of users was relatively small (n=116)	Entering data	Mobile PHR known as My Chart in My Hand	None
21	Powell and Deroche [56], 2020	United States	Exploring the determinants of portal use among patients with multiple chronic conditions	Patients with multiple morbidities (n=500) with diabetes, heart failure, hypertension, and coronary artery disease	Vital signs (eg, weight and blood pressure)	Entering data	FollowMyHealth (AllScripts)	None
22	Prey et al [57], 2018	United States	Exploring the extent to which an electronic home medication review tool engaged patients in the medication reconciliation process and how this affected medication safety during hospitalization	Patients (n=65) arriving at the emergency department and their health care providers (n=20)	Medication list	Reviewing and entering and modifying data	AllScripts	Internally developed home medication review tool
23	Raghu et al [58], 2015	United States	Exploring the extent to which secure messaging helps patients to update their medication list in an ambulatory care setting	Patients (n=18,702) of a clinical practice that focused on surgical care for adults, of which 7818 had portal access	Medication list	Reviewing and entering data	Not specified	A secure messaging feature (alongside phone calls) was used by patients to update their medication list
24	Schnipper et al [59], 2012	United States	Investigating the extent to which a PHR-linked medications review module affects medication accuracy and safety	Patients in primary care (n=541), of which 267 were in the intervention arm	Intervention arm: medication list, list of allergies, and diabetes management information; control arm: family health history	Reviewing and modifying data	Patient Gateway, LMR	Patient Gateway medications module; electronic journals
25	Seeber et al [60], 2017	Germany	Validating the accuracy of VaccApp in helping parents to report their children's vaccine history	Parents (n=456) of infants and children with suspected vaccine-preventable diseases (eg, influenza-like illness or infections of the central nervous system)	Immunization record	Reviewing and entering data	Vaccination app (VaccApp)	None
26	Sun et al [61], 2019	United States	Exploring how patients with type 2 diabetes use their patient portals and what determines their portal use	Parents (n=456) of children with diabetes, of which 178 used the app	Medication list, list of allergies, and medical history	Reviewing and entering data	Epic	Questionnaire for recording medical history

Number	Study	Country	Study aim	Sample	Type of data	Data activity	Portal	Data entry tools
27	Tsai et al [62], 2019	United States	Exploring the characteristics of portal users and the activities that users perform within their patient portals	Patients (n=505,503), of which 109,200 were registered for a portal	Problem list, medication list, and list of allergies	Reviewing and entering and modifying data	MyChart (Epic)	None
28	Wald et al [63], 2010	United States	Exploring patients' and health care providers' experiences of using previsit electronic journals to record core medical data and survey data	Patients in primary care (n=2027 in the intervention arm and n=2345 in the postintervention survey) and 84 physicians	Arm 1: medication list, list of allergies, and diabetes items; arm 2: health maintenance, personal history, and family health history	Reviewing and entering and modifying data	Patient Gateway, LMR	Previsit electronic journals with tailored and untailored questions
29	Yu et al [64], 2015	United States	Exploring and identifying the needs and preferences of individuals with dexterity impairments when they use iMHere.	Patients with dexterity impairments (n=9)	Medication list and problem list	Entering reasons for taking medication and modifying medication reminders	Interactive mobile health and rehabilitation apps. iMHere is a system that connects smartphone apps to clinicians' web-based portal.	MyMeds app (medication management) and SkinCare app (monitoring and reporting skin breakdown)
30	Zettel-Watson and Tsukerman [65], 2016	United States	Exploring the use patterns among users of web-based health management tools and identifying barriers to use among nonusers	Nonclinical population (n=166)	Vital Signs (cholesterol, blood pressure, and glucose levels; uploading data from a monitoring device)	Reviewing and entering data	Most participants used tools provided by their physician's office, hospital, or insurance company (type of records unspecified)	None
31	Siek et al [66], 2011	United States	Testing the usability of an open source, web-based personal health app that provides older adults and their caregivers the ability to manage their personal health information during care transitions	Older adult patients with multiple morbidities (n=31)	Medication list	Reviewing and entering data	Colorado Care Tablet, personal health app	Pharmacy fulfillment and barcode scanning and a Prepare For Appointments wizard
32	Lober et al [67], 2006	United States	Exploring the barriers that older adults and disabled persons face when using PHRs	Nonclinical population (n=38) specified as low-income older adults with disabilities residing in a publicly subsidized housing project	Family health history, list of allergies, medication list, medical history, and immunization record	Reviewing and entering and modifying data	Personal Health Information Management System	A nurse was available to help with data entry
33	Arar et al [68], 2011	United States	To assess the facilitators of and barriers to Veterans' use of the Surgeon General's web-based tool to capture their family health history	Veterans (n=35)	Family health history	Entering data	My HealtheVet (The Veterans Health Administration)	The Surgeon General: My Family Health Portrait

Number	Study	Country	Study aim	Sample	Type of data	Data activity	Portal	Data entry tools
34	Wu et al [69], 2014	United States	Assessing the content and quality of the MeTree family health history tool	Patients in primary care (n=1184)	Family health history	Entering data	MeTree	None
35	Cimino et al [70], 2002	United States	Exploring patients' portal use, the cognitive effects of portal use and how it affects the patient–health care provider relationship	Patients (n=12) and health care providers (n=3)	Vital signs (height, weight, blood pressure, pulse, and temperature) and diabetes diary	Reviewing and entering data	Patient Clinical Information System, New York Presbyterian Hospital clinical data repository	None
36	Witry et al [71], 2010	United States	Exploring family practice physician and staff views on the (dis)advantages of PHR use	Health care providers (n=28) of a family medicine department	Medical history, medication list, and vital signs (blood pressure and glucose levels)	Entering data	Not specified	None
37	Kim and Johnson [72], 2004	United States	Exploring whether and how different types of data entry methods used by PHRs affect the accuracy of patient-generated data	Patients with disorders requiring treatment with thyroid hormone preparations (n=14)	Problem list and medication list	Reviewing and entering data	Password-protected website used to test data entry methods	Free-text entry (recall or abstraction) and selection methods

[a]PHR: patient health record.

[b]LMR: longitudinal medical record.

Table 3. Categorization of patient management papers and study type (N= 37).

Categories	Records[a], n (%)	Study types and references
Frequency of portal use	27 (73)	• Observational [38,42,49,55,56,58,62,70] • Content analysis [44,46,51,63] • RCT[b] [42,53,59,63] • RT[c] [57] • NRT[d] [52] • Cohort [43,61] • Interview [44,47,50] • Usability [47] • Survey [54,65,70]
Facilitators and barriers		
Patient-related	33 (89)	• Observational [38,42,49,55,56,58,62,63,70] • Content analysis [39,44,46,69] • RCT [42,53,63] • RT [57] • Cohort [61] • Interview [44,47,50,66,68,71] • Usability [47,66,67] • Prototype testing [45] • Survey [40,54,65,68,70]
Provider-related	7 (19)	• Content analysis [39,46,51] • Interview [48,50,71] • RCT [53]
System-related	28 (76)	• Observational [55,63] • Content analysis [44,46,51] • NRT [72] • RCT [42,53,63] • Cohort [61] • Interview [44,47,50,66,68,71] • Prototype testing [45] • Usability [37,41,48,64,66,67] • Survey [40,54,65,68]
Impact on patient care	26 (70)	• Observational [29,38,42,63] • RCT [42,53,59,63] • NRT [52,72] • RT [57] • Cohort [43,60] • Interview [44,47,48,50,68] • Content analysis [39,44,46,51,69] • Usability [47] • Survey [40,54]

[a]The total number of records exceeds the total number of included studies because records contributed to more than one category.

[b]RCT: randomized controlled trial.

[c]RT: randomized trial.

[d]NRT: nonrandomized trial.

Actual Use Information

Few Registered Users Enter Core Medical Data

Figure 3 and Table 4 display the distribution of the core medical data components managed (entered, modified, or updated) by the patients in the included records. In more than half (25/37, 68%) of the included records, patients performed predefined data management tasks in which the usability of the tool or the effects of patients' data management on data quality were explored, and 3 records explicitly reported that their patients wanted to update more information than they were allowed to [40,44,45]. Reviewing the 13 papers in which patients' data management was not constrained by task demands [41,46,49,53-56,58,61,62,65,66,70] showed that the percentage of patients making changes to their core medical data ranged from 0.2% [46] to 22% [54] of registered users. Patients appreciated having insight into their recorded data but were otherwise not adding or updating this information [46,56]. A study investigating the number and content of amendment requests showed that over a period of 6 years, the number of

patients requesting changes to their core medical data was extremely small relative to the number of patients requesting access to their patient records (0.2% of the access requests) [46]. Even when patients did request changes to their medical records (N=818), these changes were mostly related to clinical notes (308/818, 37.7%) and discharge summaries (84/818, 10.3%) [46] and not to the core medical data components (eg, admission history and physical; 19/818, 2.3%). In line with this, studies have shown that portal features that only allowed patients to view their medical information [54,61,62,70] or to message their health care provider [41,54,56] were more frequently used than features that allowed the self-entry of medical data. These passive features were valued more than self-entry features [41,54]. When patients did use self-entry features, they seemed to prefer to enter information about their vital signs (eg, blood pressure, blood glucose values, and weight) compared with other core medical data components [41,49,53,55,65,70].

Figure 3. Distribution of the core medical data components managed (entered, updated, and modified) by patients. PEHR: personal electronic health record.

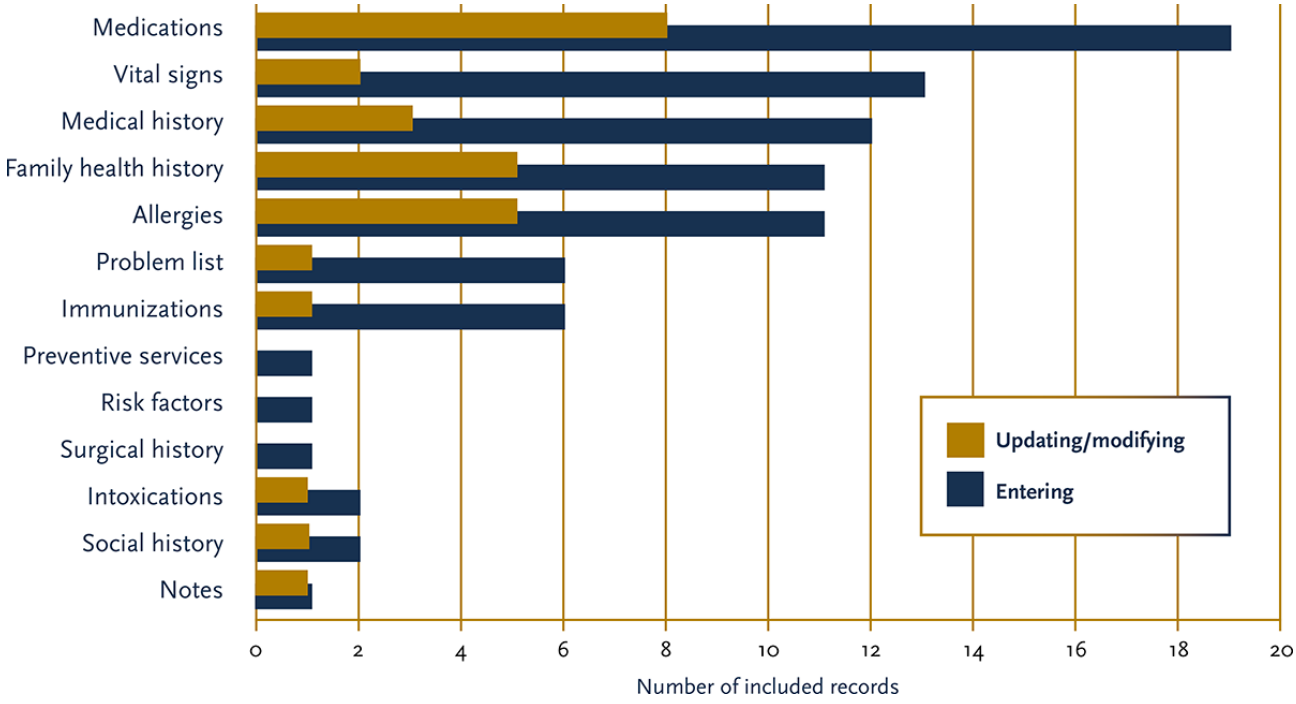


Table 4. Distribution of core medical data components managed and associated tasks across the included records.

Data component and activity, constrained or unconstrained by task demands	Records, n (%)	References
Generating core medical data (entering and sharing data)		
Constrained	24 (64.8)	[29,37-40,42-45,47,48,50-52,57,59,60,63,64,67-69,71,72]
Unconstrained	13 (35.1)	[41,46,49,53-56,58,61,62,65,66,70]
Medications		
Constrained	12 (32.4)	[42,44,47,48,51,57,59,63,64,67,71,72]
Unconstrained	7 (18.9)	[53-55,58,61,62,66]
Vital signs		
Constrained	5 (13.5)	[38,48,59,63,71]
Unconstrained	8 (21.6)	[41,49,53-56,65,70]
Medical history (including personal history)		
Constrained	8 (21.6)	[29,37,39,42,48,63,67,71]
Unconstrained	4 (10.8)	[46,53,55,61]
Family health history		
Constrained	10 (27)	[29,40,43,50,52,59,63,67-69]
Unconstrained	1 (2.7)	[46]
Allergies		
Constrained	5 (13.5)	[42,51,59,63,67]
Unconstrained	6 (16.2)	[49,53-55,61,62]
Problems list (including symptom diary and health conditions and issues)		
Constrained	4 (10.8)	[29,42,64,72]
Unconstrained	2 (5.4)	[53,62]
Immunizations		
Constrained	5 (13.5)	[39,45,48,60,67]
Unconstrained	1 (2.7)	[53]
Preventive services		
Constrained	0 (0)	—
Unconstrained	1 (2.7)	[53]
Risk factors		
Constrained	1 (2.7)	[29]
Unconstrained	0 (0)	—
Surgical history		
Constrained	1 (2.7)	[39]
Unconstrained	0 (0)	—
Intoxications		
Constrained	1 (2.7)	[39]
Unconstrained	1 (2.7)	[46]
Social history		
Constrained	1 (2.7)	[39]
Unconstrained	1 (2.7)	[46]
Clinical notes, discharge summaries, and emergency department notes		
Constrained	0 (0)	—

Data component and activity, constrained or unconstrained by task demands	Records, n (%)	References
Unconstrained	1 (2.7)	[46]
Managing core medical data (updating, modifying, and requesting changes to data)		
Constrained	8 (21.6)	[40,44,47,51,57,59,63,67]
Unconstrained	2 (5.4)	[46,62]
Medications		
Constrained	7 (18.9)	[44,47,51,57,59,63,67]
Unconstrained	1 (2.7)	[62]
Vital signs		
Constrained	2 (5.4)	[59,63]
Unconstrained	0 (0)	—
Medical history (including personal history)		
Constrained	2 (5.4)	[63,67]
Unconstrained	1 (2.7)	[46]
Family health history		
Constrained	4 (10.8)	[40,59,63,67]
Unconstrained	1 (2.7)	[46]
Allergies		
Constrained	4 (10.8)	[51,59,63,67]
Unconstrained	1 (2.7)	[62]
Problem list (including symptom diary and health conditions and issues)		
Constrained	0 (0)	—
Unconstrained	1 (2.7)	[62]
Immunizations		
Constrained	1 (2.7)	[67]
Unconstrained	0 (0)	—
Intoxication		
Constrained	0 (0)	—
Unconstrained	1 (2.7)	[46]
Social history		
Constrained	0 (0)	—
Unconstrained	1 (2.7)	[46]
Clinical notes, discharge summaries, and emergency department notes		
Constrained	0 (0)	—
Unconstrained	1 (2.7)	[46]

Continued Use Drops as Time Increases

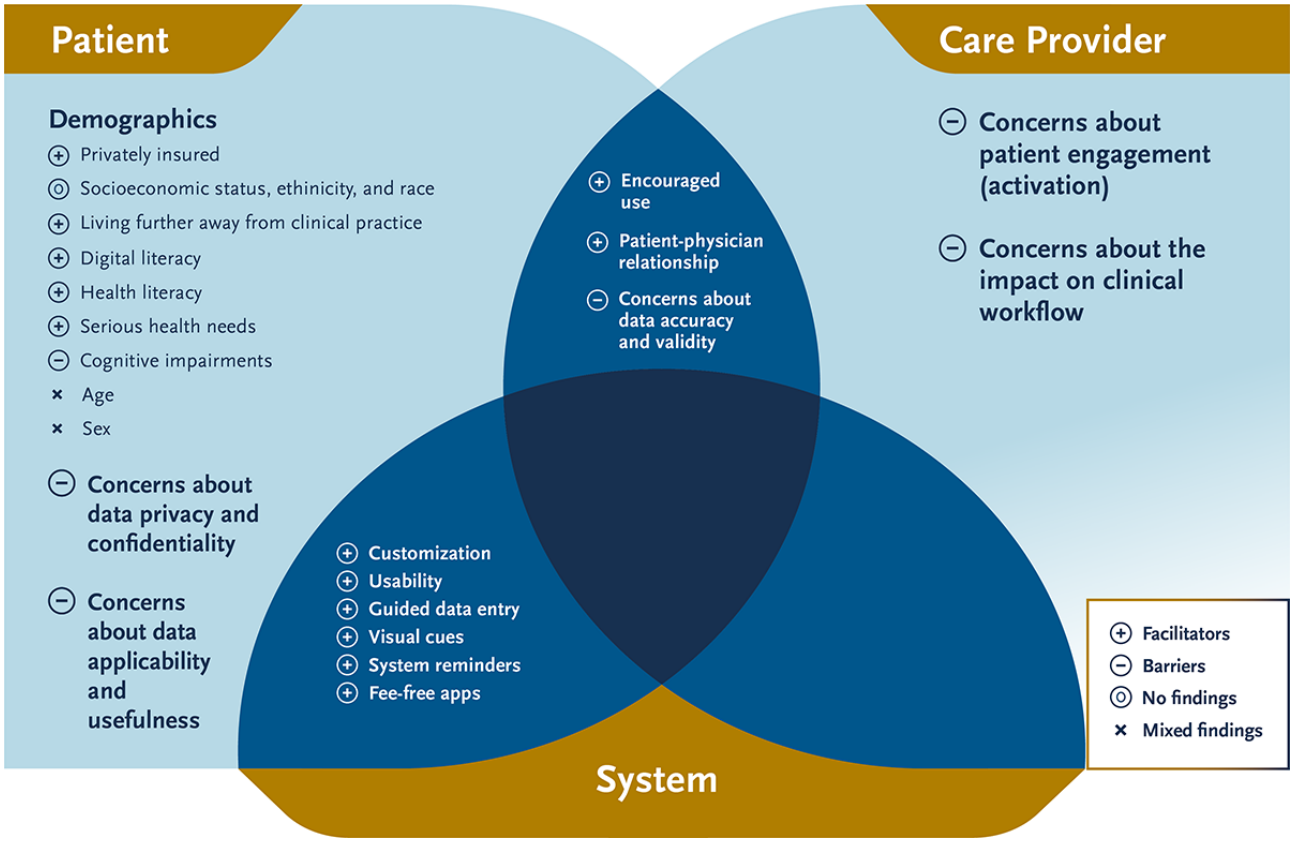
Of the 37 included studies, 23 (62%) provided information about the frequency of patients' portal uptake [38-40,42-47,49-51,53-58,61-63,65,70]. Most of the sample (>50%) used the portal's features [42,47,53,54,70] or specific tools [57], such as an app [43], electronic journal [63], or a computer terminal kiosk in the lobby [51], to enter or update their core medical data in only 9 (24%) of these records. In the remaining studies, a minority of patients (ranging from 0.04% to 44.16% of the population) used the portal's features [45,46,49,55,56,58,61,62,65], an implemented flow sheet [38], a questionnaire [39], a feedback form [44], or a family health history module [50] to manage their core medical data. Most of these records identified patients' use patterns at a specific time point, and only 19% (7/37) of the records explicitly considered patients' frequency of portal use over time [42,49,53-55,61,70]. These latter studies showed that although active portal users usually have more multiple inputs than passive users [42,49], continued use is very limited. Users who

manage their data for longer than a year represent only 5% to 9% of the user population [42,53-55,61], and continued use further decreases as time increases [45,55,61,70]. In the remainder of this paper, we explore what prevents patients from actively managing or helps patients to actively manage their core medical data.

Factors Affecting Active Data Management

We categorized the facilitators and barriers associated with patients actively managing their core medical data through a patient portal into one of the three categories: those dealing with patient characteristics, those dealing with health care provider characteristics, or those dealing with system characteristics. A brief overview of how the important factors affecting patients' personal data management are related to each other is presented in Figure 4.

Figure 4. Patient-related, health care provider–related, and system-related factors affecting patients' management of their personal and medical data.



Patient-Related Determinants

Overview

We identified the following 6 themes that determined whether patients entered, updated, or modified their core medical data: patient demographics; digital and health literacy; concerns related to the accuracy, validity, privacy**,** and confidentiality of recorded data; misconceptions about the applicability; and usefulness of patient-entered data.

Patient Demographics

There is little consensus on whether and how a patient's age or sex influence active data management. While 6 retrospective studies indicated that younger patients are more likely to manage their core medical data [38,42,49,58,61,65], 4 similar studies showed the exact opposite pattern [55-57,62]. In all records, comparisons were predominantly made within rather than across age categories. Taken together over all included records, we see that the age of active portal users ranges from approximately 30 to 70 years [38,42,55,61,62,65], with the most active users being more likely to be in their 30s or 60s [62]. In terms of patients' sex, in 4 retrospective studies, active portal users were more likely to be male than female [42,49,55,61], but 2 other similar studies showed the opposite [62,65]. Thus, age and sex are not very indicative of patients' level of involvement in the generation and management of their core medical data. It may be more informative to look at other patient demographics.

A total of 5 (13.5%) retrospective studies showed that compared with inactive or less active users, active portal users are more likely to be privately insured [58], to have a higher median household income and education level [61], to live farther away from a clinical practice [56], or to reside in urban centers [49,61]. Furthermore, 3 retrospective use pattern studies did not find any significant differences in socioeconomic status, race, or ethnicity of active versus nonactive users [38,42,62]. In 2 other retrospective studies [42,57] and 1 cluster randomized controlled trial [53], active users were found to be digitally competent with a computer or tablet and were already using technology to improve their health [53]. In addition, 3 retrospective user evaluations showed that active users wanted to ensure that their provider had the most accurate and complete information [40] and reported to have already managed their

medical data offline [42] or on the web [65]. We also found that active use might depend on patients' medical condition and health needs, as user pattern studies have shown that active users have a more serious health condition [38,42,53,56,57,61,70] and more clinical encounters [38,62] than other users. In a related vein, a randomized pilot study showed that active users were more interested in improving their understanding of their medical problems and treatments [54]. A usability study showed that cognitive impairments (eg, Alzheimer disease and dementia) and physical limitations (eg, hearing and vision impairments and joint diseases) negatively affected patients' ability to independently manage their medical data in an electronic system [67].

Digital and Health Literacy

Limited internet or computer access, digital illiteracy, and computer anxiety are barriers to patients entering and modifying their core medical data electronically [67,68]. Interviewed users of a web-based family health history tool reported that a lack of knowledge about how to use a computer or web-based technology might limit patients' ability to manage their data electronically without assistance, especially when tasks become more complex [68]. In addition, older adult patients with disabilities reported that their lack of understanding or knowledge of the terminology used for core medical data and how they should report it prevented their data entry [67]. This negative impact of health literacy on active data management was also addressed by interviewed primary care physicians evaluating another implemented family health history tool [50] and by patients recording their family health history in a retrospective data analysis [69] and a user evaluation study [40].

Concerns About Data Accuracy and Validity

An interesting factor that might explain whether patients manage their core medical data is their belief and reassurance that they are not bypassing clinical staff by directly entering or modifying their data in their record [44,45,66]. Patients with multiple morbidities [66] and patients with diabetes or parents managing asthma for their children [45] reported that they preferred having health care providers updating their medical record on their behalf, in fear that their own modifications might alter their physicians' information. In addition, interviewed patients with chronic conditions (ie, chronic obstructive pulmonary disease, asthma, hypertension, diabetes, or heart failure) who were reviewing and modifying their medication list indicated that they found it reassuring to know that all recommended changes were first checked by their provider before they were actually recorded in their medical records [44]. This reassurance can be corroborated by implementing visual features or cues into the interface that convey that patients are modifying personal information that is independent from their physician's records [66]. Patients might also fear that they will provide inaccurate information to their caregivers because they cannot reliably recall medical information such as their family health history [40,43]. Patients who generated their family health history using prepopulated questionnaires stressed that they wanted to include this uncertainty in their records, explicitly stating that they would be more willing to share medical information if they could provide more contextual information to the reported data [40].

Concerns About Data Privacy and Confidentiality

Concerns about data loss and breach of privacy further prevent patients from maintaining their medical records electronically [40,65,68,71]. Patients seek the assurance of data confidentially and protection of their privacy. In a focus group interview, health care providers voiced that patients might fear that their identity might be stolen or that they might purposely omit medical information in fear that it might affect their health insurance or future employment [71]. This concern was indeed confirmed by patients evaluating an implemented family history module in a survey [40] and interview study [68] and by a nonclinical population reporting on their experience with web-based health management tools [65]. Owing to privacy and autonomy concerns, patients do not prefer to share identifiable information, such as their relatives' names and ages [40].

Perceived Applicability and Usefulness

(Mis)conceptions about the applicability and usefulness of patient-generated health data may also prevent patients from taking on a more active role in the management of their personal and medical data via a PEHR. As was mentioned by interviewed patients [66] and interviewed health care providers [71], patients may not see the need to manage their medical information in a web-based portal, as they assume that their providers have access to and share more medical information among specialists than they actually do. Moreover, patients reported that not knowing the benefit of managing and updating medical information [65] or not knowing whether their health care provider actually used the information and found it to be useful [63] prevent their active participation.

Health Care Provider–Related Determinants

Overview

Encouraged use by health care providers and the patient-clinician relationship are identified as the 2 important factors determining whether patients actively manage their core medical data. However, we noticed that health care professionals' recommendations to use the system are dependent on whether they believe that there are benefits associated with patient-entered data in terms of data quality and reliability and cost-effectiveness.

Encouraged Use

Being encouraged by health care providers to manage core medical data plays an important role in the adoption and continued use of PEHRs among patients. First, in both a qualitative content analysis of patient-initiated amendment requests [46] and in a retrospective use pattern study by Ancker et al [38] in which patients managed their blood glucose values, it was suggested that the low amount of generated data was caused by patients not knowing whether they could make changes to their records or how they should go about it. Second, most (84%) respondents voiced that they used web-based health management tools because they were recommended to do so by their clinician [65]. Clinicians also realized that their own

recommendations are important and that reminding patients to use the tools is an important activator of portal use [53]. Clinicians even went so far as to suggest that portal use could be a prerequisite for receiving regular care [53]. In addition, showing the added value of patient-generated health data during an outpatient visit might stimulate patient participation [45,65,67]. Patients with multiple morbidities in a retrospective user pattern study indicated they would stop using tools to record and maintain their core medical data if they did not have someone showing them how to use them, especially when they found it to be difficult to use the tools [65]. In particular, older patients with disabilities both seek and need assistance when it comes to entering and modifying their electronic core medical data [67].

We identified several beliefs that health care providers have about patient-generated and patient-managed medical data that may determine whether they are likely to encourage or assist their patients in managing their core medical data in their PEHR. First, health care providers are often unaware of the benefits that are associated with patients' management of their own data [71]. Second, health care providers do not believe that their patients are motivated [71] or able to provide and maintain accurate and reliable information [44,48,71]. Moreover, health care providers may believe that reviewing patient-entered data may have a significant impact on time spent on outpatient visits and practice workflow [39,46,48,50]. Interviewed physicians who treated patients with spinal cord injuries and disorders voiced concerns that a patient's medical and emotional state may affect their ability to record their data in a reliable fashion and that if patients misinterpret data retrieved from the portal, it might negatively affect their own documentation [48] or treatment information [71]. Pharmacists [44] and family physicians [71] were also skeptical about their patients' ability to enter core medical data accurately. Physicians of a family medicine department explicitly voiced concerns that patient-entered data might be subjective and that health care providers should, therefore, always be in control of data input. Physicians stated that their patients may not know what is appropriate to put in their health records, causing them to enter information that is verified by a professional. They even believed that allowing their patients to enter information into their medical records might facilitate narcotics abuse because patients could inappropriately request or elicit prescriptions [71]. Furthermore, the time saved by having patients enter their own data may be counterbalanced by the time it takes for providers to review patient data [39,46]. Health care providers who treated patients with spinal cord injuries and disorders stressed that checking the patient portals impacts their time and workflow [48]. This view was shared by health care providers who specialized in internal (family) medicine, obstetrics, and gynecology in a study that explored their initial experiences with a family history screening tool implemented in a patient portal. Physicians reported a lack of time for using the tool and stressed that patient-generated and -managed data may only benefit their workflow if patients are able to fill out all the information before their outpatient visit [50].

Patient-Clinician Relationship

Patients testing a medication reconciliation tool via a secure messaging feature within the portal indicated that they appreciated the possibility of communicating directly with health care providers when they had questions about their medications or wanted to request refills. Most (90%) users said they would use the tool again, frequently emphasizing how it allowed them to have instant access to their health care provider [47]. On a related note, patients may refrain from managing their medical data if they want to avoid communicating with their clinicians. Patients with diabetes and parents managing asthma for dependent children voiced that they would rather not use the secure message feature when they did not trust or like their health care provider [45]. This study recommends design implications for the portal that could amplify the positive aspects of the patient–health care provider relationship, such as profile pictures accompanying health care providers' messages or allowing patients to view or hide profiles from a care team in the portal.

System-Related Determinants

Overview

Patients' satisfaction with the system used to collect and maintain their core medical data is an important factor that stimulates active data management [44,64]. A total of 6 main themes emerged from the data extraction that concerned system-related facilitators and barriers affecting patients' satisfaction with the tools used to record their medical core data: the level of customization, usability of the system or tool, guided versus free data entry, presence of visual cues, reminders, and fee-free access to the system/tool.

Customization

A total of 4 studies stressed the importance of offering a level of customization to patient portals [45,63,64,66]. To increase the usability of the system, patients could be allowed to prioritize frequently used portal features [45,63] by, for instance, adding these features to the front page of their portal [45]. Patients also prefer to personalize the system by assigning a personally selected background [64] or self-selected icons for portal features [66], increasing or decreasing the size of these buttons/icons [64], and changing the background and text colors to improve the readability of the portal [64].

Usability

Patients' (continued) use of their electronic patient portal to generate and update their core data depends on the perceived complexity and thus the usability of the system or tools used [37,45,47,63,64,66,68]. Failure to record and maintain core medical data might result from patients not finding the area where it should be recorded [45] or because patients might misinterpret medical terms or encounter terms within the portal that they do not understand, causing frustration and self-doubt [37]. In general, participants prefer to have clear on-screen instructions and directions [53,64,66,68] and short drop-down menus [53]. Using thematic colors also improves the usability of a system [64]. Patients also prefer to have access to previously entered data and to be allowed to mark this information as

unchanged when updating their core medical data in the system [63].

Guided Data Entry

Unless patients are being asked to enter information about simple diagnoses or prescriptions, systems should use guided entry of data elements [55,66,72]. Patients in 5% (2/37) of studies experienced problems during medication reconciliation when asked to enter their medication names into the system [55,66]. It was for this reason that they were reluctant to provide additional dosage and scheduling information [66]. Patients prefer a less textual way of adding medications to their list, voicing that free-text entry is too complex and time-consuming [66]. To aid the reviewing process, a prepopulated medication form [55] or a barcode scanning function [69] could be used, especially when patients need to report on a large number of medications [55]. Autofilling processes also give patients some reassurance about the accuracy of their data entry [66]. Free-text entries are undesirable when patients are asked to add information to their problem list, as they may be inclined to include extraneous information that does not contribute to the identification of a primary diagnosis [72]. However, in a study exploring patients' experiences with a family history tool [40], patients reported on the danger of using closed answer options. The patients expressed concerns that some answers did not allow for sufficient granularity and reliability, arguing that their family history was often far more complex than what they were allowed to record. These patients also preferred to receive more clarity and information about the diseases that they were asked to report. Allowing patients to provide contextual information when they have the desire to do so might reassure them about their answers' validity [40].

Visual Cues

Implementing visual feedback facilitates data entry by patients and patients' satisfaction with using the system. For instance, providing medication pictures alongside a selected medication assists patients' medication reconciliation [51] and allows them to confirm whether it is the correct medication to add [66]. In addition, patients prefer to receive clear feedback when performing an action within the system, such as seeing a medication being highlighted after they suggest it should be deleted from their list [66]. Visual feedback in the form of using red and green colors also helps patients to take further actions such as scheduling alerts to take the medication when a new medication is added to the list [64]. Using colors is also beneficial when they are used to demarcate separate body parts, helping patients to correctly specify the location of the problem skin areas [64].

Reminders

If reminded to do so, patients are more likely to use the portal before and after their outpatient visits [26]. Reminders generated through the portal stimulate patients to access their records [26] and enter information about their medications, allergies, and vital signs [54].

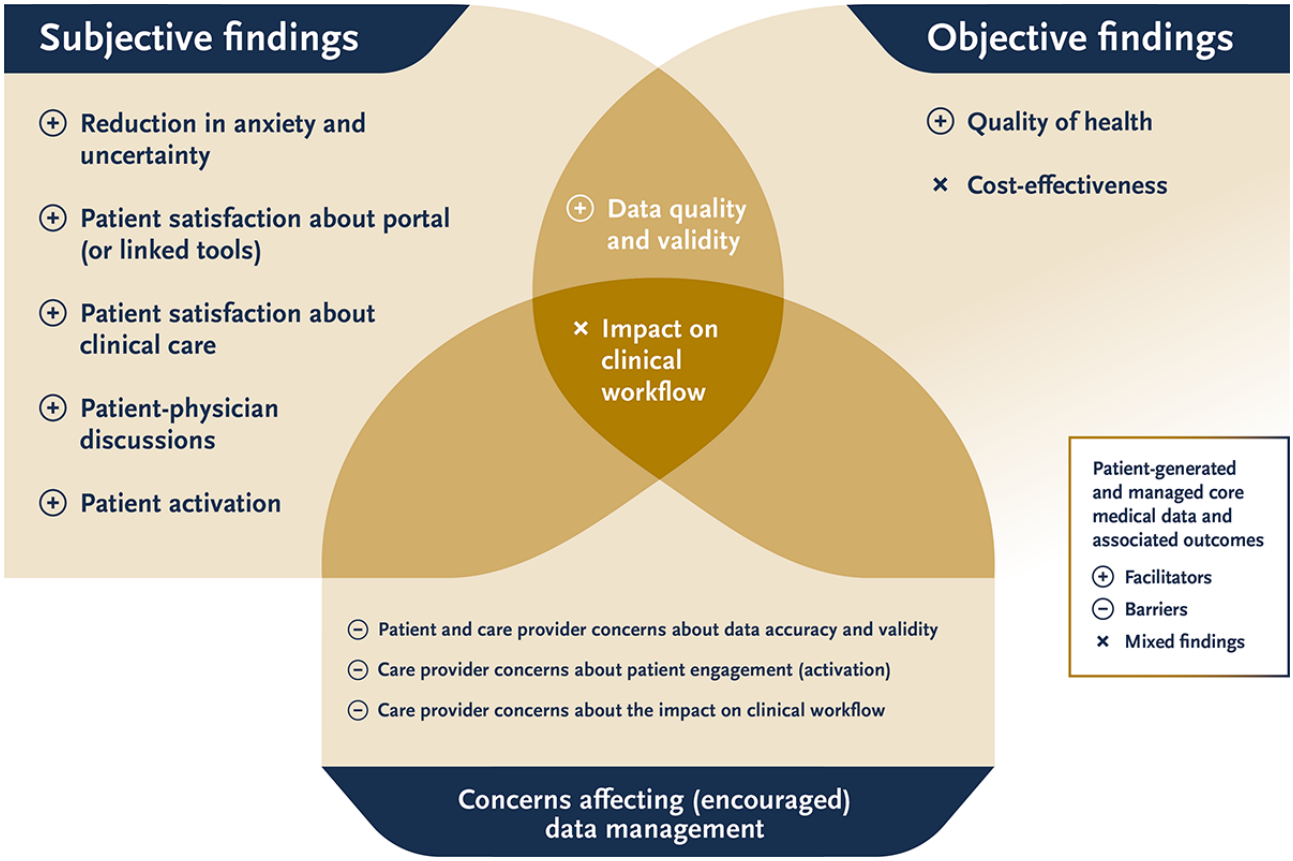
Fee-free Apps

Providing applications without charge [41] that can be downloaded by patients as well as by a more general group of users [55] stimulates the accumulation of patient-generated core medical data. A study that focused on patients' diabetes management [41] showed that patients believed that implementing fees for portal access would significantly reduce their tendency to use the portal for the self-management of their diseases. The implementation of portal fees seemed unfair according to patients because health systems also benefit from patients' self-management of their disease. Patients believed that introducing fees would increase inequities between patients who can and cannot afford using the portals, and they also feared that costs would increase when previously free services would start requiring payment [41].

Impact on Patient Health and Health Care Services

This section describes the impact of patients' data management on the quality and safety of patient care, psychological outcomes for patients, patient engagement, patient satisfaction, and clinical workflow. Figure 5 presents the important subjective and objective outcomes identified and how they are related to the concerns of both patients and health care professionals.

Figure 5. Impact of patient-generated health data (PGHD) on patients' health and health care–related services and how this impact is associated with the important concerns regarding PGHD raised by patients and health care providers.



Data Quality and Validity

Clinicians' concerns about the quality and validity of patient-entered data seem to be unfounded. Observational [29], experimental [52,57,72], usability [47], cohort [60], and content analysis [44,46,69] studies have shown that medical records are completer and more accurate when the data are generated by patients themselves. Patients are able to accurately self-report on their diagnoses [29,72], medications [29,44,47,57], medical or surgical history [46], family health history [52,69], or their children's vaccination history [60]. Patients request changes to their core medical data especially when this information is incomplete [46,47,59] or incorrect [46], and these requests are approved in approximately half [46] up to 80% [44] of cases. Studies have reported on improved medication reconciliation [44,47,51,57,59], arguing that patients' management of their medical data makes them more attentive to medication safety and monitoring [42,44,47] and even helps clinicians to identify (potential) lethal medication discrepancies [51]. In addition, the quality and validity of patients' problem lists [29], immunization records [60], and family health history [43,52,69] improves when patients enter and manage their own medical data. Clinicians even felt that the risks identified because of patients entering their family health history helped them to make informed changes to their patients' medical management [50]. Pharmacists reported being surprised to learn about patients' willingness and ability to report their medications accurately, even when patients were taking >20 medications or were taking medications that had been prescribed by physicians who were not part of the current health system [44]. Only 1 content analysis study did not show the added value of patient-generated data [39]. In this study, patients entered information about their medical, surgical, and social history, using closed question questionnaires with "yes" and "no" answer options. Patients were allowed to give additional information in the comments section. The researchers concluded that the new information added to a patient's record often lacked sufficient granularity to be found meaningful. However, they did not reflect on how the closed nature of the questionnaire could have contributed to this outcome.

Quality of Health

Another theme we identified was a significant objective [38,53] and subjective [42,63] improvement in patients' health because of them actively managing their medical data. First, an observational study of patients with diabetes who were uploading (and thus tracking) their blood glucose values showed a significant drop in their average BMI and mean glycated hemoglobin values compared with nonuploaders (nontrackers) [38]. Second, patients who entered and tracked their vital signs and preventive services were more likely to receive all recommended immunizations than control groups [53]. These objective findings are corroborated by patients' self-reports [42,63]. Older adults reported more changes in medication use and improved medication reconciliation behaviors than less active recorders and nonrecorders. These patients also reported more side effects [42]. In a similar vein, patients in primary care who entered and modified their lists of medications and allergies felt that their health care provider had more accurate information

about them and that this improved the quality of care at the visit [63].

Psychological Outcomes for Patients

Insight into medical data might reduce anxiety and uncertainty in patients. This point was explicitly raised by interviewed health care providers who were evaluating a tool that helped the patients under their care to report on their family health history to identify possible genetic diseases [50]. Patients felt less anxious when the tool identified no increased risk and they were able to discuss the findings with their clinician.

Patient Engagement

We identified two themes in this subsection: (1) the extent to which patients' data management improves patient-physician discussions and (2) feelings of ownership among patients and future patient participation.

Improved Patient-Physician Discussions

Patients who update their core medical data before an outpatient visit, feel better informed [44] and better prepared for the visit [44,63,70] and experience improvement in their interaction with their health care providers [50-52,54,59,63,65,70]. Patients indicate that they can provide more comprehensive information about complex and sensitive health issues at home than in their physician's office because in the latter case, they feel more stressed and uncomfortable [40]. Patients [43,52] and primary care physicians [50] believe that patients who update their family health history are more aware of its (medical) importance, facilitating both patient-physician [50,52] and patient-family [43,50] discussions about associated family history–related health risks and ways to improve their health. Patients who manage their vital signs data prepare their questions before visiting their provider [70], thereby improving treatment-related discussions and decisions [65,70]. Regarding medication reconciliation, nurse practitioners mentioned that allowing patients to review, update, and modify their medication lists improved their medication dispensing information and identification of errors [51,59]. In their turn, practitioners [51] and patients in primary care [59] stated that patients asked more questions about their regimens [51], were more likely to report adverse reactions [51] or to address medication-related problems and new symptoms [59], and requested more refills for medications that were nearing their expiration date [51]. Active patients feel more confident when asking questions about medications during their outpatient visits [44], and they recall more questions that they want their physicians to answer. Patients also feel that such preparation saves time during the visit [63] or even reduces the need for an outpatient visit [44]. This viewpoint is shared by primary care clinicians, who stress that they would recommend that other clinicians ask their patients to review, update, and modify their list of medications, allergies, and diabetes items before an outpatient visit [63].

Patient Activation

Patients who generate and manage their own medical data feel that they have more control over their health care and health-related decisions [40,44,53,65,70,71]. A randomized controlled trial comparing patients who managed their core medical data against nonactive patients showed that active patients were not only more confident and knowledgeable about their health in general and about making health-related decisions but were also more likely to actually take action to improve their health [53]. These findings are supported by studies that focus on patients who managed their family health history [40,68], vital signs [65,70,71], medical history [71], and medications [44,71]. Patients feel that their participation improves their clinician's knowledge [40,70]. Patients experience a sense of ownership when they manage their own medical data [70] and report that they consider their contributions to be valuable to an extent that makes them feel empowered [40] and motivated [68] to improve their health condition. This viewpoint is shared by family physicians [71] and health care providers who treat patients with spinal cord injuries and disorders [48]. These clinicians feel that if patients maintain their medical data, they may become more organized and adherent to medications [48] and improve their involvement in their care, which may result in better outcomes [71].

Patient Satisfaction

Patients were generally satisfied with the tools that they used to update their medical data [43,63,64,68]. Only 2 records discussed whether active management of data by patients affected patients' satisfaction with their clinical care [40,63]. One of these records measured patient satisfaction using a 1-item survey question [63], showing that 37.7% of the respondents were more satisfied with their visit after they had first entered or updated their medical information using electronic journals implemented in a patient portal. The second study found that their patients were more satisfied with reviewing their free-text responses after they had entered or updated their family health history in their web-based records [40]. In the comment section of that study [40], patients reported that they felt welcomed, cared for, and safe when asked to share their medical information.

Impact on Clinical Workflow and Costs

A study that interviewed health care providers who treated patients with spinal cord injuries and disorders found that health care providers believed that patient-generated health data collected via patient portals can improve the coordination of medical care, especially for those patients who receive health care in nonclinical settings [48]. However, we found mixed evidence concerning the effects of patients' active management of their medical data on clinical and patient throughput. Both clinicians [57,70] and patients [63,70] believed that asking patients to review and update their medical data before an outpatient visit positively affects clinical throughput because consultations can be executed more efficiently. For instance, pharmacists and physicians stated that they spent half of the usual amount of time on medication reconciliation on outpatient visits when patients generated this information themselves [44]. Active involvement of patients in the generation and management of their data may even reduce the need to schedule an outpatient visit [44], especially when physicians can address their patients' questions via a secure messaging feature [48]. However, interviewed family physicians were concerned that patient-generated data would negatively impact consultation

time if it required logging in and searching for relevant information [71].

We identified only 4 records that objectively measured the cost-effectiveness of patients' data management. A retrospective cross-sectional study investigating the impact of patients updating their medication list via a secure message feature showed that its use did not significantly decrease the cost burden of outpatient clinics [58]. However, another retrospective study found that asking patients to review and update their medical history via a computer terminal kiosk in the waiting room of a chemotherapy clinic reduced the medication reconciliation time by nearly 50% [51]. A retrospective longitudinal cohort study also found that active portal users were less likely to contact or visit their health care providers [61], whereas another retrospective analysis of portal use showed that nonusers visited the emergency room more often than active users, even though active users had more outpatient and inpatient visits [62].

Discussion

Principal Findings

This synthesis of literature explored the barriers and facilitators that patients face when they decide to generate and manage their core medical data in (tools linked to) their PEHRs. First, we found that a minority of registered users entered, updated, or modified their personal and medical data. More specifically, less than half of the registered users entered their data and less than a quarter of users updated or modified their already recorded data; continued use further dropped to <10% of the user population as time increased. Patients preferred to take on a passive rather than an active role regarding the self-management of their health information, and they seemed to prefer tracking vital signs above more complex medical information, such as medications and their family health history. We identified both patients' and health care professionals' (positive) perceptions about the validity, applicability, and confidentiality of patient-generated data as well as patients' digital and health literacy as important facilitators of patients' active management of their personal and medical data. However, we also found that patients' and health care providers' concerns about the validity and applicability of patient-generated data seem to be unfounded. Patients accurately reported on their diagnoses, medications, immunizations, medical history, and family health history, making their medical records more complete. Moreover, patients who managed their medical data felt more knowledgeable, more in control of their own health care, and more adherent to their treatment than less active patients. Both patients and clinicians felt that active patients were also more prepared for their clinical visits because they knew which questions they wanted answered by their health care provider. In the following sections, we propose recommendations that health care practices can adopt for stimulating patient participation in the generation and management of their electronic core medical data.

The Health Care Provider as Ambassador and Gatekeeper

Patients felt that they were bypassing clinical staff when they self-managed their medical data. Patients were concerned that they would provide their physicians with inaccurate information, especially when the nature of the medical information is complex and sensitive. Clear guidelines and information regarding the added value of patient-entered data for both patients and clinicians may reduce these concerns. Clinical staff are important ambassadors for informing their patients about the added value of patient-generated and management data and in reminding and encouraging their patients to prepare themselves for each visit by reviewing the medical data in their PEHRs. Moreover, we also found that self-management of medical data may be higher for those patients who feel that they are able to directly contact their provider for support. Design features within the PEHR systems that amplify the visibility of the health care providers' availability for support and guidance as well as visual feedback elements in the PEHR system that indicate to the patients that their entered or modified data will be checked by a professional may reassure patients that they are not altering their medical record without their provider's knowledge or approval.

Ethical and Comprehensive by Design

We also found that patients were generally concerned that their medical data were unprotected against unauthorized access and could, therefore, be used for non–health care–related purposes. Stressing data confidentiality and allowing patients to give their informed consent on an opt-in and opt-out basis may diminish their potential unease about confidentiality. Furthermore, we have also seen that customization features may enhance the self-management of core medical data because they make the system more understandable and easier to use. Helping patients to remember medical information by using prepopulated forms or guided data entry might further aid and encourage them to record information that might be inaccurate. This may also address health care providers' concerns that patients are not able to accurately report on their medical information.

Future Directions

On the basis of our findings and recommendations, we have outlined several priority questions for future studies (Textbox 1) that we address briefly in this section. The first 2 questions are related to the finding that health care providers play an important role in their patients' uptake and continued use of (tools linked to) their PEHRs to manage their core medical data. It is still not known what providers need for addressing their concerns about the validity and applicability of patient-generated data. Thus, we invite future studies to explore the needs of professionals in terms of (portal) assistance or (system) requirements so that they are willing to encourage the practice of patients' self-management medical data and their patients feel stimulated and supported to manage their core medical data during their entire care journey as a result.

Textbox 1. Priority questions for future research based on our 3 recommendations.

1. The health care provider as ambassador and gatekeeper

- What are the unmet needs of health care professionals with respect to encouraging and supporting their patients to share and manage their personal and medical data during their care journey?
- What are the unmet needs of patients in terms of feeling encouraged and supported by their health care providers to share and manage their personal and medical data during their care journey?

2. Ethical and comprehensive by design

- What do patients need in terms of assistance, support, and system requirements, to generate and manage their personal data during their care journey?
- To what extent does the type of personal and medical data affect patients' data management?

3. Stimulating the patient-provider partnership

- When do patients consider themselves to be "active" managers of their personal and medical data, and to what extent does this correspond to health care professionals' perspectives?
- To what extent do patients' perspectives on their personal data management activity and role preference affect their data management?

For fear of reporting inadequate information, patients prefer to report their core medical data in a structured, guided manner. Our review showed that this was the case for data that were perceived to be error-prone and sensitive, such as information about the types, names, and dosages of patients' medications or information about patients' family health history that would be used for genetic counseling. This finding corresponds to the findings of Esmaeilzadeh et al [73], who showed that individuals were more willing to share sensitive and private information about their mental or physical illnesses when they could enter this information by following a structured, organized, and predefined data entry model, as opposed to using an unstructured, text-heavy interface [73]. Taken together, this seems to indicate that guided data entry interfaces may stimulate patients to share personal health information they would not otherwise share because they do not feel confident or knowledgeable enough to share it or because confidentiality or privacy concerns prevent them from doing so. However, we also found that in case of sensitive information, patients may feel that closed answer options do not offer sufficient granularity and feel the need to add additional contextual information to their answers. Hence, we invite future studies to explore the extent to which patients' preference for structured data entry models is dependent on the type of data that they wish to record.

We have also shown that patients prefer to update and monitor data about their vital signs (eg, blood glucose levels and BMI) over updating information about their medications, allergies, intoxications, and social and family history. To the best of our knowledge, no studies to date have examined the reasons for these differences. On the basis of the findings of our review, we hypothesize that patients prefer to manage data about their vital signs to managing information about other core medical data because they are trackable over time and thereby give patients a more direct, visible insight into their health status compared with other core medical data. We encourage future studies to explore this explanation.

We have shown that the number of studies that focus on actual portal use—by exploring how patients use their portal, whether and when patients consider themselves to be active users, which data patients share, and how frequently they do this—remains scarce. Interestingly, it is not common practice for patient data management papers to describe in full detail whether, how, and how frequently and what type of medical information is entered, updated, or modified by patients. We believe that this is mainly caused by an undifferentiated definition of the term "active user." In the retrieved literature, users were predominantly considered to be active based solely on whether they activated their account [74], the number of times they logged in or accessed a certain page or implemented tool [75], or their self-reported (undefined and abstract) use of the portal [76]. Patients were described to be active when they performed an activity once [40,42,53,56-58,65,67,70], more than once [49], >3 times [38], >20 times [61], or more than once every 4 months [62]. It would be a promising endeavor for future research to define "active data management" from both the patients' and their care professionals' perspectives.

Our findings are in line with research that has investigated the extent to which patients participate in making decisions together with their physicians regarding treatment plans. Shared decision-making entails the collaborative exchange and discussion of health care information among patients and their health care providers, including information about patient preferences and the pros and cons of all possible treatment options [77,78]. Collaboration is the key here [79], meaning that both patients and health care providers are jointly responsible for reducing asymmetries in information exchange so that treatment decisions that patients can adhere to because they optimally align with their wishes and abilities are reached [80]. One line of research claims that not all patients have the desire to participate in decision-making processes [80-82] and that this is especially the case for older and less healthy patients who, ironically, might benefit the most from being involved [83]. Another line of research claims that most patients do in fact want to be informed and involved, but that they cannot fulfill this desire because it is not acknowledged or afforded to them by their health care provider [80,84]. Patients' preferred and assumed roles often do not match [85], leading to decisional role regret [86]. In many cases, physicians do not know their

patients well enough. Patients believe that the medical expertise and knowledge of their health care provider are more important than their own knowledge and preferences. Thus, our advice is to inform patients about the complementary value that they bring to the shared decision-making process and to improve patients' confidence in their capability to acquire and understand the information that is necessary to make informed decisions based on the available options [84,87]. Our literature review showed that these recommendations also apply when clinical staff want to involve patients in the management of their medical data. We invite future studies to explore the extent to which discrepancies in patients' preferred versus assumed roles in the management of their medical data affect their engagement and satisfaction with their clinical care.

Limitations

This scoping review has some limitations. We retrieved a limited set of highly heterogeneous papers because they provided detailed information about patients' actual data management activities. Despite the considerable heterogeneity in the study objectives, designs, and outcome measures used in these papers, we were able to identify key themes regarding the facilitators and barriers that patients face when they decide to generate and manage their medical data. In addition, this review concentrated on measurable uses of PEHRs (ie, entering, updating, and modifying data) to identify what stimulates or prevents patients' use. Although patients who evaluate their core medical data and subsequently decide not to add or modify information are actively engaging with their PEHR, we chose not to include this group because we would then need to rely on log-in frequencies to determine the patients' (level of) engagement with their health data. Not only may log-in frequencies be biased by false log-in data resulting from log-in problems, but they also do not inform us whether a log-in moment resulted in meaningful use of the portal. A promising endeavor for future studies would be to identify whether and how frequently patients review and approve of the core medical data recorded in their PEHR and which factors contribute to this type of use.

Conclusions

Most patients do not actively review and enter, update, or modify their medical data in a PEHR. Patients refrain from generating and managing their medical data, especially when medical information is complex and sensitive. The reasons for patients' passive behavior are their concerns about the validity, applicability, and confidentiality of patient-generated data, although we found that patient-generated data are often accurate and helpful in stimulating patient engagement and satisfaction. We have offered recommendations for implementing design features within the (tools linked to) PEHRs and the creation of a dedicated policy to inform both clinical staff and patients about the added value of patient-generated data, with clinicians being involved as important ambassadors in informing, reminding, and encouraging patients to manage the data in their PEHR.

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Authors' Contributions

All authors contributed to developing the aim of the scoping review and construing the study protocol. DJD took the lead by developing the search strategy, by retrieving and screening the identified records, by analyzing and interpretating the data for the article, and by drafting the first version of the manuscript. GGS, BM, and SP contributed by screening the identified records. All authors proofread the manuscript and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Filled-in PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) checklist [31].
[PDF File (Adobe PDF File), 102 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Search strategy for the MEDLINE, PsycINFO, CINAHL, Cochrane Library, Embase, Web of Science, and Google Scholar databases.
[PDF File (Adobe PDF File), 174 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Data extraction form.
[PDF File (Adobe PDF File), 83 KB-Multimedia Appendix 3]

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Abbreviations

PEHR: personal electronic health record
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews

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Review

Patient-Centered Digital Health Records and Their Effects on Health Outcomes: Systematic Review

Martijn R Brands[1], MD; Samantha C Gouw[1], MD, PhD; Molly Beestrum[2], MLiS; Robert M Cronin[3], MS, MD; Karin Fijnvandraat[1,4], MD, PhD; Sherif M Badawy[5,6], MBBCh, MS, MD

[1]Department of Pediatric Hematology, Emma Children's Hospital, Amsterdam Reproduction & Development, Public Health, Amsterdam UMC location University of Amsterdam, Amsterdam, Netherlands

[2]Galter Health Sciences Library at Northwestern University, Chicago, IL, United States

[3]Department of Medicine, The Ohio State University, Columbus, OH, United States

[4]Department of Molecular Cellular Hemostasis, Sanquin Research and Landsteiner Laboratory, Amsterdam, Netherlands

[5]Department of Pediatrics, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States

[6]Division of Hematology, Oncology, and Stem Cell Transplant, Ann and Robert H Lurie Children's Hospital of Chicago, Chicago, IL, United States

Corresponding Author:
Sherif M Badawy, MBBCh, MS, MD
Department of Pediatrics
Feinberg School of Medicine, Northwestern University
420 E Superior St
Chicago, IL, 60611
United States
Phone: 1 312 227 4789
Email: sherif.badawy@northwestern.edu

Abstract

Background: eHealth tools such as patient portals and personal health records, also known as patient-centered digital health records, can engage and empower individuals with chronic health conditions. Patients who are highly engaged in their care have improved disease knowledge, self-management skills, and clinical outcomes.

Objective: We aimed to systematically review the effects of patient-centered digital health records on clinical and patient-reported outcomes, health care utilization, and satisfaction among patients with chronic conditions and to assess the feasibility and acceptability of their use.

Methods: We searched MEDLINE, Cochrane, CINAHL, Embase, and PsycINFO databases between January 2000 and December 2021. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were followed. Eligible studies were those evaluating digital health records intended for nonhospitalized adult or pediatric patients with a chronic condition. Patients with a high disease burden were a subgroup of interest. Primary outcomes included clinical and patient-reported health outcomes and health care utilization. Secondary outcomes included satisfaction, feasibility, and acceptability. Joanna Briggs Institute critical appraisal tools were used for quality assessment. Two reviewers screened titles, abstracts, and full texts. Associations between health record use and outcomes were categorized as *beneficial*, *neutral or clinically nonrelevant*, or *undesired*.

Results: Of the 7716 unique publications examined, 81 (1%) met the eligibility criteria, with a total of 1,639,556 participants across all studies. The most commonly studied diseases included diabetes mellitus (37/81, 46%), cardiopulmonary conditions (21/81, 26%), and hematology-oncology conditions (14/81, 17%). One-third (24/81, 30%) of the studies were randomized controlled trials. Of the 81 studies that met the eligibility criteria, 16 (20%) were of high methodological quality. Reported outcomes varied across studies. The benefits of patient-centered digital health records were most frequently reported in the category health care utilization on the "use of recommended care services" (10/13, 77%), on the patient-reported outcomes "disease knowledge" (7/10, 70%), "patient engagement" (13/28, 56%), "treatment adherence" (10/18, 56%), and "self-management and self-efficacy" (10/19, 53%), and on the clinical outcome "laboratory parameters," including HbA_{1c} and low-density lipoprotein (LDL; 16/33, 48%). Beneficial effects on "health-related quality of life" were seen in only 27% (4/15) of studies. Patient satisfaction (28/30, 93%), feasibility (15/19, 97%), and acceptability (23/26, 88%) were positively evaluated. More beneficial effects were reported for digital health records that predominantly focus on active features. Beneficial effects were less frequently observed among patients with a high disease burden and among high-quality studies. No unfavorable effects were observed.

Conclusions: The use of patient-centered digital health records in nonhospitalized individuals with chronic health conditions is potentially associated with considerable beneficial effects on health care utilization, treatment adherence, and self-management or self-efficacy. However, for firm conclusions, more studies of high methodological quality are required.

Trial Registration: PROSPERO (International Prospective Register of Systematic Reviews) CRD42020213285; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=213285

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KEYWORDS

telemedicine; health records; personal; electronic health records; outcome assessment; health care

Introduction

Background

The prevalence and disease burden of chronic health conditions is on the rise. The World Health Organization predicts that by 2030, chronic noncommunicable health conditions will account for >50% of the total disease burden [1,2]. In particular, cardiovascular conditions, cancer, respiratory conditions, and diabetes have the highest morbidity and mortality [1]. Currently, 60% of the US population has at least 1 chronic condition and 42% of the population has multiple chronic conditions [3]. This results in a high individual disease burden owing to the large impact on social participation and required patient self-management skills. Self-management refers to a person's ability to manage the clinical, psychosocial, and societal aspects of their illness and its care [4]. In contrast, self-efficacy is a person's belief that he or she can successfully execute this behavior [4]. Apart from a high individual disease burden, the prevalence of chronic conditions imposes a high macroeconomic burden [5]. Furthermore, an increasing shortage of health care providers is expected, among others in the United States [6] and Europe [7,8]. In combination with the increased pressure put on health systems by unexpected events such as the COVID-19 pandemic, this shortage threatens the delivery of essential health services [9]. To preserve the access to care for all patients, new technologies are increasingly being developed and adopted, including patient-centered digital health records.

Such patient-centered digital health records can significantly help engage and empower patients with a chronic health condition [10-13]. Patient-centered digital health records enable patients to take on a more active role in their care by allowing them to view parts of their medical records, such as medication lists, laboratory and imaging results, allergies, and correspondence. Other common features include secure messaging, requesting prescription refills, video consultation, paying bills, and managing appointments. Examples of patient-centered digital health records include patient portals and personal health records (PHRs). Patient-centered digital health records differ in the volume and detail of the provided medical data, functionalities, and level of patient control, as shown in Textbox 1. Highly engaged patients are reported to have increased disease knowledge, better self-management, more self-efficacy, and improved clinical outcomes [14-16]. The effects of using patient-centered digital health records may be most substantial for patients with chronic conditions. Many self-management skills are required, and their potential gains are the highest. Not only patients but the entire health care system might benefit from an increased adoption of patient-centered digital health records.

Textbox 1. Proposed taxonomy of patient-centered digital health records [10,17-21].

- Electronic health record (EHR): a digital version of a health care provider's paper chart, used by health care professionals alone. Patients cannot access data in an EHR. An EHR might contain data from one health care institution or from multiple institutions. Its scope can range from regional, to national, or international.
- Patient portal: the patient-facing interface of an EHR that enables people to view sections of their medical record. This might include access to test results, medication lists, or therapeutic instructions. Health care providers or health care offices determine what health information is accessible for patients. Patient portals often have additional features such as patient-professional messaging, requesting prescription refills, scheduling appointments, or communicating patient-reported outcomes. By definition, patient portals are "tethered," in which "tethered" refers to a patient portal's connection to an EHR. Occasionally, a patient portal is referred to as a tethered personal health record (PHR).
- PHR: a PHR is similar to a patient portal and can have similar features. However, the main difference is that contents are managed and maintained by individuals, not health care providers. People can access, manage, and share their health information, and that of others for whom they are authorized, such as parents or caretakers. Health information from different health care institutions may reside in a single patient-managed PHR. In general, PHRs are not tethered unless otherwise specified. Few tethered PHRs currently exist but are increasingly being developed [22].
- Patient-centered digital health records: an umbrella term referring to patient portals, tethered PHRs, and part of the untethered PHRs. Patient-centered digital health records enable a 2-way exchange of health information between patients and the health care system and provide patients with the ability to view, download, or transmit their health information on the web. This health information is updated at regular intervals. In addition, it enables communication between patients and the health care system, either by adding or editing health information, exchanging patient-reported outcomes, or by using communication tools such as messaging. Additional functionalities are often present.
- "Electronic medical record" is an outdated term [21]. It can be considered a professional-centered EHR with limited functionalities.

Currently, huge investments of time and resources are made in patient-centered digital health records. However, limited insight exists in how the use of patient-centered digital health records by patients with a broad range of chronic conditions affects clinical and patient-reported outcomes and health care utilization. Moreover, we lack an overview of their effects on patient satisfaction, and the feasibility and acceptability of their use by people with chronic conditions. Previous systematic reviews focused on one health condition [23], focused on one type of digital health record [24-27], investigated a select set of health outcomes [24,26,28], or are now obsolete in this rapidly changing technological landscape [23,25,27].

Objectives

Therefore, in this systematic review, we summarized the available evidence on patient-centered digital health records. Our primary objective was to assess how patient-centered digital health records for nonhospitalized patients with chronic conditions affect clinical and patient-reported health outcomes and health care utilization. Our secondary objective was to evaluate patient satisfaction with and feasibility and acceptability of using patient-centered digital health records. Results of this systematic review may help guide future development and implementation.

Methods

The protocol for this study was registered in the International PROSPERO (International Prospective Register of Systematic Reviews) Register of Systematic Reviews (CRD42020213285) [29]. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were followed [30].

Literature Search

A medical librarian (MB) conducted the original literature search using the following databases: MEDLINE, Cochrane Library, CINAHL, Embase, and PsycINFO. All original studies published between January 1, 2000, and December 1, 2020, were assessed. A search update in MEDLINE was performed for all studies published between December 1, 2020, and December 31, 2021. Multimedia Appendix 1 presents the full search strategy. Articles published before 2000 were excluded because of the rapidly changing field of digital health technology [30].

Eligibility Criteria

Patient-centered digital health records were defined as mobile health (mHealth) or eHealth technologies that enable a 2-way exchange of health information between patients and the health care system, such as patient portals, PHRs, or mHealth apps with a health record functionality. A patient-centered digital health record provides patients with the ability to view, download, or transmit their health information on the web. This health information was updated at regular intervals. In addition, a patient-centered digital health record allows for communication between patients and the health care system, either by adding or editing health information, exchanging patient-reported outcomes, or by using communication tools such as messaging. Several other functionalities are common, but were not considered essential; for example, appointment scheduling, requesting prescription refill, viewing educational material, using decision support tools, and using connected wearables. Exclusion criteria were nondigital health records, digital health records intended for hospitalized patients, and digital health records that are not accessible to patients, such as the clinician-facing components of the electronic health record (EHR).

Studies

Studies investigating patient-centered digital health records intended for nonhospitalized patients with a chronic health condition were included. Only studies published in English were included. Eligible studies included randomized controlled trials (RCTs), quasi-experimental studies, nonexperimental observational studies (including cohort and cross-sectional studies), and pilot or feasibility studies. Of mixed methods studies, only nonqualitative parts were used for data extraction. Studies that only described health care providers' experiences were excluded.

Participants

Studies on patients with a chronic health condition of all age groups were considered. Chronic conditions included all diseases with a moderate to high disease burden and moderate to high impact on daily life. Consequently, these conditions demand considerable self-management skills from patients to manage the clinical, psychosocial, and societal aspects of chronic condition and its care. The selection of chronic conditions included in our search strategy was based on the Charlson Comorbidity Index, other literature, and clinical expertise [31,32]. Diseases included cancer, arthritis, HIV, AIDS, asthma, chronic obstructive pulmonary disease, chronic heart conditions, hematologic disease, chronic kidney disease, celiac disease, inflammatory bowel disease, cystic fibrosis, diabetes mellitus, and multiple sclerosis (MS).

Outcomes

Studies were required to report at least one primary or secondary outcome. Primary outcomes were clinical outcomes (including disease events and complications, vital parameters, and laboratory parameters), patient-reported outcomes (including self-management and self-efficacy, patient engagement, health-related quality of life (HRQoL), stress and anxiety, and treatment adherence), and health care utilization (including the number of emergency department [ED] visits and hospitalizations, the use of preventive or recommended care services by patients, and regular workload for health care professionals). Secondary outcomes included technology-related outcomes (including patient satisfaction, feasibility, and acceptability). Definitions and examples of these 13 outcomes are presented in Table 1.

Table 1. Definitions and examples of all health outcomes included in this systematic review.

Included study outcomes	Definitions and examples
Clinical outcomes	
Disease events and complications	• For example, asthma exacerbation, chronic kidney disease progression, and death
Vital parameters	• For example, blood pressure, BMI, weight, and respiratory parameters
Laboratory parameters	• For example, HbA_{1c}[a], LDL[b], cholesterol, eGFR[c], HIV viral load, and CD4+ T-cell count
Patient-reported outcomes	
Self-management and self-efficacy	• Self-management is a person's ability to manage the clinical, psychosocial, and societal aspects of illness and its care. • Self-efficacy is the belief that a person can successfully execute this behavior (eg, measured by the validated Diabetes Empowerment Scale) [4]

Patient engagement	• Patient engagement comprises 3 suboutcomes:
	  • Patient activation: patients believe that their own role in managing their care is important, patients' confidence and knowledge to take action, how much they take action, and if patients are capable of staying on course under stress (eg, measured by the Patient Activation Measure PAM13) [33]
	  • Patient involvement: patients' involvement and participation in treatment decisions, and patients' involvement in sharing information, preparing and conducting a medical consultation, and accepting instructions from doctors and nurses [34] (eg, measured by the number of patients that is in possession of an Asthma Action Plan)
	  • Disease knowledge: patients' knowledge of a disease and its related care activities (eg, measured by the Brief Diabetes Knowledge Test) [35]

Health-related quality of life	• All aspects of one's quality of life that are health-related, including physical functioning, social functioning, and mental health (eg, measured by the 36-Item Short Form Survey SF-36) [36] • A reduction in anxiety or stress was considered a suboutcome (eg, measured by the parenting stress index) [37]
Treatment adherence	• The extent to which a person's behavior (taking medication, following a diet, or the execution of lifestyle changes) corresponds with health care providers' recommendations [38] (eg, adherence to HIV medication)
Health care utilization: >all types of encounters between patients and health care providers, including ED[d] visits, hospitalizations, outpatient clinic appointments, and telephone calls	
ED visits and hospitalizations	• Reductions in undesirable events (eg, reductions in emergency department visits and hospitalizations)
Recommended care services	• Increased use of recommended care services by people with uncontrolled disease, and the improved use of preventive care services (eg, follow-up outpatient clinic visits among people with uncontrolled HIV, eye examinations in people with diabetes)
Regular workload	• A decrease in regular workload for health care professionals (eg, patients use email instead of interruptive telephone calls as a first method of contact)
Technology-related outcomes	
Patient satisfaction	• Patient satisfaction with accessing and using patient-centered digital health records • Patient satisfaction with the effects of using patient-centered digital health records (eg, sense of control, perceived quality of care)
Feasibility	• Adherence to patient-centered digital health records and user retention rates, for which no universal cut-off values are available
Acceptability	• The perceived usability of patient-centered digital health records and how these affect behavior, as well as identified facilitators and barriers

[a]HbA_{1c}: glycated hemoglobin.

[b]LDL: low-density lipoprotein.

[c]eGFR: estimated glomerular filtration rate.

[d]ED: emergency department.

Data Extraction

Two independent reviewers (MB and SB) assessed titles, abstracts, and full texts for eligibility. Disagreements were resolved by discussion, if necessary, with a third reviewer (SG).

A modified, electronic version of the standardized Cochrane data extraction form [39] was used to extract the following data items: first author's name; publication year; study design; disease or diseases studied; study aim; country and setting; participants' age and sex; sample size; inclusion and exclusion criteria; follow-up duration; description, features, and purpose of the patient-centered digital health record and (if applicable) of the comparator; size and description of the control group (if applicable); device used; description of health outcomes and results; and main study findings.

Quality Appraisal

For quality appraisal, Joanna Briggs Institute (JBI) critical appraisal tools for RCTs, cross-sectional studies, cohort studies, and quasi-experimental studies were used [40]. JBI tools were modified to better suit the assessment of digital health record studies. Several items were added, including adequate patient-centered digital health record descriptions and selection bias measures, as presented in Multimedia Appendix 2. As the JBI tools differed in the number of items, all scores were converted to a 15-point scale. Articles with a score of ³12 were considered of "high quality," between 8.5 and 11.9 of "medium quality," and <8.5 of "low quality."

Data Synthesis

Associations between patient-centered digital health record use and health outcomes were categorized in 3 groups: "beneficial," "neutral or clinically nonrelevant," or "undesired." Categorizations were determined by our interpretation of study findings, based on meaningful clinical effects and statistical significance (P<.05), and could therefore differ from the authors' conclusions. Statistical significance was considered relevant only if the effect size were clinically significant. If available, minimal clinically important differences were used to assess effect sizes. The summarization of effects was based on the vote-counting method, as no meta-analysis could be performed. The findings were summarized for all conditions, grouped by disease category (diabetes mellitus, cardiopulmonary diseases, hematology-oncology diseases, and other diseases), and grouped according to outcome type (clinical outcomes, patient-reported outcomes, health care utilization, and technology-related outcomes).

Subgroup Analyses

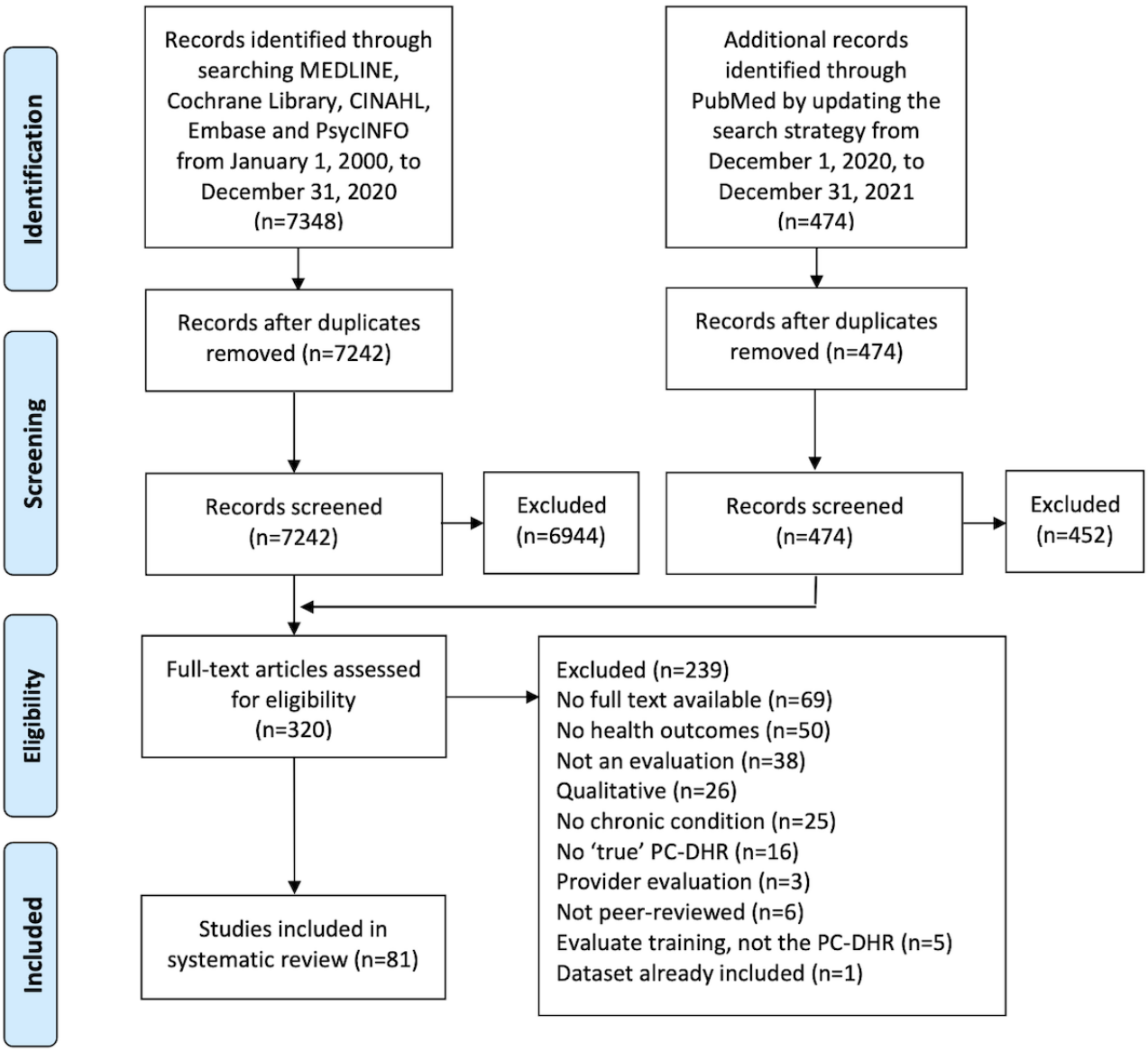
Several subgroup analyses were performed. The first subgroup included conditions with a high disease burden. These included conditions with either impaired social participation or that require a high level of self-management skills. Impaired social participation was defined as being unable to participate in work or school or engage with friends and family as desired because of the condition or its treatment. High self-management skills are defined as recurrent actions demanded from patients to prevent or treat the disease or its consequences, including high disease-related knowledge needed to actively engage in decision-making. This subgroup was determined based on clinical expertise of the study team. Second, we assessed 2 subgroups: patient-centered digital health records that predominantly offered passive features and those that predominantly offered active features. Passive features are those through which the patient receives information but does not actively add information. Active features are those in which the patient performs an action and actively engages with the digital health record. The third subgroup of interest included studies with high methodological quality. A sensitivity analysis was performed to investigate whether our results were influenced by poor quality studies. Finally, the subgroups of interest were studies that included older participants (mean age >55 years), a high number of female participants (>45%), or a racially diverse population (<50% White participants).

Results

Overview

The search yielded 7716 unique publications. After screening the titles and abstracts, 320 full-text articles were retrieved. A total of 81 articles met the inclusion criteria. No non-English articles that met the inclusion criteria were identified. Figure 1 shows the study PRISMA flowchart. In total, 1,639,556 participants were included in the studies of this systematic review. Most (74/81, 91%) studies included only adult participants. Of the total 1,369,913 participants, 99% (n=1,629,660) were adults. Nine studies included children or their parents, with a total number of 9297 children and 599 parents. Sample sizes of studies varied from 10 to 267,208 participants. Furthermore, 46% (747,370/1,639,556) of the participants were female. Of the 81 included studies, health literacy was reported by 7 (9%) studies and insurance status by 15 (20%) studies. Race distribution was reported by 74% (60/81) of studies, of which 47 (78%) studies included a population of which more than half were White and 26 (43%) studies of which >75% were White.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. PC-DHR: patient-centered digital health record.



Study Characteristics

Study characteristics are presented in Tables 2-5 (36 studies are listed in Table 2; 11 studies are listed in Table 3, 14 studies are listed in Table 4, and 20 studies are listed in Table 5). Most investigated conditions were type 1 or 2 diabetes mellitus (37/81, 46%), cardiovascular conditions (14/81, 17%), and malignancies (11/81, 14%). Studies were mostly conducted in the following countries: United States (58/81, 72%), the Netherlands (7/81, 9%), Canada (5/81, 6%), and United Kingdom (3/81, 4%). In addition, 30% (24/81) of the studies were RCTs, 27% (22/81) were cross-sectional studies, 20% (16/81) were retrospective observational cohort studies, and 23% (18/81) were quasi-experimental studies, including pretest-posttest and feasibility studies. One study was a secondary data analysis of the intervention group in an RCT. Of the 55 studies that reported follow-up durations, 6 (7%) studies had a follow-up of less than a month, 25 (31%) studies between 1 and 6 months, 14 (17%) studied between 7 and 12 months, and 10 (12%) studies of >12 months.

Explanations of the patient-centered digital health records investigated in each study are presented in Tables 6-9. Patient-centered digital health records range from a pilot patient portal enabling patients to view a limited set of their medical data to comprehensive PHRs, offering extensive data access and enabling appointment scheduling and prescription refill requests. A minority (12/81, 15%) of studies specifically evaluated ≥1 digital health record features such as secure messaging or a medication adherence module. In addition, 15% (12/81) of studies used a hybrid approach to assess a combination of a digital health record with a connected device, or with training, coaching, or face-to-face visits.

Table 2. Study characteristics of studies investigating diabetes mellitus (of 37 studies investigating diabetes mellitus, 36 are listed in Table 2).[a]

Author, year	Country, setting	Study population, disease, controlled?	Burden[b]	Study design	Sample size	Age (years)[c], mean (SD)	Gender[c] (female), n (%)	Race[c] (White), n (%)
Bailey et al [41], 2019	United States, 2 academic hospitals	Adults with DM[d], on high-risk medication	−	Pilot or feasibility	100	56 (11)	57 (57)	48 (48)
Boogerd et al [42], 2017	Netherlands, 7 medical centers	Parents of children <13 years with DM type 1	+	Pilot or feasibility	I[e]=54, C[f]=51	9.1 (2.7): Children	30 (56)	NR[g]
Byczkowski et al [43], 2014	United States, 1 academic hospital	Parents of children with DM (or CF[h] or JIA[i])	±	Cross-sectional	I=126, C=89	11 (NR)	69 (54.8)	115 (91.3)
Chung et al [44], 2017	United States, outpatient care organization	Adults with DM	−	Cohort	I=12,485, C=2831	56 (12)	5493 (44)	5119 (41)
Conway et al [45], 2019	United Kingdom, Scotland's health system	Patients with DM	−	Cross-sectional	1095	58 (12)	405 (36.99)	873 (78.73)
Devkota et al [46], 2016	United States, 6 PCPs[j]	Patients with DM type 2	−	Cohort	I=409, C=1101	58 (12)[k]	235 (57.5)	250 (61.1)
Dixon et al [47], 2016	United States, 3 community centers	Adults with DM type 2	−	Pilot or feasibility	96	53 (11)	56 (58)	47 (49)
Graetz et al [48], 2018	United States, integrated health system	Adults with DM	−	Cross-sectional	267,208	NR	127,458 (47.7)	116,770 (43.7)
Graetz et al [49], 2020	United States, integrated health system	Adults with DM with at least 1 oral drug	−	Cross-sectional	111,463	64 (13)	51,545 (46.24)	45,205 (40.56)
Grant et al [50], 2008	United States, 11 PCPs	Adults with DM using medication	−	RCT[l]	I=126, C=118	59 (10)	54 (42.9)	117 (92.9)
Lau et al [51], 2014	Canada, 1 academic hospital	Adults with DM	−	Cohort	I=50, C=107	55 (14)	22 (44)	NR
Lyles et al [52], 2016	United States, integrated health system	Adults with DM type 2 using statins	−	Cohort	I=8705, C=9055	61 (11)[k]	4013 (46.1)	3134 (36)[k]
Martinez et al [53], 2021	United States, 4 medical centers	Adults with DM type 2 using medication	−	Pilot or feasibility	60	58 (13)	33 (55)	41 (68)
McCarrier et al [54], 2009	United States, 1 diabetes clinic	Adults <50 years with uncontrolled DM type 1	+	RCT	I=41, C=36	57 (8)	15 (37)	39 (95)
Osborn et al [55], 2013	United States, 1 academic hospital	Adults with DM type 2 using medication	−	Cross-sectional	I=62, C=13	57 (8)	39 (63)	46 (74)
Price-Haywood and Luo [56], 2017	United States, integrated health system	Adults with DM or HT[m]	−	Cohort	I=10,497, C=90,522	NR	6205 (59.11)	8055 (76.74)
Price-Haywood et al [57], 2018	United States, integrated health system	Adults with DM or HT	−	Cohort	I=11,138, C=89,880	58 (13)	6,204 (55.7)	NR
Quinn et al [58], 2018	United States, 26 PCPs	Adults <65 years with DM type 2	−	RCT	I=82, C=25	54 (8)	39 (48)	51 (62)
Reed et al [59], 2015	United States, integrated health system	Adults with DM, HT, CAD[n], asthma, or CHF[o]	±	Cross-sectional	1041	NR	587 (56.4)	618 (59.4)
Reed et al [60], 2019	United States, integrated health system	Adults with DM+HT, CAD, asthma, or CHF	±	Cross-sectional	165,477	NR	79,594 (48.1)	NR (60.9)
Reed et al [61], 2019	United States, integrated health system	Adults with DM, asthma, HT, CAD, CHF or CV event risk	±	Cross-sectional	I=1392, C=407	NR	719 (51.7)	816 (58.6)

Author, year	Country, setting	Study population, disease, controlled?	Burden[b]	Study design	Sample size	Age (years)[c], mean (SD)	Gender[c] (female), n (%)	Race[c] (White), n (%)
Riippa et al [62], 2014	Finland, 10 PCPs	Adults with DM, HT or HC[p]	–	RCT	I=80, C=57	61 (9)	45 (56)	NR
Riippa et al [63], 2015	Finland, 10 PCPs	Adults with DM, HT or HC	–	RCT	I=80, C=57	61 (9)	45 (56)	NR
Robinson et al [64], 2020	United States, 1 veteran hospital	Veterans with uncontrolled DM type 2	–	Cross-sectional	I=446, C=754	66 (8)	28 (6.3)	384 (86.1)
Ronda et al [65], 2014	Netherlands, 62 PCPs+1 hospital	Adults with DM	–	Cross-sectional	I=413, C=758	64 (12)	154 (37.3)	383 (93.6)
Ronda et al [66], 2015	Netherlands, 62 PCPs+1 hospital	Adults with DM	–	Cross-sectional	I=413, C=219	59 (13)	154 (37.3)	383 (93.6)
Sabo et al [67], 2021	United States, 21 practices	Adults with DM type 2	–	Cohort	I=189, C=148	61 (13)	75 (40.9)	113 (72.9)
Sarkar et al [68], 2014	United States, integrated health system	Adults with DM	–	Cohort	I=8705, C=9055	61 (11)[k]	4013 (46.1)	5072 (58.27)
Seo et al [69], 2020	South Korea, 1 academic hospital	Patients with DM	–	Cohort	I=133, C=7320	54 (10)	23 (17.3)	NR
Sharit et al [70], 2018	United States, 1 veterans center	Overweight veterans with prediabetes	–	Pilot or feasibility	38	58 (8)	9 (24)	8 (21)[k]
Shimada et al [71], 2016	United States, Veteran registry	Veterans with uncontrolled DM, HT or LDL[q]	–	Cohort	I=50,482, C=61,204	61 (10)	2060 (4.08)	35,761 (70.84)
Tenforde et al [72], 2012	United States, 1 community hospital	Adults <75 years with DM	–	Cohort	I=4036, C=6710	59 (10)	1857 (46)[k]	3,390 (84)[k]
van Vugt et al [73], 2016	Netherlands, 52 PCPs	Patients with DM type 2	–	RCT	I=66, C=66	68 (10)	54 (41)	91 (69)
Vo et al [74], 2019	United States, integrated health system	Adults <80 years with DM type 2	–	RCT	I=673, C=603	61 (10)	296 (44)	394 (58.5)
Wald et al [75], 2009	United States, 230 PCPs	Patients with DM type 2	–	RCT	126	59 (NR)	53 (42.1)	117 (92.9)
Zocchi et al [76], 2021	United States, nationwide	Patients with DM type 2, partly uncontrolled	–	Cohort	95,043	63 (10)	4,339 (4.57)	68,954 (72.55)

[a]All studies are listed in Tables 2-5 and are reported in the disease category of the condition that is most prominently investigated. The study by Druss et al [77] is therefore listed in Table 5.

[b]If conditions are considered to have a high disease burden or demand high self-management skills, a positive sign is shown. Otherwise, a sign is indicated. A ± sign indicates that multiple diseases have been studied, and only some of the diseases were considered to have a high disease burden.

[c]If available, age (years), gender, and race were reported by digital health record users (“the intervention group”).

[d]DM: diabetes mellitus.

[e]I: intervention.

[f]C: control.

[g]NR: not reported.

[h]CF: cystic fibrosis.

[i]JIA: juvenile idiopathic arthritis.

[j]PCP: primary care practice.

[k]Presented numbers were estimated based on the data provided in the original articles.

[l]RCT: randomized controlled trial.

[m]HT: hypertension.

[n]CAD: coronary artery disease.

[o]CHF: congestive heart failure.

[p]HC: hypercholesterolemia.

[q]LDL: low-density lipoprotein.

Table 3. Study characteristics of studies investigating cardiopulmonary diseases (of 21 studies investigating cardiopulmonary diseases, 11 are listed in Table 3).[a]

Author, year	Country, setting	Study population, disease, controlled?	Burden[b]	Study design	Sample size	Age (years)[c], mean (SD)	Gender[c] (female), n (%)	Race[c] (White), n (%)
Aberger et al [78], 2014	United States, renal transplant clinic	Postrenal transplant patients with HT[d]	+	Pilot or feasibility	66	54 (NR[e])	34 (52)[f]	48 (72)[f]
Ahmed et al [79], 2016	Canada, 2 academic hospitals	Adults with asthma using medication	+	RCT[g]	I[h]=49, C[i]=51	NR	32 (68)	NR
Apter et al [80], 2019	United States, multicenter hospitals	Adults with asthma using prednisone	+	RCT	I=151, C=150	49 (13)	270 (89.7)	4 (1.3)
Fiks et al [81], 2015	United States, 3 PCPs[j]	Children aged 6-12 years with asthma, partly uncontrolled	+	RCT	I=30, C=30	8.3 (1.9)	26 (87) among parents	13 (43)
Fiks et al [82], 2016	United States, 20 PCPs	Children aged 6-12 years with asthma, partly uncontrolled	+	Pilot or feasibility	I=237, C=8896	NR	101 (42.8)	144 (61.5)
Kogut et al [83], 2014	United States, 1 community hospital	Adults aged >49 years with cardiopulmonary disorders	±	Pilot or feasibility	30	NR	14 (47)	NR
Kim et al [84], 2019	South Korea, 1 academic hospital	Patients with obstructive sleep apnea	−	RCT	I=30, C=13	43 (10)[f]	NR (15)	NR
Lau et al [85], 2015	Australia, nationwide	Adults with asthma	+	RCT	I=154, C=176	40 (14)	124 (80.5)	NR
Manard et al [86], 2016	United States, PCP registry	Adults with uncontrolled HT	−	Cohort	I=400, C=1171	61 (12)	262 (65.5)	72
Toscos et al [87], 2020	United States, 1 community hospital	Patients with nonvalvular AF[k] with OAC[l]	+	RCT	I=76, C=77	71 (9)	60 (37.5)	153 (99.4)
Wagner et al [88], 2012	United States, 24 PCPs	Patients with hypertension, partly uncontrolled	−	RCT	I=193, C=250	55 (12)	145 (75.1)	96 (50.5)

[a]All studies are listed in Tables 2-5 and are reported in the disease category of the condition that is most prominently investigated. The studies by Price-Haywood and Luo [56], Price-Haywood et al [57], Reed et al [59], Reed et al [60], Reed et al [61], Riippa et al [62], Riippa et al [63], Shimada et al [71] are listed in Table 2. The study by Martinez Nicolás et al [89] is listed in Table 4. The study by Druss et al [77] is therefore listed in Table 5.

[b]If conditions are considered to have a high disease burden or demand high self-management skills, a positive sign is shown. Otherwise, a sign is indicated. A ± sign indicates that multiple diseases have been studied, and only some of the diseases were considered to have a high disease burden.

[c]If available, age (years), gender, and race were reported by digital health record users ("the intervention group").

[d]HT: hypertension.

[e]NR: not reported.

[f]Presented numbers were estimated based on the data provided in the original articles.

[g]RCT: randomized controlled trial.

[h]I: intervention.

[i]C: control.

[j]PCP: primary care practice.

[k]AF: atrial fibrillation.

[l]OAC: oral anticoagulant drug.

Table 4. Study characteristics of studies investigating hematological and oncological diseases (n=14).

Author, year	Country, setting	Study population, disease, controlled?	Burden[a]	Study design	Sample size	Age (years)[b], mean (SD)	Gender[b] (female), n (%)	Race[c] (White), n (%)
Cahill et al [90], 2014	United States, cancer center	Adults with glioma	+	Cross-sectional	186	44 (13)	87 (46.8)	149 (86.1)
Chiche et al [91], 2012	France, 1 community hospital	Adults with ITP[c]	±	RCT[d]	I[e]=28, C[f]=15	48 (15)[g]	21 (75)	NR[h]
Collins et al [92], 2003	United Kingdom, hemophilia centers	Patients with hemophilia >11 years	+	Pilot or feasibility	10	NR	NR	NR
Coquet et al [93], 2020	United States, cancer center	Patients with cancer+chemotherapy	+	Cohort	I=3223, C=3223	59 (15)	1,554 (49.78)	1,804 (49.68)
Groen et al [94], 2017	Netherlands, cancer center	Patients with lung cancer	+	Pilot or feasibility	37	60 (8)	16 (47)	37 (100)
Hall et al [95],2014	United States, Cancer Center	Patients with resection for CRC[i] or EC[j]	+	Pilot or feasibility	49	59 (12)[g]	37 (76)	48 (98)
Hong et al [96], 2016	United States, academic pediatric hospital	Children aged 13-17 years with cancer or a blood disorder+parents	+	Cross-sectional	46	15 (1.2)[g]	10 (63) among children	NR
Kidwell et al [97], 2019	United States, multicenter hospitals	Patients aged 13-24 years with sickle cell disease	+	Pilot or feasibility	44	19 (NR)	24 (55)	0 (0)
Martinez Nicolás et al [89], 2019	Spain, 4 community hospitals	Patients with COPD[k], CHF[l], or hematologic malignancy	+	Pilot or feasibility	577,121	42 (23)	319,725[g] (55)	NR
O'Hea et al [98], 2021	United States, cancer centers	Adult women with nonmetastatic breast cancer ending treatment	+	RCT	I=100, C=100	61 (11)	100 (100)	85 (85)
Pai et al [99], 2013	Canada, cancer center	Adult men with prostate cancer	+	Cross-sectional	17	64 (7)[g]	0 (0)	16 (95)
Tarver et al [100], 2019	United States, academic hospital	Patients with colorectal cancer	+	Cross-sectional	22	58 (10)	10 (45)	NR
Wiljer et al [101], 2010	Canada, breast cancer registry	Patients with breast cancer	+	Pilot or feasibility	311	NR	303 (99.7)	NR
Williamson et al [102], 2017	United States, pediatric cancer center	Pediatric cancer survivors	+	Cohort	56	NR	27 (48)	49 (88)

[a]If conditions are considered to have a high disease burden or demand high self-management skills, a positive sign is shown. Otherwise, a sign is indicated. A ± sign indicates that multiple diseases have been studied, and only some of the diseases were considered to have a high disease burden.

[b]If available, age (years), gender, and race were reported by digital health record users ("the intervention group").

[c]ITP: idiopathic thrombocytopenic purpura.

[d]RCT: randomized controlled trial.

[e]I: intervention.

[f]C: control.

[g]Presented numbers were estimated based on the data provided in the original articles.

[h]NR: not reported.

[i]CRC: colorectal cancer.

[j]EC: endometrial cancer.

[k]COPD: chronic obstructive pulmonary disease.

[l]CHF: congestive heart failure.

Table 5. Study characteristics of studies investigating other diseases (of 21 studies investigating other diseases, 20 are listed in Table 5). Diseases include kidney disease (n=3, 15%), mental health disorders (n=3, 15%), multiple sclerosis (n=2, 10%), inflammatory bowel disease (n=2, 10%), rheumatologic conditions (n=2, 10%), and others (n=8, 40%).[a]

Author, year	Country, setting	Study population, disease, controlled?	Burden[b]	Study design	Sample size	Age (years)[c], mean (SD)	Gender[c] (female), n (%)	Race[c] (White), n (%)
Anand et al [103], 2017	Thailand, HIV clinic	MSM[d] and transgender women with HIV, partly uncontrolled	+	RCT[e]	186	30 (10)[f]	7 (4)	0 (0)
Bidmead and Marshall [104], 2016	United Kingdom, 1 community hospital	Patients with IBD[g]	+	Cross-sectional	60	NR[h]	NR	NR
Crouch et al [105], 2015	United States, 1 HIV clinic	Veterans with HIV, partly uncontrolled	+	Cross-sectional	I[i]=20, C[j]=20	43 (11)	1 (5)	19 (95)
Druss et al [106], 2014	United States, 1 mental health center	Patients with a mental disorder+chronic condition	+	RCT	I=85, C=85	49 (7)	42 (49)	13 (15)
Druss et al [77], 2020	United States, 2 mental health centers	Patients with a mental disorder+DM[k], HT[l], or HC[m]	+	RCT	I=156, C=155	51 (6.5)	95 (61)	29 (19)
Jhamb et al [107], 2015	United States, 4 nephrology clinics	Adults visiting nephrology clinics, partly uncontrolled	+	Cross-sectional	1098	58 (16)	549 (50)	952 (86.7)
Kahn et al [108], 2010	United States, HIV clinic	Patients with HIV or AIDS	+	Pilot or feasibility	136	NR	15 (11)[f]	106 (78)[f]
Keith McInnes et al [109], 2013	United States, 8 Veteran hospitals	Veterans with HIV, partly uncontrolled	+	Cross-sectional	1871	NR	51 (2.73)	342 (18.28)
Keith McInnes et al [110], 2017	United States, Veterans care system	Veterans with HIV+detectable viral load, partly uncontrolled	+	Cohort	3374	NR	128 (3.79)	1130 (33.49)
Kiberd et al [111], 2018	Canada, dialysis clinic	Adult with home dialysis	+	Pilot or feasibility	41	57 (2)	13 (48)	NR
Lee et al [112], 2017	South Korea, 1 surgery department	Patients with cleft lip or cleft palate surgery	−	Pilot or feasibility	50	36 (NR)	33 (66)	NR
Miller et al [113], 2011	United States, MS[n] clinic	Patients with MS	+	RCT	I=104, C=102	48 (9)	73 (71.6)	80 (78.4)
Navaneethanet al [114], 2017	United States, multiple health centers	Adults with chronic kidney disease, partly uncontrolled	+	RCT	I=152, C=57	68 (NR)[f]	79 (52)	117 (77)
Plimpton [115], 2020	United States, HIV clinic	Women with HIV, partly uncontrolled	+	Pilot or feasibility	22	41 (11)	22 (100)	7 (32)
Reich et al [116], 2019	United States, 1 community hospital	Adults with IBD[o]	+	RCT	I=64, C=63	42 (16)	28 (46)	48 (77)
Scott Nielsen et al [117], 2012	United States, 1 academic center	Adults with MS	+	Cross-sectional	I=120, C=120	45 (11)	90 (75)	115 (95.8)
Son and Nahm [118], 2019	United States, online senior community	Patients >49 years with 1 or more chronic conditions	±	Secondary data analysis	272	70 (9)	191 (70.2)	213 (78.3)
Tom et al [119], 2012	United States, integrated health system	Parents of children age <6 years with 1 or more chronic conditions	±	Cross-sectional	I=166, C=90	3 (1)	66 (39.8)	113 (68.1)
van den Heuvel et al [120], 2018	Netherlands, 3 hospitals	Adults with bipolar disorder	+	Cross-sectional	39	45 (11)	44 (67)	NR

Author, year	Country, setting	Study population, disease, controlled?	Burden[b]	Study design	Sample size	Age (years)[c], mean (SD)	Gender[c] (female), n (%)	Race[c] (White), n (%)
van der Vaart et al [121], 2014	Netherlands, 1 hospital	Patients with rheumatoid arthritis	+	Cross-sectional	214	62 (13)	140 (65.4)	NR

[a]All studies are listed in Tables 2-5 and are reported in the disease category of the condition that is most prominently investigated. The study by Byczkowski et al [43] is therefore listed in Table 2.

[b]If conditions are considered to have a high disease burden or demand high self-management skills, a positive sign is shown. Otherwise, a sign is indicated. A ± sign indicates that multiple diseases have been studied, and only some of the diseases were considered to have a high disease burden.

[c]If available, age (years), gender, and race were reported by digital health record users (“the intervention group”).

[d]MSM: men who have sex with men.

[e]RCT: randomized controlled trial.

[f]Presented numbers were estimated based on the data provided in the original articles.

[g]IBD: inflammatory bowel disease.

[h]NR: not reported.

[i]I: intervention.

[j]C: control.

[k]DM: diabetes mellitus.

[l]HT: hypertension.

[m]HC: hypercholesterolemia.

[n]MS: multiple sclerosis.

[o]IBD: inflammatory bowel disease.

Table 6. Patient-centered digital health record descriptions for disease category diabetes mellitus (of 37 studies investigating diabetes mellitus, 36 are listed in Table 6).[a]

Author, year	Name	Type	What is evaluated?[b]	Passive features	Active features	Focus[c]
Bailey et al [41], 2019	Electronic Medication Complete Communication	PP[d]	Adherence module alone	View health information (medical summary), read after-visit summary, read educational material	Report medication concerns, monitor medication use	Active
Boogerd et al [42], 2017	Sugarspace	PP	PP	View treatment goals, read educational material	Parent-professional communication, peer support	Active
Byczkowski et al [43], 2014	In-house developed	PP	PP	View health information (including laboratory results, medication), view appointments, read disease-specific information	Messaging, upload documents, receive reminders	Passive
Chung et al [44], 2017	Not reported	PP	Messaging	View health information	Messaging	Active
Conway et al [45], 2019	My Diabetes My Way	Tethered PHR[e]	PHR	View health information from primary and secondary care (including clinical parameters, medication, and correspondence), read educational material	Report self-measurements	Passive
Devkota et al [46], 2016	MyChart	PP	PP	View health information (including laboratory results, diagnoses, medication, vital signs), read educational material	Messaging, request prescription refills, schedule appointments, pay bills	Passive
Dixon et al [47], 2016	CareWeb	PP	Medication module alone	View health information (including measurements, medication)	Report barriers to medication adherence	Passive
Graetz et al [48], 2018 and Graetz et al [49], 2020	"Kaiser Permanente portal"	PP	PP	View health information (including laboratory results)	Messaging, schedule appointments, request prescription refills, pay bills	Active
Grant et al [50], 2008	Not reported	PP	PP	View health information (including medication, laboratory results)	Edit medication lists, messaging, report adherence barriers or adverse effects	Active
Lau et al [121], 2014	BCDiabetes	PP	PP	View health information (including laboratory results), view care plan, read educational material	Messaging, use a journal	Passive
Lyles et al [52], 2016	"Kaiser Permanente portal"	PP	Medication module alone	View health information (including medical history, laboratory results, and visit summaries)	Messaging, schedule appointments, request prescription refills	Active
Martinez et al [53], 2021	My Diabetes Care, part of My Health at Vanderbilt	PP	Diabetes module	View health information (including laboratory results and vaccinations), visualize information, read educational material	Messaging, peer support, decision support tools	Active
McCarrier et al [54], 2009	Living with Diabetes Intervention	PP	PP+case manager	View health information (including correspondence, action plans, and laboratory results), read diabetes-related information	Upload blood glucose readings, use a journal	Active
Osborn et al [55], 2013	My Health At Vanderbilt	PP	PP	View health information (including vital signs, laboratory results, and medication), read educational information	Messaging, manage appointments, use health screening tools, pay bills	Passive
Price-Haywood and Luo [56], 2017 and Price-Haywood et al [57], 2018	MyOchsner	PP	PP	View health information (including an after-visit summary, allergies, and laboratory results)	Messaging, request prescription refills, schedule appointments	Passive
Quinn et al [58], 2018	Not reported	PP	PP	View self-reported health information (including medication and measurements), read educational material	Messaging, report self-measurements and medication changes, receive automated feedback	Active

Author, year	Name	Type	What is evaluated?[b]	Passive features	Active features	Focus[c]
Reed et al [59], 2015	"Kaiser Permanente portal"	PP	Messaging alone	View health information (including laboratory results and correspondence)	Messaging, request prescription refills, schedule appointments	Active
Reed et al [60], 2019 (1) and Reed et al [61], 2019	"Kaiser Permanente portal"	PP	PP	View health information from primary care and secondary care (including laboratory results and visit summaries)	Messaging, request prescription refills, schedule visits	Passive
Riippa et al [62], 2014 and Riippa et al [63], 2015	Not reported	PP	PP	View health information (including diagnoses, laboratory results, vaccinations, and medication), view care plan, read educational material	Messaging	Passive
Robinson et al [64], 2020	My HealtheVet	PP	Messaging alone	View health information (including medication and correspondence), view appointments	Messaging, request prescription refills, receive reminders, upload notes and measurements, use a journal	Passive
Ronda et al [65], 2014 and Ronda et al [66], 2015	Digitaal logboek	PP	PP	View diabetes-specific health information (including laboratory results, diagnoses, and medication), view treatment goals, view appointments	Messaging, upload self-measurements	Passive
Sabo et al [67], 2021	Diabetes Engagement and Activation Platform	PP	PP	View health information (including medication and self-reported glucose measurements)	Report diet, physical activity, blood glucose measurements, complications, mental health and goals, receive alerts	Active
Sarkar et al [68], 2014	"Kaiser Permanente portal"	PP	PP	View health information (including medical history, laboratory results, and visit summaries), view appointments	Messaging, request prescription refills	Passive
Seo et al [69], 2020	My Chart in My Hand	Tethered PHR	PHR+sugar function	View health information (including laboratory results, medication, allergies, diagnoses)	Edit information, schedule appointment; sugar function: log treatment, food intake, and exercise	Active
Sharit et al [70], 2018	My HealtheVet	PP	Track Health module+wearable	View health information (including medication and correspondence), view appointments	Messaging, request prescription refills, receive reminders; track Health module: record diet and activity, upload data from connected accelerometer	Active
Shimada et al [71], 2016	My HealtheVet	PP	Messaging, prescription refills	View health information (including medication and correspondence), view appointments	Messaging, request prescription refills, receive reminders, upload notes and self-measurements, use a journal	Active
Tenforde et al [72], 2012	MyChart	PP	PP	View health information (including diagnoses and laboratory results), read diabetes educational material	Messaging, view glucometer readings, receive reminders	Passive
van Vugt et al [73], 2016	e-Vita	Tethered PHR	PHR+personal coach	View health information (measurements), read diabetes education	Messaging, self-management support program for personal goal setting and evaluation	Active
Vo et al [74], 2019	"Kaiser Permanente portal"	PP	PP+PreVisit Prioritization messaging	View health information (including medical history, laboratory results, and visit summaries), view appointments	PreVisit Prioritization messaging to report priorities before a clinic visit, request prescription refills	Active

Author, year	Name	Type	What is evaluated?[b]	Passive features	Active features	Focus[c]
Wald et al [75], 2009	Patient Gateway	Tethered PHR	PHR	View health information (including medication, allergies, and laboratory results)	Suggest corrections, report care concerns, ask for referrals, create care plans before visits	Active
Zocchi et al [76], 2021	My HealtheVet	PP	PP	View health information (including medication, laboratory results, imaging, and correspondence)	Messaging, requesting prescription refills, download health information	Active

[a]All studies are listed once in Tables 2-5 and are reported in the disease category of the condition that is most prominently investigated. We have included only the functionalities that the authors have reported in their articles. We have applied the taxonomy as presented in Textbox 1 on the information provided by the authors. Therefore, our classification of patient-centered digital health records might not correspond with the term used by the authors.

[b]In this column, we indicated whether authors evaluated the complete patient-centered digital health record, or only part of it.

[c]By definition, patient-centered digital health records have both passive and active features. In this column, we indicate whether patient-centered digital health records predominantly offer passive or active features. In passive features, patients receive information but do not actively add it. In terms of active features, patients perform an action and actively engage with the portal.

[d]PP: patient portal.

[e]PHR: personal health record.

Table 7. Patient-centered digital health record descriptions for disease category cardiopulmonary diseases (of 21 studies investigating cardiopulmonary diseases, 11 are listed in Table 7).[a]

Author, year	Name	Type	What is evaluated?[b]	Passive features	Active features	Focus[c]
Aberger et al [78], 2014	Good Health Gateway	PP[d]	PP+BP[e] cuff	View BP measurements, view treatment goals	Communicate self-reported adherence, receive automated and tailored feedback	Active
Ahmed et al [79], 2016	My Asthma Portal	PP	PP	View health information (including medication and diagnoses), read general and tailored asthma information	Monitor and receive feedback on self-management practices	Passive
Apter et al [80], 2019	MyChart	PP	PP	View health information (including laboratory results, vaccinations, and medication), view appointments	Messaging, request prescription refills, schedule appointments	Passive
Fiks et al [81], 2015 and Fiks et al [82], 2016	MyAsthma	PP	PP	View care plan, read educational material	Report symptoms, treatment adherence, concerns and side effects	Active
Kim et al [84], 2019	MyHealthKeeper	Tethered PHR[f]	PHR+activity tracker	View previously uploaded self-reported data	Upload self-reported data (eg, diet, sleep, weight, BP, step count), connect with wearables, receive feedback from health care providers	Active
Kogut et al [83], 2014	ER-Card	Untethered PHR	PHR+home visits by pharmacists	View patient-reported medication list	Pharmacists view and review patient-reported medication lists, and discuss potential concerns in home visits	Active
Lau et al [85], 2015	Healthy.me	Untethered PHR	PP+extra feature	View Asthma Action Plan, read educational content	Schedule appointments, peer support, self-report medication, use a journal	Passive
Manard et al [86], 2016	Not reported	PP	PP+BP cuff	View health information (including laboratory results, vital signs, and diagnoses)	Messaging, request prescription refills, upload measurements from connected BP cuff	Passive
Toscos et al [87], 2020	MyChart	PP	PP+smart pill bottle	View health information (including laboratory results, vaccinations, and medication), view appointments	Messaging, request prescription refills, schedule appointments Smart Pill Bottle: a device that sends notifications when a user opens or fails to open the lid, based on the dose schedule	Active
Wagner et al, 2012 [88]	MyHealthLink	Tethered PHR	PHR	View health information (including diagnoses, medication, and allergies), read educational material	Messaging, goal setting, upload self-measurements (including BP)	Active

[a]All studies are listed once in Tables 2-5 and are reported in the disease category of the condition that is most prominently investigated. We have included only the functionalities that the authors have reported in their articles. We have applied the taxonomy as presented in Textbox 1 on the information provided by the authors. Therefore, our classification of patient-centered digital health records might not correspond with the term used by the authors.

[b]In this column, we indicated whether authors evaluated the complete patient-centered digital health record, or only part of it.

[c]By definition, patient-centered digital health records have both passive and active features. In this column, we indicate whether patient-centered digital health records predominantly offer passive or active features. In passive features, patients receive information but do not actively add it. In terms of active features, patients perform an action and actively engage with the portal.

[d]PP: patient portal.

[e]BP: blood pressure.

[f]PHR: personal health record.

Table 8. Patient-centered digital health record descriptions for disease category hematological and oncological diseases (n=14).[a]

Author, year	Name	Type	What is evaluated?[b]	Passive features	Active features	Focus[c]
Cahill et al [90], 2014	MyMDAnderson	Tethered PHR[d]	PHR	View health information (including correspondence, operative reports, laboratory results, and imaging), read education material	Messaging, request prescription refills, schedule appointments	Passive
Chiche et al [91], 2012	Sanoia	PP[e]	PP+ITP[f] features	View health information (including allergies, vaccinations, medication, and test results), ITP-specific educational material, read emergency protocols	Messaging	Passive
Collins et al [92], 2003	Advoy	PP	PP	View health information (treatment regimen), read educational material	Registration of symptoms and medication use, automated alerts are sent to professionals	Active
Coquet et al [93], 2020	MyHealth portal	PP	Email use	View health information (including laboratory results)	Messaging, schedule appointments, request prescription refills, pay bills	Active
Groen et al [94], 2017	MyAVL	PP	PP	View health information (including laboratory results, lung function, and correspondence), view appointments, read personalized information	Upload patient-reported outcomes, receive tailored physical activity advice	Active
Hall et al [95], 2014	MyFoxChase	PP	Genetic screening	View health information (including laboratory results), view appointments, read educational material	Messaging, receive alerts if genetic screening results are available	Passive
Hong et al [96], 2016	MyChart	PP	PP	View health information (including laboratory results, medication, allergies)	Messaging, schedule appointments, request prescription refills, use a journal	Passive
Kidwell et al [97], 2019	MyChart	PP	PP	View health information (including laboratory results, medication, diagnoses, and allergies), view appointments, read information about sickle cell disease	Messaging	Passive
Martinez Nicolás et al [89], 2019	Not reported	PP	PP	View health information (including laboratory results, imaging, and medication)	Messaging, teleconsulting, schedule appointments, upload glucose measurements	Active
O'Hea et al [98], 2021	Polaris Oncology Survivorship Transition	PP	PP	View health information (including diagnoses, operative reports, and medication), view appointments, read educational material	Request a referral	Passive
Pai et al [99], 2013	PROVIDER	Tethered PHR	PHR	View health information (including laboratory results, medication, pathology, imaging, and correspondence), read educational material	Messaging, use decision support tools, fill in questionnaires	Passive
Tarver et al [100], 2019	OpenMRS	Tethered PHR	PHR+extra feature	View health information (including treatment history, diagnoses, and care plan), view a treatment summary, read educational material	Messaging, peer support	Passive
Wiljer et al [101], 2010	InfoWell	Tethered PHR	PHR	View health information (including medication, laboratory results, imaging, and pathology), view appointments	Patients can organize and upload care information	Passive
Williamson et al [102], 2017	SurvivorLink	Untethered PHR	PHR	Read educational material	Upload health documents and share these with professionals	Active

[a]All studies are listed once in Tables 2-5 and are reported in the disease category of the condition that is most prominently investigated. We have included

only the functionalities that the authors have reported in their articles. We have applied the taxonomy as presented in Textbox 1 on the information provided by the authors. Therefore, our classification of patient-centered digital health records might not correspond with the term used by the authors.

[b]In this column, we indicated whether authors evaluated the complete patient-centered digital health record, or only part of it.

[c]By definition, patient-centered digital health records have both passive and active features. In this column, we indicate whether patient-centered digital health records predominantly offer passive or active features. In passive features, patients receive information but do not actively add it. In terms of active features, patients perform an action and actively engage with the portal.

[d]PHR: personal health record.

[e]PP: patient portal.

[f]ITP: idiopathic thrombocytopenic purpura.

Table 9. Patient-centered digital health record descriptions for disease category other diseases (of 21 studies investigating other diseases, 20 are listed in Table 9).[a]

Author, year	Name	Type	What is evaluated?[b]	Passive features	Active features	Focus[c]
Anand et al [103], 2017	Adam's Love	PP[d]	PP	View health information (HIV test results), receive appointment reminders	Schedule HIV test appointments, use e-counseling, receive appointment reminders	Active
Bidmead et al [104], 2016	Patients Know Best	Tethered PHR[e]	PHR	View health information (including medication, laboratory results, and correspondence), read educational material	Communication with health care providers, upload and share health information	Active
Crouch et al [105], 2015	My HealtheVet	PP	PP	View health information (including laboratory results and correspondence)	Messaging, request prescription refills	Passive
Druss et al [106], 2014	MyHealthRecord	PP	PP+training	View health information (including diagnoses, measurements, laboratory results, medication, and allergies), view treatment goals	Prompts remind patients of routine preventive service	Passive
Druss et al [77], 2020	Not reported	PP	PP+training	View health information (including medication, allergies, measurements, and laboratory results)	Formulate long-term goals, that are translated into action plans with progress tracking	Active
Jhamb et al [107], 2015	Not reported	PP	PP	View health information (including diagnoses, allergies, immunizations, and laboratory results)	Messaging, schedule appointments, request prescription refills	Passive
Kahn et al [108], 2010	MyHERO	PP	PP	View health information (including diagnoses, medication, laboratory results, and allergies), view appointments, read information on interpreting test results	Upload notes and self-measurements	Passive
Keith McInnes et al [109], 2013 and Keith McInnes et al [110], 2017	My HealtheVet	PP	PP	View health information (including medication and correspondence), view appointments	Messaging, request prescription refills, receive reminders, upload notes and self-measurements, use a journal	Passive
Kiberd et al [111], 2018	RelayHealth	PP	PP	View health information (including test results and medication)	Messaging	Active
Lee et al [112], 2017	CoPHR	PP	PP	View health information (including diagnoses, laboratory results, medication, allergies, vital signs, and correspondence), view appointments, view treatment plan, read educational information	Manage and edit appointments and health information	Passive
Miller et al [113], 2011	Mellen Center Care Online	Untethered PHR	PHR	Review previously entered symptoms and HRQoL[f]	Messaging, report symptoms and HRQoL and evaluate changes, preparation for appointments	Active
Navaneethan et al [114], 2017	MyChart	PP	PP+part of users received training	View health information (including medication and laboratory results), read educational material	Messaging, schedule appointments, request prescription refills	Passive
Plimpton [115] 2020	Not reported	PP	PP	View health information	Messaging	Passive
Reich et al [116], 2019	MyChart	PP	PP	View health information (including laboratory results, diagnoses, medication, and vital signs)	Messaging	Passive
Scott Nielsen et al [117], 2012	PatientSite10	PP	PP	View health information (including laboratory results, and imaging), read educational material	Messaging, schedule appointments, request prescription refills, upload self-measurements, pay bills	Active

Author, year	Name	Type	What is evaluated?[b]	Passive features	Active features	Focus[c]
Son and Nahm [118], 2019	MyChart	PP	PP+training	View health information (including medication and laboratory results), read educational material	Messaging, schedule appointments, request prescription refills	Passive
Tom et al [119], 2012	My-GroupHealth	PP	PP	View health information (including diagnoses, medication, and test results), read after-visit summaries, proxy access	Messaging, schedule appointments	Passive
van den Heuvel et al [120], 2018	"PHR-BD"	Tethered PHR	Tethered PHR+mood chart	View health information (including diagnoses, laboratory results, medication, and correspondence), read educational material	Messaging, report symptoms in a mood chart, view personal crisis plan	Active
van der Vaart et al [121], 2014	Not reported	PP	PP	View health information (including diagnoses, medication, and laboratory results), read educational material	Report and monitor HRQoL outcomes	Active

[a]All studies are listed once in Tables 2-5 and are reported in the disease category of the condition that is most prominently investigated. We have included only the functionalities that the authors have reported in their articles. We have applied the taxonomy as presented in Textbox 1 on the information provided by the authors. Therefore, our classification of patient-centered digital health records might not correspond with the term used by the authors.

[b]In this column, we indicated whether authors evaluated the complete patient-centered digital health record, or only part of it.

[c]By definition, patient-centered digital health records have both passive and active features. In this column, we indicate whether patient-centered digital health records predominantly offer passive or active features. In passive features, patients receive information but do not actively add it. In terms of active features, patients perform an action and actively engage with the portal.

[d]PP: patient portal.

[e]PHR: personal health record.

[f]HRQoL: health-related quality of life.

Outcomes

An overview of reported associations for each health outcome is shown in Figure 2. The proportions of beneficial effects reported per health outcome are presented in Multimedia Appendices 3 and 4. For high-quality studies, proportions are presented in Multimedia Appendix 3. An overview of study conclusions and associated outcomes is presented in Tables 10-13. Studies were grouped according to disease group.

Figure 2. Health outcomes associated with patient-centered digital health record use. Associations refer to meaningful clinical effects or statistical significance. If studies report multiple health outcome within 1 category, each health outcome is included separately. *The proportion of health outcomes for which beneficial effects were reported. ED: emergency department.

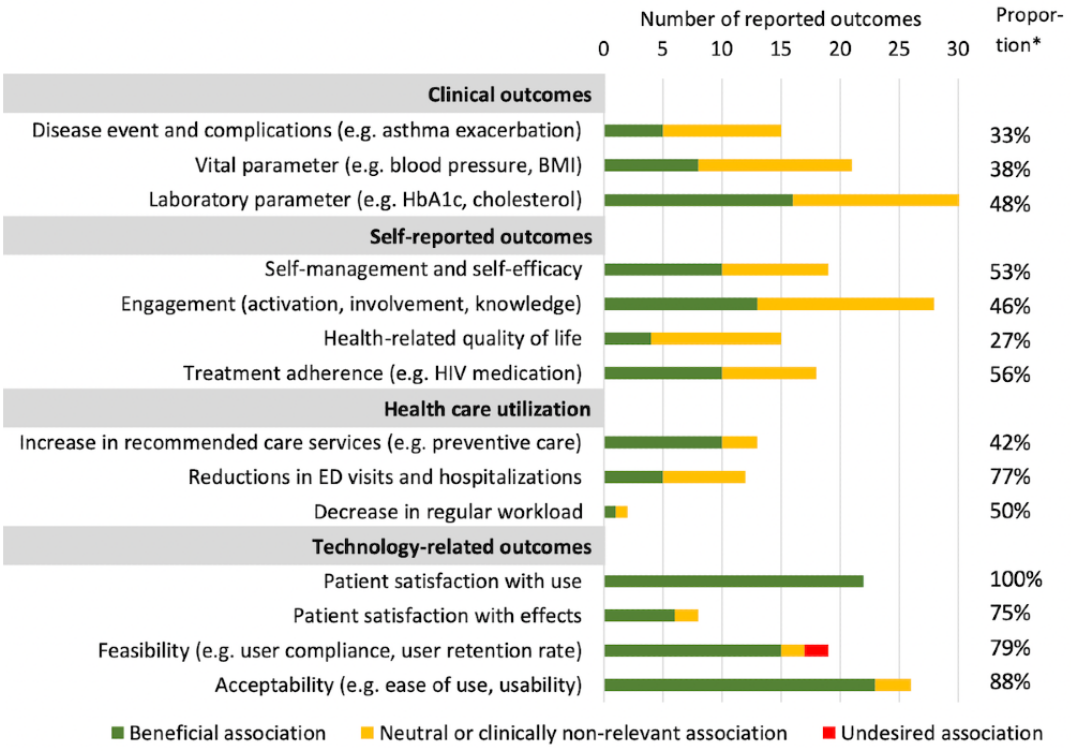


Table 10. Conclusions and health outcomes: all studies investigating diabetes (n=37), of which 8 (22%) are of high methodological quality.[a]

Author, year	Participants	Comparison	Main conclusion	Study design	Clinical	Patient reported	Care utilization	Technology	Quality[b]
Boogerd et al [42], 2017	Parents of children with DM[c] type 1	PP[d] users versus PP nonusers	Patient portal use is not associated with less parental stress. The more stress, the more parents use the portal.	QE[e]	○	○	—[f]	●	●
Lau et al [51], 2014	Patients with DM	Pretest PP nonuse versus posttest PP use	Patient portal use is associated with improved glycemic control.	Cohort	●	—	—	—	●
Lyles et al [52], 2016	Adults with DM type 2 using statins, registered for PP	Prescription refill use versus no refill use	Requesting prescription refills is associated with improved statin adherence.	Cohort	—	●	—	—	●
McCarrier et al [54], 2009	Adults aged <50 years with uncontrolled DM type 1	Nurse-aided PP users versus PP nonusers	Patient portal use results in improved self-efficacy, but not in improved glycemic control.	RCT[g]	○	●	—	●	●
Price-Haywood and Luo [56], 2017	Adults with DM (or HT[h])	PP users versus PP nonusers	Patient portal use is associated with more primary care visits and telephone encounters, but not with less hospitalizations or ED[i] visits.	Cohort	○	—	◔	—	●
Sarkar et al [68], 2014	Adults with DM, registered for PP	Recurrent prescription refill use versus occasional refill use versus no refill use	Recurrent use of prescription refills is associated with improvements in adherence and lipid control.	Cohort	●	—	—	—	●
Shimada et al [71], 2016	Veterans with uncontrolled DM, registered for PP	Messaging and prescription refills users versus PP users who use neither	Messaging or requesting prescription refills is associated with improved glycemic control.	Cohort	●	—	—	—	●
van Vugt et al [73], 2016	Patients with DM type 2, registered for PHR[j]	PHR+personal coach versus PHR use alone	PHR use does not result in improved glycemic control, self-care, distress, nor well-being, regardless of personal coaching.	RCT	○	○	—	○	●
Dixon et al [47], 2016	Adults with DM type 2	Pretest PP nonusers versus posttest PP users	Patient portal use is associated with improved adherence, but not with changes in clinical outcomes nor care utilization.	QE	○	◔	○	—	○
Druss et al [77], 2020	Patients with a mental disorder+DM, HT or HC[k]	PP users versus PP nonusers	Patient portal use does not result in clinically relevant improvements in perceived quality of care, patient activation nor HRQoL[l].	RCT	○	○	●	—	○
Graetz et al [49], 2020	Adults with DM with at least 1 oral drug	PP users versus PP nonusers	Patient portal use is associated with small, likely irrelevant improvements in glycemic control and medication adherence.	Cross	○	○	—	—	○
Grant et al [50], 2008	Adults with DM using medication	Tethered PP use versus untethered PP use	Using a tethered patient portal results in increased patient participation, but not improved glycemic control.	RCT	○	●	—	—	○
Reed et al [60], 2019	Adults with DM+HT, asthma, CAD[m], or CHF[n]	PP users versus PP nonusers	Patient portal use is associated with more outpatient office visits, and with reduced ED visits and preventable hospitalizations.	Cross	●	—	◔	—	○
Riippa et al [62], 2014	Adults with DM, HT, or HC	PP users versus PP nonusers	Patient portal use does not result in clinically relevant improvements in patient activation, except among adults with low baseline activation.	RCT	—	◔	—	—	○

Author, year	Participants	Comparison	Main conclusion	Study design	Clinical	Patient reported	Care utilization	Technology	Quality[b]
Riippa et al [63], 2015	Adults with DM, HT, or HC	PP users versus PP nonusers	Patient portal use does not result in clinically relevant improvement in patient activation nor HRQoL.	RCT	—	●	●	●	●
Robinsonet al [64], 2020	Veterans with uncontrolled DM type 2, registered for PP	Responders on team-initiated messages versus nonresponders	Responding on messages is associated with improved self-management and self-efficacy.	Cross	—	●	—	—	●
Ronda et al [65], 2014	Adults with DM	Recurrent PP users versus PP nonusers	Recurrent patient portal use is associated with better self-efficacy and knowledge.	Cross	—	●	—	◐	●
Ronda et al [66], 2015	Adults with DM, registered for PP	Persistent users versus early quitters	Recurrent users believe the patient portal increases disease knowledge, and they find it useful.	Cross	—	●	—	●	●
Sabo et al [67], 2021	Adults with DM type 2, registered for PP	PP users versus PP nonusers	Patient portal use has minor, clinically irrelevant effects on BMI, and no effects on glycemic control nor blood pressure.	RCT	●	—	—	—	●
Seo et al [69], 2020	Patients with DM, registered for PHR	Continuous users versus noncontinuous users	Continuous use of a tethered PHR is associated with slightly improved glycemic control. Clinical implications are doubtful.	Cohort	◐	—	—	—	●
Sharit et al [70], 2018	Overweight veterans with prediabetes	Pretest PP nonuse versus posttest PP use	Using an accelerometer-connected patient portal is associated with improvements in physical activity and blood pressure.	QE	●	◐	—	●	●
Tenforde et al [72], 2012	Adults aged <75 years with DM	PP users versus PP nonusers	Patient portal use is associated with slightly improved diabetes control, lipid profile, and blood pressure. Clinical implications are doubtful.	Cohort	◐	—	●	—	●
Vo et al [74], 2019	Adults aged <80 years with DM type 2, registered for PP	Previsit message use versus no previsit message use	Sending previsit prioritization messages does not result in improved glycemic control, but does result in improved perceived shared-decision-making.	RCT	●	●	—	—	●
Zocchi et al [76], 2021	Patients with DM type 2, registered for PP	PP users	Among existing patient portal users with uncontrolled DM or high LDL[o], increased use is associated with improved control.	Cohort	◐	—	—	—	●
Bailey et al [41], 2019	Adults with DM, on high-risk medication	PP users	Patients are satisfied with the patient portal.	QE	—	—	—	●	●
Byczkowski et al [43], 2014	Parents of children with DM (or CF[p] or JIA[q])	PP users	Patients consider the patient portal to be useful in managing and understand their child's disease.	Cross	—	●	—	●	●
Chung et al [44], 2017	Adults with DM, registered for PP	Message users versus message nonusers	Using secure messaging is associated with better glycemic control.	Cohort	●	●	●	—	●
Conway et al [45], 2019	Patients with DM, registered for PP	PP users	Patients believe the tethered diabetes PHR might improve their diabetes self-care.	Cross	—	●	—	●	●
Devkota et al [46], 2016	Patients with DM type 2	PP users who read and write emails versus PP nonusers	Reading and writing emails is associated with improved glycemic control.	Cohort	●	●	—	—	●

Author, year	Participants	Comparison	Main conclusion	Study design	Clinical	Patient reported	Care utilization	Technology	Quality[b]
Graetz et al [48], 2018	Adults with DM	PP users versus PP nonusers	Patient portal use is associated with improved adherence to medication and preventive care utilization.	Cross	—	Green	Green	—	Red
Martinez et al [53], 2021	Adults with DM type 2 using medication, registered for PP	Pretest PP nonuse versus posttest PP use	Patient portal use results in clinically not relevant improvements in patient activation and self-efficacy. This is related to the very short follow-up period of the study.	QE	—	Yellow	—	Half green, half yellow	Red
Osborn et al [55], 2013	Adults with DM type 2 using medication	PP users versus PP nonusers	Patient portal use is not associated with improved glycemic control, as compared with nonusers. However, among users, more frequent use is associated with improved glycemic control.	Cross	Half green, half yellow	—	—	—	Red
Price-Haywood et al [57], 2018	Adults with DM (or HT)	PP users versus PP nonusers	Messaging is associated with improved glycemic control.	Cohort	Green	—	—	—	Red
Quinn et al [58], 2018	Adults aged <65 years with DM type 2	PP+extra module users versus PP users	Messaging is associated with better glycemic control. Note: glycemic parameters were predicted and not represent measurements.	RCT	Green				Red
Reed et al [59], 2015	Adults with DM, HT, asthma, CAD, or CHF, registered for PP	PP users	One-third of patients report that messaging in a patient portal results in less health care visits and improved overall health.	Cross	—	Green	Green	—	Red
Reed et al [61], 2019	Adults with DM, asthma, HT, CAD, CHF, or CV[r] event risk	PP users versus PP nonusers	One-third of patients report that using the patient portal improves overall health.	Cross	—	Green	—	Green	Red
Wald et al [75], 2009	Patients with DM type 2	PHR users who created a previsit plan	Users who create a previsit care plan feel better prepared for visits.	RCT	—	Half green, half yellow	—	Green	Red

[a]Studies are listed multiple times in Tables 10-13. Per disease category, the relevant subconclusion and health outcomes are described. Associations with health outcomes are color-coded as green for beneficial, yellow for neutral or clinically nonrelevant, or red for undesired. The half green and half yellow symbol implies that one study investigated multiple outcomes in one category and reported beneficial associations for some outcomes and neutral associations for others.

[b]Quality appraisal—green: high quality; yellow: medium quality; red: low quality.

[c]DM: diabetes mellitus.

[d]PP: patient portal.

[e]QE: quasi-experimental, including pretest-posttest studies and feasibility studies.

[f]The study did not assess any health outcome in a certain category.

[g]RCT: randomized controlled trial.

[h]HT: hypertension.

[i]ED: emergency department.

[j]PHR: personal health record.

[k]HC: hypercholesteremia.

[l]HRQoL: health-related quality of life.

[m]CAD: coronary artery disease.

[n]CHF: congestive heart failure.

[o]LDL: low-density lipoprotein.

[p]CF: cystic fibrosis.

[q]JIA: juvenile idiopathic arthritis.

[r]CV: cardiovascular.

Table 11. Conclusions and health outcomes: studies investigating cardiopulmonary diseases (n=21), of which 6 (29%) are of high methodological quality.[a]

Author, year	Participants	Comparison	Conclusion	Study design	Clinical	Patient reported	Care utilization	Technology	Quality[b]
Ahmed et al [79], 2016	Adults with asthma using medication	PP[c] users versus PP nonusers	Patient portal use does not result in durable improvements in HRQoL[d] nor asthma control.	RCT[e]	○	○	○	●	●
Fiks et al [81], 2015	Children aged 6-12 years with asthma	PP users versus PP nonusers	Patient portal use results in improved asthma control.	RCT	●	◑	●	●	●
Lau et al [85], 2015	Adults with asthma	PHR[f] users versus PHR nonusers	PHR use does not increase the use of asthma action plans, and does not affect asthma control, health care utilization nor work or school participation.	RCT	○	○	○	—[g]	●
Manard et al [86], 2016	Adults with uncontrolled HT[h]	PP users versus PP nonusers	Using a patient portal linked with a blood pressure cuff is not associated with improved blood pressure control.	Cohort	○	—	—	—	●
Price-Haywood and Luo [56], 2017	Adults with HT (or DM[i])	PP users versus PP nonusers	Patient portal use is associated with more primary care visits and telephone encounters, but not hospitalizations or ED[j] visits. Effects on blood pressure control are not clinically relevant.	Cohort	○	—	◑	—	●
Shimada et al [71], 2016	Veterans with uncontrolled HC[k] or HT, registered for PP	Users of both messaging and prescription refills versus nonusers	Messaging or requesting prescription refills are both associated with improved lipid control. Requesting prescription refills is associated with improved blood pressure control.	Cohort	◑	—	—	—	●
Apter et al [80], 2019	Adults with asthma using prednisone	PP use+training versus PP use+assistance via home visits	Patient portal use results in minor improvements in asthma control and HRQoL. Conducting home visits results in more improvements in these outcomes.	RCT	●	●	●	—	○
Druss et al [77], 2020	Patients with a mental disorder+DM[i], HT[j], or HC[k]	PP users versus PP nonusers	Patient portal use does not result in clinically relevant improvements in perceived quality of care, patient activation, nor HRQoL.	RCT	○	○	●	—	○
Fiks et al [82], 2016	Children aged 6-12 years with asthma	PP users versus PP nonusers	Patient portal use is associated with improved treatment adherence. Among patients with uncontrolled asthma, its use is associated with more care visits. Adoption is low.	QE[l]	—	●	●	●	○
Martinez Nicolás et al [89], 2019	Patients with COPD[m] or CHF[n]	Pretest PP nonuse versus posttest PP use	Patient portal use is associated with less hospitalizations, readmissions, and ED visits among patients with CHF and COPD.	QE	●	—	●	—	○
Reed et al [60], 2019	Adults with DM+HT, asthma, CAD[m], or CHF[n]	PP users versus PP nonusers	Patient portal use is associated with more outpatient office visits, and with reduced ED visits and preventable hospitalizations.	Cross	●	—	◑	—	○
Riippa et al [62], 2014	Adults with DM, HT, or HC	PP users versus PP nonusers	Patient portal use does not result in clinically relevant improvements in patient activation, except for patients with low baseline activation.	RCT	—	◑	—	—	○
Riippa et al [63], 2015	Adults with DM, HT, or HC	Patient portal versus usual care	Patient portal use does not result in clinically relevant improvement in patient activation nor HRQoL.	RCT	—	○	—	○	○

Author, year	Participants	Comparison	Conclusion	Study design	Clinical	Patient reported	Care utilization	Technology	Quality[b]
Toscos et al [87], 2020	Patients with nonvalvular AF[o] with an oral anticoagulant drug	PP users versus PP nonusers	Using a patient portal connected to a Smart Pill Bottle does not result in improved drug adherence.	RCT	—		—	—	
Wagner et al [88], 2012	Patients with HT	PHR users versus PHR nonusers	Using a tethered PHR does not result in clinically relevant improvements in blood pressure control, patient activation nor health care utilization. Adoption is low.	RCT					
Aberger et al [78], 2014	Postrenal transplant patients with HT	PP users	Using a patient portal–linked blood pressure monitoring system is associated with improved blood pressure control.	QE		—	—	—	
Kim et al [84], 2019	Patients with obstructive sleep apnea	PHR+activity tracker versus PHR alone versus nonusers	Using a tethered PHR results in more weight loss, regardless of its connection to an activity tracker. No sleep-related outcome improvements are seen.	RCT		—	—		
Kogut et al [83], 2014	Adults aged >49 years with cardiopulmonary disorders	PHR users versus PHR nonusers	Pharmacists reviewing patient-reported medication lists in a PHR might identify more medication-related problems.	QE		—	—	—	
Price-Haywood et al [57], 2018	Adults with HT or DM	PP users versus PP nonusers	Messaging is not associated with improved blood pressure control.	Cohort		—	—	—	
Reed et al [59], 2015	Adults with DM, HT, asthma, CAD[p], or CHF, registered for PP	PP users	One-third of patients report that messaging in a patient portal results in less health care visits and improved overall health.	Cross-sectional	—			—	
Reed et al [61], 2019	Adults with DM, asthma, HT, CAD, CHF, or CV[q] event risk	PP users versus PP nonusers	A third of patients reports that using the patient portal improves overall health.	Cross-sectional	—		—		

[a]Studies are listed multiple times in Tables 10-13. Per disease category, the relevant subconclusion and health outcomes are described.

[b]For color coding of quality appraisal and health outcomes, see Table 10.

[c]PP: patient portal.

[d]HRQoL: health-related quality of life.

[e]RCT: randomized controlled trial.

[f]PHR: personal health record.

[g]The study did not assess any health outcome in a certain category.

[h]HT: hypertension.

[i]DM: diabetes mellitus.

[j]ED: emergency department.

[k]HC: hypercholesteremia.

[l]QE: quasi-experimental, including pilot or feasibility studies.

[m]COPD: chronic obstructive pulmonary disease.

[n]CHF: Congestive heart failure.

[o]AF: atrial fibrillation.

[p]CAD: coronary artery disease.

[q]CV: cardiovascular.

Table 12. Conclusions and health outcomes: studies investigating hematological and oncological diseases (n=14), of which 2 are of high methodological quality (14%).[a]

Author, year	Participants	Comparison	Conclusion	Study design	Clinical	Patient reported	Care utilization	Technology	Quality[b]
Cahill et al [90], 2014	Adults with a brain tumor	PHR[c] users versus PHR nonusers	Using a tethered PHR is associated with improvements in patient uncertainty.	Cross-sectional	—	Green	—[d]	—	Green
Coquet et al [93], 2020	Patients with cancer+chemotherapy, registered for PP[e]	Email users versus email nonusers	Sending emails is associated with improved 2-year survival, less missed appointments, and less hospitalizations.	Cohort	Green	—	Green/yellow	—	Green
Chiche et al [91], 2012	Adults with ITP[f]	PP users versus PP nonusers	Patient portal use does not result in improved HRQoL[g]. The portal is acceptable and feasible.	RCT[h]	—	Yellow	—	Green	Yellow
Groen et al [94], 2017	Patients with lung cancer	PP users	Patient portal use does not affect HRQoL nor patient engagement. It is feasible and acceptable.	QE[i]	—	Green/yellow	—	Green	Yellow
Hall et al [95], 2014	Patients with cancer resection	PP users	Disclosing results of genetic cancer screening in a patient portal might be feasible and acceptable, and is not associated with more anxiety. Yet, few abnormal results were observed.	QE	—	Green	—	Green	Yellow
Kidwell et al [97], 2019	Patients aged 13-24 years with sickle cell disease	PP users	Patient portal use is not associated with improved medical decision-making by patients. It is acceptable and easy to use.	QE	—	Yellow	—	Green	Yellow
Martinez Nicolás et al [89], 2019	Patients with hematologic malignancy	Pretest PP nonuse versus posttest PP use	Patient portal use is not associated with less hospitalizations, readmissions, nor ED[j] department visits.	QE	Green	—	Green	—	Yellow
Williamson et al [102], 2017	Pediatric cancer survivors	PHR users versus PHR registrants	Patient portal use is not associated with less missed appointments.	Cohort	—	—	Yellow	Yellow	Yellow
Collins et al [92], 2003	Patients with hemophilia >11 years	Users	An electronic treatment log is considered feasible and easy to use.	QE	—	—	—	Green	Red
Hong et al [96], 2016	Children aged 13-17 years with cancer or a blood disorder+parents	PP users	A small cohort considers a patient portal to be feasible and useful.	Cross-sectional	—	Green/yellow	—	Green/yellow	Red
O'Hea et al [98], 2021	Women with breast cancer	PP users versus PP nonusers	Patient portal use does not result in improved HRQoL nor disease knowledge.	RCT	—	Yellow	—	—	Red
Pai et al [99], 2013	Men with prostate cancer	PHR users	Patients are satisfied with a tethered PHR and find it increases disease knowledge.	Cross-sectional	—	Green	—	Green	Red
Tarver et al [100], 2019	Patients with colorectal cancer	Tethered PHR users	Patients are satisfied with an integrated care plan and find it useful.	Cohort	—	—	—	Green	Red
Wiljer et al [101], 2010	Patients with breast cancer	Pretest PHR nonusers versus posttest PHR users	PHR use is not associated with improved self-efficacy, nor with a clinically relevant decrease in anxiety. Satisfaction is high.	QE	—	Yellow	—	Green	Red

[a]Studies are listed multiple times in Tables 10-13. Per disease category, the relevant subconclusion and health outcomes are described.

[b]For color coding of quality appraisal# and health outcomes, see Table 10.

[c]PHR: personal health record.

[d]The study did not assess any health outcome in a certain category.

[e]PP: patient portal.

[f]ITP: idiopathic thrombocytopenic purpura.
[g]HRQoL: health-related quality of life.
[h]RCT: randomized controlled trial.
[i]QE: quasi-experimental, including pilot or feasibility studies.
[j]ED: emergency department.

Table 13. Conclusions and health outcomes: studies investigating other diseases (n=21), of which 2 (10%) are of high methodological quality.[a]

Author, year	Participants	Comparison	Conclusion	Study design	Clinical	Patient reported	Care utilization	Technology	Quality[b]
Miller et al [113], 2011	Patients with multiple sclerosis	PHR[c] use versus PHR that only enables messaging	Using an untethered PHR results in slightly improved HRQoL[d], but not in improved self-efficacy, disease control nor health care utilization.	RCT[e]	—	◔	○	—[f]	●
Navaneethan et al [114], 2017	Adults with chronic kidney disease	PP[g] users+coach versus PP users versus PP nonusers	Patient portal use, regardless of added training, does not result in improved kidney function, nor altered health care utilization.	RCT	○	—	○	—	●
Anand et al [103], 2017	MSM[h] and transgender women with HIV	PP users	The patient portal is feasible and acceptable.	RCT	—	—	—	●	○
Druss et al [106], 2014	Patients with a mental disorder+chronic condition	PP users versus PP nonusers	Patient portal use results in increased use of preventive health services and medical visits, but not in improved HRQoL.	RCT	●	○	●	—	○
Druss et al [77], 2020	Patients with a mental disorder+DM[i], HT[j], or HC[k]	PP users versus PP nonusers	Patient portal use does not result in clinically relevant improvements in perceived quality of care, patient activation, nor HRQoL.	RCT	○	○	●	—	○
Jhamb et al [107], 2015	Adults visiting nephrology clinics	PP users versus PP nonusers	Patient portal use might be associated with improved blood pressure control, although its clinical relevance is unclear.	Cross-sectional	◔	—	—	●	○
Keith McInnes et al [109], 2013	Veterans with HIV	PP users versus PP nonusers	Patient portal use is associated with improved adherence to HIV medication.	Cross-sectional	—	●	—	●	○
Keith McInnes et al [110], 2017	Veterans with HIV+detectable viral load, registered for PP	Messaging or prescription refill users versus nonusers	Requesting prescription refills is associated with improved HIV control, but messaging is not.	Cohort	◔	—	—	—	○
Kiberd et al [111], 2018	Adult with home dialysis	Pretest PP nonuse versus posttest PP use	Patient portal use is not associated with improvements in HRQoL nor perceived quality of care. Both were already high at baseline.	QE[l]	—	○	—	●	○
Lee et al [112], 2017	Patients with cleft lip or cleft palate surgery	PP users versus PP tailored for lip or cleft palate surgery	Using a tailored, disease-specific patient portal is associated with increased disease knowledge.	QE	—	●	—	●	○
Reich et al [116], 2019	Patients with inflammatory bowel disease	PP users versus PP nonusers	Patient portal use does not result in improved HRQoL, but results in a higher vaccination rate. Patient satisfaction is high.	RCT	—	○	●	●	○
Scott Nielsen et al [117], 2012	Patients with multiple sclerosis	PP users versus PP nonusers	Messaging in a patient portal is associated with more clinic visits, but not with less ED[m] visits nor hospitalizations.	Cross-sectional	—	—	○	●	○
Tom et al [119], 2012	Parents of children age <6 years with 1 ore more chronic condition(s)	PP users versus PP nonusers	Patient portal use is not associated with improved access to care, nor perceived quality of care. It is considered feasible.	Cross-sectional	—	○	—	◔	○
van den Heuvel et al [120], 2018	Adults with bipolar disorder	Pretest PHR nonusers versus posttest PHR users	PHR use is not associated with improved HRQoL, patient empowerment, symptom reduction, nor disease burden.	Cross-sectional	—	○	—	●	○

Author, year	Participants	Comparison	Conclusion	Study design	Clinical	Patient reported	Care utilization	Technology	Quality[b]
van der Vaart et al [121], 2014	Patients with rheumatoid arthritis	Pretest PP nonusers versus posttest PP users	Patient portal use is not associated with improved patient empowerment. It is considered useful and understandable.	Cross-sectional	—	◐	—	●	●
Bidmead et al [104], 2016	Patients with inflammatory bowel disease	PHR users	PHR use is not associated with improved self-management.	Cross-sectional	●	●	●	●	●
Byczkowski et al [43], 2014	Parents of children with CF[o] or JIA[p] (or DM)	PP users	Patients consider the patient portal to be useful in managing and understand their child's disease.	Cross	—	●	—	●	●
Crouch et al [105], 2015	Veterans with HIV	PP users versus PP nonusers	Patient portal use is associated with improved patient activation, disease knowledge, HIV load, but not with improved CD4-count nor treatment adherence	Cross-sectional	—	◐	—	●	●
Kahn et al [108], 2010	Patients with HIV or aids	PP users	Patients are satisfied with the patient portal and consider it to be helpful in managing their problems.	QE	—	●	—	●	●
Plimpton [115], 2020	Women with HIV	Pretest PP nonuse versus posttest PP use	Patient portal use is associated with an increase in planned visits, but not with a decrease in missed visits. A trend toward improved viral load is seen.	QE	●	—	●	—	●
Son et al [118], 2019	Patients aged >49 years with 1 or more chronic condition(s)	PP users	Patients consider a patient portal to be helpful in increasing self-management.	Cohort	—	●	—	●	●

[a]Studies are listed multiple times in Tables 10-13. Per disease category, the relevant subconclusion and health outcomes are described.

[b]For color coding of quality appraisal and health outcomes, see Table 10.

[c]PHR: personal health record.

[d]HRQoL: health-related quality of life.

[e]RCT: randomized controlled trial.

[f]The study did not assess any health outcome in a certain category.

[g]PP: patient portal.

[h]MSM: men who have sex with men.

[i]DM: diabetes mellitus.

[j]HT: hypertension.

[k]HC: hypercholesteremia.

[l]QE: quasi-experimental, including pilot or feasibility studies.

[m]ED: emergency department.

[o]CF: cystic fibrosis.

[p]JIA: juvenile idiopathic arthritis.

Clinical Outcomes

In 44 studies investigating a total of 69 clinical outcomes, a beneficial association with digital health record use was reported for 42% (29/69) of the outcomes. Hospitalizations and exacerbations were the most frequently studied disease events and complications, with beneficial effects reported in half of the studies (2/4 and 2/4, respectively). Blood pressure was the most frequently studied vital parameter, with beneficial effects reported in 36% (5/14) of the studies. HbA_{1c} and cholesterol levels were the most frequently studied laboratory parameters, with beneficial effects reported in 53% (10/19) and 57% (4/7) of the studies, respectively. No clinical outcomes were unfavorably affected by patient-centered digital health record use. In comparison with the total population, higher proportions of beneficial effects were reported for diabetes mellitus and cardiopulmonary diseases. When focusing on 14 high-quality studies, beneficial effects were observed less frequently, in only 30% (7/23) of the clinical outcomes.

Studies that assessed vital parameters generally reported few other health outcomes. However, among the studies that assessed disease events and complications, and laboratory parameters, beneficial effects were often associated with improved treatment adherence [52,68,71,81]. We hypothesize that this might be related to the removal of logistical barriers for patients in

obtaining web-based prescription refills, as opposed to having to call health care providers or send them an email. Of the 6 high-quality studies that investigated treatment adherence, 2 studies assessed patient-centered digital health records that enabled patients to request prescription refills and found beneficial effects on adherence [52,68].

Patient-Reported Outcomes

Overall, in 53 studies investigating a total of 86 patient-reported outcomes, a beneficial association with digital health record use was reported for 45% (39/86) of the outcomes. Of the 18 studies investigating 19 self-management or self-efficacy outcomes, beneficial effects were reported in 53% (9/19). Of these 9 studies, 56% (5/9) used validated questionnaires. For patient engagement outcomes, large differences in the proportions of beneficial effects were observed: from 11% (1/9) for patient activation, to 56% (5/9) for patient involvement, and 70% (7/10) for disease knowledge. However, only in measuring patient activation, validated questionnaires were principally used (8/9, 88% of studies). For HRQoL, beneficial effects were reported in 27% (4/15) of the studies, of which half used validated HRQoL questionnaires. No patient-reported outcomes were unfavorably affected by patient-centered digital health record use. In comparison to the total population, higher proportions of beneficial effects were reported for diabetes mellitus, especially for patient engagement and treatment adherence. Lowest proportions were reported for cardiopulmonary diseases, especially for patient engagement. When focusing on 10 high-quality studies, a lower proportion (7/19, 37%) of beneficial effects was observed.

We observed that improvements in patient engagement were especially facilitated by strengthening patient-professional communication; for example, through secure messaging [71,81,93]. In addition, both self-efficacy and HRQoL primarily seemed to be reinforced through the use of 2 functionalities: patient-professional communication [54,90,113] and information on disease progression [90,113].

Health Care Utilization

For 24 studies investigating a total of 27 health care utilization outcomes, a beneficial association with digital health record use was observed for 59% (16/27) of the outcomes. The highest proportion (10/13, 77%) of beneficial effects was reported for an increased use of recommended care services. Of these 13 studies, 5 (38%) focused on recommended care services for people with uncontrolled disease, 4 (31%) on the use of preventive care services, and 4 (31%) on medical follow-up rates. In 25% (3/12) of the studies that assessed reductions in ED visits and hospitalizations, these were accompanied by an increased use of other care services, including outpatient clinic appointments and secure messaging. Compared with the total population, highest proportions of beneficial effects were reported for diabetes mellitus and hematological and oncological diseases. When focusing on 7 high-quality studies, lower proportions (3/9, 33%) of beneficial effects were observed.

Technology-Related Outcomes

For 39 studies investigating a total of 75 technology-related outcomes, a beneficial association with digital health record use was observed for 88% (66/75) of the outcomes. All (22/22, 100%) studies reported high patient satisfaction with accessing and using digital health records. Furthermore, 75% (6/8) of the studies reported high patient satisfaction with the effects of using digital health records. High feasibility was reported by 79% (15/19) of the studies, and high acceptability by 88% (23/26) of the studies. Highest feasibility was reported for digital health records intended for people with hematological and oncological diseases. Lowest feasibility and acceptability were reported for digital health records intended for people with cardiopulmonary diseases. When focusing on 6 high-quality studies, proportions of studies that found beneficial effects were similar.

High Disease Burden or Self-management

A subgroup of 47 studies that investigated patients with a high disease burden or high self-management was assessed. The following conditions were included: malignancies (11 studies), asthma (9 studies), HIV infection and AIDS (6 studies), hematologic conditions (5 studies), chronic kidney disease (3 studies), chronic heart failure (4 studies), mental disorders (3 studies), multiple sclerosis (2 studies), inflammatory bowel disease (2 studies), rheumatologic conditions (2 studies), insulin-dependent diabetes mellitus (2 studies), atrial fibrillation (1 study), cystic fibrosis (1 study), and posttransplant patients (1 study). In general, the digital health records assessed in this subgroup were more often tailored to specific patient populations through the addition of specialized functionalities or connected wearables.

In comparison with studies investigating patients with no high disease burden, studies investigating patients with a high disease burden reported considerably higher proportions of beneficial effects for vital parameters, patient engagement, reductions in ED visits and hospitalizations, and for all technology-related outcomes. Considerably lower proportions of beneficial effects were reported for laboratory parameters, health-related quality of life, treatment adherence, and increased use of recommended care services. For the 9 high methodological quality studies on high disease burden or self-management, the proportions of studies that found beneficial effects were roughly similar.

Focus on Passive Versus Active Features

Of the 81 studies, 41 (51%) of the studied patient-centered digital health records focused on passive features and 40 (49%) focused on active features. In comparison with digital health records with an active focus, more beneficial effects were observed among digital health records with a passive focus for laboratory parameters (9/16, 56% vs 7/17, 41%), self-management and self-efficacy (7/11, 64% vs 3/8, 38%), patient engagement (9/15, 60% vs 4/13, 31%), and for an increased use of recommended care services (5/6, 83% vs 5/7, 71%). Compared with digital health records with a passive focus, more beneficial effects were observed among digital health records with an active focus on disease events or complications (4/10, 40% vs 1/5, 20%) and reductions in ED visits and hospitalizations (4/6, 67% vs 1/6, 17%). However, when focusing on high-quality studies, higher proportions of beneficial effects were seen for digital health records with an active focus on all clinical outcomes, patient-reported outcomes,

reductions in ED visits and hospitalizations, patient satisfaction, and acceptability.

Quality Appraisal

Of the 81 included studies, 27 (33%) studies were graded as low quality, 38 (47%) as medium quality, and 16 (20%) as high quality (Tables 10-13). Studies investigating cardiopulmonary conditions were of the highest quality, with 29% (6/21) of the studies graded as high quality. Of the 24 included RCTs, 7 (29%) were of high quality. Only 38% (9/24) of the RCTs concealed allocation to treatment groups, and 67% (16/24) used intention-to-treat analyses. Of the 57 studies with other designs, 9 (16%) were graded as high quality. Overall, 15% (12/81) of studies reported power calculations.

Among the 65 studies that were graded as medium or low quality, only 35% (23/65) used reliable or validated tools for the measurement of all their outcomes and 48% (31/65) for part of their outcomes. Of these 65 studies, 10 (15%) studies took adequate measures to limit selection bias and 17 (26%) studies used a control group or randomized participants.

When focusing on the 16 high-quality studies, 3 functionalities appeared to be the most effective: secure messaging to lower barriers in patient-professional interaction, prescription refill functions to improve medication adherence, and information provision on disease progression. In addition, in 16 high-quality studies, the proportions of beneficial effects were similar for a subgroup of studies that included older participants (mean age >55 years), which included a high number of female participants (>45%), or included a racially diverse population (<50% White participants), as compared with the total population.

Discussion

Principal Findings

In this systematic review, we evaluated evidence on the effects of the use of patient-centered digital health records in nonhospitalized patients with chronic health conditions on clinical and patient-reported outcomes, health care utilization, and technology-related outcomes. Beneficial effects were most frequently reported for the use of recommended care services (10/13, 77%) and for 4 patient-reported outcomes: disease knowledge (7/10, 70%), patient involvement (5/9, 56%), treatment adherence (10/18, 56%), and self-management and self-efficacy (10/19, 53%). Regarding clinical outcomes, beneficial effects were reported in 42% (29/69) of the studies. Beneficial effects were least frequently reported for disease events and complications (5/15, 33%) and health-related quality of life (4/15, 27%). For digital health records that predominantly focused on active features, higher proportions of beneficial effects on nearly all health outcomes were observed among the high-quality studies.

In this study, we observed that patient-centered digital health record use may be associated with an increased use of recommended care services. Beneficial effects on ED visits and hospitalizations were mainly observed when accompanied by an increased rate of follow-up appointments or secure messaging [60,89,93]. This might imply that reducing ED visits and hospitalizations is primarily achieved by facilitating patient-professional communication.

Beneficial effects were most often reported for patients with diabetes or cardiopulmonary disorders. We suggest 2 explanations. First, the focus of digital health records has been directed toward patients with diabetes and asthma for some time because of the sheer number of people with these conditions. This could have resulted in higher-quality patient-centered digital health records and patients who were more accustomed to their use. Second, the relative improvements in health outcomes might be smaller among patients with a condition with a high disease burden because of a higher baseline level of self-management skills and disease knowledge.

The proportions of beneficial effects varied considerably between health outcomes, which may be explained by 2 reasons. First, outcomes with a higher proportion of beneficial effects were more often the primary study outcomes than the secondary outcomes. Digital health records were more frequently tailored for these outcomes, yielding higher beneficial effects. Second, outcome assessment was generally less robust for outcomes with a higher proportion of beneficial effects, such as self-management and patient engagement, which might have resulted in more false-positive effects.

Comparison With Earlier Evidence

Our results are more positive than those of the previous systematic reviews. This might be because of the increasing acceptance of digital health records, their improving quality, the increasing body of literature, or variations in digital health record definitions used. Two previous reviews found mixed effects on the use of portals on health outcomes and health care utilization [27] and reported positive effects on qualitatively assessed self-management in only one-third of the studies [25]. A recent systematic review that focused on portals intended for hospitalized patients found mixed results for patient engagement [26]. A systematic review that included only qualitative studies found that portal use was associated with positive effects on self-efficacy, treatment adherence, and disease knowledge [28]. In a review on eHealth interventions that aim to promote medication use, a weak association between digital health record use and health-related quality of life was observed [10]. This implies that digital health record engagement is not yet sufficient to affect patients' overall health-related quality of life.

Strengths and Limitations

This systematic review has several strengths. Our search strategy was comprehensive, to account for the lack of consensus in digital health record terminology. In addition, a wide variety of health outcomes were considered relevant to determine the impact of digital health record use. However, several limitations of this study must be considered. First, comparisons between studies were difficult because of the variety in evaluated functionalities. A similar diversity was observed among the reported follow-up durations, participants' ages, study sample sizes, and outcomes. Second, because it was not possible to perform a meta-analysis owing to the heterogeneity in reported (disease-specific) outcome measurements and effects, we used the vote-counting method. Therefore, we could not report the

effect estimates and indicated directions of effects [122]. Third, owing to a lack of agreement on feasibility and acceptability thresholds, much is left to the authors' discretion. Fourth, JBI critical appraisal tools rank every item equally despite being not equally important. Finally, publication bias could have resulted in overestimation of the positive effects of patient-centered digital health records. More studies with positive results have been published. In addition, many of the included studies assessed more "mature" patient-centered digital health records, which could have overestimated the effects.

We observed that high patient satisfaction rates did not fully reflect in other health outcomes. This can be partly attributed to acquiescence bias and satisficing [123]. Moreover, satisfaction was often reduced to a narrow ease-of-use questionnaire, instead of satisfaction with the contribution to overall disease management. Finally, several studies only included recurrent users in their analyses, which could falsely increase feasibility. Moreover, these recurrent users likely experienced positive effects of using digital health records, which would have resulted in an overestimation of effects in randomized studies with no intention-to-treat analysis and in all nonrandomized studies.

The voluntary adoption of patient-centered digital health records by patients might reflect an intrinsic, preexisting motivation for self-management and care engagement bias, which may overestimate their effects. Patient-centered digital health record use could even be considered a surrogate measure for engagement [109,124,125]. Thus, it might be best to consider digital health records as vehicles for empowerment, strengthening existing self-management capabilities [126,127].

The effects of using patient-centered digital health records on health outcomes are not always direct but often depend on intermediate steps. For example, requesting prescription refills might depend on the actions performed by (slow-responding) physicians, nurses, or pharmacies. Thus, if using a digital health record would have no observable effects on health outcomes, this could also be a result of these intermediate steps or unforeseen processes and may not be attributable to the use of the patient-centered digital health record.

The proportion of beneficial effects reported in high-quality studies was lower as compared with all included studies for clinical outcomes (30% vs 42%), patient-reported outcomes (37% vs 45%), and health care utilization (33% vs 59%). Nevertheless, the proportions are clinically relevant and promising considering this newly emerging field. The observed differences might be related to 4 factors. First, the selection of motivated, well-educated, digitally minded participants might have overestimated the results in most low- and moderate-quality studies. Second, most studies did not measure ongoing user activity, and assumed that registered users became recurrent users. Third, nearly all low- and moderate-quality studies reported high dropout rates, which could overestimate acceptance rates. Finally, the lack of consensus on digital health record terminology hindered the interpretation of findings. We would advocate the use of uniform definitions, such as those presented in Textbox 1 [10,17-20].

Future Research

Future studies should adopt additional measures to adhere to a uniform taxonomy, use log data, and limit selection bias. The exclusion of less-engaged people could further expand the digital divide between patients who are digitally proficient and those who are not, resulting in an increasingly unequal distribution of care services. We suggest that researchers include a diverse population based on age, gender, disease burden, race, education level, and health literacy [128]. Finally, further research should focus on determining which functionalities are mostly responsible for the effects on the outcomes.

Conclusions

The use of patient-centered digital health records in chronic conditions is potentially associated with beneficial effects on several patient-reported outcomes and recommended care services in a considerable number of studied digital health records. The rates of the effects were approximately similar for different patient groups. Feasibility and acceptability were high. Our findings support further implementation of patient-centered digital health records in clinical practice. Yet, higher-quality research is needed to identify effects per disease category and per health outcome and to learn which patients might benefit from specific functionalities.

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Authors' Contributions

All authors were involved in the design of the research protocol. MB performed the search strategy. MRB and SMB assessed all titles, abstracts, and full texts for eligibility. SCG helped resolve the discussion if necessary. MRB and SMB performed data extraction and synthesis. All authors provided feedback on the manuscript and approved the final manuscript.

Conflicts of Interest

SCG received an unrestricted medical research grant from Sobi. The authors have no futher interests to declare.

Multimedia Appendix 1

The search strategy used, that includes terms related to the search categories: “patient,” “intervention,” and “outcome.”.
[DOCX File , 19 KB-Multimedia Appendix 1]

Multimedia Appendix 2

The 4 modified Joanna Briggs Institute critical appraisal tools used in this study.
[DOCX File , 24 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Proportion of beneficial effects reported per health outcome of all studies, presented per disease category.
[DOCX File , 18 KB-Multimedia Appendix 3]

Multimedia Appendix 4

The proportion of beneficial effects reported per health outcome of 16 high quality studies, presented per disease category.
[DOCX File , 26 KB-Multimedia Appendix 4]

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Abbreviations

ED: emergency department
JBI: Joanna Briggs Institute
PHR: personal health record
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO: International Prospective Register of Systematic Reviews
RCT: randomized controlled trial

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Original Paper

Interpretable Machine Learning Prediction of Drug-Induced QT Prolongation: Electronic Health Record Analysis

Steven T Simon[1], MD; Katy E Trinkley[2], PharmD; Daniel C Malone[3], PhD; Michael Aaron Rosenberg[4], MD

[1]Division of Cardiology, University of Colorado School of Medicine, Aurora, CO, United States

[2]Department of Clinical Pharmacy, School of Pharmacy, University of Colorado, Aurora, CO, United States

[3]College of Pharmacy, University of Utah, Salt Lake City, UT, United States

[4]Division of Cardiac Electrophysiology, University of Colorado School of Medicine, Aurora, CO, United States

Corresponding Author:
Michael Aaron Rosenberg, MD
Division of Cardiac Electrophysiology
University of Colorado School of Medicine
12631 E. 17th Ave
Aurora, CO, 80045
United States
Phone: 1 720 500 3621
Email: michael.a.rosenberg@cuanschutz.edu

Abstract

Background: Drug-induced long-QT syndrome (diLQTS) is a major concern among patients who are hospitalized, for whom prediction models capable of identifying individualized risk could be useful to guide monitoring. We have previously demonstrated the feasibility of machine learning to predict the risk of diLQTS, in which deep learning models provided superior accuracy for risk prediction, although these models were limited by a lack of interpretability.

Objective: In this investigation, we sought to examine the potential trade-off between interpretability and predictive accuracy with the use of more complex models to identify patients at risk for diLQTS. We planned to compare a deep learning algorithm to predict diLQTS with a more interpretable algorithm based on cluster analysis that would allow medication- and subpopulation-specific evaluation of risk.

Methods: We examined the risk of diLQTS among 35,639 inpatients treated between 2003 and 2018 with at least 1 of 39 medications associated with risk of diLQTS and who had an electrocardiogram in the system performed within 24 hours of medication administration. Predictors included over 22,000 diagnoses and medications at the time of medication administration, with cases of diLQTS defined as a corrected QT interval over 500 milliseconds after treatment with a culprit medication. The interpretable model was developed using cluster analysis (K=4 clusters), and risk was assessed for specific medications and classes of medications. The deep learning model was created using all predictors within a 6-layer neural network, based on previously identified hyperparameters.

Results: Among the medications, we found that class III antiarrhythmic medications were associated with increased risk across all clusters, and that in patients who are noncritically ill without cardiovascular disease, propofol was associated with increased risk, whereas ondansetron was associated with decreased risk. Compared with deep learning, the interpretable approach was less accurate (area under the receiver operating characteristic curve: 0.65 vs 0.78), with comparable calibration.

Conclusions: In summary, we found that an interpretable modeling approach was less accurate, but more clinically applicable, than deep learning for the prediction of diLQTS. Future investigations should consider this trade-off in the development of methods for clinical prediction.

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KEYWORDS

drug-induced QT prolongation; predictive modeling; interpretable machine learning; ML; artificial intelligence; AI; electronic health records; EHR; prediction; risk; monitoring; deep learning

Introduction

Drug-induced long-QT syndrome (diLQTS) [1,2] is a major concern for inpatients worldwide and has been identified as a key target for clinical decision support tools [3-7]. Importantly, although certain medications have been implicated as having significant clinical risk [8,9], for others, despite a known risk of diLQTS, clinical validation has been lacking [10-12]. In the past few years, several groups have sought to apply prediction models using electronic health record (EHR) data to model risk [13-17] toward the goal of developing an automated approach that leverages innovations in data science and machine learning. In prior work [18], we performed a comparative evaluation of machine learning methods to predict diLQTS using EHR data, in which we found that the most accurate prediction method was a deep learning model (6-layer neural network). However, each of the models carried the limitation of lacking interpretability for its predictions [19], as we were unable to assess which clinical features were the most predictive. As such, we were unable to construct a meaningful decision support approach based on these models to reduce the risk of diLQTS or determine whether our model could be easily exported to other systems.

Beyond the role of increasing trust [20] in a prediction model, interpretability plays a critical role in the assessment of prediction models [21], particularly in the age of artificial intelligence, where increasingly complex models can be created using relatively raw, or unprocessed, clinical features. Limitations in interpretability are critical not only because the users may not understand why a model makes the recommendations that it does but also because a lack of interpretability increases the risk of bias in the form of data shifts [22-24]. Data shifts occur when a model is developed in one population and then applied in a different population; note that this effect could also occur within the same hospital system if the treatment paradigm changes dynamically over time. The inclusion of interpretable models also allows a detailed investigation to uncover confounding and identify situations where a critical factor was excluded from the prediction framework and to assess for reverse causality, a critical consideration in big data models. Although “interpretability” itself cannot be well quantified in the same manner as accuracy or calibration, it remains a critical consideration in the development of predictive models.

The promise of EHR data is that it provides a scale (ie, power) to draw clinical inferences across thousands of patients and potentially millions of data points, at the cost of lacking the ability for facile clinical validation. With this power comes the ability to predict clinical outcomes across a large number of heterogenous subjects, integrating the breadth of the clinical record and, with it, the range of possible diagnoses and medications that could have nonlinear associations that cannot be as easily detected using standard (ie, regression-based) methods. However, methods to leverage EHR data using machine learning have been limited by the ability to include interpretability along with predictive accuracy.

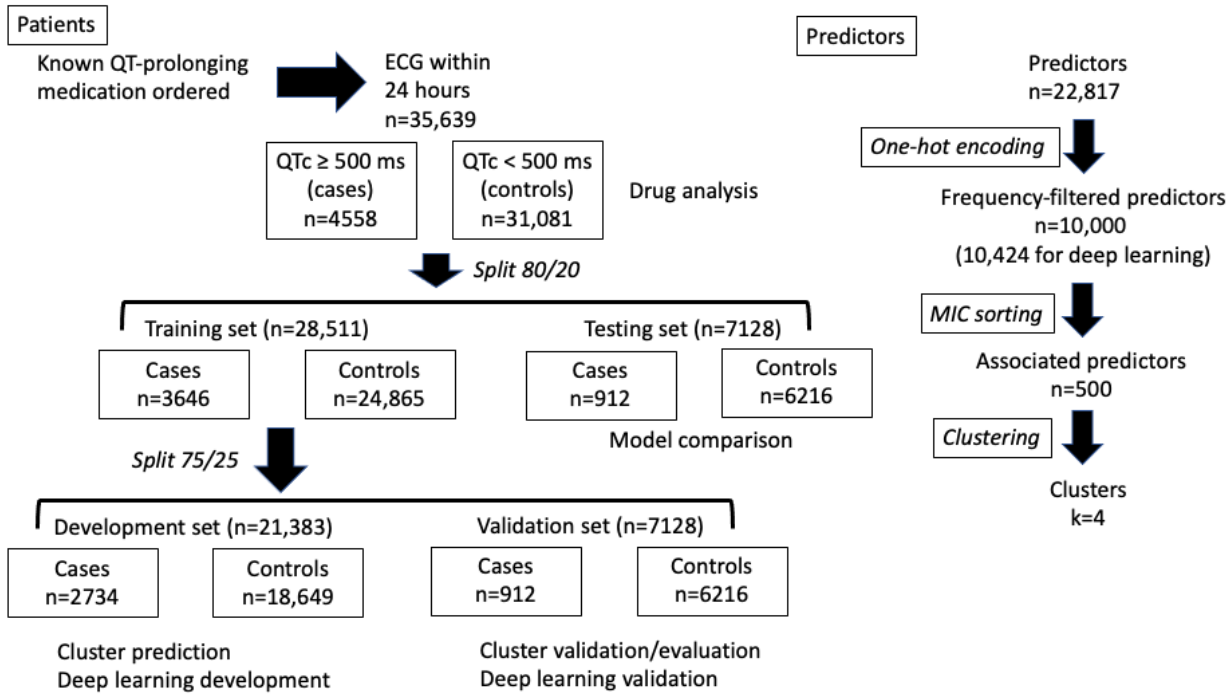
In this follow-up investigation to our previous work [18], we examined the application of an interpretable approach to predictive modeling applied at scale to EHR data to predict diLQTS. We specifically examined the use of clustering as a bridge to interpretability and compared this approach with a deep learning, noninterpretable method previously identified as providing superior predictive accuracy within our health care system.

Methods

Data Source and Study Population

The data for this investigation have been previously described [19]. Briefly, we examined EHR data from 35,639 inpatients within the UCHealth system treated between 2003 and 2018 with at least 1 of 39 medications associated with the risk of drug-induced QT prolongation and who had an electrocardiogram (ECG) in the system performed within 24 hours of medication administration (Figure 1). The primary outcome of drug-induced QT prolongation was based on any corrected QT interval over 500 milliseconds during the encounter, after the exclusion of ECGs with conduction disease (eg, bundle branch block, intraventricular conduction disease, and ventricular pacing). Predictors included any medication or diagnosis (International Classification of Diseases, Ninth or Tenth Edition) listed in the medical record that was present at the time of medication administration.

Figure 1. Data management schema. Left: patient data ascertained by order for known QT-prolonging medication with an electrocardiogram (ECG) performed within 24 hours to define cases (QTc ≥500 ms) and controls (QTc <500 ms), followed by subsequent splitting for models and validation. All splits stratified by case status. Right: processing of predictors using frequency filters, information coefficient, and clustering. MIC: maximum information coefficient; QTc: corrected QT interval.



Initial Drug Analysis

Varying formulations for each of the 39 culprit medications were combined (ie, oral and intravenous amiodarone were analyzed together). We first performed an unadjusted association analysis with each medication and the risk of diLQTS using a chi-square calculation. Those with significant associations after adjustment for multiple comparison (Bonferroni correction, *P* value for significance = .05/29 = .0017) were categorized as "high risk" for a combined analysis, as well as further model development (see below).

Predictor Filtering and Data Splitting

The medications and diagnoses in the raw data set were extracted from the EHR for each subject as a string array, following which we performed one-hot encoding (*keras.Tokenizer* [25]; version 2.8.0) to create a separate variable for each, labeled as 0 if the diagnosis or medication was absent at the time of QT-associated medication administration and 1 if it was present. As such, missing values were coded as 0, under the assumption that if the medication or diagnosis was not present in the EHR, the patient was not taking the medication or did not have that diagnosis. This process resulted in a data set containing 22,817 unique medications and diagnostic codes, from which we filtered the top 10,000 based on frequency. Of note, the 10,000th most frequent predictor was present in only 5 of 36,639 subjects. The unadjusted association for each of these 10,000 predictors with diLQTS was examined using the maximum information coefficient (MIC; *minepy.MIC*; version 1.2.6), which examines both linear and nonlinear associations based on mutual information [26]. After sorting by MIC, the top 500 most associated diagnoses and medications were selected for cluster analysis (see below). For deep learning analysis, the top 10,424 predictors after one-hot encoding were directly inputted into the model. Data splitting (Figure 1) was performed by subject index, stratified by the diagnosis of diLQTS (*sklearn.train_test_split*; version 1.1.2). The data were first split into training (28,511/35,639, 80%) and testing (7128/35,639, 20%) sets; the training set was then further split into development (21,383/28,511, 75%) and validation (7128/28,511, 25%) sets. The development set was used to fit clusters (cluster analysis) as well as to train the deep neural network. The validation set was used to examine cluster patterns and predictive accuracy, as well as to examine the training of deep learning. The testing set was used for comparative testing of cluster and deep learning models as outlined below.

Cluster Development and Evaluation

Clustering was performed using only diagnostic codes to facilitate comparisons of risk by drugs. To identify the optimal number of clusters, we first applied KMean clustering (*sklearn*; version 1.1.2) to the development set to create clusters from K=2 to K=50 and then examined inertia plot and silhouette scores (Figures S1A and S1B in Multimedia Appendix 1). After identification of K=4 as the optimal cluster number, we fitted the validation set with cluster assignments. To identify which diagnoses were the most overrepresented in each cluster (ie, which were the most different from other clusters), we calculated the proportion of each diagnosis for each cluster and assigned a value based on the product of the proportion within that cluster and the difference between this proportion and the cluster with the next highest proportion (termed the "proportion product"). The clinical interpretation of each cluster was performed by a clinician expert (MAR) after ranking the proportion product

within each cluster. Clinical interpretation included evaluating each cluster for themes of diagnoses (eg, critical care–related diagnoses and gastrointestinal-related diagnoses) to provide an overarching framework of the "types" of patients that each cluster was composed of. Clusters were examined using chi-square test for independent association the risk of diLQTS, as well as using logistic regression (unpenalized) for the proportionate risk of any high-risk medication or combinations of high-risk medications. Margin plots were created using Stata IC software (version 16; StataCorp).

Deep Learning Model Development

Hyperparameters for the deep learning model (deep neural network) were applied from our prior investigation [19]. Specifically, the deep neural network was composed of 6 layers, with 1024 neurons in the first layer and 512 neurons in the subsequent 5 layers; sigmoid activation function; 50% dropout for each layer; and batch normalization between layers. The final output was a binary prediction (the presence of diLQTS), with a binary cross-entropy loss function (*RMSprop optimizer*; learning rate=1×10^{-5}; ρ=0.9), and a validation metric of area under the receiver operating characteristic curve (AUC). The model was run over 500 planned epochs, with early stopping (*keras.callbacks.EarlyStopping*) if no improvement over 50 epochs, resulting in 118 total epochs of training. Training was monitored using learning curves (Figures S2A and S2B in Multimedia Appendix 1). The development set was used for training, and the validation set was used for validation after each epoch. In total, the deep learning model had 12,265,473 total parameters, with 12,258,305 trainable parameters and 7168 nontrainable parameters.

Model Comparison

Prediction from the cluster model was performed on the held-out testing set using logistic regression by cluster and the number of high-risk medications to obtain a predicted probability. Prediction from the deep learning model was performed through the application of the trained model to the testing set to obtain a predicted probability of diLQTS. Models were first compared using AUC, average precision score (*sklearn.metrics.average_precision_score*), and area under precision recall curve to obtain a threshold-independent comparison. The optimal probability cutoff was selected for each using the method of Youden [27]. After the selection of a cutoff, models were then compared on classification accuracy using F_1-score, recall, precision, and contingency tables. Calibration was assessed using calibration curves. Platt rescaling was performed on neural network predictions through the creation of a logistic regression model to predict actual labels.

Analysis

All analyses were conducted using Python (version 3.9.7; Python Software Foundation), run on Jupyter Notebook (Anaconda). Graphs for margin plots for cluster analysis and rescaling was performed using Stata IC software (version 16). The final script is available in Table S1 in Multimedia Appendix 1.

Ethics Approval

This project was approved by the University of Colorado Internal Review Board (COMIRB #18-0251).

Results

Initial Drug Analysis

In the initial medication evaluation, we found that amiodarone, dofetilide, fluconazole, propofol, and sotalol were significantly associated with unadjusted increased risk for diLQTS (Table 1 and Table S1 in Multimedia Appendix 1). Interestingly, medications previously highly associated with inpatient diLQTS, such as haldoperidol [5], methadone [8], citalopram [28], and azithromycin [29], were either borderline or not significantly associated with diLQTS. Additionally, it was noteworthy that ondansetron [30] was significantly associated with a decreased risk of diLQTS (P=1.12×10^{-39}).

Table 1. Association with drug-induced long-QT syndrome for selected medications. Statistically significant associations emphasized with italics.

QT-associated medication	Odds ratio (95% CI)	Chi-square (*df*)	*P* value
Dofetilide	*5.75 (4.68-7.06)*	*354.80 (4)*	*1.61×10^{-75}*
Amiodarone	*4.41 (4.0-4.87)*	*1010.70 (4)*	*1.69×10^{-217}*
Sotalol	*2.88 (2.28-3.65)*	*85.04 (4)*	*1.49×10^{-17}*
Propofol	*2.71 (2.49-2.96)*	*541.36 (4)*	*7.58×10^{-116}*
Fluconazole	*1.39 (1.21-1.59)*	*22.25 (4)*	*1.78×10^{-4}*
Methadone	1.39 (1.10-1.76)	7.45 (4)	.11
Citalopram	1.19 (1.00-1.40)	4.46 (4)	.35
Haloperidol	1.10 (1.00-1.21)	3.54 (4)	.47
Azithromycin	0.99 (0.88-1.12)	0.0085 (4)	.99
Ondansetron	*0.65 (0.61-0.69)*	*188.49 (4)*	*1.12×10^{-39}*

Association With diLQTS

Among the top 10,000 most common diagnoses and medications, the 100 with the highest MIC for association with the label of diLQTS are listed in Table S2 in Multimedia Appendix 1, with the top 500 kept for cluster analysis (minimum MIC 0.000443). The top diagnoses associated with diLQTS included long-QT syndrome, acidosis, cardiogenic shock, atrial fibrillation, and acute respiratory failure; the top medications associated included potassium chloride, furosemide, amiodarone, magnesium, and albumin (Table S2 in Multimedia Appendix 1). These results highlight the potential for possible reverse causation, as it seems more likely that potassium chloride and magnesium would be administered as treatment of or to prevent diLQTS, rather than themselves being causative. The strong association with a prior diagnosis of long-QT syndrome provides a meaningful proof of principle, as congenital long-QT syndrome is a well-known risk factor for diLQTS [1,31-34].

Cluster Analysis

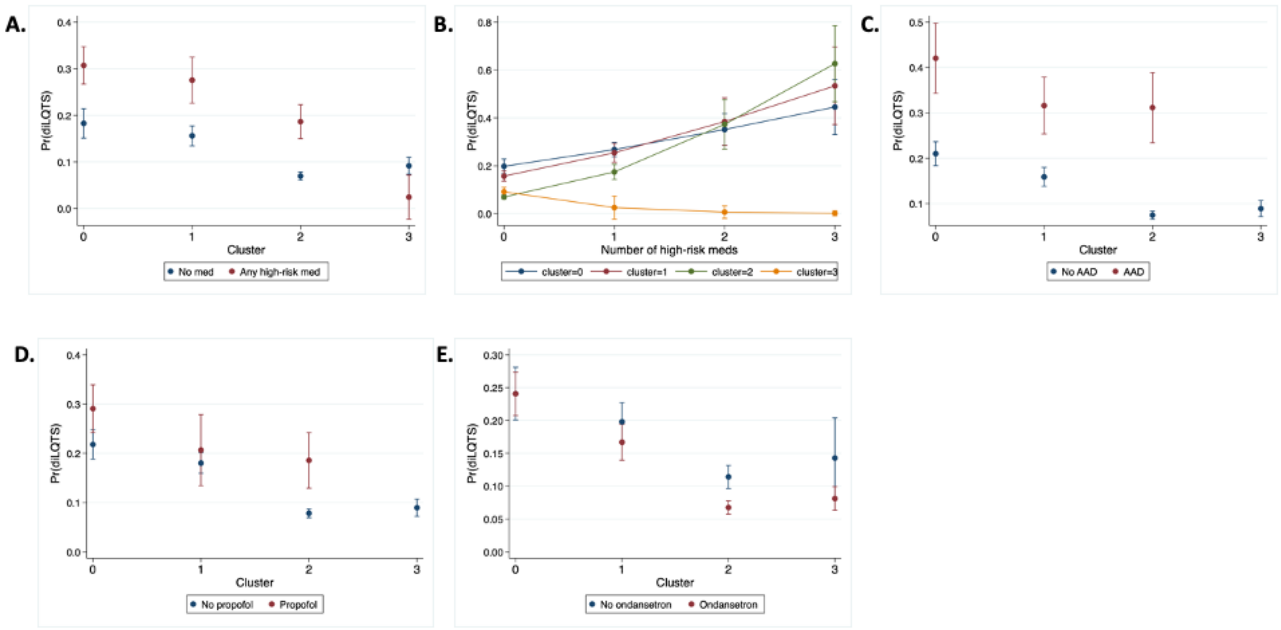
Cluster number optimization identified 4 clusters as the highest silhouette score (Figure S1A in Multimedia Appendix 1), which was validated using the elbow method applied to the inertia score (Figure S1B in Multimedia Appendix 1). Manual inspection of the cluster components (Table 2 and Table S3 in Multimedia Appendix 1) indicated that cluster 0 seemed to include a large number of critical care diagnoses; cluster 1 included diagnoses suggestive of cardiovascular disease; cluster 2 included diagnoses consistent with drug intoxication and injuries; and cluster 3 included diagnoses of nausea, abdominal pain, and headaches. In the validation set, we found that clusters 0 and 1 had an increased baseline risk of diLQTS compared with clusters 2 and 3 (Table 2), which increased with exposure to high-risk medications (Figure 2A) and combinations of high-risk medications (Figure 2B). Subjects in cluster 3 were not treated with any of the high-risk antiarrhythmic medications (amiodarone, sotalol, or dofetilide), but for all 3 other clusters, treatment with one of these agents increased the risk of diLQTS (Figure 2C). Interestingly, the use of propofol was only significantly (P=.0002) associated with risk of diLQTS for subjects in cluster 2 (Figure 2D) but not clusters 0 (P=.0161) or 1 (P=.4920; cluster 3 was not exposed), and the use of ondansetron was significantly associated with decreased risk of diLQTS in cluster 2 (P=6.371 × 10^{-6}) but not the other clusters (0: P=.996, 1: P=.129, and 3: P=.0577; Figure 2E). These results indicate that although antiarrhythmic drugs increased the risk of diLQTS broadly across all clusters, for non-antiarrhythmic medications, the impact was primarily seen in cluster 2, where propofol increased the risk of diLQTS and ondansetron decreased risk.

Table 2. Cluster composition and association with drug-induced long-QT syndrome (diLQTS). Cluster 3 represents baseline comparator group (odds ratio for the risk of diLQTS are compared with cluster 3).

Cluster	Representative diagnoses	Odds ratio (95% CI)	*P* value
0	Kidney failure, sepsis, respiratory failure, and anemia	3.25 (2.51-4.21)	<.001
1	Coronary artery disease, hypertension, hyperlipidemia, diabetes, and myocardial infarction	2.29 (1.77-2.95)	<.001
2	Live birth, motor vehicle accident, drug overdose, and alcohol intoxication	0.94 (0.73-1.20)	.61
3	Nausea, abdominal pain, and headache	1	N/A[a]

[a]N/A: not applicable.

Figure 2. Probability of diLQTS. (A) Probability of diLQTS for each cluster with treatment with high-risk medication. (B) Probability of diLQTS with increasing numbers of high-risk meds, by cluster. (C) Probability of diLQTS for each cluster with treatment with antiarrhythmic medication (AAD). (D) Probability of diLQTS for each cluster with treatment with propofol. (E) Probability of diLQTS for each cluster with treatment with ondansetron. diLQTS: drug-induced long-QT syndrome.



Comparison of Predictive Accuracy

The AUC for deep learning was 0.776 (Figure 3A) compared with the AUC of the cluster analysis of 0.636 (Figure 3B); the area under precision recall curve was 0.373 for deep learning (Figure 3C) compared with 0.322 for cluster analysis (Figure 3D); and the average precision score for deep learning was 0.379 and 0.193 for cluster analysis. Based on the Youden's method for cutoff selection, the optimal cutoff for the prediction of diLQTS from deep learning was Pr(diLQTS) of 0.12, and for cluster analysis, it was 0.15. Based on these cutoffs, the F_1-score for deep learning was 0.39, and for cluster analysis, it was 0.29. Contingency tables for both are in Tables S4A and S4B in Multimedia Appendix 1, with classification comparison in Table 3 demonstrating an agreement of 71.4% for the 2 approaches. Calibration comparison is provided in Figure 4, in which we noted that the neural network was poorly calibrated and generally overpredicted the risk of diLQTS (ie, actual proportion of diLQTS cases less than predicted probability), which had been described with these models in our previous work [18]. With Platt rescaling (Figures S3A and S3B in Multimedia Appendix 1), calibration of the neural network was improved and was similar to calibration of the cluster analysis (Figure S3B in Multimedia Appendix 1).

Figure 3. Accuracy assessment of models. (A) receiver operating characteristic (ROC) curve for neural network. (B) ROC curve for cluster model. (C) Precision-recall for neural network. (D) Precision-recall for cluster model. AUC: area under ROC curve; NN: neural network.

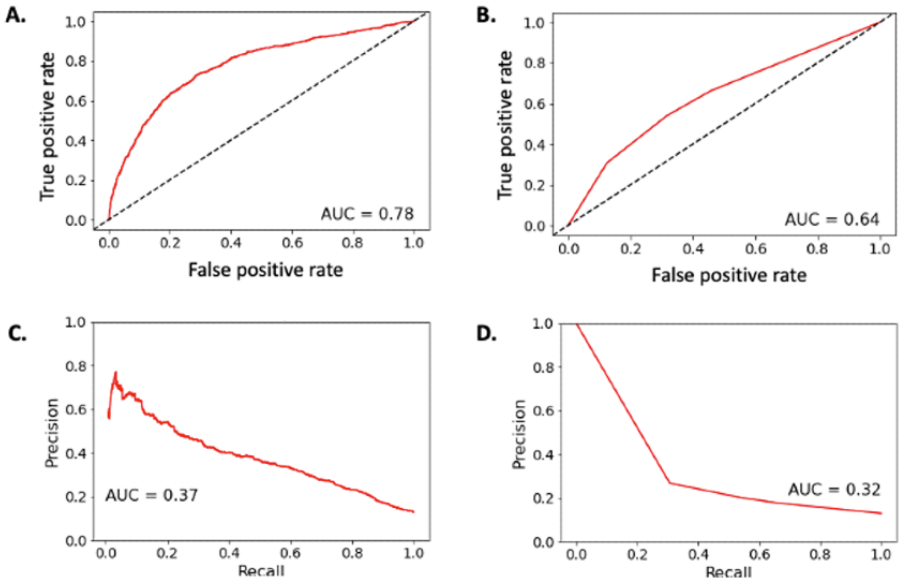
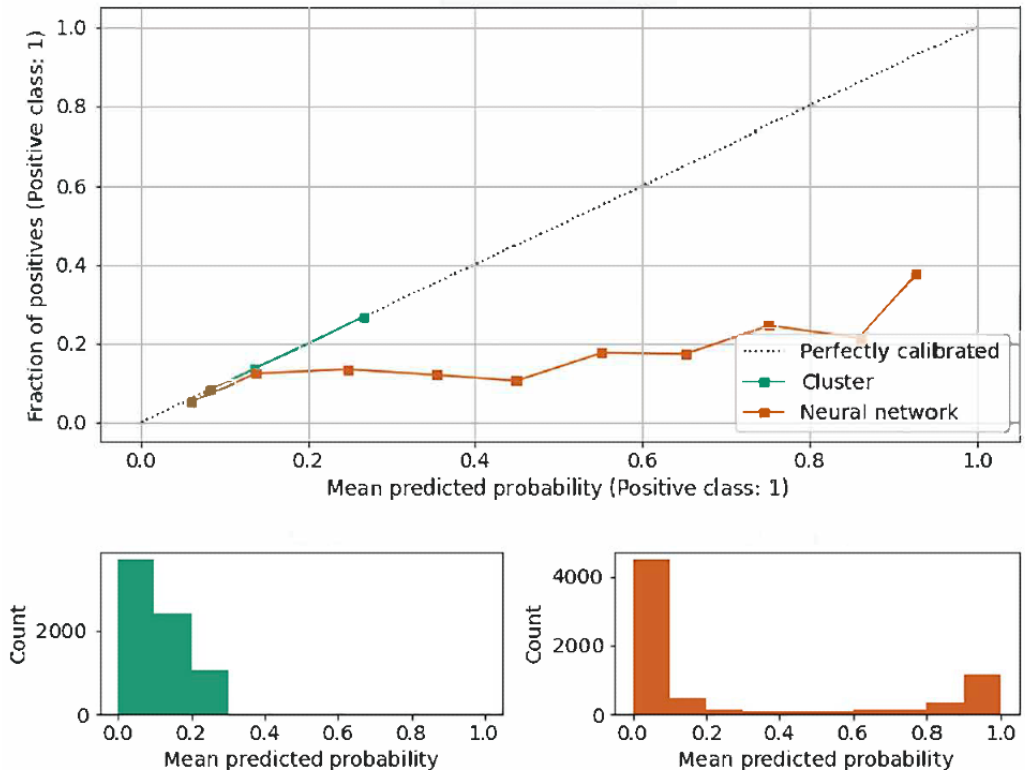


Table 3. A 2 × 2 table of comparative predictions at selected cutoffs. For deep learning models, the cutoff was probability of drug-induced long-QT syndrome (diLQTS) of 0.12, and for cluster analysis, it was 0.15. These values are based on predictive models for which the probability of diLQTS is produced for each individual, and the cutoff represents the probability above, in which an individual would be predicted to be at risk, and below, in which one would not be at risk.

	Cluster model (N=7128)		
	Predicted low risk, n (%)	Predicted high risk, n (%)	Total, n (%)
Neural network model			
Predicted low risk	3653 (51.2)	1018 (14.3)	4671 (65.6)
Predicted high risk	1017 (14.3)	1440 (20.2)	2457 (34.4)
Total	4670 (65.5)	2458 (34.5)	7128 (100)

Figure 4. Calibration analysis of neural network and cluster-based models. Top: Calibration plot for each model, with abscissa corresponding to the binned predicted probability of diLQTS (positive class) from the model and ordinate corresponding to the proportion of actual positives (diLQTS cases) within each bin. Bottom: Histogram of predicted probability for each model (left: cluster, right: neural network). Note that cluster-based model did not predict probability over 0.5 for any individual. diLQTS: drug-induced long-QT syndrome.



Discussion

Principal Findings

In this EHR-based follow-up analysis, we sought to compare 2 divergent methods for the integration of machine learning to guide clinical decisions to prevent diLQTS, with a focus on clinical interpretability and predictive accuracy. In one, we applied cluster analysis to group individuals by patterns of diagnostic codes to identify potentially recognizable clinical subgroups from which a treating clinician could identify patients who might be at risk for diLQTS to guide future decision-making. For comparison, we applied a deep learning algorithm that was identified based on prior work in this same population to obtain a "gold standard" level of predictive accuracy, to quantify the potential loss in predictive accuracy with the use of a more interpretable methodology. From a clinical perspective, our findings revealed some interesting insights regarding which specific medications have the greatest risk of diLQTS, as well as which subpopulations appear to be the most susceptible. However, we also found that there was a fairly substantial loss of predictive accuracy using this interpretable method in comparison with a "black box" method, which should be considered in future work on the integration of predictive models in clinical care.

Among the clinical insights, several are noteworthy. First, we found that when examined independent of patient characteristics, certain medications such as haldoperidol or methadone, which are well established with diLQTS, were not associated with increased risk, whereas others, such as ondansetron, were actually associated with decreased risk in our population. This finding points to the multifactorial nature of diLQTS, highlighting the need to consider other relevant contextual factors in assessing risk. However, it may also suggest that in the inpatient setting, there might be more benefit than risk with

using these medications, which is also consistent with prior studies [9-12], including one where a clinical decision support tool to prevent diLQTS had a paradoxical decrease in mortality for patients in whom the treating provider ignored the alert and prescribed the known QT-prolonging medication despite risk [4]. Particularly in subjects who were not critically ill (not in cluster 0) and without a history of cardiovascular disease (not in cluster 1), there appeared to be more benefit to using ondansetron, balanced against more risk with using propofol. However, these insights should be taken with caution, as we do not know the specific timing of the administration of QT-associated medications in relation to obtaining the ECG nor whether a medication was administered once, several times, or not at all (merely listed as an as needed pro re nata medication). Such a limitation seems likely for several of the known QT-associated medications that are frequently ordered pro re nata, such as haldoperidol and ondansetron, in which we found no (former) or an inverse (latter) association with QT-prolongation. Regardless of the underlying impact, this consideration highlights the limitations of the use of clinical decision support tools applied broadly across all medications associated with diLQTS and a need to focus on the relative population risk and indication when designing future tools.

Second, we found that, perhaps not surprisingly, the cluster of patients (cluster 0) with diagnoses suggestive of critical illness were the most susceptible to use of high-risk medications for diLQTS, and that patients in clusters 2 and 3 with more benign diagnoses were less likely to have diLQTS. This finding has direct clinical implications, as it suggests that decision support tools might be the most effectively targeted toward patients in an intensive care unit, where risk is the greatest, rather than broadly across all inpatients, with the caveat that the use of propofol might need to be more closely monitored in subjects without cardiovascular disease or critical illness. Our findings also suggest that specific combinations of medications, such as amiodarone and propofol, should either be avoided or administered with close monitoring and aggressive treatment of other factors that could predispose risk of diLQTS, such as electrolyte abnormalities.

Finally, our findings highlight the critical trade-off between model interpretability and accuracy, as we found that a black-box prediction model using deep learning was significantly more accurate (greater AUC and area under precision recall curve) than the more interpretable cluster-based model. This finding raises a key question for all practitioners of predictive modeling: Is the improvement in predictive accuracy worth the lack of understanding for why the model makes the predictions it does? More specifically, without understanding how a model makes its predictions, how can it be challenged if a treating clinician believes it is less applicable for a particular patient, and what changes should be made if the predictive accuracy diminishes (a so-called “data shift” occurs [23,24]). It is not difficult for an experienced clinician to understand why patients who are critically ill (cluster 0) would be at increased risk or why combinations of medications with high risk of diLQTS would increase risk, and a method that can uncover these categories would seem to be more useful clinically than a black-box approach. Such clinical interpretation is unavailable for the deep learning model, which creates a challenge of trust in application. Further, in prior work, we demonstrated that reinforcement learning can be applied to cluster-based decision models (using a Q table) to allow a decision support tool to improve over time [35]; it is unclear whether a deep learning model could be as easily integrated with reinforcement learning or whether there would be sufficient prospective data to update the over 20 million parameters of such a model. Broadly, as increasing numbers of predictive models based on deep learning are applied to predict diLQTS, especially those applied directly to the ECG tracing itself [36,37], the trade-off with interpretability will remain a critical consideration in clinical applications.

Limitations

Principal among the limitations of this investigation is the high degree of noise inherent in studies of EHR data at scale and the challenges with having a lack of ability to perform detailed validation of diagnoses, medications, or outcomes, beyond what can be performed in silico without manual chart review. Several of these limitations related to reverse causation or lack of temporal granularity with medication administration are highlighted above. On the one hand, this common limitation of big data science limits what can be done in terms of granular validation; on the other hand, it provides both the improvement in statistical power for modeling and some protection against population bias, as might occur with studies at a single clinic or single provider level. With the increased expansion of EHR use worldwide, it is likely that methods to explore interpretability within these large data models will be increasingly relevant, for which our investigation should provide some foundation for how interpretability can be balanced against predictive accuracy.

Future Directions

Importantly, our findings provide the opportunity for direct clinical implementation of “smart” clinical decision tools that incorporate patient characteristics along with an understanding of patient risk to improve the accuracy of predictions of diLQTS, as well as guide clinical decisions including monitoring for those at high risk or selecting alternative agents where they are available. When combined with dynamic learning models, such as Q learning [35], our approach offers the opportunity to improve overall patient safety and clinical outcomes.

Conclusion

In summary, we found that interpretable methods to predict diLQTS allow for evaluation in a manner that facilitates deeper inspection of specific medication interactions and the identification of meaningful clinical populations to target for prevention. This interpretability comes at the expense of predictive accuracy, which must be considered among organizations seeking to integrate predictive modeling into clinical decision support tools to prevent diLQTS.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Supplemental Documents.
[PDF File (Adobe PDF File), 459 KB-Multimedia Appendix 1]

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Abbreviations

AUC: area under the receiver operating characteristic curve
diLQTS: Drug-induced long-QT syndrome
ECG: electrocardiogram

EHR: electronic health record
MIC: maximum information coefficient

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Original Paper

Assessment of Clinical Information Quality in Digital Health Technologies: International eDelphi Study

Kayode Philip Fadahunsi[1], MBBS, MPH; Petra A Wark[1,2], MSc, PhD; Nikolaos Mastellos[1], BSc, MSc, PhD; Ana Luisa Neves[1], MSc, MD, PhD; Joseph Gallagher[3], BA, MBChB, BAO, MD; Azeem Majeed[1], MD; Andrew Webster[4], MBBS, MSc, PGDip; Anthony Smith[5], MSc, MBChB; Brian Choo-Kang[6], BSc, MBChB, PGDip, PhD; Catherine Leon[7], BPharm, MSc; Christopher Edwards[8], BSc, MBChB; Conor O'Shea[9], MBChB, BAO; Elizabeth Heitz[10], MBBS; Olamide Valentine Kayode[11], MBBS; Makeba Nash[10], BSc, MA, MSc; Martin Kowalski[12], MD; Mateen Jiwani[1], MBBS, PGDip; Michael Edmund O'Callaghan[13], BEng, BMBS, MSc; Nabil Zary[14], MD, PhD; Nicola Henderson[15], BSc, MSc; Niels H Chavannes[16], MD, PhD; Rok Čivljak[17,18], MD, PhD; Olubunmi Abiola Olubiyi[19], MBBS, MPH; Piyush Mahapatra[20], MA, MBBS; Rishi Nannan Panday[21], MD, PhD; Sunday O Oriji[22], MBBS; Tatiana Erlikh Fox[23], MSc, MD; Victoria Faint[4], DipHE, BSc, PGCert; Josip Car[1,23], MSc, MD, DIC, PhD

[1]Department of Primary Care and Public Health, Imperial College London, London, United Kingdom

[2]Centre for Intelligent Healthcare, Institute for Health and Wellbeing, Coventry University, Coventry, United Kingdom

[3]gHealth Research Group, School of Medicine, University College Dublin, Dublin, Ireland

[4]Leeds Teaching Hospital National Health Service Trust, Leeds, United Kingdom

[5]Health Board, Hywel Dda University, Wales, United Kingdom

[6]Glasgow Royal Infirmary, National Health Service Greater Glasgow and Clyde, Glasgow, United Kingdom

[7]Oxford University National Health Service Foundation Trusts, Oxford, United Kingdom

[8]Leeds Children's Hospital, Leeds, United Kingdom

[9]Wheaton Hall Medical Practice, Drogheda, Co Louth, Ireland

[10]Croydon Health Services, Croydon, United Kingdom

[11]Department of Paediatrics and Child Health, Evercare Hospital Lekki, Lagos, Nigeria

[12]Department of Ophthalmology, University Eye Hospital Tübingen, Tübingen, Germany

[13]School of Medicine, University of Limerick, Limerick, Ireland

[14]Institute for Excellence in Health Professions Education, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates

[15]National Health Service Forth Valley, Scotland, United Kingdom

[16]National eHealth Living Lab, Department of Public Health and Primary Care, Leiden University Medical Center, Leiden, Netherlands

[17]University Hospital for Infectious Diseases, Zagreb, Croatia

[18]University of Zagreb School of Medicine, Zagreb, Croatia

[19]Medical Research Council Unit The Gambia, London School of Hygiene & Tropical Medicine, Fajara, Gambia

[20]West Hertfordshire Teaching Hospitals National Health Service Trust, Watford, United Kingdom

[21]Acute Medicine Section, Department of Internal Medicine, Amsterdam University Medical Centers, VU Medical Center Location, Amsterdam, Netherlands

[22]Department of Mental Health, Nnewi Campus, Nnamdi Azikiwe University Teaching Hospital, Nnewi, Nigeria

[23]Centre for Population Health Sciences, Lee Kong Chian Medicine, Nanyang Technological University, Singapore, Singapore

Corresponding Author:
Josip Car, MSc, MD, DIC, PhD
Department of Primary Care and Public Health
Imperial College London
The Reynolds Building, St Dunstan's Road
London, W6 8RP
United Kingdom
Phone: 44 020 7594 0799
Email: josip.car@imperial.ac.uk

Abstract

Background: Digital health technologies (DHTs), such as electronic health records and prescribing systems, are transforming health care delivery around the world. The quality of information in DHTs is key to the quality and safety of care. We developed a novel clinical information quality (CLIQ) framework to assess the quality of clinical information in DHTs.

Objective: This study explored clinicians' perspectives on the relevance, definition, and assessment of information quality dimensions in the CLIQ framework.

Methods: We used a systematic and iterative eDelphi approach to engage clinicians who had information governance roles or personal interest in information governance; the clinicians were recruited through purposive and snowball sampling techniques. Data were collected using semistructured online questionnaires until consensus was reached on the information quality dimensions in the CLIQ framework. Responses on the relevance of the dimensions were summarized to inform decisions on retention of the dimensions according to prespecified rules. Thematic analysis of the free-text responses was used to revise definitions and the assessment of dimensions.

Results: Thirty-five clinicians from 10 countries participated in the study, which was concluded after the second round. Consensus was reached on all dimensions and categories in the CLIQ framework: informativeness (accuracy, completeness, interpretability, plausibility, provenance, and relevance), availability (accessibility, portability, security, and timeliness), and usability (conformance, consistency, and maintainability). A new dimension, searchability, was introduced in the availability category to account for the ease of finding needed information in the DHTs. Certain dimensions were renamed, and some definitions were rephrased to improve clarity.

Conclusions: The CLIQ framework reached a high expert consensus and clarity of language relating to the information quality dimensions. The framework can be used by health care managers and institutions as a pragmatic tool for identifying and forestalling information quality problems that could compromise patient safety and quality of care.

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KEYWORDS

information quality; digital health technology; patient safety; perspective; digital health technologies; DHT; thematic analysis; clarity; understandable; understandability; readability; searchability; security; decision support system; framework development; framework

Introduction

Digital health technologies (DHTs), such as electronic health records, electronic prescribing systems, and clinical decision support systems, have transformed health care delivery around the world [1]. However, the quality of information obtained from DHTs varies and can compromise quality and safety of care [2-4]. Several incidents of delayed, missing, partial, or wrong information in DHTs have been documented, resulting in adverse patient outcomes, including death [3-5]. To reduce the risk of such incidents, we need a pragmatic approach to assessing the quality of clinical information in DHTs. The importance of such an information quality assessment tool continues to grow with increasing automation and use of artificial intelligence (AI) in health care, as human checks are reduced and clinical information feeds into AI tools and algorithms [6].

A systematic review of the literature identified existing frameworks and dimensions that are relevant to assessing clinical information in DHTs [7]. However, the review found that the existing frameworks did not provide assessment tools for clinical practice [7]. In addition, most of the existing frameworks were developed without input from clinicians who use clinical information from DHTs [7]. Drawing on the review's findings, we developed a clinical information quality (CLIQ) framework as a pragmatic approach to assessing the quality of clinical information in DHTs. The CLIQ framework defined 13 dimensions relevant to the quality of clinical information in DHTs and was accompanied by a questionnaire for assessing information quality. The current study explored clinicians' perspectives on the relevance, definition, and assessment of information quality dimensions in the CLIQ framework (Textbox 1 shows the original dimensions in the CLIQ framework).

Textbox 1. Information quality dimensions in the original CLIQ framework.

- Informativeness (accuracy, completeness, interpretability, plausibility, provenance, and relevance)
- Availability (accessibility, portability, security, and timeliness)
- Usability (conformance, consistency, and maintainability)

Methods

Study Design

In this study, the eDelphi method was used to obtain direct input from clinicians to contextualize the CLIQ framework to the needs of the information users. This method uses a systematic process for engaging and integrating the opinions of multiple experts to reach consensus [8,9]. Thus, the eDelphi method was suitable for this study, which sought to obtain the consensus of clinicians from different countries on the information quality dimensions that are relevant to assessing clinical information in DHTs. In addition, the asynchronous approach gave the panelists an opportunity for equal participation, in contrast to physical meetings, which are usually dominated by a few outspoken participants [10]. The iterative process of the eDelphi method enabled the participants to provide feedback and reconsider their opinions based on collective responses [11]. The flexibility of the eDelphi method allowed collection of quantitative and qualitative data, which were useful in addressing the research question.

Ethics Approval

The protocol of this study was published to promote transparency [12]. Ethics approval was obtained for the study from the Imperial College Research Ethics Committee (20IC6396).

Steering Committee

This eDelphi study was coordinated by a steering committee comprising health care researchers and clinicians with interest in digital health. The committee developed the original CLIQ framework [7] and the accompanying questionnaire from which the initial items of the eDelphi study were generated. The committee recruited the participants to the study and made decisions regarding retention, removal, or redefinition of information quality dimensions based on the input of the participants according to prespecified decision and stoppage rules.

Decision and Stoppage Rules

The decision and stoppage rules on consensus were predefined to prevent bias during analysis [11]. An information quality dimension was considered relevant and was retained in the final framework when at least 70% of the participants, in any round of the survey, chose the options “strongly relevant” or “somewhat relevant.” The choice of 70% as a cutoff was a pragmatic choice based on the literature, as most Delphi studies use 60% agreement or higher as a threshold for consensus [10]. The study was planned to be concluded whenever consensus was reached on at least 80% of the dimensions or at the end of the third round, irrespective of the level of consensus [11].

Participant Recruitment

Clinicians with information governance roles or interest were invited to participate in the eDelphi panel based on the following eligibility criteria [12]: (1) prior or current experience of using DHTs in patient care, (2) information governance role or personal interest in information governance, and (3) willingness to participate in a multiple-round eDelphi study (up to 3 rounds). The heterogeneity of the participants provided a wide range of perspectives and increased the study’s external validity. The recruitment of the participants included both purposive and snowball sampling. Clinicians with information governance roles (eg, chief clinical information officer, chief nursing information officer, or Caldicott guardian) were targeted, as they have both DHT user experience and information governance expertise. However, participation was not restricted to these roles, as they do not exist in many low- and middle-income countries. Therefore, participants with interest in information governance without any formal information governance role were also recruited, such as clinicians who have published papers relating to information governance.

The steering committee members nominated clinicians from within and beyond their professional networks. Each eligible clinician was invited by an introductory email containing a link to the survey; the email also encouraged them to share the invitation with other eligible clinicians. Two reminders were sent at least 2 weeks apart to encourage participation [8]. Thirty-five clinicians from 10 countries participated in the study, including doctors, nurses, pharmacists, and other health care professionals.

Survey Content and Administration

The initial survey (Multimedia Appendix 1) was generated from the CLIQ framework [7] and the accompanying assessment questionnaire. The accompanying assessment questionnaire was developed by the steering committee based on the findings of a systematic review of information quality frameworks [7] and further evidence from literature. The survey was administered in English.

The introductory section of the survey provided brief information about the study, a link to the participant information sheet, and the electronic consent form. Demographic data were collected from participants who gave informed consent, and only these participants were shown the remainder of the survey.

The second section of the survey consisted of questions relating to the CLIQ framework. The first part of this section included 5-point Likert scale questions on the relevance of the dimensions in the CLIQ framework to quality and safety of care. The Likert scale captured a range of options (strongly relevant, somewhat relevant, neither relevant nor irrelevant, somewhat irrelevant, and strongly irrelevant) that represent categories people naturally create and thus did not require a heavy cognitive load. The second part comprised multiple-choice and free-text questions on the definition, assessment, and categories of the dimensions in the CLIQ framework. Finally, the email addresses of participants were collected for feedback purposes and as a contact method for the next round of the survey. The survey was set up using Qualtrics software (Qualtrics) and piloted by the steering committee members before its administration. The study was conducted between June 2021 and March 2022.

Data Analysis

The data on the relevance of the dimensions were summarized using descriptive statistics and used to inform decisions on retention of dimensions and termination of the study. The data were also used to provide feedback to the participants during

the second round of the survey. The free-text suggestions were analyzed using a reflexive thematic analysis approach, which allowed the steering committee members to go beyond the text to decode the meaning intended by the participants [13]. The thematic analysis process was adapted to include the following key stages: (1) studying the free-text suggestions to become familiar with the contributions made by the participants; (2) data coding to highlight key issues identified by the participants with regards to the definition and assessment of the dimensions; and (3) identifying patterns in the suggested modifications, developing themes, reflecting on these themes in the context of the overall data set, and defining the essence of each theme.

The themes were then used to revise the definitions and the assessment of the dimensions as appropriate. Feedback from the free-text suggestions and the changes that were made were also incorporated into the second round of the survey.

Results

Statistical Summary of Findings in the First Round

Thirty-five clinicians (including 26 doctors, 5 nurses, 2 pharmacists, 1 dietician, and 1 health system specialist) from 10 countries participated in the first round of this eDelphi study, with most being doctors (n=26, 74%) and male (n=23, 66%). About half of the participants had more than 10 years of digital health experience (n=18, 51%), and about half were from the United Kingdom (n=18, 51%). Most of the countries from which the participants came were high-income countries (8/10, 80%), although 1 of the 10 countries (10%) was lower middle income (Nigeria) and 1 (10%) was low income (the Gambia). Table 1 provides more detailed information on the sociodemographic characteristics of the participants.

In the first round of the eDelphi study, 86% to 97% of the clinicians ranked each of the 13 information quality dimensions in the proposed framework as relevant. These values were above the predefined threshold of 70% for the study and indicated consensus on the relevance of all 13 proposed dimensions in the framework. The ranking of the information quality dimensions is shown in Table 2.

Table 1. Sociodemographic characteristics of the eDelphi participants (N=35).

Characteristics	Participants, n (%)
Occupation	
Doctor	26 (74)
Nurse/nurse practitioner/advanced care practitioner	5 (14)
Pharmacist/clinical pharmacist	2 (6)
Dietician	1 (3)
Health system specialist	1 (3)
Digital health experience (years)	
Less than 10	17 (49)
10 or more	18 (51)
Country	
Croatia	1 (3)
The Gambia	1 (3)
Germany	1 (3)
Ireland	5 (14)
The Netherlands	3 (9)
Nigeria	2 (6)
Singapore	1 (3)
United Arab Emirates	1 (3)
United Kingdom	18 (51)
United States of America	2 (6)
Sex	
Male	23 (66)
Female	12 (34)

Table 2. Ranking of the dimensions in the clinical information quality framework in the first round of the eDelphi study, with number of responses by participants (N =35) in selected categories.

Rank	Information quality dimension	"Strongly relevant," n (%)	"Somewhat relevant," n (%)	Combined relevance ("strongly relevant" or "somewhat relevant"), n (%)
1	Accuracy	30 (86)	2 (6)	32 (92)
2	Completeness	18 (51)	14 (40)	32 (91)
3	Interpretability	23 (66)	8 (23)	31 (89)
4	Plausibility	13 (37)	18 (51)	31 (89)
5	Provenance	27 (77)	7 (20)	34 (97)
6	Relevance	18 (51)	15 (43)	33 (94)
7	Accessibility	28 (80)	4 (11)	32 (91)
8	Portability	18 (51)	12 (34)	30 (86)
9	Security	25 (71)	5 (14)	30 (86)
10	Timeliness	25 (71)	9 (26)	34 (97)
11	Conformance	15 (43)	16 (46)	31 (89)
12	Consistency	10 (29)	20 (57)	30 (86)
13	Maintainability	20 (57)	14 (40)	34 (97)

Changes Based on Free-Text Suggestions in the First Round

The changes that were made by the steering committee members based on the suggestions of the panel members in the first round are presented in Multimedia Appendix 2. The themes from the reflective thematic analysis of the free-text suggestions during the first round that informed these changes are presented in this section and summarized in Textbox 2.

Textbox 2. Themes from the free-text suggestions in the first round.

- Avoiding ambiguity: this expresses the need to avoid ambiguous terms and phrases.
- Relatable examples: this indicates the recommendation to include examples relating to daily activities to make the questions and definitions more explicit.
- Renaming the dimensions: this relates to suggestions for naming and renaming of dimensions.
- Rephrasing for clarity: this expresses the need to rephrase aspects of the questionnaire to improve clarity.

Avoiding Ambiguity

The participants described some terms in the questionnaire as "vague," "odd," and "confusing." For example, a participant stated the following about "errors":

> *The term "errors" needs to be further defined, now it is too vague, and I have no idea what to think of when I read it.*

In addition, some definitions were considered too complex to be understood by clinicians without informatics experience, as demonstrated by this comment:

> *Just at this point, I am thinking that it is relevant to understand who your audience is with these questions. Not all clinicians would understand these questions, but clinical informatics professionals would.*

Several changes were made across the dimensions to avoid ambiguity, as recommended by the participants, including replacing or removing terms such as "free of errors," "occasionally," and "very" that were considered ambiguous by the participants.

Relatable Examples

Participants were unanimous that examples were useful in making questions more explicit. One participant advocated including an example for each option:

> *Give examples in each of the options, that would make it easier to differentiate.*

On the other hand, another participant suggested including an example in the main question:

> *Perhaps include the example within the question, rather than the choice of answers.*

Participants also advocated using specific examples that were relevant to daily activities of the clinicians. They proceeded to suggest examples they considered appropriate for each option.

> *Phone call to IT [information technology] dept is not sufficiently accessible, it's another barrier (with a potential to fail- on hold, engaged, deadline, etc).*
>
> *Pharma/tobacco or any other commercial marketing would be "very untrustworthy."*

However, participants acknowledged that it might be difficult to find suitable examples to illustrate some response options.

> *I'm struggling with the plausible/very plausible examples but can't at this time think of an alternative.*

Changes relating to this theme include introducing examples such as "two-factor authentication" to describe secure information and reassigning examples as suggested by participants, such as reassigning "access requiring phone call to IT [information technology] department" under "inaccessible" information.

Renaming Dimensions

Although all the dimensions were considered relevant, the free-text suggestions indicated a need for renaming some dimensions:

> *I don't like the use of the word "interpretable" in the context of digital health records as it is too similar to "interoperable" and easily mis-read. Comprehensibility? Information clarity?*

Some suggestions seemed to imply a need for a new dimension. A free-text suggestion on accessibility expressed concerns on how it might be difficult to search for information in a system holding the data.

> *I'd have the second option in the list, information is present in EHR [electronic health record] but have to spend time looking for it.*

Multiple suggestions on "timeliness" seemed to indicate "currency" was favored over "timeliness."

> *You could quickly log into a system that doesn't contain the most up to date patient information which would be far more concerning in terms of data quality than logging in slowly to a system with the most recent info in it.*

A new dimension, "searchability," was introduced. In addition, "timeliness," "provenance," and "consistency" were renamed "currency," "trustworthiness," and "consistency of presentation," respectively. Two suggestions from panel members that related to the renaming of dimensions but were not adopted to avoid ambiguity are presented in Multimedia Appendix 2.

Rephrasing for Clarity

Most of the suggested modifications related to the phrasing of the questionnaire. Each question and the associated options were rephrased as appropriate to clarify them. These modifications ranged from simple corrections such as typos to major changes introducing new ideas; these were addressed on a case-by-case basis.

> *The definition of an adverse event is too narrow. Consider reflecting both critical (patient safety) and non-critical (quality of care). Also, there is an implicit assumption that data will directly impact care - maybe use "contribute to" as opposed to "lead to."*

Thus, "adverse event" was replaced with an explanation of the likelihood that inaccurate information would affect quality of care and patient safety and the potential impact. Similarly, the phrase "intended task" was replaced with the term "patient care," which is more all-encompassing. Other instances of rephrasing are presented in Multimedia Appendix 2.

Results of the Second Round

A second round was conducted because the free-text suggestions indicated a need for an additional dimension. This round was also used to present the results of the first round to the participants and obtain further feedback on the modifications to the questionnaire. Full details on the modifications and point-by-point responses to the participants' full-text suggestions for each of the dimensions are included in the questionnaire for the second round (Multimedia Appendix 3).

Among clinicians who provided their email addresses during the first round, 22 of 30 (73%) completed the second round. The threshold for consensus was reached for the new dimension "searchability." Most of the participants agreed with the changes made to the definitions and assessments of the dimensions, ranging from 86% (n=19) for consistency of presentation to 100% (n=22) for accuracy, completeness, interpretability, maintainability, and searchability, with no further modifications suggested. Minor suggestions were made regarding rephrasing the definitions of plausibility, trustworthiness, accessibility, portability, security, conformance, and consistency of presentation. Multiple free-text suggestions indicated that the term "currency" was not as acceptable as "timeliness":

> *I think timeliness and currency are two different terms that could not be used interchangeably. Therefore, I would prefer timeliness was not removed. if a result of an investigation is timely, it means it would be useful for decision making.*

> *I don't like the word currency in this context (it sounds like it's referring to money).*

The dimension "currency" was therefore reverted to the original name "timeliness." The modified CLIQ framework is made up of 14 dimensions, as outlined in Table 3. The accompanying assessment questionnaire is presented in Multimedia Appendix 4.

Table 3. Clinical information quality framework for digital health.

Dimension	Description
Informativeness (the usefulness of digital information for clinical purposes)	
Accuracy	The extent to which information is accurate.
Completeness	The extent to which no required information is missing.
Interpretability	The extent to which information can be interpreted.
Plausibility	The extent to which information makes sense based on clinical knowledge.
Trustworthiness	The extent to which the source of information is trustworthy and verifiable.
Relevance	The extent to which information is useful for patient care.
Availability (the functionality of the system holding clinical information)	
Accessibility	The extent to which information is accessible.
Portability	The extent to which information can be moved or transferred between different systems.
Searchability	The extent to which needed information can be found.
Security	The extent to which information is protected from unauthorized access, corruption, and damage.
Timeliness	The extent to which information is up-to-date.
Usability (the ease of use of clinical information)	
Conformance	The extent to which information is presented in a format that complies with institutional, national, or international standards.
Consistency of presentation	The extent to which presentation of information adheres to the same set of institutional, national, or international standards.
Maintainability	The extent to which information can be maintained (eg, modified, corrected, updated, adapted, and upgraded) to achieve intended improvement.

Discussion

Principal Findings

This study was conducted to contextualize the CLIQ framework to the needs of clinicians. Consensus was reached on the relevance of all the existing dimensions and categories of the CLIQ framework, including informativeness (accuracy, completeness, interpretability, plausibility, provenance, and relevance), availability (accessibility, portability, security, and timeliness), and usability (conformance, consistency, and maintainability). A new dimension, searchability, was introduced in the "availability" category to account for the ease of finding needed information in the DHTs. "Provenance" and "consistency" were renamed "trustworthiness" and "consistency of presentation," respectively.

The questionnaire was modified based on the suggestions of the clinicians to avoid ambiguities that could confuse users and affect the validity of the questionnaire. Nonspecific terms, such as "very," "few," or "occasionally," were removed, as their meanings vary based on context. Certain dimensions, such as conformance, were redefined using nontechnical terms, making them comprehensible to clinicians without an informatics background. In addition, the clarity of the questionnaire was improved by rephrasing the questions, incorporating relatable examples, and renaming certain dimensions. Overall, these changes made the questionnaire more user-friendly and improved its face and content validity.

Comparison With Prior Work

The CLIQ framework was developed to address gaps, including a lack of a pragmatic tool for clinical information quality assessment and the noninvolvement of clinicians in the development of existing frameworks [7]. The CLIQ framework is accompanied by a pragmatic questionnaire for assessing clinical information in DHTs, unlike theoretical frameworks, which provide no means of assessment [14-20]. The involvement of clinicians across 10 countries in the development of the CLIQ framework further differentiates the framework from existing frameworks, which were developed without input from clinicians [14,16-21]. Finally, the CLIQ framework is applicable to different DHTs, while existing frameworks are only applicable to specific DHTs, such as electronic health records [16,17,19,20,22].

Strengths and Limitations

The eDelphi method afforded a systematic, practical, affordable, and transparent approach to integrating the opinions of multidisciplinary clinicians from 10 countries. The importance of multiple eDelphi rounds, which allow feedback on changes made in preceding rounds [9,10], was demonstrated in the rejection of the attempt to rename "timeliness" as "currency." In addition, this study took advantage of the clinical experience and information governance expertise of the participating clinicians, thus combining practical user experience and subject matter expertise. The heterogeneous composition of the expert panel, which consisted of people from multiple clinical professions across 10 countries, enhanced the external validity of the CLIQ framework. However, external validity may be

limited by the low proportion of participants from low- and middle-income countries. The snowball sampling technique might have contributed to the disproportionately higher number of participants who were doctors from the United Kingdom. Nevertheless, the participants in this study were actively engaged and went out of their way to scrutinize all the definitions and offer valuable suggestions to improve the CLIQ framework. Finally, the number of participants that completed the second round of the eDelphi study was modest (22/30, 73%) but this is still more than the 8 to 15 experts recommended in the literature for a Delphi study [8].

Implications for Policy, Practice, and Future Research

This study provides insight into the information quality dimensions that are considered relevant by clinicians. Such insight could be useful when developing or choosing new DHTs for health care institutions. The consideration of relevant information quality dimensions while developing or choosing new DHTs will ensure that the information is fit for purpose. The CLIQ framework is thus a potential source of vital information to policy makers, DHT developers, and health care managers. In addition, the framework could be used to identify information quality problems in existing DHTs. As part of quality improvement projects, the CLIQ questionnaire could be used to collect data on the quality of information in existing DHTs from clinicians using these DHTs in clinical practice. Insight from such projects could then be used in planning strategies to address identified information quality problems.

The modification of the CLIQ framework has made the framework user-friendly by taking into account the views of the information users, as recommended in the information quality literature [23]. However, the adopted expert panel approach mainly improved the face and content validity of the framework [24]. Face and content validity imply that an instrument measures what it is intended to measure [24]. Therefore, a follow-up study to evaluate the construct validity and reliability of the CLIQ framework is ongoing across the United Kingdom among health care professionals who use the SystmOne electronic patient record system. Similar studies could be replicated in the future in low- and middle-income countries to further assess and, if needed, improve the applicability of the framework in such settings. The CLIQ framework will be made available under a Creative Commons (CC BY) license to facilitate its use in future works by other researchers who are interested in adapting the questionnaire based on their needs.

Conclusions

The CLIQ framework reached a high expert consensus and clarity of language relating to the information quality dimensions. The study contextualized the questionnaire by obtaining direct input from clinicians who are users of clinical information in DHTs. The contextualized CLIQ framework offers a pragmatic approach to assessing clinical information in DHTs and could be used in practice to identify and forestall information quality problems that can compromise quality and safety of care.

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Data Availability

Researchers can apply for access to the pseudonymized data by writing to the corresponding author.

Authors' Contributions

KPF conceived the study and drafted the manuscript. KPF, PAW, ALN, NM, JG, AM, and JC were members of the steering committee. PM, NHC, NZ, MEO, RC, RNP, OAO, TEF, BCK, SOO, CO, CE, AS, AW, MN, OVK, VF, NH, CL, MK, MJ, and EH were members of the expert panel. All authors revised the manuscript for important intellectual content.

Conflicts of Interest

PM is an executive director of Open Medical Limited, a digital health company. The authors have no further interests to declare.

Multimedia Appendix 1

First round eDelphi survey.
[DOCX File , 208 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Changes based on free-text suggestions.
[DOCX File , 16 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Second round eDelphi survey.
[DOCX File , 31 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Clinical information quality (CLIQ) assessment questionnaire.
[DOCX File , 18 KB-Multimedia Appendix 4]

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Abbreviations

AI: artificial intelligence
CLIQ: clinical information quality
DHT: digital health technology

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Original Paper

Factors Associated With the Acceptance of an eHealth App for Electronic Health Record Sharing System: Population-Based Study

Junjie Huang[1,2], PhD; Wing Sze Pang[1], BSocSci; Yuet Yan Wong[1], MPH; Fung Yu Mak[1], BSocSci; Florence S W Chan[3], MPH; Clement S K Cheung[3], MD; Wing Nam Wong[3], MD; Ngai Tseung Cheung[3], MD; Martin C S Wong[1,2], MD

[1]The Jockey Club School of Public Health and Primary Care, Faculty of Medicine, Chinese University of Hong Kong, Sha Tin, Hong Kong

[2]Centre for Health Education and Health Promotion, Faculty of Medicine, Chinese University of Hong Kong, Sha Tin, Hong Kong

[3]Information Technology and Health Informatics Division, Hospital Authority, Kowloon, Hong Kong

Corresponding Author:
Martin C S Wong, MD
The Jockey Club School of Public Health and Primary Care
Faculty of Medicine
Chinese University of Hong Kong
Room 407, 4/F, School of Public Health Building
Prince of Wales Hospital
Sha Tin, 999077
Hong Kong
Phone: 852 2252 8782
Email: wong_martin@cuhk.edu.hk

Abstract

Background: In the second stage of the Electronic Health Record Sharing System (eHRSS) development, a mobile app (eHealth app) was launched to further enhance collaborative care among the public sector, the private sector, the community, and the caregivers.

Objective: This study aims to investigate the factors associated with the downloading and utilization of the app, as well as the awareness, perception, and future improvement of the app.

Methods: We collected 2110 surveys; respondents were stratified into 3 groups according to their status of enrollment in the eHRSS. The primary outcome measure was the downloading and acceptance of the eHealth app. We collected the data on social economics factors, variables of the Technology Acceptance Model and Theory of Planned Behavior. Any factors identified as significant in the univariate analysis (P<.20) will be included in a subsequent multivariable regression analysis model. All P values ≤.05 will be considered statistically significant in multiple logistic regression analysis. The structural equation modeling was performed to identify interactions among the variables.

Results: The respondents had an overall high satisfaction rate and a positive attitude toward continuing to adopt and recommend the app. However, the satisfaction rate among respondents who have downloaded but not adopted the app was relatively lower, and few of them perceived that the downloading and acceptance processes are difficult. A high proportion of current users expressed a positive attitude about continuing to adopt and recommend the app to friends, colleagues, and family members. The behavioral intention strongly predicted the acceptance of the eHealth app (β=.89; P<.001). Attitude (β=.30; P<.001) and perceived norm; β=.37; P<.001) played important roles in determining behavioral intention, which could predict the downloading and acceptance of the eHealth app (β=.14; P<.001).

Conclusions: Despite the high satisfaction rate among the respondents, privacy concerns and perceived difficulties in adopting the app were the major challenges of promoting eHealth. Further promotion could be made through doctors and publicity. For future improvement, comprehensive health records and tailored health information should be included.

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KEYWORDS

digital health; eHealth; electronic health record; system; mobile app; app; public; private; community; caregiver; awareness; perception; improvement; utility; technology; model; health information

Introduction

In Hong Kong, a substantial proportion of hospital services is provided by the public sector (90% of all in-patient bed-days) and up to 70% of the outpatient services are offered by the private sector [1]. In view of the dual-track health care system, the Electronic Health Record Sharing System (eHRSS) was developed by the Hospital Authority (HA) to facilitate the information flow between the public and private sectors. It was launched in March 2016 [2] as an electronic platform to provide accurate and quick retrieval of clinical details, such as patient demographics, clinical information, and prescription profiles. The benefits of eHRSS are facilitation of patient communication, improvement of patient care continuity, accuracy of drug prescription, and enablement of holistic management [3]. Stage 2 development of the eHRSS started in July 2017, which further expanded the benefits to the relevant stakeholders and users. These include the broadening of the scope of sharable data by the system; provision of patients' choice over data sharing scope; and their access to some of the data in the eHRSS [4]. As of May 2022, over 5.5 million citizens, 50,000 health care professionals, all the 13 private hospitals, and over 2400 health care professionals working in the private sectors have enrolled in the eHRSS [5].

In stage 2 development, a mobile app, an "eHealth app," was launched in January 2021 [6]. It facilitates users to access their integrated health records and manage own health. Our team has previously evaluated the perceptions of and factors associated with the acceptance of the eHRSS in 2018 among 2000 patients in Hong Kong [7]. More than 70% (707/1000, 70.70%) of the patients were satisfied with the overall performance of the eHRSS. The expansion of sharable scope in the eHRSS (32/124, 25.8%) and allowing patients to access their medical records (30/124, 24.2%) were considered as the features to be developed in the future development of the eHRSS by the enrollees. This is one of the survey findings that provides support for the second stage of the eHRSS, where the users may access their health records and other health information via the utilization of an eHealth app. This mobile app further enhances collaborative care among the public sector, private sector, community, and caregivers. Importantly, citizens could be empowered in self-health management and disease prevention by recording health data within the app. It further empowers citizens' self-care ability by involving family members and other stakeholders to understand their current health status.

Across the world, similar mobile health apps were developed for people to upload and view health records, manage personal health care activities, share clinical information with doctors, and improve public health. Apps such as "Capzule PHR," "Health and Family," and "Health Notes" allow patients to view and get access to their medical information and record their data at any time and any place through the internet or by offline access [8]. The government of various countries is promoting electronic medical health records. For example, "MIDATA" is the UK government program with the goal of providing consumers a better control over their data [9]. The Mi Health App was developed accordingly to record health data and support long-term health management [10]. In 2019, the Korean government initiated the "MyData" program, which aims to give citizens increased access to personal data through mobile phones. In the medical field, it enables the public to manage their medical record [11]. The My HealthWay app was launched in 2021 by the Korean Ministry of Health and Welfare to integrate scattered medical data [12].

To further promote quality and efficiency, as well as to recommend the future development of the mobile (eHealth) app, perceptions and views from users are required to inform a more system-friendly design. The objectives of this project are to evaluate the factors associated with the downloading and utilization of the eHealth app; to examine the awareness, use, and acceptability of the mobile eHealth app; to explore whether eHealth app use may be associated with the joining of the eHRSS; the reasons for nonuse among those who joined the eHRSS; the extent to which the app improves user experience and influences health service utilization; and to recommend a potential room for improvement of the eHealth apps.

Methods

Sampling Frame and Recruitment

A self-administered questionnaire was adopted in this study. Prospective study participants were based on a list of patients provided by the HA. A simple random sampling methodology was mainly used. Over 5.5 million existing eHRSS users were included in the population, and computer-generated numbers were listed correspondingly for participant recruitment. An invitational SMS was first sent by the HA to existing eHRSS users. This served to alert the participants that they would receive a subsequent survey invitation by Chinese University of Hong Kong via SMS [13]. Then research teams at the Chinese University of Hong Kong sent messages to those people who had received an invitation from the HA through a bulk SMS sending platform (MD SMS by Media Digital Technologies Corporation Limited). Supplemented by a convenience sampling methodology, the online survey link was shared on the website of the HA, eHealth Facebook and Instagram page, eHealth app, eHealth website so that both health care recipients and non–health care recipients could access the questionnaires. The overall response rate was 66.71% (3026/4536).

Survey Instruments

Survey items focused on the awareness, use, and acceptability of the eHealth app; the association between the use of the eHealth app and the joining of the eHRSS; the reasons why some users did not use the eHealth app after joining the eHRSS; the extent to which the eHealth app improved user experience, modified health service access, and health management; and recommendations for possible improvement of the eHealth app.

The surveys were designed by an academic physician with relevant experience in projects related to the eHRSS, and extensive expertise in both clinical and public health research studies. The questionnaire draft was face-validated by a panel of epidemiologists, biostatisticians, and professionals in the field of health care policy, public health, and primary care. It was subsequently pilot tested for feasibility and item comprehensiveness among 20 people. The completion rate was 65% (13/20), and the average response time was 7 minutes and 40 seconds (Multimedia Appendix 1).

The surveys were available in both Chinese and English versions. All surveys were anonymous, and written consent was provided by the participants at the start of the questionnaire. The study participants were informed that all information presented would be in the form of aggregated data that could not identify any individuals.

Ethics Approval

This study was approved by the Survey and Behavioral Research Ethics Committee of the Chinese University of Hong Kong (approval number SBRE-21-0184).

Statistical Analysis

All surveys were checked for their completeness and the presence of participant consent. All data entry and analysis were conducted using SPSS version 26.0 (IBM, Inc.). As part of quality control, at least 20% (422/2110) of all surveys were randomly checked for the validity, quality, and accuracy. All items in the survey were analyzed as stratified according to the status of enrollment. The primary outcome measure was the downloading and acceptance of the eHealth app. We tested for the presence of statistical association by identifying potential associated factors using univariate and multivariate regression analyses. We included age, gender, educational level, job status, monthly household income, the types of mobile phone operating systems currently in use, the eHRSS enrollment status, perceived enablers of acceptance, and perceived barriers of the eHealth app use. Any factors identified as significant in univariate analysis (P<.20) will be included in a subsequent multivariable regression analysis model. All Pvalues ≤.05 will be considered statistically significant in the multiple logistic regression analysis. Assuming the proportion of the primary outcomes was 50%, which would provide the largest sample size, a total of 2110 surveys would result in precision of approximately 2.2%. In addition, we performed structural equation modeling to identify interactions among the variables.

Health Behavioral Models

To investigate the factors that could predict downloading and acceptance of the eHealth app, we used 2 internationally recognized models that have been widely adopted to examine the use of new technologies. These were the Technology Acceptance Model (TAM), which was first developed by Fred D Davis, Richard P Bagozzi, and Paul R Warshaw [14]. It is an adaptation of the Theory of Reasoned Action (TRA) to the discipline of information systems. The TAM hypothesizes that perceived usefulness and perceived ease of use could influence an individual's intention to use an information system [15]. The meditator of actual acceptance of the system is the intention to use. The model also considered perceived ease of use as a direct determinant of perceived usefulness. The TAM has been simplified by omitting the construct pertinent to attitude, as used in the TRA model. In the survey, perceived usefulness has been assessed using a series of questions related to the convenience and the benefit of using the app. To measure the ease of use, respondents have been asked about their experience in the downloading and acceptance processes, whether the app is easy to download, easy to find function, and contains the health information they want. For perceived barriers, respondents were asked about factors preventing them from downloading or adopting the app, such as doctors do not recommend or participate and concerns about personal privacy (Multimedia Appendix 2).

Furthermore, we employed the Theory of Planned Behavior (TPB), a commonly used psychological theory that links people's beliefs and behaviors [16]. The underpinning theory identified 3 core predictors, namely, attitude (A1-4), subjective norms (SN1-3), and perceived behavioral control (BI1-2) as modifiers of intention. Items from these 3 constructs, for example, suggestions from people who influence users' behavior, were recoded into the questionnaire as measurement (Multimedia Appendix 3) [17,18]. A 5-point Likert scale (strongly disagree, disagree, neutral, agree, and strongly agree) and a 2-point Likert scale (yes and no) were used in the survey design. Survey questions related to the acceptance and use of the app were designed according to the components of the TAM and TPB models. In our survey, attitude was the measurement of enabling factors, and the subjective norm referred to how the respondents viewed the idea of other people's perceptions about the app, including the recommendation from doctors, friends, and family members. The specific questions related to attitude and subjective norm are "Do you agree with the following reasons that can increase your motivation to continuously use/start to use the eHealth app" and "Do you agree with the following reasons that hinder your motivation to continuously use/start to use the eHealth App" (Multimedia Appendix 4). The theory hypothesized that behavioral intention is the most antecedent influencer of behavior. In the current structural equation modeling, we included the following additional variables into the TAM: age, gender, educational level, occupation, types of mobile phone operating systems, and enrollment status of the eHRSS. All P values ≤.05 were regarded as statistically significant.

Results

Participant Characteristics

A total of 2110 completed surveys were collected (Table 1). Overall, there were more male than female respondents (1184/2110, 56.11%, vs 926/2110, 43.89%). Among the study participants, 46.16% (974/2110) were aged between 41 and 60, while 39.72% (838/2110) were aged above 60. Over one-half of the respondents attained secondary educational level (1118/2107, 53.06%). Nearly half of the respondents had full-time or part-time jobs (999/2024, 49.36%). For income level, the highest proportion of monthly household income was HK $10,000-19,999 (1HK $=US $0.12; 458/2110, 26.44%).

Table 1. Participant characteristics (N=2110).

Characteristics	Values, n (%)
Age (years)	
16-30	136 (6.45)
31-40	162 (7.68)
41-50	343 (16.26)
51-60	631 (29.91)
61-70	636 (30.14)
>70	202 (9.57)
Gender	
Male	1184 (56.11)
Female	926 (43.89)
Educational level (n=2107)	
Primary or below	150 (7.12)
Secondary	1118 (53.06)
Tertiary or above	839 (39.82)
Other	3 (not counted)[a]
Job status (n=2024)	
Employed (Full-time/part-time)	999 (49.36)
Unemployed	100 (4.94)
Retired	695 (34.34)
Housewives	138 (6.82)
Students	53 (2.62)
Others	39 (1.93)
Refuse to answer	86 (not counted)[a]
Monthly household income (HK $; n=1732)[b]	
<10,000	373 (21.54)
10,000-19,999	458 (26.44)
20,000-29,999	335 (19.34)
30,000-39,999	154 (8.89)
40,000-59,999	180 (10.39)
≥60,000	232 (13.39)
Refuse to answer	378 (not counted)[a]
Phone currently in use	
Apple iOS	700 (33.18)
Android	1110 (52.61)
Huawei	174 (8.25)
Others	126 (5.97)

[a]As these options are out of the original categories, the answers were “not counted” and thus not used in the analysis.

[b]1HK $=US $0.12.

Participants were classified into several groups according to downloading and acceptance of the eHealth app (Multimedia Appendix 5). A total of 1242 respondents have enrolled in the eHRSS, downloaded, and adopted the eHealth app (group 1). There were 275 participants who have enrolled in the eHRSS, downloaded the eHealth app, but did not adopt the app (group 2). The third group included 203 respondents that have enrolled in the eHRSS, but have neither downloaded nor adopted the

app (group 3). In the following paragraphs, the findings were stratified according to these 3 groups of respondents.

The COVID-19 vaccination program (649/2110, 30.76%), medical doctors (647/2110, 30.66%), publicity (posters, pamphlets, television, outdoor advertisements; 533/2110, 25.26%), and friends or family members (388/2110, 18.39%) were the 4 major sources of information about the eHealth app among respondents (Multimedia Appendix 6). We did not observe a distinct difference in the distribution of sources among the 3 groups.

Perceived Enablers and Barriers of the App

In group 1, the majority of participants agreed that the app can show their accurate vaccination records (1118/1242, 90.02%) and other health records (1081/1242, 87.04%). They also expressed that the app provides useful administrative functions, including giving consent to health care providers for sharing their data (1044/1242, 84.06%), easier management of eHealth accounts (1005/1242, 80.92%), and empowerment of their family members and own health (940/1242, 75.68%). A similar result was also noted in the other 2 groups (Tables 2 and 3).

Among the study participants in group 1 (Tables 4 and 5), the major barrier was that their physicians had not joined the eHealth app (505/1028, 49.12%) and that their doctors did not mention, recommend, or think it is necessary to use the eHealth app (417/1078, 38.68%). Respondents in groups 2 and 3 perceived that the downloading procedure is complicated (172/382, 45%) and were concerned about their personal information and privacy (243/461, 52.7%), respectively.

Table 2. Perceived enablers of downloading the eHealth app.

Enablers of downloading	Downloaded and used eHealth app (n=1242)	Downloaded but not used eHealth app (n=399)	Not having downloaded and used eHealth app (n=469)
	Strongly agree or agree, n (%)	Strongly agree or agree, n (%)	Strongly agree or agree, n (%)
It is convenient to get information about different government-subsidized medical programs	920 (74.07)	293 (73.43)	332 (70.79)
I can view my accurate health records	1081 (87.04)	309 (77.44)	380 (81.02)
I can manage my eHealth account easily (eg, update the communication means)	1005 (80.92)	281 (70.43)	359 (76.55)
I can give sharing consents to health care providers easily so that they can view my health records	1044 (84.06)	307 (76.94)	378 (80.60)
I can find the health care providers and doctors that are participating in different health programs with ease	899 (72.38)	269 (67.42)	368 (78.46)
I can check the remaining balance and record of the Elderly Health Care Voucher Scheme	904 (72.79)	270 (67.67)	371 (79.10)
I can show the vaccination record/QR code	1118 (90.02)	321 (80.45)	383 (81.66)
It helps to manage my health and my families' health	940 (75.68)	274 (68.67)	367 (78.25)
My friend recommended me to use the "eHealth" app	691 (55.64)	202 (50.63)	244 (52.03)
My family recommended me to use the "eHealth" app	777 (62.56)	225 (56.39)	282 (60.13)
My doctor recommended me to use the "eHealth" app	797 (64.17)	240 (60.15)	312 (66.52)
Government's advertisement of the "eHealth" app	730 (58.78)	216 (54.14)	271 (57.78)
I can get souvenirs	466 (37.52)	148 (37.09)	201 (42.86)

Table 3. Perceived enablers of acceptance of the eHealth app.

Enablers of acceptance	Downloaded and used eHealth app (n=1242)			Downloaded but not used eHealth app (n=399)			Not having downloaded and used eHealth app (n=469)		
	n	Mean (SD)	95% CI	n	Mean (SD)	95% CI	n	Mean (SD)	95% CI
It is convenient to get information about different government-subsidized medical programs	920	3.84 (0.78)	3.80-3.89	293	3.75 (0.85)	3.66-3.83	332	3.76 (0.75)	3.69-3.82
I can view my accurate health records	1081	4.15 (0.79)	4.11-4.20	309	3.87 (0.87)	3.78-3.96	380	3.96 (0.71)	3.89-4.02
I can manage my eHealth account easily (eg, update the communication means)	1005	3.99 (0.73)	3.95-4.03	281	3.70 (0.86)	3.62-3.79	359	3.86 (0.71)	3.79-3.92
I can give sharing consents to health care providers easily so that they can view my health records	1044	4.07 (0.73)	4.03-4.11	307	3.84 (0.85)	3.75-3.92	378	3.92 (0.71)	3.86-3.99
I can find the health care providers and doctors that are participating different health programs with ease	899	3.86 (0.75)	3.82-3.90	269	3.68 (0.80)	3.61-3.76	368	3.89 (0.69)	3.82-3.95
I can check the remaining balance and record of the Elderly Health Care Voucher Scheme	904	3.90 (0.81)	3.86-3.95	270	3.71 (0.86)	3.63-3.80	371	3.88 (0.72)	3.82-3.95
I can show the vaccination record/QR code	1118	4.22 (0.72)	4.18-4.26	321	3.95 (0.86)	3.86-4.03	383	4.00 (0.73)	3.93-4.06
It helps to manage my health and my families' health	940	3.93 (0.79)	3.89-3.98	274	3.73 (0.89)	3.64-3.82	367	3.89 (0.72)	3.83-3.96
My friend recommended me to use the "eHealth" app	691	3.55 (0.91)	3.50-3.60	202	3.41 (0.94)	3.32-3.50	244	3.44 (0.86)	3.37-3.52
My family recommended me to use the "eHealth" app	777	3.68 (0.89)	3.63-3.73	225	3.5 (0.95)	3.40-3.59	282	3.56 (0.87)	3.48-3.64
My doctor recommended me to use the "eHealth" app	797	3.7 (0.88)	3.65-3.75	240	3.58 (0.88)	3.49-3.67	312	3.71 (0.77)	3.64-3.78
Government's advertisement of the "eHealth" app	730	3.61 (0.88)	3.56-3.66	216	3.49 (0.92)	3.40-3.58	271	3.52 (0.86)	3.44-3.59
m. I can get souvenirs	466	3.21 (1.08)	3.15-3.27	148	3.15 (1.05)	3.05-3.25	201	3.24 (0.99)	3.15-3.33

Table 4. Perceived barriers to downloading of the eHealth app.

Barrier	Downloaded and used the eHealth app (n=1028-1222)	Downloaded but not used the eHealth app (n=301-391)	Not having downloaded and used the eHealth app (n=365-461)
	Strongly agree or agree, n (%)	Strongly agree or agree, n (%)	Strongly agree or agree, n (%)
One's physician has not joined	505/1028 (49.12)	133/310 (42.90)	151/365 (41.37)
Only see 1 doctor who is familiar with my health records	392/1092 (35.90)	144/347 (41.50)	181/425 (42.59)
No sickness	295/1157 (25.50)	97/358 (27.09)	156/441 (35.37)
Concerned about personal information and privacy	408/1222 (33.39)	168/388 (43.30)	243/461 (52.71)
My doctor did not mention about/recommend/think it is necessary to use the "eHealth" app	417/1078 (38.68)	136/333 (40.84)	183/403 (45.41)
I do not know how to use a smartphone/mobile app	203/1167 (17.40)	94/372 (25.27)	119/441 (26.98)
Not willing for others to read one's own health records	372/1216 (30.59)	161/391 (41.18)	209/455 (45.93)
Uncertain about the benefits of the eHealth app	266/1198 (22.20)	134/374 (35.83)	172/437 (39.36)
Complicated downloading procedures	321/1216 (26.40)	172/382 (45.03)	173/423 (40.90)

Table 5. Perceived barriers to acceptance of the eHealth app.

Barrier	Downloaded and used the eHealth app (n=1242)			Downloaded but not used the eHealth app (n=399)			Not having downloaded and used the eHealth app (n=469)		
	n	Mean (SD)	95% CI	n	Mean (SD)	95% CI	n	Mean (SD)	95% CI
One's physician has not joined	505	3.30 (1.08)	3.23-3.37	133	3.30 (0.92)	3.18-3.41	151	3.16 (0.95)	3.05-3.26
Only see 1 doctor who is familiar with my health records	392	3.03 (1.02)	2.96-3.09	144	3.09 (0.93)	2.97-3.2	181	3.12 (0.92)	3.02-3.23
No sickness	295	2.73 (1.02)	2.66-2.80	97	2.83 (0.95)	2.71-2.95	156	2.97 (0.97)	2.86-3.08
Concerned about personal information and privacy	408	2.94 (1.14)	2.86-3.02	168	3.09 (1.05)	2.96-3.22	243	3.46 (1.06)	3.34-3.58
My doctor did not mention about/recommend/think it is necessary to use the "eHealth" app	417	3.11 (0.98)	3.05-3.18	136	3.22 (0.84)	3.12-3.33	183	3.23 (0.86)	3.14-3.33
I do not know how to use a smartphone/mobile app	203	2.43 (1.11)	2.36-2.51	94	2.70 (1.07)	2.57-2.83	119	2.78 (1.00)	2.67-2.89
Not willing for others to read one's own health records	372	2.89 (1.09)	2.82-2.96	161	3.08 (0.99)	2.95-3.2	209	3.28 (1.00)	3.17-3.39
Uncertain about the benefits of the eHealth app	266	2.70 (1.04)	2.63-2.77	134	3.06 (0.95)	2.95-3.18	172	3.15 (0.93)	3.05-3.26
Complicated downloading procedures	321	2.79 (1.05)	2.73-2.86	172	3.20 (1.01)	3.07-3.32	173	3.23 (0.88)	3.13-3.33

Perception of Processes of Acceptance of the App

The proportion of participants in group 1 who were positive about the downloading and acceptance processes was in general higher than those in group 2. Most respondents in group 1 were satisfied with the downloading processes (908/1242, 73.11%; Multimedia Appendix 7). However, the proportion of group 2 participants expressing satisfaction about the downloading process was lower (239/399, 59.90%). Regarding the acceptance process, respondents in group 1 were satisfied with the app's user experience and interface. They agreed that the fonts and size of the words were easy to read (947/1242, 76.25%), that the icon and tables were easy to understand (880/1242, 70.85%), and that the app was easy to use overall (869/1242, 69.97%). Among respondents in group 2, 60.6% (242/399) agreed that the fonts and size of the words were easy to read, and nearly half of them agreed that the icons and tables were easy to understand (190/399, 47.6%).

Applicability and Perception of the App

In terms of applicability, vaccine records (1108/1242, 89.21%), appointment records (1055/1242, 84.94%), medication records (1015/1242, 81.72%), allergy records (924/1242, 74.40%), and health management (786/1242, 63.29%) were the top 5 useful functions among the users (Multimedia Appendix 8). These proportions were higher in group 1 than in group 2.

Turning to the perception of the app (Multimedia Appendix 9), a high percentage of group 1 respondents (ie, app users) were satisfied with the app overall (975/1242, 78.50%), agreed that it enhanced the experience of health services (962/1242, 77.46%), enhanced concerns about health information (926/1242, 74.56%), and enhanced management of health on their own (889/1242, 71.58%). Over 50% (211/399, 52.9%) agreed that the app improved the health of family members. Group 2 respondents (ie, nonusers) also reported a positive perception of the app, although the proportion agreeing with these items was lower.

Expectations on the Future Development of the App

A high proportion of group 1 respondents, current users, expressed a positive attitude about continuing to adopt (1105/1242, 88.97%) and recommend the app to friends, colleagues, and family members (1024/1242, 82.45%; Multimedia Appendix 10). The proportion agreeing to continuously use and recommend among the nonusers in groups 2 and 3 was also high. Over 70% and 60% of the respondents in groups 2 (283/399, 70.9%, and 290/399, 72.7%) and 3 (320/469, 68.2%, and 304/469, 64.8%), respectively, expressed positive attitude toward future acceptance and recommendation of the app, respectively. Among all respondents, they expected to access more health records via the app, for example, the laboratory results (1707/2110, 80.90%) and the radiographic images (1484/2110, 70.33%), and to have customized health information, for example, age-specific health care recommendations (1378/2110, 65.31%) and tailored health tips (1121/2110, 53.13%). In group 1, the inclusion of the laboratory result was the most frequently cited item (1094/1242, 88.08%), followed by radiographic images (980/1242, 78.90%) and age-specific health care recommendations (843/1242, 67.87%). The results were similar compared with responses in groups 2 and 3.

Factors Associated With Downloading and Acceptance

Respondents were more likely to download the app when they had joined the eHRSS (adjusted odds ratio [aOR] 9.2, 95% CI 6.35-13.32; P<.001); had attained secondary educational level (aOR 1.63, 95% CI 1.08- 2.46; P=.02); reported being able to view their accurate health records (aOR 1.41, 95% CI 1.02-1.95; P<.035); reported being able to show the vaccination records or QR codes (aOR 1.43, 95% CI 1.03-1.98; P=.031); and reported one's physician had not joined the eHRSS (aOR 1.45,

95% CI 1.18-1.77; *P*<.001; Tables 6 and 7). Housewives (aOR 0.44, 95% CI 0.23-0.84; *P*=.013) and participants who were concerned about personal information and privacy (aOR 0.74, 95% CI 0.60-0.90; *P*=.003) were significantly less likely to download the eHealth app.

The independent factors associated with the acceptance of the eHealth app were similar to those associated with downloading, except that male participants (aOR 1.85, 95% CI 1.36-2.52; *P*<.001) were more likely to adopt, whereas individuals with primary educational level or below (aOR 0.49, 95% CI 0.25-0.94; *P*=.03) and study participants who were uncertain about the benefits of the eHealth app (aOR 0.80, 95% CI 0.66-0.96; *P*=.02) or perceived the downloading procedures as complicated (aOR 0.81, 95% CI 0.68-0.96; *P*=.01) were less likely to adopt (Tables 6 and 7).

Table 6. Factors associated with downloading and acceptance of the eHealth app.

Factor	Users, n (n=1159)	Downloading			Acceptance		
		Values, n (%)	aOR[a] (95% CI)	*P* value	Values, n (%)	aOR (95% CI)	*P* value
Age (years)				.63			.53
16-40	150	105 (70)	1 (reference)		82 (54.7)	1 (reference)	
41-60	571	440 (77.1)	1.22 (0.70-2.11)	.48	347 (60.8)	1.31 (0.81-2.13)	.27
>60	438	361 (82.4)	1.40 (0.71-2.78)	.33	280 (63.9)	1.35 (0.75-2.43)	.32
Gender							
Male	680	553 (81.3)	1.19 (0.83-1.73)	.35	458 (67.4)	1.85 (1.36-2.52)	<.001
Female	479	353 (73.7)	1 (reference)		251 (52.4)	1 (reference)	
Educational level				.03			.04
Primary or below	73	50 (68.5)	0.91 (0.44-1.91)	.81	32 (43.8)	0.49 (0.25-0.94)	.03
Secondary	617	491 (79.6)	1.63 (1.08-2.46)	.02	373 (60.5)	1.05 (0.75-1.48)	.76
Tertiary or above	469	365 (77.8)	1 (reference)		304 (64.8)	1 (reference)	
Job status				.01			.48
Full-time/part-time	642	504 (78.5)	1 (reference)		404 (62.9)	1 (reference)	
Unemployed	49	36 (73.5)	1.38 (0.59-3.21)	.46	26 (53.1)	1.21 (0.57-2.56)	.62
Retired	352	297 (84.4)	1.12 (0.67-1.88)	.67	230 (65.3)	0.89 (0.58-1.35)	.58
Housewives	74	45 (60.8)	0.44 (0.23-0.84)	.01	29 (39.2)	0.63 (0.34-1.15)	.13
Students	22	13 (59.1)	0.49 (0.15-1.57)	.23	11 (50)	0.82 (0.27-2.52)	.73
Others	20	11 (55)	0.27 (0.09-0.82)	.02	9 (45)	0.47 (0.16-1.38)	.17
Monthly household income (HK $)[b]				.27			.82
<10,000	228	170 (74.6)	1 (reference)		118 (51.8)	1 (reference)	
10,000-19,999	300	227 (75.7)	0.91 (0.55-1.51)	.72	177 (59)	1.20 (0.78-1.85)	.41
20,000-29,999	225	174 (77.3)	0.74 (0.43-1.29)	.29	141 (62.7)	1.07 (0.67-1.70)	.79
≥30,000	406	335 (82.5)	1.22 (0.71-2.08)	.47	273 (67.2)	1.18 (0.75-1.86)	.46
Phone currently in use				.05			.19
Apple iOS	392	295 (75.3)	1 (reference)		239 (61)	1 (reference)	
Android	615	501 (81.5)	1.22 (0.82-1.82)	.34	391 (63.6)	0.93 (0.67-1.31)	.69
Huawei	93	73 (78.5)	1.24 (0.63-2.46)	.53	54 (58.1)	0.83 (0.47-1.46)	.51
Others	59	37 (62.7)	0.46 (0.22-0.97)	.04	25 (42.4)	0.47 (0.24-0.94)	.03
Joining of eHRSS[c]							
Yes	924	807 (87.3)	9.20 (6.35-13.32)	<.001	665 (72)	9.77 (6.64-14.38)	<.001
No	235	99 (42.1)	1 (reference)		44 (18.7)	1 (reference)	

[a]aOR: adjusted odds ratio.

[b]1HK $=US $0.12.

[c]eHRSS: electronic Health Record Sharing System.

Table 7. Factors associated with perceived enablers and barriers of the eHealth app.

Factors	aOR[a] (95% CI)	*P* value	aOR[a] (95% CI)	*P* value
Perceived enablers (score: 1 [strongly disagree] to 5 [strongly agree])				
It is convenient to get information about different government-subsidized medical programs	0.94 (0.69-1.28)	.70	0.95 (0.74-1.23)	.71
I can view my accurate health records	1.41 (1.02-1.95)	.04	1.40 (1.08-1.81)	.01
I can manage my eHealth account easily (eg, update the communication means)	0.82 (0.55-1.22)	.32	1.26 (0.90-1.75)	.18
I can give sharing consents to health care providers easily so that they can view my health records	1.14 (0.80-1.63)	.47	1.12 (0.84-1.50)	.44
I can find the health care providers and doctors who participated in different health programs with ease	0.49 (0.33-0.73)	.001	0.62 (0.45-0.85)	.003
I can check the remaining balance and record of the Elderly Health Care Voucher Scheme	0.99 (0.70-1.40)	.95	1.03 (0.78-1.37)	.82
I can show the vaccination record/QR code	1.43 (1.03-1.98)	.03	1.33 (1.02-1.75)	.03
It helps to manage my health and my families' health	0.73 (0.51-1.06)	.09	0.76 (0.56-1.01)	.06
My friend recommended me to use the "eHealth" app	1.28 (0.88-1.86)	.20	0.98 (0.72-1.35)	.92
My family recommended me to use the "eHealth" app	1.10 (0.75-1.62)	.63	1.14 (0.82-1.59)	.42
My doctor recommended me to use the "eHealth" app	0.83 (0.60-1.13)	.23	0.85 (0.65-1.11)	.23
Government's advertisement of the "eHealth" app	1.00 (0.76-1.32)	.97	1.01 (0.80-1.27)	.96
I can get souvenirs	1.14 (0.93-1.39)	.22	1.13 (0.95-1.34)	.17
Perceived barriers (score 1 [strongly disagree] to 5 [strongly agree], discard those answering "N/A")				
One's physician has not joined	1.45 (1.18-1.77)	<.001	1.18 (1.01-1.39)	.04
Only see 1 doctor who is familiar with my health records	1.01 (0.82-1.26)	.90	1.08 (0.90-1.29)	.42
No sickness	0.94 (0.76-1.16)	.58	0.97 (0.81-1.16)	.75
Concerned about personal information and privacy	0.74 (0.60-0.90)	.003	0.89 (0.75-1.05)	.16
My doctor did not mention about/recommend/think it is necessary to use the "eHealth" app	1.20 (0.95-1.51)	.12	1.05 (0.87-1.27)	.58
I do not know how to use a smartphone/mobile app	0.97 (0.81-1.17)	.77	1.04 (0.89-1.22)	.62
Not willing for others to read one's own health records	1.05 (0.84-1.31)	.66	1.04 (0.87-1.24)	.68
Uncertain about the benefits of the eHealth app	0.81 (0.64-1.01)	.06	0.80 (0.66-0.96)	.02
Complicated downloading procedures	0.88 (0.71-1.08)	.23	0.81 (0.68-0.96)	.02

[a]aOR: adjusted odds ratio.

Findings From the Health Behavioral Models

In the TAM, perceived usefulness (β=.52; *P*<.001) and behavioral intention (β=.19; *P*<.001) were determined by perceived ease of use. The behavioral intention strongly predicted the acceptance of the eHealth app (β=.89; *P*<.001). Age (β=.07; *P*<.001) and whether the participant is a student or not (β=–0.09; *P*<.001) predicted the perceived usefulness. However, perceived usefulness did not significantly predict behavioral intention (β=.03; *P*=.32; Figure 1).

Turning to the TPB, attitude (β=.30; *P*<.001) and subjective norm (β=.37; *P*<.001) played important roles in determining behavioral intention, which could predict the downloading and acceptance of the eHealth app (β=.14; *P*<.001). The downloading and acceptance of the eHealth app could also be predicted by perceived behavior control (β=.14; *P*<.001). For the 3 core predictors, attitude was predicted by the subjective norm (β=.36; *P*<.001) and perceived behavior control (β=.23; *P*<.001). Subjective norm was predicted by attitude (β=.36; *P*<.001) and perceived behavior control (β=.11; *P*<.001). Perceived behavior control was predicted by attitude (β=.23; *P*<.001) and subjective norm (β=.27; *P*<.001; Figure 2).

Figure 1. Factors predictive of downloading and acceptance of the eHealth app by the Technology Acceptance Model. *P<.05 (2-tailed).

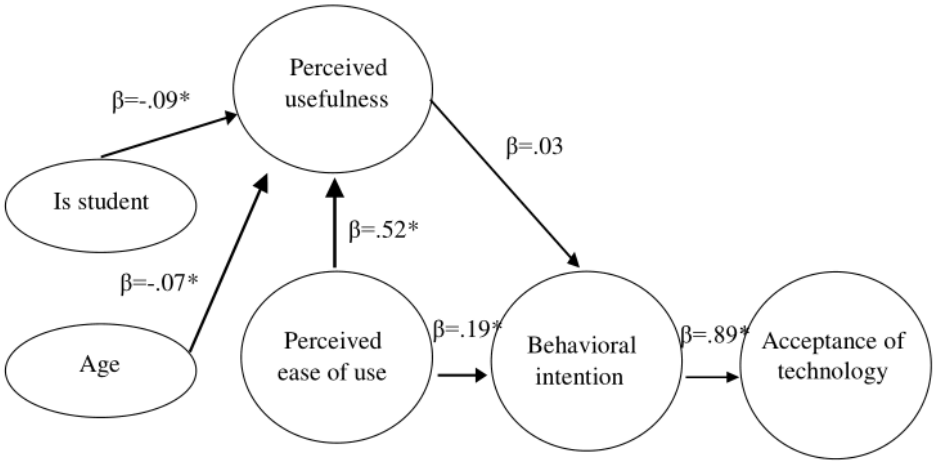
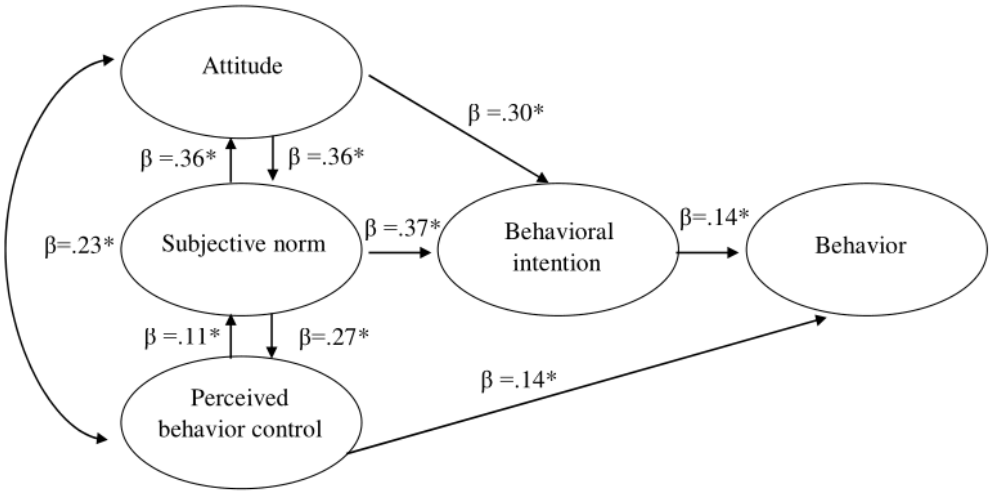


Figure 2. Factors predictive of downloading and acceptance of the eHealth app by the Theory of Planned Behavior. *P<.05 (2-tailed).



Discussion

Principal Findings

Overall, the satisfaction rate among the respondents was high. The satisfaction rate among group 2 respondents was relatively lower, and few of them perceived the downloading process as complicated. The willingness to continue to use and recommend the app was strong among all respondents. The 3 major enablers of adopting the app were the viewing of health records, especially the vaccination record; managing their eHealth accounts and sharing consent; and managing their family members' and their own health. However, respondents of the 3 groups had different perceived barriers. These include one's physician had not joined the eHRSS or had not recommended the eHealth app to them, a complicated downloading process, and privacy concerns. Most of the respondents expected to access more health records in the app, such as laboratory results and radiographic images, and have more personalized health information and health tips based on their age groups and health condition.

Limitations

This study has a few limitations. First, the survey was cross sectional, and so only the correlation could be measured instead of the causal relationship with the possibility of reverse causality. To corroborate the enablers and barriers, prospective longitudinal studies are required. In addition, face validity rather than construct validity was applied in the design of the questionnaire. The consistency reliability of the survey measurements has not yet been evaluated. Besides, some variables that could affect the downloading and acceptance of eHealth app may not be discussed in this study. Hence, there was a possibility of residual confounding. Finally, the study focused on acceptance of the app and examined individual factors affecting its use, which was based on a more individual level by using the TAM and TPB models in study design and analysis. Referring to Shachak et al's [19] study on the complexity of the health information technology implementation, a more sociotechnical-level study that examines the complex and overall cyber-social system in which users, cultures, networks, technologies, and processes are involved should be conducted in the future.

Comparison With Prior Work

eHealth app provides accurate and quick retrieval of clinical details for the citizens, as well as a platform for citizens to record self-monitoring health data. Thus, the app also facilitated the work of health care professionals with the integration and sharing of health records [5,7]. A medical app that contained medication, vaccine, and appointment records was convenient

for the users of health care services. This helps to contribute to a user-friendly system that enhanced more patients' use of the app. Among the eHealth app users in different studies, ease of use, user-friendliness, and availability of resources were the success factors facilitating the use of the app [20]. The eHealth app seems to empower the users to participate in health services, access health information, and manage their family members' and their own health, which has contributed to the overall satisfaction (975/1242, 78.50%) with the eHealth app.

Similar to our previous studies in 2020, many participants learned about the eHRSS from others, including medical doctors, posters, television, and outdoor advertisement [7,21]. However, the occurrence of the coronavirus pandemic has raised public awareness of eHealth technology [22]. Our results showed that the COVID-19 vaccination program has become the major source for people to learn about the app. The practical use of the eHealth app, including COVID-19 vaccination record and vaccine pass, has encouraged a large group of citizens to download and adopt the eHealth app. Based on the systematic analysis of 8 studies from the United States, China, and Switzerland, patient engagement has been enhanced by eHealth technologies, as these supported contact tracing and improved access to surveillance data [23]. A group of Canadian scholars found that the use of an eHealth app could be enhanced and made available widely in a pandemic context when eHealth technologies are integrated with public health policy and programs, which in turn could facilitate the flow of information and communication [24]. These helped to explain why the downloading and acceptance of the eHealth app, as a medical informatics technology, had a large increase during the pandemic.

The participation of doctors was decisive to encourage the citizens to download and use the eHealth app. Our previous study in 2020 found that the actual use of the eHRSS among patients was also significantly associated with the enrollment among physicians [7]. Giving sharing consent to health care providers was one of the major enablers for people to download and use the app. However, if their doctor did not join eHealth, it is of no use for them to give sharing consent to the doctor. This may lower the perceived usefulness of the app and discourage people to adopt. In our result, the TPB implied that subjective norm, doctor's recommendation, could largely determine the participants' willingness to download and adopt the app. The downloading and acceptance processes have been found satisfactory in the responses, especially among the respondents in group 1. However, the respondents hesitated to adopt the app because of perceived complicated downloading procedures. The eHealth app had users with a wide range of demographic characteristics and different levels of technical proficiency. Besides, the elderly and less educated citizens might have difficulties in adopting mobile apps. It was also found that the respondents in group 2 reported a lower satisfaction rate with the app. Based on the TAM, perceived usefulness and perceived ease of use are the key factors in the process of adopting new technology. A cross-sectional study by Canadian medical practitioners found that perceived ease of use was the strongest facilitator for electronic health record use, whereas usefulness and ease of use were the main factors influencing system acceptance among nonusers [25]. A systematic review also stated that lower perceived ease of use may lead to resistance to further acceptance and require additional effort and time [26]. In our study, respondents who faced difficulties in the downloading and acceptance processes had reduced willingness to download and use the app.

Privacy was an important perceived barrier to the acceptability of the eHealth app. The respondents in group 3 were worried about their personal information and privacy. As supported by international studies, privacy was a common concern raised by the public about eHealth technologies [27], especially when patients' lifestyles and activities were collected by multiple mobile health apps [28]. By contrast, our result showed that a significantly lower percentage of the users expressed concern about privacy, and that they had a generally high satisfaction rate with the app. Those who have already used the app valued their experience and benefits outweighed the privacy issue. This result was also suggested by a previous study on perceived benefits and concerns toward health information exchange [29]. Data security was also found to be a major barrier for non-enrollees not registering for the eHRSS in our 2020 study [7].

Implication

More assistance and support should be provided regarding the perceived difficulties in using mobile apps. To enhance the acceptance rate among people who have not adopted or downloaded the app, the utility and benefit of the app should be emphasized among the public. We suggest further promoting the app through doctors by sharing the benefits of health management in using the app with the citizens. For future development, more sharable scope of the health record, such as laboratory results and radiographic images, and customized health information, including age-specific health care recommendations and tailored health tips, should be included.

Regarding the perception of difficulties in using mobile apps, the user interface and user experience should be further enhanced. The acceptance of the eHealth app requires a certain level of technology literacy and a fair understanding of digital technology [30]. To have a full experience of eHealth, users are required to develop fundamental skills in health, information, science, media, computer, and the internet [31]. The publicity channels could be used to educate and provide some quick tips to the citizens. Users should also be encouraged to manage their family members, who are less familiar with the mobile apps, via the eHealth app.

Regarding the privacy issue, the security and privacy measures applied to the eHealth app should be reinforced. Further, it is an effective way to ensure widespread participation in the eHealth app by emphasizing the utility and benefits of the app [29,32]. The strategy is to present positively framed messages to the participants [33]. The usefulness and convenience of the eHealth app should be emphasized as they were strong predictive factors of acceptance of the eHealth app. A high percentage of respondents agreed that using the app could enhance their experience of health services, their concerns about health information, their management of health, and improve the health of family members.

In our findings, doctors had an important role in determining people's acceptance of the app. Doctors could recommend citizens managing the eHealth account and sharing function, which were the top-rated perceived enablers. The app could also improve the workflow of the doctors by allowing them to access patients' health records that have been shared in the eHRSS. Doctor was an important source for citizens to acknowledge the eHealth app. Therefore, it was also important to introduce the eHealth app to doctors and health care providers, encourage them to manage patients' health, and facilitate comanagement by patients and their family with the assistance of the eHealth app.

For future improvement, personalized and age-specific health care recommendations should be provided to facilitate a more patient-centered eHealth app [34]. Health information, health care recommendation, and support could be individualized to the patients. Tailored health information was processed and selected by human or computer algorithms from a database developed for the citizens. The self-monitoring health data recorded in the app by the citizens are also one of the sources for the database. With more self-input health data in the app (eg, BMI, health vital, and medication list), the data collected could be used to provide tailor-made health tips. Tailored health messages or recommendations could thus be individualized according to the patients' needs that were able to command greater attention and were easier to be understood [35]. Health information could be specific to the age and chronic diseases or other personal backgrounds of the citizen, which could improve the design of the app.

Conclusions

Overall, the respondents had a high satisfaction rate and a positive attitude toward continuing to adopt and recommend the app. The eHealth app seemed to empower citizens and their family members by enhancing their health information, self-management strategies, and experience with health services. However, privacy concerns and perceived difficulties in adopting were the major challenges of promoting eHealth. More comprehensive health records and tailored health information were recommended to be included for future improvement.

Acknowledgments

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Data Availability

The data used for the analyses are available upon reasonable request from the corresponding author.

Authors' Contributions

JH and MCSW participated in the conception of the research ideas, study design, interpretation of the findings, and provided intellectual input to the translational aspects of the study. JH, WSP, YYW, and FYM contributed to the implementation of the study, statistical analysis, and writing of the first draft of the manuscript. MCSW, FSWC, CSKC, WNW, and NTC made critical revisions on the manuscripts and provided expert opinions on implications of the study findings.

Conflicts of Interest

FSWC, CSKC, WMW, and NTC are from the funding authority.

Multimedia Appendix 1

Factors predictive of downloading and adoption of the eHealth app by the Technology Acceptance Model (TAM).
[DOCX File , 13 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Factors predictive of downloading and adoption of the eHealth app by the Technology Acceptance Model (TAM).
[DOCX File , 23 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Factors predictive of downloading and acceptance of the eHealth app by the Theory of Planned Behavior (TPB).
[DOCX File , 22 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Survey administered for the different respondents in this study.
[DOCX File , 7119 KB-Multimedia Appendix 4]

Multimedia Appendix 5

Distribution of study participants according to downloading and acceptance of the eHealth app.
[DOCX File , 14 KB-Multimedia Appendix 5]

Multimedia Appendix 6

Sources where the study participants learnt about the eHealth app.
[DOCX File , 15 KB-Multimedia Appendix 6]

Multimedia Appendix 7

Perception on processes of current and future acceptance of the eHealth app.
[DOCX File , 17 KB-Multimedia Appendix 7]

Multimedia Appendix 8

Applicability of the eHealth app.
[DOCX File , 17 KB-Multimedia Appendix 8]

Multimedia Appendix 9

Perception of the eHealth app.
[DOCX File , 15 KB-Multimedia Appendix 9]

Multimedia Appendix 10

Expectations on future development of the eHealth app.
[DOCX File , 17 KB-Multimedia Appendix 10]

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Abbreviations

eHRSS: Electronic Health Record Sharing System
HA: Hospital Authority
TAM: Technology Acceptance Model
TPB: Theory of Planned Behavior
TRA: Theory of Reasoned Action

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Original Paper

A Hybrid Architecture (CO-CONNECT) to Facilitate Rapid Discovery and Access to Data Across the United Kingdom in Response to the COVID-19 Pandemic: Development Study

Emily Jefferson[1], BSc, PhD; Christian Cole[1], BSc, PhD; Shahzad Mumtaz[1], BSc, MCS, PhD; Samuel Cox[2], MMath, PhD; Thomas Charles Giles[2], BSc, PhD; Sam Adejumo[2], MSc; Esmond Urwin[2], BEng, MSc, PhD; Daniel Lea[2], BSc, MSc; Calum Macdonald[3], BSc, MPhys, PhD; Joseph Best[2,4]; Erum Masood[1], BE, MSc; Gordon Milligan[1], BSc, MSc; Jenny Johnston[1]; Scott Horban[1], BSc; Ipek Birced[1], BSc, BA, MSc; Christopher Hall[1], BSc; Aaron S Jackson[1], BSc, PhD; Clare Collins[2], BA; Sam Rising[2], BSc; Charlotte Dodsley[2]; Jill Hampton[1], BA; Andrew Hadfield[2], BSc; Roberto Santos[2], PhD; Simon Tarr[2], PhD; Vasiliki Panagi[2], BSc, MSc; Joseph Lavagna[2], BSc, MSc; Tracy Jackson[3], BA, MSc, PhD; Antony Chuter[5]; Jillian Beggs[1], BSc; Magdalena Martinez-Queipo[6], DipNur, RN, BSc, MClinRes; Helen Ward[7], PhD; Julie von Ziegenweidt[8,9]; Frances Burns[10], BA, PhD; Joanne Martin[11], BS, MA, MB, PhD; Neil Sebire[12], MBBS, BClinSci, MD; Carole Morris[13], BSc; Declan Bradley[14,15], PhD; Rob Baxter[16], BSc, MSc, PhD; Anni Ahonen-Bishopp[17], PhD; Paul Smith[17], BSc, MBA; Amelia Shoemark[18], BSc, ClinSci, PhD; Ana M Valdes[19], PhD; Benjamin Ollivere[19], MBBS, MA, MD; Charlotte Manisty[20], MBBS, MA, PhD; David Eyre[21], BM, BCh, DPhil; Stephanie Gallant[18], BN, MA, MSc; George Joy[22], MBBS; Andrew McAuley[23], BA, MSc, PhD; David Connell[24], BM BCh, MA, PhD; Kate Northstone[25], BSc, MSc, PhD; Katie Jeffery[26,27], BCh, BM, MA, PhD; Emanuele Di Angelantonio[28,29,30,31,32], MSc, MD, PhD; Amy McMahon[28,30], BSc, PhD; Mat Walker[28,30], BSc, PhD; Malcolm Gracie Semple[33,34], BSc, BM, BCh, PhD; Jessica Mai Sims[35], BA, MSc; Emma Lawrence[36], BSc, PhD; Bethan Davies[7], MB, BChir, MPH, PhD; John Kenneth Baillie[37], BSc, MBChB, PhD; Ming Tang[38], BSc, MBA; Gary Leeming[39], BA; Linda Power[40]; Thomas Breeze[41], BA (Hon), PGCE, MSc; Duncan Murray[42,43], BM, BCh, MA, PhD; Chris Orton[44], BA, MSc; Iain Pierce[45,46], BSc, MSc, PhD; Ian Hall[47], BA, BM, BCh, DM; Shamez Ladhani[48], PhD; Natalie Gillson[49], BSc; Matthew Whitaker[7], BA, MSc; Laura Shallcross[50], BA, MBBS, MSc, PhD; David Seymour[4], BSc; Susheel Varma[4], BEng, MSc, MBA, PhD; Gerry Reilly[4], BSc, MSc; Andrew Morris[4], MD, PhD; Susan Hopkins[40], BA, MB, MSc, MD; Aziz Sheikh[51], BSc, MBBS, MSc, MD; Philip Quinlan[2,19], BSc, PhD

[1]Health Informatics Centre, Division of Population and Health Genomics, School of Medicine, University of Dundee, Dundee, United Kingdom

[2]Digital Research Service, University of Nottingham, Nottingham, United Kingdom

[3]Usher Institute, University of Edinburgh, Edinburgh, United Kingdom

[4]Health Data Research UK, London, United Kingdom

[5]Lay Partnership in Healthcare Research, Lindfield, United Kingdom

[6]National Health Service Digital, London, United Kingdom

[7]School of Public Health, Imperial College London, London, United Kingdom

[8]Department of Haemotology, University of Cambridge, Cambridge, United Kingdom

[9]National Institute for Healthcare Research BioResource, Cambridge University Hospitals NHS Foundation, Cambridge Biomedical Campus, Cambridge, United Kingdom

[10]Centre for Public Health, Belfast Institute of Clinical Science, Queens University Belfast, Belfast, United Kingdom

[11]Blizard Institute, Faculty of Medicine and Dentistry, Queen Mary University of London, London, United Kingdom

[12]Institute of Child Health, Great Ormond Street Hospital, London, United Kingdom

[13]Public Health Scotland, Edinburgh, United Kingdom

[14]Centre for Public Health, Institute of Clinical Science, Queen's University Belfast, Belfast, United Kingdom

[15]Public Health Agency, Belfast, United Kingdom

[16]EPCC, University of Edinburgh, Edinburgh, United Kingdom

[17]BC Platforms, Espoo, Finland

[18]Molecular and Clinical Medicine, School of Medicine, University of Dundee, Dundee, United Kingdom

[19]School of Medicine, University of Nottingham, Nottingham, United Kingdom

[20]Institute of Cardiovascular Sciences, University of College London, London, United Kingdom
[21]Big Data Institute, University of Oxford, Oxford, United Kingdom
[22]Barts Heart Centre, London, United Kingdom
[23]Clinical and Protecting Health Directorate, Public Health Scotland, Glasgow, United Kingdom
[24]School of Medicine, University of Dundee, Dundee, United Kingdom
[25]Population Health Sciences, Avon Longitudinal Study of Parents and Children, Bristol, United Kingdom
[26]Radcliffe Department of Medicine, Oxford University, Oxford, United Kingdom
[27]Oxford University Hospitals NHS Foundation Trust, John Radcliffe Hospital, Oxford, United Kingdom
[28]British Heart Foundation Cardiovascular Epidemiology Unit, Department of Public Health and Primary Care, University of Cambridge, Cambridge, United Kingdom
[29]British Heart Foundation Centre of Research Excellence, University of Cambridge, Cambridge, United Kingdom
[30]National Institute for Health Research Blood and Transplant Research Unit in Donor Health and Behaviour, University of Cambridge, Cambridge, United Kingdom
[31]Health Data Research UK Cambridge, Wellcome Genome Campus, University of Cambridge, Cambridge, United Kingdom
[32]Health Data Science Research Centre, Human Technopole, Milan, Italy
[33]Health Protection Research Unit in Emerging and Zoonotic Infections, Institute of Infections, University of Liverpool, Liverpool, United Kingdom
[34]Respiratory Department, Alder Hey Children's Hospital, Liverpool, United Kingdom
[35]University College London, London, United Kingdom
[36]BioIndustry Association, London, United Kingdom
[37]Outbreak Data Analysis Platform, University of Edinburgh, Edinburgh, United Kingdom
[38]NHS England, Worcestershire, United Kingdom
[39]Civic Data Cooperative, Digital Innovation Facility, University of Liverpool, Liverpool, United Kingdom
[40]Public Health England, London, United Kingdom
[41]Avon Longitudinal Study of Parents and Children, Bristol Medical School, University of Bristol, Bristol, United Kingdom
[42]University of Birmingham, Birmingham, United Kingdom
[43]University Hospital Coventry & Warwickshire NHS Trust, Coventry, United Kingdom
[44]Population Data Science, Swansea University Medical School, Swansea, United Kingdom
[45]Barts Heart Centre, St Bartholomew's Hospital, Barts Health NHS Trust, London, United Kingdom
[46]Institute of Cardiovascular Science, University College London, London, United Kingdom
[47]Nottingham Biomedical Research Centre, School of Medicine, University of Nottingham, Nottingham, United Kingdom
[48]Immunisation and Countermeasures Division, Public Health England Colindale, London, United Kingdom
[49]UK Health Security Agency, London, United Kingdom
[50]Institute of Health Informatics, UCL, London, United Kingdom
[51]Centre for Population Health Sciences, Usher Institute, University of Edinburgh, Edinburgh, United Kingdom

Corresponding Author:
Emily Jefferson, BSc, PhD
Health Informatics Centre
Division of Population and Health Genomics
School of Medicine, University of Dundee
Ninewells Hospital
Dundee, DD1 9SY
United Kingdom
Phone: 44 01382 383 353
Email: e.r.jefferson@dundee.ac.uk

Abstract

Background: COVID-19 data have been generated across the United Kingdom as a by-product of clinical care and public health provision, as well as numerous bespoke and repurposed research endeavors. Analysis of these data has underpinned the United Kingdom's response to the pandemic, and informed public health policies and clinical guidelines. However, these data are held by different organizations, and this fragmented landscape has presented challenges for public health agencies and researchers as they struggle to find relevant data to access and interrogate the data they need to inform the pandemic response at pace.

Objective: We aimed to transform UK COVID-19 diagnostic data sets to be findable, accessible, interoperable, and reusable (FAIR).

Methods: A federated infrastructure model (COVID - Curated and Open Analysis and Research Platform [CO-CONNECT]) was rapidly built to enable the automated and reproducible mapping of health data partners' pseudonymized data to the Observational Medical Outcomes Partnership Common Data Model without the need for any data to leave the data controllers' secure environments, and to support federated cohort discovery queries and meta-analysis.

Results: A total of 56 data sets from 19 organizations are being connected to the federated network. The data include research cohorts and COVID-19 data collected through routine health care provision linked to longitudinal health care records and demographics. The infrastructure is live, supporting aggregate-level querying of data across the United Kingdom.

Conclusions: CO-CONNECT was developed by a multidisciplinary team. It enables rapid COVID-19 data discovery and instantaneous meta-analysis across data sources, and it is researching streamlined data extraction for use in a Trusted Research Environment for research and public health analysis. CO-CONNECT has the potential to make UK health data more interconnected and better able to answer national-level research questions while maintaining patient confidentiality and local governance procedures.

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KEYWORDS

COVID-19; clinical care; public health; infrastructure model; health data; meta-analysis; federated network; health care record; data extraction; data privacy; data governance; health care

Introduction

COVID-19 introduced a new set of conditions to existing challenges in health and clinical data collection within the United Kingdom. Regularly updated data were required at pace to inform decision-making and research, but were being generated by heterogenous sources, such as new "Lighthouse" laboratories [1] set up specifically for the pandemic, academic research laboratories, and usual primary and secondary care settings [2]. The diversity of data sources and the lack of awareness of them made it challenging to identify and access these data sources, as was highlighted by the UK Government Chief Scientific Adviser [3]. In our experience, it was often the case that each research or public sector group had to contact each potential data source individually to obtain information about the data they host, making the process complex and lengthy even for high-level questions, such as simply finding out what data are available. Such challenges are described in detail in the Goldacre Review [4] and across many studies [5-8].

Typically, any analysis of patient data or electronic health records (EHRs) requires many steps covering legal (eg, General Data Protection Regulations [GDPR] compliance) [9], operational (eg, data sharing agreements) [10,11], and security aspects (eg, access to unconsented pseudonymized or anonymized data in a secure environment where the data cannot be exported, ie, a Trusted Research Environment [TRE] [12]) [13]. These steps are crucial to ensure appropriate reuse of data but can take many months to complete before any data analysis can take place [14].

The need for more streamlined and efficient methods for discovering and analyzing EHRs is not new [15], but the COVID-19 pandemic has played a catalytic role in highlighting the need for these methods more than ever before. Data are federated when held at different locations and often hosted by different data controllers. The World Economic Forum has recently published a guideline document that focuses on sharing of sensitive health data in a federated consortium model considering the post–COVID-19 world [16]. Large-scale projects, such as the Global Alliance for Genomics and Health [17]; Canadian Distributed Infrastructure for Genomics [18]; Common Infrastructure for National Cohorts in Europe, Canada, and Africa [19]; and European Health Data and Evidence Network [20] projects, have laid out principles and frameworks supporting safe use of patient data [17,21]. While federated academic tooling (software that works on federated data sets) exists [22-25], the commercial sector appears to have more capability than the best in academia [26-28]. However, commercial systems usually come with contracts and licensing terms that may not be suitable for everyone and also focus on finding patients for recruitment to clinical trials rather than cohort discovery and meta-analysis from EHR data. Equally, the commercial nature of the systems means they are usually based on proprietary standards, which results in further fragmentation and lack of accessibility of data sets.

Given the need for more impactful solutions in accessing aggregated health data, accelerated by the pandemic [29], the COVID - Curated and Open Analysis and Research Platform (CO-CONNECT) was established at scale and at pace. The Health Data Research (HDR) Innovation Gateway [30] (Gateway) is a web resource enabling discovery of and accessibility to UK health research data, and supporting health data research in a safe and efficient manner. The Gateway provides detailed metadata descriptions of over 700 data sets held by members of the UK Health Data Research Alliance, including the Health Data Research Hubs [31]. CO-CONNECT enhances the capabilities of the Gateway by providing a query engine (the Cohort Discovery Tool) to support dynamic cohort building and meta-analysis across individual-level data from multiple data partners.

The aim of CO-CONNECT is to transform the way public health organizations and researchers discover and access COVID-19 data and associated longitudinal health care data from across the United Kingdom. This paper describes how CO-CONNECT maintains patient confidentiality and data security while supporting access to data for research at pace, and how a multidisciplinary team tackled the architecture of this platform as an asset for public health in the United Kingdom.

Methods

Project Initiation and Governance

CO-CONNECT was conceived early after the start of the pandemic when both researchers and public sector bodies were frantically trying to find what data existed across different data custodians to answer pressing questions, which would then inform public policy. Many research studies were being rapidly commissioned, and data were being collected via routine health care, but there was no easy way for different funders and research groups to understand what data were being collected. Once data sets had been identified, it took significant time to set up the agreements for data sharing and access.

For example, a key question at the time was whether someone would be immune to COVID-19 after contracting the disease, and if so, for how long. Low-level detailed serology results, rather than simply "positive/negative" results, were required for calibration of assays and to understand antibody responses related to individual levels of immunity. However, it was challenging for researchers to find which data controllers may be capturing low-level data, and if so, how to rapidly access the data for analysis.

These challenges where widely recognized at the time. When answering questions on the lessons to be learnt from the pandemic at the Science and Technology Committee meeting in July 2020 [3], Sir Patrick Vallance stressed the importance of data flows and data systems to support the pandemic response:

> *One lesson that is very important to learn from this pandemic, and for emergencies in general, is that data flows and data systems are incredibly important. You need the information in order to be able to make the decisions. Therefore, for any emergency situation those data systems need to be in place up front to be able to give the information to make the analysis and make the decisions.*

The CO-CONNECT leads reached out to 26 individuals/organizations who were collecting research cohorts of data or collecting data as part of routine health care provision from the 4 devolved UK Nations to join the project as collaborators. The benefits of the platform, how it would protect patient confidentiality, and how individual-level data would not have to leave the control of the data partner needed to be rapidly communicated for each data partner to agree to the collaboration. There were 4 co-leads on CO-CONNECT, who each bought different expertise to the project and could share the duties of leading such a large project delivered within a tight timeframe during the COVID pandemic.

CO-CONNECT partnered with the National Core Studies program [32] and reported to the UK Scientific Advisory Group for Emergencies [33] through this program. The Advisory Steering Committee meets every 3 months with representatives from the 4th Pillar Testing Programme and the UK Joint Biosecurity Centre, a Chief Scientific advisor, an ethics expert, and the funders.

Architecture of CO-CONNECT Infrastructure

Overview

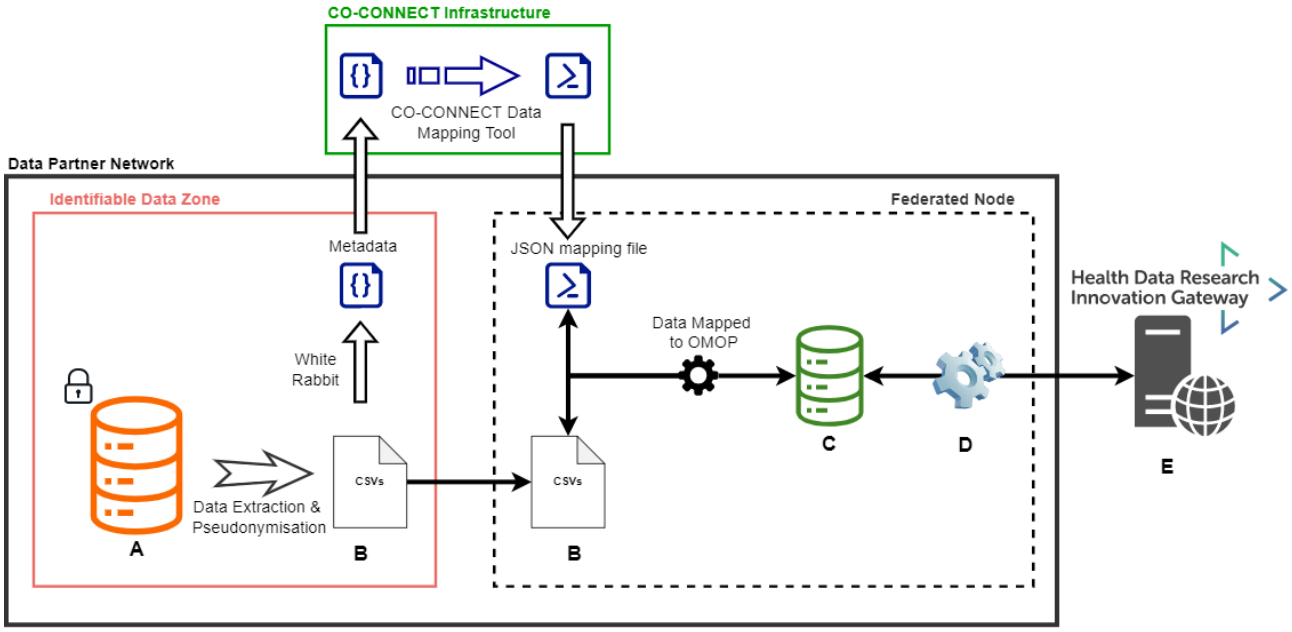
CO-CONNECT delivers a federated capability that enables the discovery of data across multiple sources, referred to as CO-CONNECT data partners, to make them findable, accessible, interoperable, and reusable (FAIR) [34]. The federation has been designed to ensure that data can be processed in line with the GDPR and common law confidentiality requirements.

Figure 1 provides an architecture overview of the components that reside within the secure environment of each data partner's network, with no inbound connectivity, and those that are available externally to researchers and the CO-CONNECT team via a secure login. Throughout the methods section, we reference the components as labeled in Figure 1 (Components A-E) in brackets after the description. Our overview video explains how the system works [35].

In summary, a secure virtual machine (VM) (Federated Node, dashed black box) is set up by the data partner, which is separate from the location where identifiable data are stored (Identifiable Data Zone, red box), but still part of their secure infrastructure. The data partner sends metadata ("Metadata" within the red box) about the data they hold to the CO-CONNECT technical team that determines the rules to map the data into the Observational Medical Outcomes Partnership (OMOP) [36] data standard format (CO-CONNECT Infrastructure, green box). The mapping script (JSON mapping file), developed by the CO-CONNECT technical team, is sent to the data partners who then apply the mapping rules to a pseudonymized version of their data (Data Mapped to OMOP). This generates a database of relevant linked and pseudonymized data sets in OMOP format within their VM (Component C, green database).

Software is installed within the VM, called BC|LINK (Component D), which provides access to the pseudonymized OMOP database (Component C, green database) and is configured to communicate with the Gateway tool (Component E) where approved users can submit queries. The Gateway contains the BC|RQUEST software (Component E) that stores the user-submitted queries and allows the BC|LINK software (Component D) to download these queries and run them against the OMOP database. Only aggregate counts are posted in response and displayed to the user. This is simultaneously repeated across all UK-wide data partners within the federation, which enables users to perform feasibility analysis (to discover relevant data from different sources) and carry out aggregate-level analysis across different UK data partners through one system.

Figure 1. The CO-CONNECT federated architecture. A data partner (dark box) has potentially identifiable data (A) from which an extraction is made and pseudonymized (B). A metadata extraction is performed with WhiteRabbit (within the identifiable Data Zone, red box) and sent to the CO-CONNECT infrastructure (green box). A mapping script to the OMOP CDM is created using the CO-CONNECT data mapping tool (CaRROT-Mapper). The pseudonymized data are securely transferred (B) into a secure virtual machine hosted by the data partner (Federated Node, dashed dark box), mapped to OMOP (CaRROT-CDM), and connected to the federation software (C and D). From there, the data are queryable by the Innovation Gateway (E). Only aggregated fully anonymous data discovery and meta-analysis results are returned to the Gateway (D). CDM: Common Data Model; OMOP: Observational Medical Outcomes Partnership.



Detailed Components of the Architecture

CaRROT Software

All CO-CONNECT developed tools (termed CaRROT [Convenient and Reusable Rapid Ontology Transformer]) are open source and freely available [37,38]. This suite of tools automates the mapping of the data into OMOP and the loading of the data into a database for external querying.

Access to Individual-Level Data

All individual-level data remain under the control of the data partner, and there is no requirement for any direct interaction from the CO-CONNECT pipeline with the data partner's data systems (Database A). The federated node (dashed black box) is established on a VM that is separate from any systems that hold identifiable data.

ID Management and Data Linkage

All patient identifiable data are pseudonymized locally by data controllers (Data Extraction and Pseudonymization) through (1) obfuscation of potentially sensitive information, such as date of birth, and (2) removal of personal identifiable information, such as given names and addresses.

Generating Metadata

WhiteRabbit, from Observational Health Data Science and Informatics (OHDSI) [39], is a software tool to profile data sets to generate metadata that includes descriptions on tables, fields, and the distribution of values within each field [40]. WhiteRabbit resides within the Identifiable Data Zone but is only ever run against a pseudonymized extract of the data in CSV format (Files B), from which the WhiteRabbit report is generated. The data partner always retains control over what data WhiteRabbit can access, the configuration of the parameters, and what is shared to the CO-CONNECT team.

Data Mapping Tool

To ensure consistency of data across the data partners, all of the data sets are on-boarded using OMOP Common Data Model (CDM) version 5.3 [36] developed as part of the OHDSI.

We developed a data mapping tool (CaRROT-Mapper [37]; CO-CONNECT Infrastructure, green box), which ingests WhiteRabbit reports and enables the data team to generate a mapping rule to replace each field or field value to a standard OMOP vocabulary concept ID. From this concept ID, the domain can be established, which in turn confirms which table in the OMOP CDM should be used to store the data. Importantly, rules that were generated previously can be reused by other data partners that have similar data structures or for subsequent updates to the data, rather than starting from scratch. At the time of writing, the CaRROT-Mapper supports transformation to the Person, Observation, Condition Occurrence, Measurement, and Drug Exposure tables.

The conversion and destination tables are captured as "mapping rules" in a single JSON file, which is sent to the data partner.

Extract, Transform, and Load Pipeline

The mapping rules developed are used by the Python Extract, Transform, and Load (ETL) pipeline (CaRROT-CDM) [38,41], to convert the data from its native CSV format into the OMOP CDM. The ETL pipeline can be scheduled to run either on demand or whenever new data are available.

Federated Querying

The BC|RQUEST query portal (Component E) was licensed as a white-labeled instance from BC Platforms [26-28] and integrated into the Gateway as the Cohort Discovery Search Tool [42]. This component provides an interface allowing approved users (bona fide researchers) to create the definition of their cohort (cohort queries) via a drag and drop interface of available OMOP concepts. Cohort queries (also known as study feasibility queries) are created within the query portal and queued to be collected every few seconds by the BC Platforms BC|LINK software installed (Component D) within the data partners' Federated Nodes. BC|LINK executes the queries and returns the aggregated results to the query portal.

A single BC|LINK instance can interact with multiple OMOP data sets held by each data partner, and allows each data partner to independently set all data disclosure rules, including data rounding, low number suppression, and whether metadata analysis can be performed. This allows each data partner to determine risk and set appropriate controls as required for each data set rather than a single setting for all data sets. Although the data are stored in software from BC Platforms, they have no mechanism to access the data. All access to the data remains strictly under the control of the data partner.

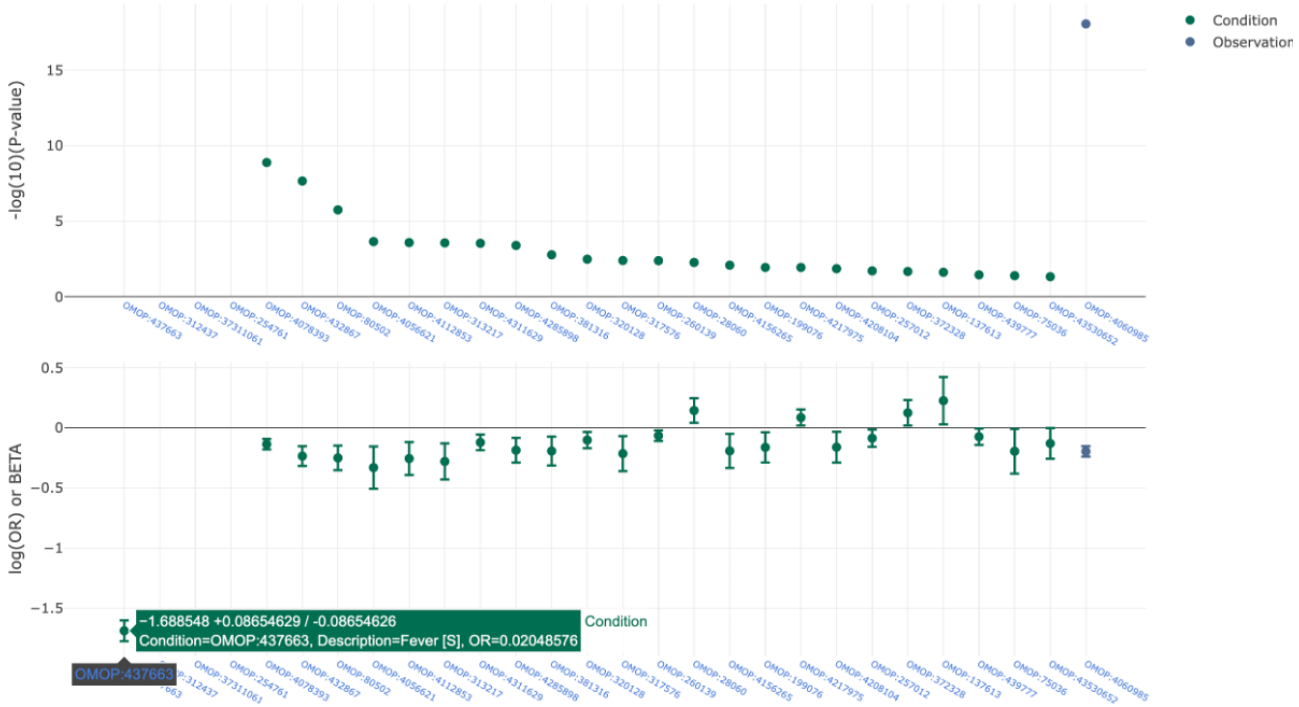
Feasibility Questions

The system allows researchers to dynamically and in real time define the cohorts of interest [42]. They will receive responses from across the network usually within a minute. Such an approach allows the feasibility of potential studies to be understood based on the actual data available and without intervention from data partners. This important feature ensures that researchers understand what is feasible in near real time, while always ensuring the disclosure controls are applied by each data partner.

Meta-Analysis

The capability to perform meta-analysis queries across their data sets is configured by the data partners through an "opt-in" mechanism. Researchers are able to request predefined analyses, through a common user interface, to run across the "opted-in" data sets. An example of a meta-analysis query is to undertake a phenome-wide association study (PheWAS) analysis to understand what phenotypes are linked to different levels of antibody response. In the out-of-the-box capability from BC Platforms, the PheWAS analysis is initially treated as 2 availability queries, one for the case and the other for the control section of the selected cohorts. The subsets of individuals returning within each availability query are then selected from the database, and a PheWAS/Forest analysis is performed across the OMOP CDM search space. This identifies the most overrepresented and underrepresented terms within each cohort. The output is returned to BC|RQUEST as an array of data, which is combined with the information from other cohorts to find the common "META" terms that are overrepresented and underrepresented across all the cohorts. This information is displayed back to the user in the form of a PheWAS plot or a forest plot, or downloaded as a Boolean table of the results. An example is shown in Figure 2.

Figure 2. An example phenome-wide association study plot across 4 test data sets comparing females with pneumonia against a background population of female-only samples. The most overrepresented classes include fever (OMOP:437663), disease caused by 2019-nCoV (OMOP:37311061), dysphenia (OMOP:312437), and cough (OMOP:254761). OMOP: Observational Medical Outcomes Partnership.



Custom meta-analytic modules can also be implemented within the BC Platforms ecosystem. These can be developed in either R or Python. Work to develop more advanced statistical meta-analysis and investigations into potential biases or statistical challenges will form future research.

Data Access Requests

The data discovery and meta-analysis tools only report aggregated-level data. Details of the data sources queried are provided, so that when an appropriate cohort is identified, direct contact with the appropriate data partner can be made to initiate data governance approvals for a specific research study, which requires individual-level data analysis using the cohort identified. The Gateway-standardized governance application process (Five Safes [safe projects, safe people, safe settings, safe outputs, and safe data] [43,44] form) can be used to streamline the effort required to obtain approvals from data partners who have adopted the standard [45].

Engagement With Patients and the Public

We have patient and public representatives co-leading the project, with 2 lay member co-investigators and a public and patient group. Representatives attend our work package, leadership team, and advisory board meetings. Representatives reviewed all the controls developed for CO-CONNECT, ensuring we are protecting patient confidentiality and maintaining trust. We developed a series of public-facing videos: Overview [35], Finding Data [46], and Analyzing Data [47]. We also drafted a lay summary and Frequently Asked Questions page [48].

Ethics Considerations

Research ethics approval was not required for this project as each data partner maintains their own governance and ethics for the original research studies. Anyone requiring access to the platform to perform research needs to apply for their own ethics approval.

Results

Data Coverage

The CO-CONNECT consortium includes 41 leaders from 29 different organizations across the 4 devolved UK Nations and is currently on-boarding over 56 different data sets into the platform. The project was launched in October 2020, with 18 months of funding and extension for another 6 months.

CO-CONNECT is focused on the following 3 different types of data partners: (1) COVID-19 research consented cohorts collecting serology data; (2) routinely collected unconsented data from across the United Kingdom; and (3) research cohorts collected prior and during the current pandemic, which CO-CONNECT is enhancing with the ability to link to COVID-19 data (augmented cohorts).

The sources for each type are shown in Table 1. Approximately half of the COVID-19 research cohorts being collected are from health care workers.

Table 1. List of data sources incorporated into CO-CONNECT.

Cohort type	Source
COVID-19 serology cohorts	
Health care workers	Co-STARS[a] [49], COVIDsortium [50], MATCH [51], Oxford Healthcare Workers [52], PANTHER[b] [53], and SIREN[c] [54]
Blood donors	TRACK-COVID [55]
Care homes	VIVALDI [56]
Hospitalized patients	ISARIC[d] [57]
Schools	sKIDs[e] [58]
Education	ACE[f] [59]
Random sample of the population of adults registered with a general practitioner in England	REACT-2[g] [60]
Hospitalized and community follow-up	FOLLOW-COVID[h] [61]
Augmented cohorts	
Longitudinal cohorts	ATLAS[i] [62] (ALSPAC[j] [63], Generation Scotland [64], GASP[k] [65], NIHR-BioResource [66], TWINS-UK [67]), and Wellcome Longitudinal Population Study [68] (6 cohorts)
Respiratory cohorts	HDR[l] UK BREATHE Hub [69] (17 cohorts)
Routinely collected health data sources/Trusted Research Environments	
England	National Health Service (NHS)–Digital [70] and UK Health and Security Agency (previously Public Health England) [71]
Scotland	Public Health Scotland (PHS) [72]
Northern Ireland	HSC[m] Business Services Organisation [73] and HSC Public Health Agency [74]
Wales	Secure Anonymised Information Linkage (SAIL) service [75]
UK-wide	Office of National Statistics (ONS) [76]

[a]Co-STARS: COVID-19 Staff Testing of Antibody Responses Study.

[b]PANTHER: Pandemic Tracking of Healthcare Workers.

[c]SIREN: SARS-CoV-2 Immunity and Reinfection Evaluation Network.

[d]ISARIC: International Severe Acute Respiratory and emerging Infections Consortium.

[e]sKIDS: COVID-19 Surveillance in School Kids.

[f]ACE: Asymptomatic COVID-19 in Education.

[g]REACT-2: Real-time Assessment of Community Transmission 2.

[h]FOLLOW-COVID: Focused Longitudinal Observational Study to Improve Knowledge of COVID-19.

[i]ATLAS: Access Points to Tissue, Longitudinal Data, Archives, and Samples.

[j]ALSPAC: Avon Longitudinal Study of Parents And Children.

[k]GASP: Genetics of Asthma Severity and Phenotypes.

[l]HDR: Health Data Research.

[m]HSC: Health and Safety Commission.

Data Sets Onboarded

The HDR UK Cohort Discovery Service was first launched in April 2021. At the time of writing, the following data partners are live within the HDR Cohort Discovery Tool: ALSPAC (Avon Longitudinal Study of Parents And Children), PANTHER (Pandemic Tracking of Healthcare Workers), GASP (Genetics of Asthma Severity and Phenotypes), ACE (Asymptomatic COVID-19 in Education) Cohort, MATCH, Generation Scotland, NIHR Bioresource, FOLLOW-COVID (Focused Longitudinal Observational Study to Improve Knowledge of COVID-19), Co-STARS (COVID-19 Staff Testing of Antibody Responses Study), TRACK-COVID, and COVIDSortium. The following data partners have governance approvals in place and are in the process of being on-boarded: ISARIC4C (International Severe Acute Respiratory and emerging Infections Consortium), UKHSA (SIREN [SARS-CoV-2 Immunity and Reinfection Evaluation Network] and sKids [COVID-19 Surveillance in School Kids]), REACT-1 (Real-time Assessment of Community Transmission 1), REACT-2 (Real-time Assessment of Community Transmission 2), Oxford Healthcare Workers, TWINS-UK, Wales/SAIL (COVID Vaccination Dataset [CVVD] and COVID Test Results [PATD]), Public Health Scotland (13 different data sets), and Northern Ireland (COVID

antigen testing pillar 1 and 2, COVID-19 Vaccination, Admissions, and Discharges, Emergency Department). CO-CONNECT is currently working with the remaining data partners to obtain relevant governance approvals for their data sets to be incorporated into the platform.

This is an innovative infrastructure project to support research at scale across the United Kingdom. The unique nature of the project made it challenging to onboard data sets from different organizations in terms of (1) different data governance processes with varying information required, (2) different levels of understanding of governance requirements and the technical solution, and (3) delays in governance due to capacity during a pandemic. To overcome these challenges, approaches, such as one-to-one sessions, technical guidance workshops, and sharing a governance guidance pack [77] with data partners, were used. We also commissioned explainer videos to explain the system and how it protects patient confidentiality for both data partners and the general public [35,46,47]. We plan on describing these challenges and lessons learnt elsewhere.

User Feedback

HDR UK undertook market research in December 2021 and January 2022 led by an external agency. The research included audience mapping, analysis, and 30 interviews with health data users from a range of sectors, including industry, academia, and the National Health Service (NHS). Overall, Cohort Discovery was very positively received, and a short-term goal now for HDR is to "build on perceived successes in search functionality, that is, the Cohort Discovery Tool." The feedback from users was that the Cohort Discovery Tool could help address some of the needs around metadata and that the approach reflected the way in which many want to understand, assess, and access data. The users recognized the value of standardization across data collection/data terms to vastly increase the options for linking and comparing data and wanted to see the tool developed further. There are currently 150 active users. We expect this to increase with additional data sets live on the system and promotion of the resource.

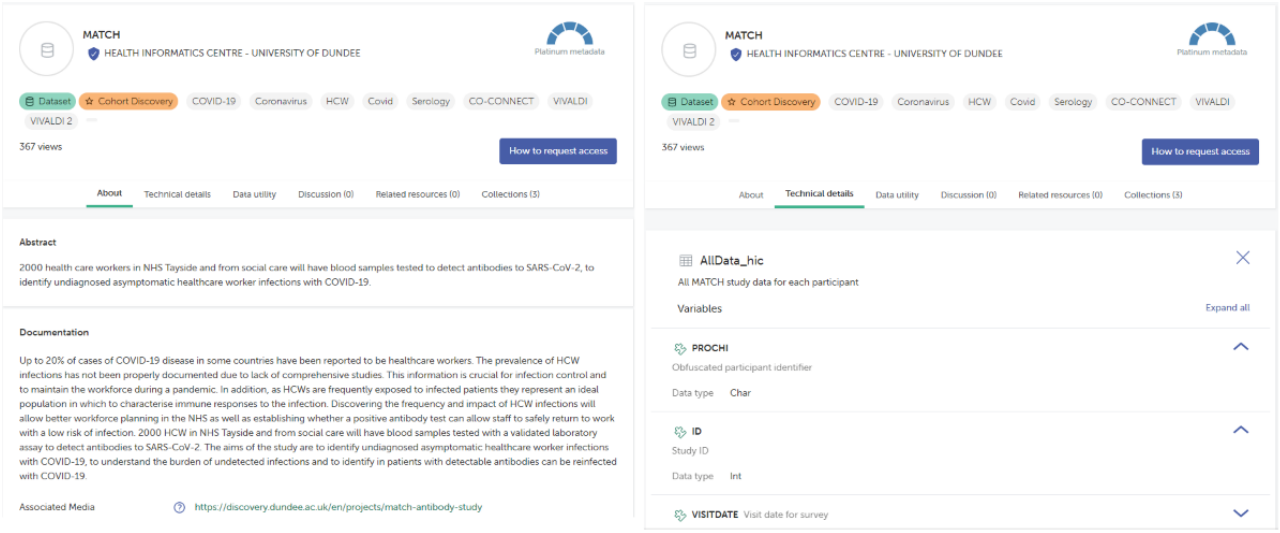
Key Outcome of the CO-CONNECT Infrastructure

CO-CONNECT is enabling rapid data discovery of data sets available from each data partner via near instantaneous aggregate-level cohort building queries. Figure 3 shows the Cohort Discovery Tool, available from the Gateway, with an example query of "all females with asthma" against all available data sets. The aggregated results presented in the Figure 3 example include overall counts, and age and gender distributions across all data partners down to the individual data set level, enabling researchers to rapidly refine their cohorts of interest.

Prior to the Cohort Discovery Tool being embedded within the Gateway, the only information a researcher could access was a static metadata catalogue of data sets/cohorts, such as overall population size, table names, and field names with their data types and descriptions, as shown in Figure 4. In contrast, the Cohort Discovery Tool enables researchers to dynamically define a cohort search query and get aggregate counts matching the cohort search criteria for the data sets.

Figure 3. The HDR UK Cohort Discovery Tool. The interface enables the user to define their cohort search criteria and displays aggregate results across different data sets. The available cohort search criteria (A) are used to create selected cohort criteria (a drag and drop feature, B). Results matching the cohort search criteria across different data sets are presented in the output once the federated queries are completed (C). HDR: Health Data Research.

Figure 4. An example of the static metadata found in the data catalogue of the HDR Innovation Gateway (MATCH data set). (A) Summary of the MATCH data set. (B) Technical details – a list of tables with their field names and data types. HDR: Health Data Research.



CO-CONNECT allows meta-analysis across the data sets, such as time series or binary comparisons. When researchers and public health groups need access to individual-level pseudonymized data for detailed analysis (over and above aggregate-level analysis available in the tool), the data for the analysis can be moved to a TRE for access by the researchers. The CO-CONNECT architecture is being enhanced to support semiautomated streamlined extracts of standardized linked data from across multiple data partners for access within a TRE [12].

Future Work

We are working with data partners to research mechanisms in which, where practical to do so, global pseudoidentifiers are identical across different data partners. This would be achieved by the use of a common one-way irreversible cryptographic hashing algorithm applied to identifiers, such as NHS and Community Health Index numbers, and would enable data linkage across data partners. These global pseudoidentifiers are never shared outside of the group of data partners. This would enable data linkage across data sets from different data sources (see section on extraction into a TRE below) and would support duplicate detection.

To support duplicate detection for the aggregate-level data discovery and meta-analysis functionality, we have a minimum viable product developed with BC Platforms ensuring that for each query, the global pseudoidentifiers are replaced by query-specific identifiers within the VM. The list of query-specific identifiers is returned along with the aggregate-level counts associated with the query to a secure temporary location, and the IDs from each data partner can then be automatically compared, providing the user who initiated the query with an estimate of the overlap of individuals across different cohorts. For example, 200 people met the search criteria from data partner A, while 350 people met the search criteria form data partner B, and 27 people were the same individuals from data partners A and B. The query-specific identifiers are never made visible to the user and are generated afresh using a new salt (random data that is used as an additional input to a one-way function that hashes data) for each query before being deleted at the query end. CO-CONNECT is working across data partners to assess the feasibility of enabling such functionality.

Extraction Into a TRE

The CO-CONNECT architecture is being enhanced to support the linkage and extraction of individual-level data from the pseudonymized databases within each data partner into a TRE. There are many TREs operating across the United Kingdom, such as the National TREs for England [70], Scotland [72], Northern Ireland [74], and Wales [75]. These example TREs were also data partners of CO-CONNECT. Data partners can choose whether to use the CO-CONNECT semiautomated pipeline or their own in-house methods for data extraction. When extracting research project–specific individual-level data into a TRE, the global pseudoidentifiers will be replaced with new project-specific pseudoidentifiers prior to export. This means that data from different data partners are linkable by the research group within the TRE for the specific research project without the global identifiers being shared. As the pseudoidentifiers are project specific, linkage across different research projects is safeguarded against.

Discussion

Hybrid Infrastructure

We have brought together EHR data of national importance into a federated platform. The data can be queried via the Cohort Discovery Tool in the HDR UK Innovation Gateway. An open-source set of tools were developed to standardize the mapping of data into the OMOP standard without the need to view the individual-level data.

CO-CONNECT evolved from a recognized need across multiple domains for a transformative step in the ability for researchers to discover data across a range of data assets. Centralized data architectures have historically been used when it is possible to set up flow of data to a single location, under a single set of governance approvals (such as national registries) and usually

from a small number of organizations. This has been very effective in the United Kingdom with flow of data from the NHS bodies to respective national data repositories, especially when there is a legal mandate, such as the registration of a disease. Such approaches are successful at supporting certain research activities, such as epidemiology, where evaluating the prevalence of a disease can be undertaken with relative ease.

Centralized infrastructure brings economy of scale and the ability to have a specialized team of technologists that can bring standardization to the process and policy. However, such centralized infrastructure cannot infinitely scale to accommodate all data that might be required to perform analyses. It is also clear that while certain aspects of epidemiological research can be undertaken via a centralized model, such as the prevalence or risk associated with different demographic characteristics, it is likely there will never be enough data held in a single location to help answer questions of causation rather than retrospective observations. There is a need to combine information from multiple sources to increase power and generalizability. Aside from technical constraints, the public are equally uncomfortable with their sensitive data being shared widely or within a central database, and thus, keeping all individual-level data local improves patient trust [78,79].

COVID-19 brought a set of challenges such that data analysis and infrastructure were required across and between the national centralized databases of the 4 nations of the United Kingdom. CO-CONNECT was tasked to deliver an overarching platform across existing centralized infrastructure, as well as cater to academic collection of data. This was not a simple distinction between federated or centralized models, but a hybrid infrastructure to support both federation across national centralized TREs and inclusion of specific research data sets into a single ecosystem of collaboration and co-existence.

Federated Cohort Discovery

CO-CONNECT has been designed to work for the whole population of the United Kingdom. These data come from many databases with thousands of fields held within each of the 4 nations. The technical novelty of the architecture lies in the fact that it supports reproducible and semiautomated processing/tooling for inclusion of new data sets and addition of new fields without significant additional effort compared with OHDSI's tooling available [80]. Therefore, while federated cohort discovery tools do exist, this is the first time such a system has been designed to be deployed at this scale. The CO-CONNECT approach federates cohort discovery from one simple-to-use application. It will enable the querying of data sets from the 4 nations within the United Kingdom without separate data governance applications. Researchers are able to query data sets immediately and interactively as part of their feasibility study without the substantial overhead of contacting each data partner to ask about running multiple bespoke feasibility queries.

Centralized Data Curation

All source data are transformed into the OMOP data model via our teams in Dundee, Nottingham, and Edinburgh. The software developed allows the maps to be created centrally but applied locally by each data partner. This retains a clear separation for data governance and importantly enables data partners to be included with minimum effort for them. This is performed via reproducible code, which ensures transformations to the data from the source to the new model are consistent across projects. The mapping of the data into OMOP is supported by the core data science team across all the data partners, ensuring standardization in mapping. Using a reproducible workflow works in concert with automation to support the regular updating of data across the platform via a consistent ETL mechanism.

Data Extraction

Federated analytics is emerging as a credible alternative, but it was recognized that certain analyses cannot be undertaken using current federated approaches. Therefore, despite putting in place a federated architecture, we are designing the approach to allow subsets of pseudonymized data for answering a specific research project to be extracted into a single TRE. Data curation to a standard will aid this process significantly, as all data have already been curated to the OMOP CDM. The automation of these steps streamlines the process of transitioning to individual-level data from a higher-level query and reduces costs. The data partners who chose to adopt the automated process will require limited resource to release data, and throughput can scale without additional investment. Researchers will receive data in a familiar format, allowing them to reuse existing methodologies. The data in the original format can also be provided to the researchers should this be required.

Comparison With Other International COVID-19 Initiatives

We reviewed other existing COVID data efforts across the world [81-86]. Most projects focus on the analysis of data sets that were already known to the researchers, whereas CO-CONNECT (as well as CODEX [84,85]) also provides the capability to search for specific cohorts of data for feasibility analysis across population-wide data.

Projects, such as 4CE [83], N3C [86], and the COVID-19 Data Exchange Platform [84], took a centralized approach. 4CE [83] transformed data into a common format at each data source and then obfuscated the values. 4CE transferred the files to a shared central location, merging the files from different sources so analysis could take place. N3C [86] supported data in 4 different CDMs: PCORnet [87], OMOP, i2b2/ACT [88,89], and TriNetX [27], bringing the data into a central cloud platform for secure analysis. The COVID-19 Data Exchange Platform supported federated nodes in the i2b2 [23] format and federated queries, and also provided a centralized analysis platform. They encountered challenges with obtaining ethical approval for transferring data onto the centralized platform, and at the time of writing, data from only 350 patients had been transferred.

The COVID-19 SCOR project [81] plans to utilize the MedCo software [82], which uses collective homomorphic encryption and obfuscation across decentralized data sources. MedCo is deployable on top of standardized systems, such as i2b2 [23]/SHRINE [90] and TranSMART [91]. The unCoVer project aims to use the DataSHIELD [25] software to perform federated analytics across 18 countries [92]. As far as we are aware, all

these federated analytics solutions require inbound connections to the data and opening ports on firewalls. In the case of MedCo, encryption of the data reduces the privacy risks associated with inbound connections to the data.

The approach taken really depends on the attitudes of the data partners. In CO-CONNECT, most partners would not accept inbound connections into their secure environment and would not be happy to place sensitive data in an area where an inbound connection could be allowed, regardless of encryption or access controls. For those reasons, CO-CONNECT was built on the assumption of never requiring an inbound connection to the federated data to either curate the data or run a feasibility analysis and meta-analysis. As an additional level of security, on top of not allowing inbound queries, the CO-CONNECT architecture could adopt homomorphic encryption in the future to support more advanced federated queries where researchers need to see the underpinning data.

CO-CONNECT, unlike other COVID-19 solutions, supports data partners to automate the mapping of their data into a CDM without having to see the underpinning data. This is advantageous as most data partners do not have their data mapped into the OMOP CDM or the technical capability to do so.

Current Status and Contributions

Metadata covering the data sources are now available to search openly within the Gateway [30]. National and international researchers can request access to the enhanced dynamic cohort discovery capability within the Gateway. Access to individual-level subsets of data by national and international researchers can also be requested via the streamlined governance application process [45].

We welcome requests to onboard data sets into CO-CONNECT; further details are available via the corresponding author.

The platform has been designed to be disease agnostic. COVID-19 has supported the need for such a platform to provide data at pace. However, the model can be reused to support research at pace for other disease areas. The platform underpins the recently funded HDR UK/MRC Alleviate Hub for Pain Research [93], and the architecture and support for cohort building will be supported and enhanced by HDR after the end of CO-CONNECT funding. Exemplar projects using the architecture are planned for the next phase of HDR funding.

Conclusions

We have introduced the CO-CONNECT federated architecture, which addresses the challenges of fragmentation of data and lack of interoperability and standardization, as well as the challenge of linkage of high value data assets to other data assets providing new scientific insights. The architecture has been designed around the following core principles: (1) maintaining patient confidentiality, trust, and data security; (2) empowering data partners to be interconnected in a sustainable environment; (3) utilization and re-enforcement of TREs to analyze data; (4) a focus on data engineering to ensure technical legacy for wider use; and (5) a standard-based approach to ensure interoperability, repeatability, and connectivity to other initiatives, responding to the most pressing needs of the public health and research communities.

The development of this platform will empower public health organizations, research groups, and industry bodies to answer key questions about the COVID-19 pandemic and its effects on human health in a streamlined timely manner, as has been needed for EHRs for many years [15,21]. The solution enables rapid cohort-building data discovery across data partners. None of the data partners had such capability for researchers prior to CO-CONNECT. CO-CONNECT has simplified the complex task of requesting access to each individual data set, by providing transparency on what data are available and from where, and how to request access if individual-level data analysis is required. CO-CONNECT provides novel real-time functionality compared to static metadata dictionaries and descriptions of cohorts already provided within the Gateway.

The immediate impact of CO-CONNECT is the fast, accessible, and standardized availability of aggregate COVID-19–related data, to inform key public health decisions and help tackle the COVID-19 pandemic at pace. As more data sets are onboarded, this will become more powerful.

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Authors' Contributions

EJ contributed to funding acquisition, writing–original draft, writing–review and editing, and supervision; C Cole contributed to writing–original draft, writing–review and editing, and supervision; SM contributed to writing–original draft, writing–review and editing, software, methodology, data curation, investigation, and formal analysis; SC contributed to writing–original draft, writing–review and editing, software, methodology, data curation, investigation, and formal analysis; TG contributed to writing–review and editing, software, methodology, data curation, investigation, and formal analysis; SA contributed to writing–review and editing, software, methodology, data curation, investigation, and formal analysis; EU contributed to writing–review and editing, software, methodology, data curation, investigation, and formal analysis; DL contributed to writing–review and editing, and software; C Macdonald contributed to writing–original draft, writing–review and editing, software, methodology, data curation, investigation, and formal analysis; J Best contributed to software, methodology, data curation, investigation, and formal analysis; EM contributed to writing–review and editing, software, methodology, data curation, investigation, and formal analysis; GM contributed to writing–original draft, writing–review and editing, supervision, software, methodology, data curation, investigation, and formal analysis; JJ contributed to writing–review and editing, supervision, and project administration; S Horban contributed to writing–original draft, writing–review and editing, software, methodology, data curation, investigation, and formal analysis; IB contributed to software, methodology, data curation, investigation, and formal analysis; CH contributed to writing–review and editing, software, methodology, data curation, investigation, and formal analysis; ASJ contributed to writing–review and editing, software, methodology, and investigation; C Collins contributed to project administration and supervision; SR contributed to software, methodology, data curation, investigation, and formal analysis; CD contributed to project administration and supervision; JH contributed to project administration; AH contributed to software, methodology, data curation, investigation, and formal analysis; RS contributed to software, methodology, data curation, investigation, and formal analysis; ST contributed to software, methodology, data curation, investigation, and formal analysis; VP contributed to software, methodology, data curation, investigation, and formal analysis; JL contributed to software, methodology, data curation, investigation, and formal analysis; TJ contributed to project administration, supervision, and writing–review and editing; AC contributed to writing–review and editing; J Beggs contributed to writing–review and editing; MMQ contributed to methodology, data curation, and investigation; HW contributed to methodology, data curation, and investigation; JvZ contributed to methodology, data curation, and investigation; FB contributed to methodology, data curation, and investigation; JM contributed to funding acquisition, writing–review and editing, and methodology; NS contributed to funding acquisition, writing–review and editing, and methodology; C Morris contributed to writing–review and editing, methodology, data curation, and investigation; DB contributed to writing–review and editing, methodology, data curation, and investigation; RB contributed to methodology and investigation; AAB contributed to methodology and investigation; PS contributed to methodology and investigation; A Shoemark contributed to methodology, data curation, and investigation; AMV contributed to funding acquisition, and writing–review and editing; BO contributed to methodology, data curation, and investigation; C Manisty contributed to writing–review and editing, funding acquisition, methodology, data curation, and investigation; DE contributed to methodology, data curation, and investigation; SG contributed to methodology, data curation, and investigation; GJ contributed to methodology, data curation, and investigation; AMA contributed to methodology, data curation, and investigation; DWC contributed to funding acquisition, methodology, data curation, and investigation; KN contributed to methodology, data curation, and investigation; KJ contributed to funding acquisition, methodology, data curation, and investigation; EDA contributed to funding acquisition, methodology, data curation, and investigation; AMM contributed to methodology, data curation, and investigation; M Walker contributed to methodology, data curation, and investigation; MGS contributed to methodology, data curation, and investigation; JMS contributed to funding acquisition and methodology; EL contributed to funding acquisition and methodology; BD contributed to methodology, data curation, and investigation; JKB contributed to writing–review and editing, funding acquisition, methodology, data curation, and investigation; MT contributed to writing–review and editing, funding acquisition, methodology, data curation, and investigation; GL contributed to methodology, data curation, and investigation; LP contributed to methodology, data curation, and investigation; TB contributed to methodology, data curation, and investigation; NG contributed to methodology and investigation; DM contributed to methodology, data curation, and investigation; CO contributed to writing–review and editing, methodology, data curation, and investigation; IP contributed to methodology, data curation, and investigation; IH contributed to funding acquisition, methodology, data curation, and investigation; SL contributed to funding acquisition, methodology, data curation, and investigation; M Whitaker contributed to methodology, data curation, and investigation; LS contributed to funding acquisition, methodology, data curation, and investigation; DS contributed to funding acquisition, and writing–review and editing; SV contributed to funding acquisition, and writing–review and editing; GR contributed to funding acquisition, writing–review and editing, and methodology; AM contributed to funding acquisition, writing–review and editing, and methodology; S Hopkins contributed to funding acquisition, writing–review and editing, and methodology; A Sheikh contributed to funding acquisition, writing–review and editing, supervision, and methodology; and PQ contributed to funding acquisition, writing–original draft, writing–review and editing, and supervision.

Conflicts of Interest

A Sheikh is a member of the Scottish Government Chief Medical Officer’s COVID-19 Advisory Group and its Standing Committee on Pandemics. PQ was previously on a paid secondment to BC Platforms and now resides on their Scientific Advisory Board as a paid consultant. AA-B and PS work for BC Platforms, whose solution CO-CONNECT utilized.

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Abbreviations

CaRROT: Convenient and Reusable Rapid Ontology Transformer
CDM: common data model
CO-CONNECT: COVID - Curated and Open Analysis and Research Platform
EHR: electronic health record
ETL: Extract, Transform, and Load
GDPR: General Data Protection Regulations
HDR: Health Data Research
NHS: National Health Service
OHDSI: Observational Health Data Science and Informatics
OMOP: Observational Medical Outcomes Partnership
PheWAS: phenome-wide association study
TRE: Trusted Research Environment
VM: virtual machine

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Original Paper

A Novel Approach to Characterize State-level Food Environment and Predict Obesity Rate Using Social Media Data: Correlational Study

Chuqin Li[1], PhD; Alexis Jordan[1], BSc; Jun Song[2], PhD; Yaorong Ge[1], PhD; Albert Park[1], PhD

[1]Department of Software and Information Systems, College of Computing and Informatics, University of North Carolina at Charlotte, Charlotte, NC, United States

[2]Department of Statistics, Korea University, Seoul, Republic of Korea

Corresponding Author:
Albert Park, PhD
Department of Software and Information Systems, College of Computing and Informatics
University of North Carolina at Charlotte
9201 University Blvd
Charlotte, NC, 28223
United States
Phone: 1 704 687 8668
Email: al.park@uncc.edu

Abstract

Background: Community obesity outcomes can reflect the food environment to which the community belongs. Recent studies have suggested that the local food environment can be measured by the degree of food accessibility, and survey data are normally used to calculate food accessibility. However, compared with survey data, social media data are organic, continuously updated, and cheaper to collect.

Objective: The objective of our study was to use publicly available social media data to learn the relationship between food environment and obesity rates at the state level.

Methods: To characterize the caloric information of the local food environment, we used food categories from Yelp and collected caloric information from MyFitnessPal for each category based on their popular dishes. We then calculated the average calories for each category and created a weighted score for each state. We also calculated 2 other dimensions from the concept of access, acceptability and affordability, to build obesity prediction models.

Results: The local food environment characterized using only publicly available social media data had a statistically significant correlation with the state obesity rate. We achieved a Pearson correlation of 0.796 between the predicted obesity rate and the reported obesity rate from the Behavioral Risk Factor Surveillance System across US states and the District of Columbia. The model with 3 generated feature sets achieved the best performance.

Conclusions: Our study proposed a method for characterizing state-level food environments only using continuously updated social media data. State-level food environments were accurately described using social media data, and the model also showed a disparity in the available food between states with different obesity rates. The proposed method should elastically apply to local food environments of different sizes and predict obesity rates effectively.

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KEYWORDS

obesity; social media; machine learning; lifestyle; environment; food; correlation; modeling; predict; rates; outcome; category; dishes; popular; mobile phone

Introduction

Background

The current obesity epidemic poses critical public health challenges. Obesity is a major risk factor for other chronic diseases, such as cardiovascular disease, cancer, diabetes, and respiratory disorders, which account for 60% of the deaths worldwide [1]. Excessive body weight has resulted in a medical expenditure of US $100 billion per year [2,3]. From 2017 to 2018, the prevalence of obesity among adults in the United States was 42.4% [4]. This number has more than tripled since the 1960s. From 1960 to 1962, the obesity rate was 13.4% [5].

Environmental factors, including the types of available food, have been identified as one of the main drivers of obesity [3,6,7]. It was reported that American adults have developed a preference for dining out with friends as opposed to cooking at home [8]. This preference could potentially impact health outcomes. A market research survey conducted in 2017 found that those who frequent fast-food restaurants are more concerned about the value of money spent and service speed than the actual healthiness of the food offered [8]. This indication that the perceived food availability tends to affect dietary outcomes has been furthered only in a literature review conducted by Caspi et al [9]. Those who live in areas highly saturated with high-fat food items tend to have health issues. In addition, those who live in lower-income areas are more likely to have at least one diet-related health issue [9]. In the United States, people tend to eat what is affordable and available to them. Environments littered with low-cost, high-fat foods tend to be obesogenic. With food expenditures for dining out increasing in recent years [3,10], understanding the food environmental factors is critical in counteracting the obesity epidemic and understanding related human behavior.

Recent studies have suggested that the local food environment can be measured by the degree of food accessibility [6,11]. These studies measured food accessibility using survey data [12], yellow pages phone books [13,14], and local business directories [15]. A limited number of samples and a significant delay between the collection and reporting of data are major limitations of these traditional methods [9]. With the proliferation of social media, the data from social media are organic, continuously updated, and generally free for large-scale collection. Several studies have used social media data to learn food environments by estimating the calorie density of the foods mentioned in tweets [16] or using the linguistic variables from tweets [17-19] to predict the local obesity rate.

In this study, we leveraged large-scale social media data sets to measure food environments at the state level and predict state-level obesity rates. It remained unclear whether we could characterize state-level food environments from the perspective of *concept of access* and predict obesity rate according to the perspective using publicly available social media data. Obesity rate was obtained from the Behavioral Risk Factor Surveillance System (BRFSS), the nation's premier system for collecting data to improve public health.

The primary aim of this descriptive study was to understand the impact of food environment on obesity with three specific research questions (RQs):

1. RQ1: Is there a difference between the available food categories in low and high obesity prevalent states?
2. RQ2: How can we use calorie information to quantify state-level food environments?
3. RQ3: Can we predict state-level obesity rate using publicly available social media data?

We reported our novel approaches and findings. To date, to our knowledge, our study is the first to combine information from Yelp and MyFitnessPal (MFP) to learn about the local food environment and then to predict the state-level obesity rate.

Related Work

Calorie With Obesity

An increase in daily calorie consumption is a major cause of the obesity epidemic [7]. The daily calorie intake rose by >500 calories in adults and >150 calories in children between 1977 and 2006 [20,21], as did the portion size in restaurants [22]. Exposure to a larger portion size increases the risk of increasing calorie intake and, therefore, weight gain [23]. Similarly, calorie intake is also affected by a higher number of local dining options. For example, the prevalence of obesity is lower in areas with supermarkets and higher in areas with higher numbers of fast-food restaurants [12].

Analysis of the data on environmental changes has identified the changes on food environment as a potential cause for the increase in caloric intake. The enormous growth in dining out, particularly at "fast-food" outlets, is a trend that has received a lot of attention. Fast-food outlets increased from approximately 30,000 in 1970 to >233,000 locations in 2004 in the United States [3]. Fast food can contribute to increasing obesity rate because it generally provides food that is poor in micronutrients, low in fiber, high in glycemic load, and excessive in portion size and calorie [24,25].

How to Characterize or Quantify Local Food Environment

Food access dimensions can be conceptualized using the *concept of access* proposed by Penchansky and Thomas [26]. The concept of access uses 5 dimensions to conceptualize the local food environment, namely availability, accessibility, affordability, acceptability, and accommodation [9,26]. Availability refers to the relationship between the number and type of food suppliers available to customers. Accessibility refers to the relationship between the location of food suppliers and the location of customers, which is more geographically inherent than availability. Accessibility could be measured by the travel time and distance between food suppliers and customers. Affordability refers to the price customers need to pay for the food. Acceptability refers to customers' attitudes toward a business. Accommodation is another dimension of access, which assesses whether local businesses accept and adapt to local customers' needs.

A variety of approaches have been used to learn about local food environments by measuring the degree of food access.

These approaches typically fall into 2 categories. The first category consists of methods that capture food environment by relying on respondent-based data. The accessibility of food stores was asked about in surveys or questionnaires. The methods in the second category used the geographic information system (GIS) technology. GIS measures the buffer distance to food stores or the density of food stores in an area [12-15]. By 2007, the GIS-based measures of food environment outnumbered the respondent-based measures, and the trend of using GIS measures continued [9,27,28]. The GIS data used in previous studies primarily used publicly available data sets, such as the United States yellow pages phone book [13,14], published data from the local Departments of Environmental Health and state Departments of Agriculture [12], and local business directories [15]. A major limitation of these traditional data collections is that they are cost-ineffective and labor intensive; moreover, these methods can only gather a limited number of samples, and there is a significant delay between the collection and reporting of data [9]. In the following section, we will illustrate quantifying the environment using social media data.

Using Social Media Data to Learn Obesity-Related Factors or Predict the Obesity Rate

Social media is used to characterize social factors [29] and food environment in relation to obesity. Nguyen et al [16] characterized food environment by calculating the calorie density of the foods mentioned in tweets and the percentage of each food theme out of all food-related Yelp entries from that state. They found that Twitter and Yelp posts that were indicative of higher caloric foods were related to higher mortality, higher prevalence of chronic conditions, and worse self-rated health [16]. Researchers also tried to understand healthy and unhealthy food images shared on social media in relation to obesity [30]. They created an image classifier and tested it out to classify Twitter images into definitively healthy, healthy, unhealthy, and definitively unhealthy categories. Social media was also used to understand obesity-preventive factors, such as physical activity [31]. The authors described how individuals organically use social media to encourage and sustain physical activity for obesity prevention.

Social media can also be used to predict obesity rate. Fried et al [17] presented "the predictive power behind the language of food on social media." They collected the food-related tweets that contained meal-related hashtags: dinner, breakfast, lunch, brunch, snack, meal, and supper. Then, they used the lexical feature from the bag-of-words model and topic features obtained from latent Dirichlet allocation to predict whether a state's obesity rate is above or below the national median. Their best model reached an accuracy of 80.39% in predicting overweight. Culotta [18] used the linguistic variables (Linguistic Inquiry and Word Count and PERMA) from tweets and demographic variables to predict health-related statistics for the 100 most populous counties in the United States. The Pearson correlation for obesity between the predicted and real rates was 0.64. Abbar et al [19] conducted a study similar to the one by Culotta [18]. Abbar et al [19] used the linguistic variables (Linguistic Inquiry and Word Count), food features, average calorie per serving for food, and demographic variables from food-related tweets to predict county-wide obesity rate, achieving a correlation of 0.775 for obesity. Public posts about food and eating behaviors may spread through social networks [32]. These studies demonstrated a successful application of Twitter data in predicting state health outcomes. Although Yelp data together with Twitter data have been used to characterize food environment by Nguyen et al [16], no previous study has been found to use Yelp and MFP data to predict state obesity.

Methods

Data Collection

Our study used 3 data sources: (1) Yelp, (2) MFP, and (3) BRFSS. The data used in this study to describe state-level food environments were collected by the research team via the Yelp application programming interface (API) [33] and the web scraping tool, BeautifulSoup.

Yelp is a leading crowd-sourced review site in the United States that allows users to search for restaurants and local businesses [34]. Users can post reviews and upload photos concerning a business's foods and services, which makes Yelp a location-based social media platform. To date, Yelp [35] ranks 52nd in the United States and 231st worldwide based on internet traffic and engagement [36].

The Yelp API allows users to search and query Yelp for more than 50 million businesses in 32 countries [33]. To obtain the data for this study, we converted 5-digit US zip codes to latitude and longitude coordinates and then queried the detailed business content via the Yelp API by searching the businesses near the provided locations. The data were collected in September 2020 and consisted of the profiles of 353,431 businesses in the United States.

An example of a restaurant's listing on Yelp [35] is shown in Figure 1. As shown in Figure 1, the profile of each business includes its name, average rating, price level, and categories and the number of reviews it has received. Each business can choose up to 3 terms (categories) to describe its services and offerings. The queried business profile returned by the Yelp API not only contains the mentioned fields but also includes other details of the business, such as the business ID, address, URL to the business's home page on Yelp [35], photos, and hours of operation. It is worth noting that chain businesses can have the same name, but each location has its unique business ID.

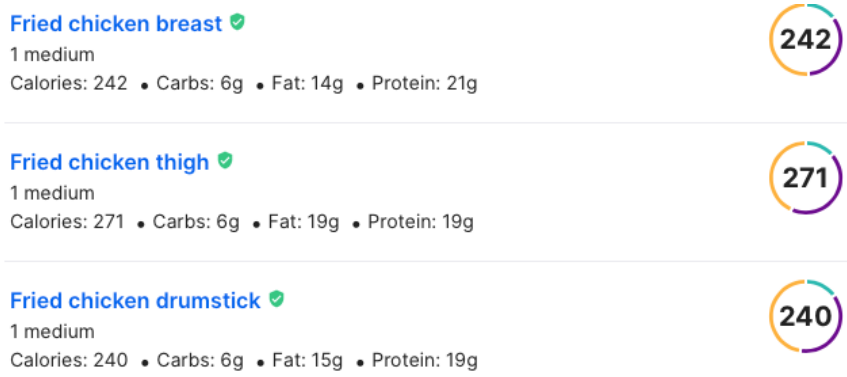
Yelp publishes reviews of many service businesses, such as restaurants, hospitals, and recreational activities. We removed businesses that were not related to the food industry in this study (eg, hardware stores). To do this, 2 independent reviewers first evaluated the relevance of each selected category to the food field independently. The 2 judgments reached 100% agreement with κ=1. A total of 226 categories were selected from 332 categories. In our collected data set, the total number of businesses is 353,431. The average rating of each business is 4.00 (SD 0.75), the average number of reviews of each business is 99.16 (SD 260.32), and the average price is US $1.60 ($ is the unit Yelp use to approximate cost per person for a meal) with an SD of 0.56.

To understand and objectively compare these categories, we further collected data on each category's most popular 100 restaurants nationwide and their most popular dishes for use as a proxy to estimate the caloric density of each category. We used BeautifulSoup [37] to collect popular dishes from each restaurant. We also used this web scraping tool to collect the nutritional information (ie, calories) of each popular dish from MFP. MFP is one of the most popular calorie-tracking smartphone apps worldwide with >10 million users [38]. MFP provides powerful tools to help users easily track their meals and physical activity. We collected food nutrition information by searching the food name in MFP's nutrition database. Figure 2 shows an example search result page, which appeared when we searched the term "Fried Chicken." We collected nutrition records for 37,295 dishes from MFP, and the total number of nutrition records is 3,110,744.

We obtained the state-level obesity rate data from the BRFSS, the nations' state-based health surveillance system that tracks the behavioral risk factors of residents in the United States. BRFSS provided the ground truth for the prevalence of obesity via self-reported obesity data among adults in the United States by state and territory in 2019. We collected the obesity rates for 49 states and the District of Columbia, excluding New Jersey, owing to insufficient data collection by the BRFSS in 2019 [39].

Figure 1. Example of the Yelp business list page.

Figure 2. Example of the MyFitnessPal nutrition fact list page.



RQ1: Is There a Difference Between the Available Food Categories in States With Low and High Obesity Prevalence?

We first characterized a local food environment based on the literature and then illustrated the quantification of the environment using social media data in RQ2. We based our characterization on food access dimensions [26]. Specifically, we focused on 3 highly distinct dimensions: availability, affordability, and acceptability [9]. Availability refers to the relationship between the number and type of food suppliers available to customers. Affordability refers to the price customers need to pay for the food. Acceptability refers to customers' attitudes toward a business.

We used the category information for each business in Yelp to calculate the availability of those food categories. Specifically, we defined the availability of a category of food as the number of available restaurants compared with the overall choices at the state level. For example, the availability of Mexican food will be equal to 1 if all the restaurants in that area sell Mexican food. Similarly, if 50% of the state's restaurants sell Mexican food, its availability will be 50%.

After calculating the availability of all food categories, we further compared the availability of food categories between states with low prevalence of obesity and those with high prevalence of obesity. We aimed to understand the impact of local food availability, a dimension that has been widely studied [3,16,40], on the state-level obesity rate. The 2 states we selected were Colorado and Mississippi. In 2019, Mississippi had the highest obesity rate (40.8%), whereas Colorado had the lowest obesity rate (23.8%) [39]. We first calculated the availability of each category in the 2 preselected locations and further analyzed what categories of restaurants are more available in locations with high or low obesity rate. The category with the

biggest availability difference was further compared by adopting dimensions from the *concept of access*.

The affordability and acceptability of the categories were then compared. Affordability refers to the food price customers need to pay. Price may affect the food choices of users. Low-income populations have a high risk of living in poor food environments and bear much of the burden of obesity and chronic diseases [14]. We estimated affordability using the price category data for each business. Here, we converted the price categories into numeric numbers for future analysis. For example, $ would have been converted to 1, and $$$$ would have been converted to 4. Acceptability refers to the client's attitude toward the service provider. We used the average customer rating and the total number of reviews of a business to measure customers' attitudes concerning a business. Studies have shown that consumers' preference increases with the number of reviews [41], and consumer-generated restaurant ratings are positively associated with the web-based popularity of restaurants [42]. The businesses with higher ratings and more reviews are considered more likely to be accepted by customers than businesses with poor ratings and a limited number of reviews.

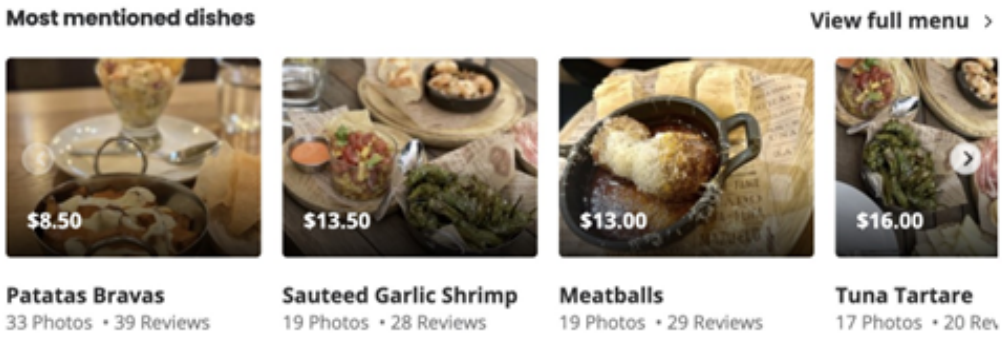
RQ2: How Can We Use Calorie Information to Quantify State-Level Food Environments?

Because calorie intake is one of the major contributors to obesity, it is critical to understand the nutritional content of food to evaluate its effect on obesity. We evaluated the state-level food environment quantitatively using the nutritional information, specifically calorie information, collected from MFP. The categories were turned into average calories per gram for popular dishes in representative restaurants. The caloric density of each food category, which was weighted by the availability of that category in a state, became the weighted score of the caloric density of the state.

To calculate the caloric density for each category, we first collected popular dishes in each category. We chose the top 100 restaurants with the highest number of reviews for each category nationwide and used the web scraping tool, BeautifulSoup, to collect the popular dishes. Yelp [35] listed the most mentioned dishes for each restaurant on the Yelp [35] pages (Figure 3). Subsequently, these popular dishes were searched in the MFP food nutrition database.

We calculated the mean calorie content of a popular dish by averaging the calories per gram of all records returned from MFP for that dish. It should be noted that the nutrition database of MFP contains a combination of foods added by MFP and foods that are added by users, and various units of measures (eg, g, gram, package, breast, oz, piece, and slices) are used. We selected gram as the unified measuring unit for comparison. We included all records that use "gram" or variations of "gram" (eg, "g," "gr," and "grams") as their measuring unit.

Figure 3. Example of the Yelp page.



RQ3: Can We Predict State-Level Obesity Rates Using Calorie Information of Different Restaurant Categories and Dimensions From the Concept of Access Using Publicly Available Social Media Data?

On the basis of the results of RQ1 and RQ2, we created features from the availability, affordability, and acceptability of food categories and state weighted score for caloric density for the state-level food environment to describe the local food environment.

We classified these features into 3 sets: (1) category availability: the degree of availability of each category at the state level; (2) category affordability and acceptability: the average price of, average rating of, and average number of reviews for each category at the state level; and (3) state weighted score for caloric density: calculated weighted score for caloric density for each state. We used the scikit-learn [43] library to build our machine learning models. We applied a combination of different feature sets and used several popular machine learning models (ie, random forest regression, support vector machine regression, and XGBoost regression) for prediction. We did not use the state-of-the-art deep learning models (eg, convolutional neural network regression) in this study because we had a limited number of samples. Deep learning models would need a large sample size to outperform traditional machine learning techniques [42]. Because we were predicting obesity rate at the state level, we used the leave-one-out cross-validation. Leave-one-out cross-validation is an extreme version of k-fold cross-validation, where k is set to N. N is the number of observations in the data set. For N times, a model is created and trained on all the data except for 1 point, and a prediction is made for that point. Thus, we used information from the District of Columbia and 49 states to predict the obesity rate for the other state. Then, we repeated this 50 times while changing the predicting location. We evaluated our approach by calculating the Pearson correlation between the real and predicted obesity rates.

Results

RQ1: Is There a Difference Between the Available Food Categories in States With Low and High Obesity Prevalence?

We extracted business profile data of the food-related businesses located in the 2 preselected areas from the collected Yelp data. A summary of the data is presented in Table 1. First, we calculated the availability of each category in the given areas. In Mississippi, the categories with high availability included "Fast Food," "Burgers," "Seafood," and "Sandwiches." In Colorado, the categories with high availability were "Mexican," "Breakfast and Brunch," "Sandwiches," and "Burgers." The "Sandwiches" and "Burgers" categories had high availability in both Mississippi and Colorado. We further explored the differences in the availability of each category to understand the state-level food environment in both state with low obesity prevalence and state with high obesity prevalence. This was also done to highlight the importance of access to different types of food. We used the net value to measure the availability differences between the 2 different locations. The net differences were used to rank the categories in descending order.

Results for the net differences are listed in Table 2. A larger net value indicated a bigger difference. The net difference for all categories is significantly different by the *z* test. We found that 42.7% (59/138) of categories showed significant differences between the 2 states.

As shown in Table 2, a total of 40% (16/40) of categories are more significantly available in Mississippi than in Colorado ($P \leq .001$), including "Fast Food," "Buffets," and "Donuts." "Diners" and "Chinese" are more significantly available in Mississippi than in Colorado ($P \leq .01$). "Ice Cream and Frozen Yogurt" is also found to be more available in Mississippi; however, the difference is not as significant as the aforementioned categories based on *P* values.

Alcohol-related businesses, including "Breweries," "Cocktail Bars," "Beer Bar," "Wine Bars," and "Pubs," were found to be significantly more available in Colorado. Moreover, "Breakfast and Brunch," "Coffee and Tea," "Mexican," "American (new)," "Pizza," "Food Truck," "Vietnamese," "Thai," "Asian Fusion," "Ramen," "Juicy Bars and Smoothies," "Indian," and "Cafes" were also found to be more available in Colorado than in Mississippi at $P \leq .001$. "Bakeries" and "Beer, Wine, and Spirits" were more available in Colorado than in Mississippi ($P \leq .01$).

"Fast Food" was found to have the biggest availability difference between Colorado and Mississippi. We further explored this category to fully understand the state-level food environment and the importance of access to different types of food. The availability of "Fast Food" in Mississippi was 13.49% (519/3845), whereas the availability of "Fast Food" in Colorado was 5.03% (358/7109). Because fast food was found to have the biggest difference in availability, we investigated the relationship between the availability of fast-food restaurants and the state-level obesity rate.

We visualized the availability of fast-food restaurants in a map (Figure 4, left) and scatter plot to show the relationship between the availability of fast-food restaurants and the prevalence of state-level obesity (Figure 4, right). We found that the availability of fast-food restaurants was positively correlated with the obesity rate at the state level, with a resulting Pearson correlation of 0.676. From the heat map, we also found that the northeast had the lowest availability of fast food, and the Midwest and south had a higher availability of fast food than the west. We further adopted dimensions from *the concept of access* to compare fast-food restaurants with other restaurants.

We compared the acceptability (rating and number of reviews; Figure 5) and affordability (price; Figure 6) between fast-food and other restaurants.

In Figures 5 and 6, the x-axis shows the state-level obesity rate, and each vertical line represents a state with its corresponding obesity rate. The blue and orange solid lines are the average rating and average number of reviews (Figure 5) and average price (Figure 6) based on restaurant type in the state, and the shadow of each line is the CI. Results showed that the acceptability of fast-food restaurants was lower than that of other restaurants, irrespective of the prevalence of obesity. We found that the average rating of fast-food restaurants showed a negative relationship with the obesity rate at the state level. The residents in areas with high obesity rate gave fast-food restaurants a lower rating than the residents in areas with low obesity rate. We also found that the range of the number of reviews showed a negative relationship with obesity rate. Results on affordability showed that the price level of fast-food restaurants was lower than that of other restaurants. In addition, the prices in fast-food restaurants and other restaurants had similar trends, which indicated that the prices in fast-food restaurants are affected by the local price indices.

Table 1. A summary of the collected data for Colorado and Mississippi.

	Region	
	Colorado	Mississippi
Business, n (%)	7109 (2.01)	3845 (1.09)
Business categories, n (%)	215 (95.1)	142 (62.8)
Rating, mean (SD)	4.02 (0.74)	3.83 (0.96)
Reviews, mean (SD)	106.59 (197.71)	22.05 (50.14)
Price (US $), mean (SD)	1.66 (0.57)	1.50 (0.55)

Table 2. The 40 categories with the highest availability difference between Colorado (low obesity rate) and Mississippi (high obesity rate).

Category	Net value
Fast food[a]	0.0844[b]
Seafood[a]	0.0824[b]
Breakfast and brunch	0.0679[b]
Burgers[a]	0.0493[b]
Southern[a]	0.0470[b]
Mexican	0.0423[b]
Bars	0.0415[b]
Chicken wings[a]	0.0364[b]
American (new)	0.0353[b]
Steakhouses[a]	0.0298[b]
Pizza	0.0278[b]
Food trucks	0.0275[b]
Breweries	0.0235[b]
Buffets[a]	0.0227[b]
Coffee and tea	0.0216[b]
Cajun or creole[a]	0.0204[b]
Cafes	0.0184[b]
Cocktail bars	0.0177[b]
Convenience stores[a]	0.0175[b]
Barbeque[a]	0.0170[b]
Soul food[a]	0.0170[b]
Vietnamese	0.0156[b]
Restaurants[a]	0.0149[b]
Italian[a]	0.0115[c]
Beer bar	0.0111[b]
Thai	0.0108[b]
Bakeries	0.0105[c]
Asian fusion	0.0103[b]
Chinese[a]	0.0098[c]
Japanese[a]	0.0097[b]
Wine bars	0.0094[b]
Ramen	0.0089[b]
Pubs	0.0085[b]
Juice bars and smoothies	0.0082[b]
Tex-Mex[a]	0.0081[b]

Category	Net value
Donuts[a]	0.0079[b]
Indian	0.0078[b]
Beer, wine, and spirits	0.0075[c]
Diners[a]	0.0075[c]
Ice cream and frozen yogurt[a]	0.0071[d]

[a]This category is more available in Mississippi, which has a higher obesity rate than Colorado.
[b]$P \leq .001$.
[c]$P \leq .01$.
[d]$P \leq .05$.

Figure 4. The relationship between the availability of fast-food restaurants and the state-level obesity rate. Left: availability of fast-food restaurants in a map; Right: scatter plot with the relationship between the availability of fast-food restaurants and the prevalence of state-level obesity.

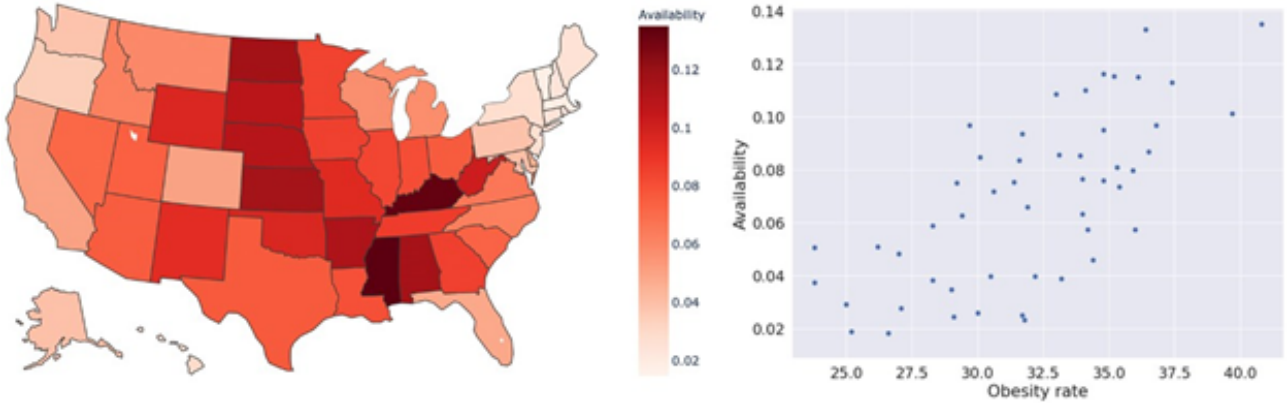


Figure 5. The relationship between the acceptability of restaurant type and the state-level obesity rate. Left: The relationship between the average rating of restaurant type and the state-level obesity rate; Right: The relationship between the average price of restaurant type and the state-level obesity rate.

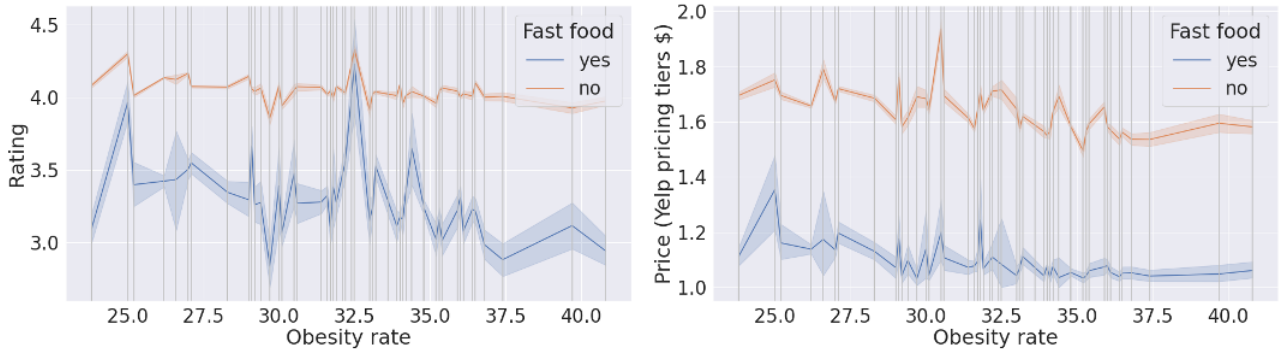
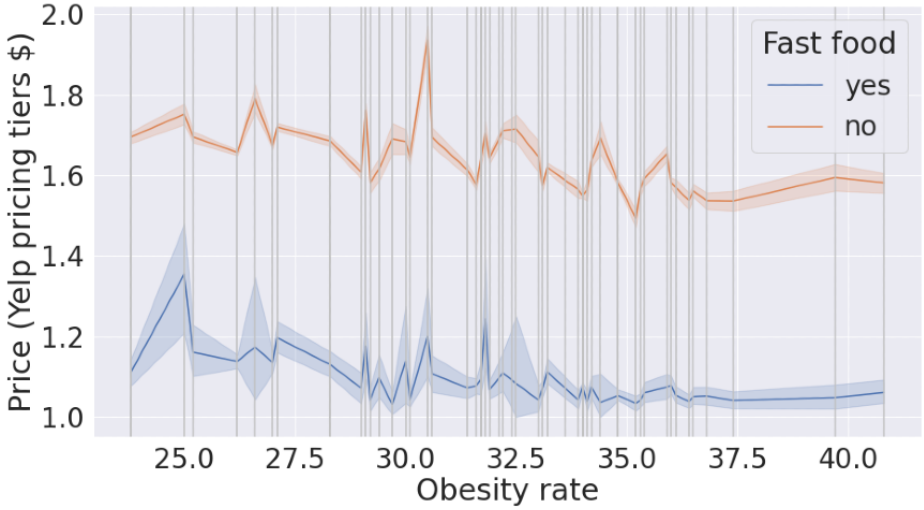


Figure 6. The relationship between the affordability of restaurant type and the state-level obesity rate.



RQ2: How Can We Use Calorie Information to Quantify State-Level Food Environments?

The first step in quantifying a food environment was to collect the popular dishes of each category. The popular dishes of the food categories gave us an idea of why some categories were more popular in areas with high obesity. We listed the most popular dishes of the categories that we found in RQ1 to be more popular in Mississippi (Table 3) and of those that we found in RQ1 to be more popular in Colorado (Table 3). Fried food in Colorado is not as popular as in Mississippi. We collected 12,316 popular dishes for the categories that were more available in Mississippi, of which 120 (1.2%) were fried chicken. In categories that were more available in Colorado, 0.44% (114/25,910) of the popular dishes were fried chicken. The statistical test showed that the difference in proportions between the fried chicken in Mississippi and the fried chicken in Colorado was significant with *a P* value less than the significant level of .001. Similarly, the percentage of other fried foods, such as fried catfish, fried shrimp, chicken, fried steak, and fried oysters, was significantly higher in Mississippi than in Colorado. This finding is consistent with literature studies showing that the intake of fried food is associated with obesity [39].

The second step was to calculate the caloric density of each category based on the calorie information of all the available popular dishes. On average, there were 166 popular dishes per category. Table 4 shows the 5 most popular dishes per category along with the caloric density of each dish and each category. We collected up to 100 most popular (ie, highest number of reviews) restaurants in each category. A table containing the caloric densities of all categories is provided in Multimedia Appendix 1.

We further calculated the caloric density of each popular dish. The caloric density of the dishes ranged from 0.556 to 62.383, with a median value of 2.399. Bakery food had a relatively high caloric density. For example, the caloric densities of almond croissant and pecan pie were >4. Fatty meat also had a high caloric density. The caloric density of Peking duck reached 8.847, which is even higher than that of fried chicken. Cooking method also affected the caloric density. For example, the caloric density for poached egg was 1.414, for scrambled egg was 1.649, and for Eggs Benedict was 2.208; likewise, the calories per gram for fried catfish was 3.283 and for fresh fish was 1.188. Salad and soup were found with low caloric densities. The calories per gram for beet salad and French onion soup were <1 based on our calculation.

Using the calorie information of these popular dishes, we calculated the caloric density of each category by averaging the caloric density of all popular dishes. The caloric density of a category varied from 1.941 to 23.452, with a median value of

5.473. The “Cheesesteaks” was the category with the highest caloric density, followed by the “Fried Chicken” with a caloric density of 17.310. “Fruits and Veggies,” “Food Tours,” “Shaved Snow,” “Gay Bars,” and “Honey” were categories with the lowest caloric density among all food categories, with caloric density <4.

Finally, we converted the caloric density for each category into a weighted score for caloric density for each state. The estimated weighted score for caloric density for the states ranged from 5.786 to 6.430. Washington had the lowest estimated weighted score for caloric density, while Georgia had the highest estimated weighted score for caloric density among all the states. Colorado’s score was 5.955, and Mississippi’s score was 6.305. We performed a 2-sample *z* test between these 2 states. The result showed a significant difference with a *z* value of 12.759 and *P*<.001. The relationship between the state estimated weighted score for caloric density and state obesity rate is shown in Figure 7. The estimated weighted score for the caloric density of states calculated using our approach showed a strong positive correlation (*r*=0.671; *P*<.001) with the state-level obesity rate. A higher estimated weighted score for the caloric density of a state indicates that the state-level food environment is more prone to obesity by serving high–calorie density food. Moreover, the estimated caloric density weighted score for southern food is higher than those for other areas in the United States, especially in Georgia, Alabama, and Mississippi.

Table 3. The most popular dishes for categories more available in Colorado and Mississippi.

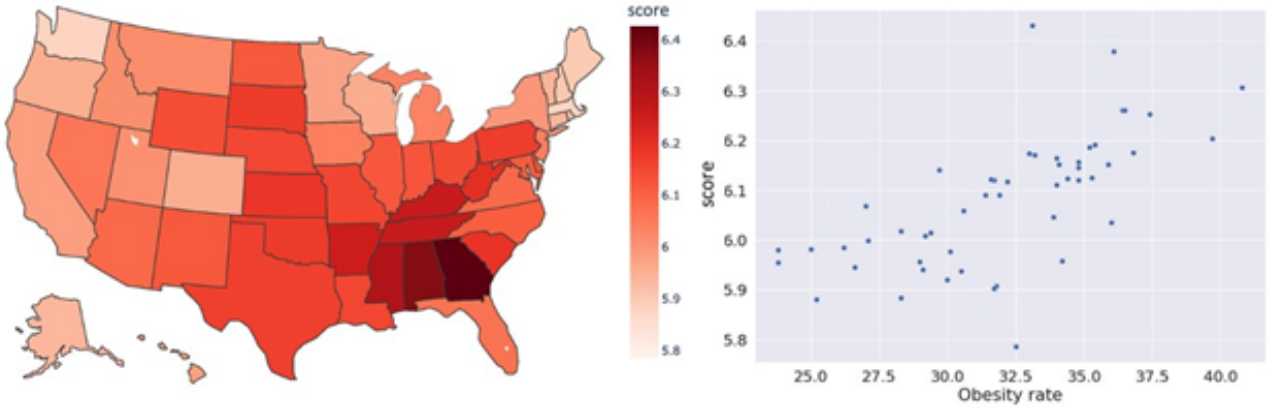
Regions	Popular dishes
Mississippi	• Fried Chicken • French Toast • Fish Tacos • Clam Chowder • Crab Cakes • Fried Catfish • Eggs Benedict • Fish and Chips • Filet Mignon • Beef Brisket
Colorado	• French Toast • Fish Tacos • Pork Belly • Eggs Benedict • Pad Thai • Fish and Chips • Fried Chicken • Spring Rolls • Caesar Salad • Avocado Toast

Table 4. The example of top 5 popular dishes and their caloric density for selected categories.

Category	Popular dish 1 (caloric density)	Popular dish 2 (caloric density)	Popular dish 3 (caloric density)	Popular dish 4 (caloric density)	Popular dish 5 (caloric density)	Caloric density for the category
Chicken wings	Fried chicken (2.240)	Boneless wings (1.836)	Buffalo wings (2.02)	Kimchi fried rice (3.271)	Chicken strips (2.108)	17.31
Diners	French toast (2.545)	Eggs Benedict (2.208)	Chicken fried steak (2.665)	Huevos rancheros (1.147)	Scrambled eggs (1.649)	7.289
Soul food	Fried chicken (2.240)	Fried catfish (3.283)	Sweet potato pie (2.525)	Red beans and rice (1.880)	Chicken breast (1.453)	6.337
Patisserie or cake shop	Almond croissant (4.102)	Chocolate croissant (3.926)	French toast (2.545)	Eggs Benedict (2.208)	Tiramisu (3.034)	6.298
Southern	Fried chicken (2.240)	Fried catfish (3.283)	Pecan pie (4.749)	Pork chop (1.590)	French toast (2.545)	5.667
Smokehouse	Pulled pork sandwich (2.452)	Baby back ribs (2.301)	Beef brisket (2.043)	Brisket sandwich (2.698)	Pulled pork (2.112)	5.51
American (new)	French toast (2.545)	Eggs Benedict (2.208)	Poached egg (1.414)	Fish tacos (1.498)	Beet salad (0.845)	5.047
Brasseries	French onion soup (0.808)	Pork chop (1.590)	Steak frites (2.465)	Duck confit (2.646)	Beef tartare (2.698)	4.78
Poke	Poke bowl (1.482)	Seaweed salad (3.510)	Spicy tuna (1.955)	Octopus (1.838)	Fresh fish (1.188)	4.716
Dim sum	Shrimp dumplings (1.620)	Peking duck (8.847)	BBQ[a] pork buns (2.505)	Har gow (1.741)	Xiao Long Bao (2.419)	4.215

[a]BBQ: barbecue.

Figure 7. The weighted score for caloric density of each state. Left: The weighted score for caloric density in a map; Right: scatter plot with the relationship between the weighted score for caloric density and the prevalence of state-level obesity.



RQ3: Can We Predict State-Level Obesity Rates Using Publicly Available Social Media Data?

We generated 3 sets of features for the prediction. The feature sets were as follows: (1) category availability, (2) category affordability and acceptability, and (3) weighted score for caloric density. Affordability and acceptability were created at the state level for the identified 226 categories. The estimated state weighted score for caloric density was calculated in RQ2. Because each state had only 1 estimated weighted score for caloric density, prediction models other than linear regression were not applicable for prediction using this set of features. For categories that did not exist in a state, we used 0 to fill in the missing values for the categories' availability, affordability, and acceptability. Approximately 24% (11,065/46,104) of the features were filled with 0. Table 5 presents the results of comparing different prediction models with different combinations of input. We used the Pearson correlation coefficient between the actual obesity rate and predicted obesity rate to evaluate it.

The random forest model with all 3 sets of features performed the best. In addition, the Pearson correlation coefficient between the predicted and real obesity rates was 0.796, which indicates that the predicted value was correlated with the real value.

Table 5. Pearson correlation coefficients for different combinations of input for prediction.

Features	Linear regression	Random forest regression	SVM[a] regression	XGBoost regression
Category availability	0.407	0.763	0.712	0.742
Category affordability and acceptability	0.402	0.776	0.593	0.743
State weighted score for caloric density	0.622	—[b]	—	—
Category availability+category affordability and acceptability	0.403	0.791	0.642	0.731
Category availability+state weighted score for caloric density	0.336	0.771	0.714	0.710
Category availability+category affordability and acceptability+state weighted score for caloric density	0.402	0.796[c]	0.643	0.708

[a]SVM: support vector machine.

[b]Not available.

[c]The best performing model.

Discussion

Principal Findings

In this study, we characterized food environments using the data from Yelp and MFP with innovative data collection and processing methods. We also predicted state-level obesity rates. In addition, our study contributed a new method to calculate food environment and data to estimate the calorie densities of different popular dishes and restaurant categories for future studies.

Our results showed a disparity in the available food categories between Colorado and Mississippi (ie, Colorado had a low obesity rate, and Mississippi had a high obesity rate). "Fast-food" restaurants were found to be more available in Mississippi than in Colorado. Fast-food consumption has been found to be strongly associated with weight gain and obesity [3]. Individual-level diet and weight outcomes are thought to improve in neighborhoods that have access to high-quality food [44]. Comparing the state-level food availability difference, we found that abundant access to fast-food options may contribute to a negative group-level health outcome. Although fast-food restaurants are notorious for serving high-calorie, low-nutritional foods [24,25] such as hamburgers, French fries, and fish and

chips [45], some differences have been found. By comparing the popularity of fast-food restaurants with other restaurants in Figure 5, we found that fast-food restaurants always have a lower number of reviews than other restaurants. However, in the District of Columbia, the average number of reviews of fast-food restaurants is higher than that of other restaurants. This may be because more alternative fast foods are available in cities, such as salad, sushi, and poke, which are considered light and healthy [46].

In addition to using the available food category to characterize the state food environment, we also used the popular dish and nutrition content of popular dishes to quantify the state food environment. To our knowledge, this is the first study to conduct a large-scale analysis of popular dishes. We compared popular dishes in Colorado and Mississippi. We found that fried foods are more popular in Mississippi. This finding is consistent with the literature showing that the intake of fried food is associated with obesity [47]. Using the collected popular dishes, we calculated the weighted score for caloric density for each state. Similar studies exist. For example, Nguyen et al [16] quantified the state food environment by calculating the caloric density of food mentions in geo-tagged tweets. They used a list of more than 1430 popular foods and beverages from the US Department of Agriculture's National Nutrient Database and calculated calories per 100 g for each food item [16]. Abbar et al [19] calculated the average calories by checking the calories per serving for the selected 500 food keywords. In contrast to these 2 studies, we used MFP, the biggest food database available [38], to obtain nutrition data. We collected nutrition data for 37,295 dishes, which allowed for an effective use of data points. In our study, Pearson correlation of weighted score for caloric density of states to state obesity rates was 0.671, which outperformed one of the aforementioned previous studies [19] in which the Pearson correlation of tweet caloric value to state obesity rates was 0.629.

To the best of our knowledge, our prediction model is the first to use Yelp and MFP data to predict state obesity rates. In contrast to previous studies that used Twitter data to predict obesity rate [17-19], our model using Yelp and MFP data had less selection bias. First, Twitter users are younger than the general public [48]; however, the user group of Yelp is more evenly distributed by age, with 33% of the users aged ≥55 years [49]. Second, the previous studies using Twitter data for prediction only used sampled data because of the massive amount of Twitter data. Although these studies used the same data source, their collection methods were different, which could have skewed the results.

Public Health Implications

Our study helped us understand the impact of the food environment and related human behavior by showing the correlation between state-level food environment and obesity rate. Because of the pervasive use of smartphones and social media apps like Yelp across the country, researchers could use social media data to gain an understanding of food environments in any part of America and other countries as well. In sum, our model has the potential to evaluate food environments.

Not only does our model map out a landscape of the local food environment but it also allows us to characterize the trajectory of public health. The copious amounts of information on social media allow public health practitioners to monitor changes in food availability and population over time and use this information to predict changes in state obesity levels. Similarly, computational methods could be used to inform dieting habits at the individual level. This allows for an early intervention in areas or individuals facing the greatest risk of increasing obesity rates or becoming obese.

Our study has reiterated a few fundamental findings related to the importance of environment [9,18,19]. Our findings suggest that those who live in areas with a considerable availability of high-calorie, fast foods are more likely to be obese. This alludes to the idea that people eat what is readily available to them. Politicians and city planners could potentially use this information to develop an infrastructure of healthy food options in areas that have been traditionally concentrated with fast-food restaurants. This sort of environmental intervention could potentially influence community behavior and lead to better health outcomes.

Limitations and Future Direction

The first limitation of our study lies in the data collection. Yelp provides substantial data for local businesses; however, the Yelp API results are restricted to 1000 results for each query. We could collect up to 1000 business data points for each zip code center up to a distance of 40 km (approximately 25 miles). In urban environments, 1 zip code may have >1000 businesses. To address this issue, we ran several rounds for each zip code and removed the duplicates. Despite this effort, missing data may skew our results, especially those about urban areas. We found a second limitation when collecting nutritional data from MFP. For each search query, MFP returned 10 pages with 10 records on each page. Some popular dishes did not have an exact match, in which case MFP returned a partially matching dish. Therefore, some caloric information may not be accurate. We averaged all the results to reduce the effects of inaccurate information. Another limitation is not capturing the actual consumption. We did not have information on the food consumed at a person's home. In this study, we calculated the caloric density of popular dishes. Nevertheless, we found that high–caloric density food is correlated with obesity rate, consistent with a previous study that was conducted at the individual level [50]. To bolster our findings, a similar analysis should be replicated at the zip code–level to better inform the local food environment. We used the state-level food environment in this study because BRFSS provides state-level obesity rate. More granular analysis will provide a better insight into how socioeconomic status and the local food environment may be correlated with obesity [14,51-53]. The information collected and calculated in this study could also be used to fuse a personalized mobile health app to help user have a better experience with obesity prevention management. For example, a specialized dashboard [54] could be added to the mobile health app when using information from GPS to measure physical activity along with a heat map showing where a person goes within their neighborhood.

Conclusions

This study used social media data to characterize state-level food environments. State-level food environments show a disparity in the available food between states with different obesity rates, suggesting the importance of food environment. Using the availability of different categories of food along with affordability and acceptability data captured on social media, we created a state-level obesity rate prediction model with a 0.796 correlation. Using our proposed method, public health practitioners could monitor the changes in areas that face the greatest risk of increasing obesity rates to counter the obesity pandemic.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The caloric density of all food categories.
[DOCX File , 28 KB-Multimedia Appendix 1]

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Abbreviations

API: application programming interface
BRFSS: Behavioral Risk Factor Surveillance System
GIS: geographic information system
MFP: MyFitnessPal
RQ: research question

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Original Paper

Measuring Digital Vaccine Literacy: Development and Psychometric Assessment of the Digital Vaccine Literacy Scale

Ilaria Montagni[1], PhD; Aude Pouymayou[1], MSc; Edwige Pereira[1], MSc; Christophe Tzourio[1], MD, PhD; Stéphane Schück[2,3], MD; Nathalie Texier[2], PharmD; Juan Luis González-Caballero[4], PhD; The CONFINS Group[5]

[1]Bordeaux Population Health UMRS1219, University of Bordeaux, Institut national de la santé et de la recherche médicale, Bordeaux, France

[2]Kappa Santé, Paris, France

[3]Kap Code, Paris, France

[4]Department of Statistics and Operational Research, University of Cádiz, Cádiz, Spain

[5]See Acknowledgments

Corresponding Author:
Ilaria Montagni, PhD
Bordeaux Population Health UMRS1219
University of Bordeaux
Institut national de la santé et de la recherche médicale
146 rue Léo Saignat
Bordeaux, 33000
France
Phone: 33 0642193363
Email: ilaria.montagni@u-bordeaux.fr

Abstract

Background: The use of the internet to look for information about vaccines has skyrocketed in the last years, especially with the COVID-19 pandemic. Digital vaccine literacy (DVL) refers to understanding, trust, appraisal, and application of vaccine-related information online.

Objective: This study aims to develop a tool measuring DVL and assess its psychometric properties.

Methods: A 7-item online questionnaire was administered to 848 French adults. Different psychometric analyses were performed, including descriptive statistics, exploratory factor analysis, confirmatory factor analysis, and convergent and discriminant validity.

Results: We developed the 7-item DVL scale composed of 3 factors (understanding and trust official information; understanding and trust information in social media; and appraisal of vaccine information online in terms of evaluation of the information and its application for decision making). The mean DVL score of the baseline sample of 848 participants was 19.5 (SD 2.8) with a range of 7-28. The median score was 20. Scores were significantly different by gender (P=.24), age (P=.03), studying or working in the field of health (P=.01), and receiving regular seasonal flu shots (P=.01).

Conclusions: The DVL tool showed good psychometric proprieties, resulting in a promising measure of DVL.

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KEYWORDS

Internet; literacy; measurement; vaccination; vaccine; health information; health literacy; online; content; validity; reliability; digital literacy

Introduction

Vaccination is one of the most commonly queried topics on the internet [1]. With the COVID-19 pandemic, the number of people seeking vaccine-related information on the internet has skyrocketed [2,3]. The Increasing Vaccination Model [4] states that information sharing and rumors contribute, among other factors, to motivation to vaccinate. The 5C (complacency, constraints, calculation, confidence, collective responsibility) Model [5] asserts that vaccine hesitancy depends also on the engagement in extensive information seeking (ie, calculation), which determines deliberation on the risks and benefits of vaccination based on retrieved data and news. Thus, according to these 2 models, the contents of online information have the potential to determine the decision to get vaccinated or not.

Online sources for vaccine-related information vary. These include websites of official institutions, blogs, forums, social media, among others. The information they convey can be either reliable and valid or unscientific and misleading. On the one hand, social media have been defined as a powerful catalyst for the "anti-vax movement" [6]. This has been emphasized during the COVID-19 pandemic with a wide circulation of false information about vaccines on social media platforms [7,8]. On the other hand, websites of official institutions, such as those of governments, are considered to be more accurate [9]. Recent studies concerning the COVID-19 pandemic have confirmed that government websites are the most trusted source of information [10,11].

Hesitancy toward vaccination remains a present and growing issue [12]. Among the various reasons for this attitude, *misconception* and *misinformation* can have a strong impact [13]. Online messages can contribute to diffuse controversial information and induce indecision and skepticism about vaccines [14].

Preliminary studies have explored the influence of the internet on growing vaccine hesitancy [15,16]. According to these studies, those who search for online information more actively are usually also the most hesitant, trusting and believing science less than other sources [17]. Furthermore, the spread of fake news and misinformation on social media is blamed as a primary cause of vaccine hesitancy [18]. However, the internet is also a source of official reliable information and might provide new instruments to fight against vaccine hesitancy, because users can also access government websites, for instance.

Digital health literacy refers to the capacity of people to adequately understand and process online health information to meet their needs [19]. This set of skills affects the health of users, as well as the quality of their health care, orienting their health behavior. Vaccine literacy is defined as not only knowledge about vaccines, but also developing a simple system to communicate and offer vaccines as a sine qua non of a functioning health system [20,21]. Digital vaccine literacy (DVL) is a construct mixing digital health literacy and vaccine literacy. DVL theoretically affects both motivation and skills involving online information seeking for clear-cut elucidated decision making about getting vaccinated or not.

A valid tool for measurement of DVL is thus essential to provide inputs to train people in better navigating vaccine-related information on the internet on both social media and official online sources. This scale developed herein also allows to provide a general and population-based assessment of DVL: given the spread of the COVID-19 pandemic and the relevance of accepting vaccination, today more than ever it is pivotal to investigate the level of DVL in the population and examine its potential contribution to vaccine uptake. Furthermore, the scale can be used as an instrument to measure the effectiveness of interventions aimed at increasing DVL for reducing vaccine hesitancy.

To the best of our knowledge, no tool exists to measure DVL. The currently used questionnaires focus on vaccine literacy in general and not on online vaccine literacy (ie, DVL) [21,22]. The aim of this study was to describe the development and psychometric properties of a scale measuring DVL (Multimedia Appendix 1).

Methods

Overview of Study Phases

Our study was conducted in 3 distinct phases: (1) development of a tool to measure DVL, (2) collection of empiric cross-sectional data from a French adult population sample, and (3) assessment of the psychometric properties of the DVL tool.

We used the COSMIN (Consensus-Based Standards for the Selection of Health Measurement Instruments) to develop the DVL tool and validate it [23].

Phase 1: DVL Tool Development

We based the conception of the DVL tool on the theories of digital health literacy and vaccine literacy, investigating the understanding, trust, appraisal, and application of vaccine-related information online [20,24], with the distinction between social media/forums and government websites. A panel of 5 public health researchers proposed a series of items inspired by the Health Literacy Questionnaire [25,26], the eHealth Literacy Scale [19], and the Vaccine Literacy Scale [22].

The construct of DVL was decided a priori and defined before any item activity. Expert judges confirmed through literature review that there were no existing instruments that will adequately serve the same purpose. A deductive method was used to identify the items through the description of the relevant field (domain), in combination with an inductive method based on the exchanges among experts. A group of 10 volunteers with characteristics similar to the target population pretested the questions. Items were worded in simple terms and unambiguously.

We narrowed the items focusing on vaccination and the digital environment to eventually obtain a total of 7 questions answered on a 4-point Likert scale (from 4 [agree] to 1 [disagree]) and an additional answer option "I do not know, I do not look for vaccine-related information." This latter option was taken into account in the descriptions, but was considered "noninformative" for the analysis of the structural validity of the scale. The total score of the DVL scale was calculated through the sum of all answers to the items. The score of the scale varied from 7 to 28. The higher the score, the better the DVL level.

We also included an item on "the online sources which were the most consulted for vaccine-related information seeking" (online journals, government websites, health institution websites, social media, forums, video platforms, other). Finally, participants had to rate the importance of the use of the internet for vaccine-related information seeking through a visual analog scale from 1 (not important at all) to 5 (very important).

Phase 2: Data Collection and Definition of the Population Under Study

We administered the DVL tool to participants from an open online cohort (CONFINS) [27]. All participants were aged more than 18 years, living in France, and were able to read and

understand French. CONFINS is a cohort collecting data on the impact of confinement on the health and well-being of the French population [28]. It included, among others, variables on opinions about vaccination and the DVL items. It also comprised sociodemographic information (age, gender, having children, being vaccinated against influenza) used in this study. Items were defined by a group of public health experts through several rounds of corrections and refinement. CONFINS consisted in a baseline questionnaire and repeated monthly follow-up questionnaires. Participants could decide whether to be contacted or not for the following phases of the survey. This study used data from the baseline questionnaire and the first follow-up questionnaire, covering the period from April to May 2020. This was a convenience sample.

CONFINS participants were recruited on a voluntary basis with no incentives through different communication channels. Posts were published on the social media (LinkedIn, Twitter, Facebook) of the University of Bordeaux and the partner contract research organization hosting the database. A total of 3 press releases were addressed to journalists. The coprinciple investigators were interviewed to promote the study. Three newsletters and weekly emails and SMS text messages were sent to the participants to remind them to complete the follow-up questionnaires. All recruitment strategies directed potential participants toward the CONFINS website including information on the objectives of the study and the investigators. Informed consent, containing details on the length of time of the survey, stored data, investigators and objectives of the study, was provided through an electronic signature.

Study Population

Concerning the population of this study, we included all participants completing all items of the DVL tool, comprising also those choosing the answer option "I do not know, I do not look for vaccine-related information" (N=2935). However, for the sake of the specific analyses required to evaluate the psychometric properties of the DVL tool, we obtained a subsample of 848 participants who did not use the answer option "I do not know, I do not look for vaccine-related information." The choice of using mainly the subsample was justified by the fact that the factor analysis mentioned later requires ordering the response modalities. As the "I do not know, I do not look for vaccine-related information" modality is difficult to classify, we decided to remove it. The subsample included those who had completed the baseline questionnaire ("test" phase). Among them, 62 participants also answered the follow-up questionnaire ("retest" phase).

Phase 3: Analysis of Other Psychometric Properties of the DVL Tool

First, a descriptive analysis of each item of the scale was performed for both the total sample of participants (N=2935) and the subsample (n=848). Participants of the subsample were also described according to their sociodemographic characteristics (ie, age, gender, working/studying in the field of health, having children, and being regularly vaccinated against flu). For quantitative variables, the mean and SD were calculated. For qualitative variables, participants were described in numbers and percentages. Answers to items were compared for each aforementioned sociodemographic characteristic. To do this, the item response options were grouped into "agree"/"rather agree" versus "disagree"/"rather disagree." The statistical tests of χ^2 independence were used to compare the responses of the participants according to their sociodemographic criteria.

Second, an exploratory factor analysis (EFA) was performed on the baseline data to identify the underlying latent factors in the set of items as well as their association. As the items were ordinal variables, the polychoric correlation matrix of observed items was explored. Two initial hypotheses were tested. The first was the test of Bartlett sphericity. If the test was significant (P<.05), the observed matrix was significantly divergent from the null matrix and an EFA had to be performed. The second hypothesis required testing the measure of sampling adequacy using the Kaiser-Meyer-Olkin index [29]. This is a measure of the proportion of variance among the observed items, equivalent to the common variance. Thus, it was used to verify for partial correlations. If the Kaiser-Meyer-Olkin index was above 0.50, the EFA was adequate. Next, the number of factors to be kept in the model had to be chosen based on different criteria using eigenvalues. The Kaiser criterion consisted of keeping factors with eigenvalues greater than 1. The Cattell criterion (also called the "elbow criterion") was based on identifying the inflection point, where the slope of the eigenvalue curve according to the number of factors in the model stabilized well below the "elbow." Thus, the number of factors above the point was retained. The third criterion was the use of a parallel analysis. In this analysis, the eigenvalues obtained were compared with those that would be obtained from random data. The number of factors extracted was the number of factors whose eigenvalues were higher than those found with random data. In addition, the item × factor matrix had to be rotated to better identify how the items were substantially related to each factor. Among the several approaches to rotation, the oblique rotation was used because it considers the correlation between factors [30]. Finally, the items were associated with a factor when their saturation weight was close or superior to 0.30 and their communalities were considered as acceptable above 0.20. We also performed a confirmatory factor analysis (CFA) considering the criteria root-mean-square error of approximation (acceptable range between 0.08 and 0.1), comparative fit index (acceptable range >0.90) and standardized root-mean-square error (acceptable range between 0 and 0.008).

Third, to complete the validation of the DVL scale, the convergent and discriminant validities of the score were assessed. The sociodemographic criteria of participants with a low DVL score were compared with those of participants with a high score, determined according to the median, using χ^2 statistical tests of independence.

Statistical significance was considered if P<.05 and all tests were 2-tailed. Statistical analyses were performed on SAS version 9.3 software (SAS Institute).

Ethics Approval

The study was approved by the French Committee for the Protection of Individuals (Comité de Protection des Personnes

[CPP], approval number 46-2020) and the French National Agency for Data Protection (Commission Nationale de l'Informatique et des Libertés [CNIL], approval number MLD/MFI/AR205600). The study follows the principles of the Declaration of Helsinki and the collection, storage, and analysis of the data comply with the European Union General Data Protection Regulation (EU GDPR).

Results

Descriptive Analysis

Responses to the 7 items on the DVL tool by the total sample and the subsample are reported in Tables 1 and 2, respectively.

Table 1. Results of all potentials items of the DVL scale[a] in the CONFINS online cohort (N=2935).

Items	Disagree, n (%)	Rather disagree, n (%)	Rather agree, n (%)	Agree, n (%)	Do not know, n (%)
1. I find vaccine-related information on social media and forums is understandable	215 (7.33)	478 (16.29)	582 (19.83)	134 (4.57)	1526 (51.99)
2. I find vaccine-related information on government websites is understandable	111 (3.78)	176 (6)	1394 (47.50)	586 (19.97)	668 (22.76)
3. I can detect vaccine-related fake news	97 (3.30)	477 (16.25)	1500 (51.11)	821 (27.97)	40 (1.36)
4. I trust vaccine-related information provided by government websites	55 (1.87)	191 (6.51)	1250 (42.59)	948 (32.30)	491 (16.73)
5. I find vaccine-related information on social networks is valid	533 (18.16)	1123 (38.26)	134 (4.53)	26 (0.89)	1119 (38.13)
6. When I read vaccination information online, I cross-reference it with other sources to verify its validity	178 (6.06)	394 (13.42)	1288 (43.88)	1060 (36.12)	15 (0.51)
7. I think the information I find online may influence my decision to get vaccinated	413 (14.07)	649 (22.11)	918 (31.28)	231 (7.97)	724 (24.67)

[a]DVL scale: Digital Vaccine Literacy scale.

Table 2. Results of all potential items of the DVL scale[a] in the CONFINS online cohort (n=848, without "do not know").

Item	Disagree, n (%)	Rather disagree, n (%)	Rather agree, n (%)	Agree, n (%)	Test-retest reliability (n=62), intraclass correlation coefficient (95% CI)
1. I find vaccine-related information on social media and forums is understandable	139 (16.4)	287 (33.8)	342 (40.3)	80 (9.4)	0.14 (0.01 to 0.37)
2. I find vaccine-related information on government websites is understandable	49 (5.8)	82 (9.7)	492 (58.0)	225 (26.5)	0.53 (0.33 to 0.69)
3. I can detect vaccine-related *fake news*	27 (3.2)	111 (13.1)	421 (49.6)	289 (34.1)	0.70 (0.55 to 0.81)
4. I trust vaccine-related information provided by government websites	23 (2.7)	82 (9.7)	409 (48.2)	334 (39.4)	0.46 (0.24 to 0.63)
5. I find vaccine-related information on social networks is valid	224 (26.4)	529 (62.4)	83 (9.8)	12 (1.4)	0.05 (0.01 to 0.29)
6. When I read vaccination information online, I cross-reference it with other sources to verify its validity	44 (5.2)	87 (10.3)	365 (43)	352 (41.5)	0.48 (0.27 to 0.65)
7. I think the information I find online may influence my decision to get vaccinated	122 (14.4)	267 (31.5)	354 (41.7)	105 (12.4)	–0.09 (–0.33 to 0.16)

[a]DVL scale: Digital Vaccine Literacy scale.

The "I do not know, I do not look for vaccine-related information" response rates were 51.99% (1526/2935) for item 1, 22.76% (668/2935) for item 2, 1.36% (40/2935) for item 3, 16.73% (491/2935) for item 4, 38.13% (1119/2935) for item 5, 5.04% (148/2935) for item 6, and 24.67% (724/2935) for item 7. Per participant, the maximum number of "I do not know, I do not look for vaccine-related information" was 5; 24.74% (726/2935) responded "I do not know, I do not look for vaccine-related information" for at least one item; 23.51% (690/2395) for at least two items; 10.97% (322/2935) for at least three items; 7.97% (234/2935) for at least four items; and 3.92% (115/2395) for at least five items. The mean of responses per participant was 1.56 (SD 1.4). In addition, the use of a factor analysis requires ordering the response modalities. As the "I do not know, I do not look for vaccine-related information" modality is difficult to classify in view of the others, we decided

to remove it from the analyses. Therefore, the study sample contained 848 participants who responded to the items as shown in Table 2.

All item response options were used, thus qualifying them as informative. In addition, Table 2 shows that the items were discriminating because the response rates for each modality were in the average. The intraclass correlation coefficient (ICC) was calculated based on data from the 62 participants. Items 1, 5, and 7 presented a low ICC, which could be explained by nonconcordant responses between the 2 measurements, and therefore less reliability, their formulation, and possible difficulty in answering them. In fact, these items had the highest percentages of the "I do not know, I do not look for vaccine-related information" responses (Table 1).

In the subsample of 848 participants, 73.1% (620/848) were females. The mean age was 29.9 (SD 12.3). Participants working or studying in the field of health were 397/848 (46.8%). The percentage of parents was 20.9% (178/848) and 557/848 (65.7%) were not vaccinated against flu (Table 3).

The mean of the importance of the use of the internet for vaccine-related information seeking was 3.7 out of 5 (SD 1.1). The most used source for vaccine-related information seeking was websites of health institutions (395/848, 46.6%), followed by government websites (184/848, 21.7%). Online journals were consulted by 56/848 individuals (6.6%), whereas other sources by 37/848 individuals (4.4%). Social networks were consulted by 70/848 individuals (8.3%), video platforms by 16/848 (1.9%), and forums by 8/848 (0.9%).

Multimedia Appendix 2 reports data on the comparison of the answer to the DVL items according to sociodemographic characteristics.

Regarding their answers to the items, women were more in agreement with the statement of item 3 (I can detect vaccine-related fake news), item 4 (I trust vaccine-related information provided by government websites), and item 7 (I think the information I find online may influence my decision to get vaccinated) than men. Participants aged 35 or over disagreed with item 1 (I find vaccine-related information on social media and forums is understandable), which was different from those under 35 years. Participants studying or working in the field of health and those receiving regular flu shots were more in agreement with items 2 (I find vaccine-related information on government websites is understandable), item 3 (I can detect vaccine-related fake news), and item 4 (I trust vaccine-related information provided by government websites) and disagreed with item 7 (I think the information I find online may influence my decision to get vaccinated) compared with those who worked or studied in another field and those who did not get a flu shot. There was no difference in responses concerning parenthood.

Table 3. Sociodemographic characteristics of the CONFINS study population.

Characteristics	Value
Age, mean (SD)	29.9 (12.3)
Categories (n=835), years , n (%)	
18-34	653 (78.2)
≥35	182 (21.8)
Gender (n=848), n (%)	
Female	620 (73.1)
Male	228 (26.9)
Study or work in the field of health (n=763), n (%)	
No	366 (48.0)
Yes	397 (52.0)
Children (n=848), n (%)	
No	670 (79.0)
Yes	178 (21.0)
Influenza vaccine (n=848), n (%)	
No	557 (65.7)
Yes	291 (34.3)

Exploratory Factor Analysis

The interitem polychoric correlation matrix was used for the first definition of the associations between items (Table 4).

In the polychoric matrix, we observed strong correlations between items 2, 3, and 4. Item 1 was more correlated with item 5.

The hypotheses justifying the performance of an EFA were validated. The Bartlett test of sphericity showed a $P<.05$ ($\chi^2_{21}=1319.37$) and the Kaiser-Meyer-Olkin index was 0.58, indicating good sampling adequacy.

The number of factors was calculated based on the Kaiser and Cattell criteria and the parallel analysis; 3 factors were kept (Figure 1).

Finally, several EFAs were performed to test the different oblique rotations. The OBLIMIN oblique rotation was the most common. Table 5 shows that items 1 and 5 were associated with factor 2; items 2, 3, and 4 with factor 1; and items 6 and 7 with factor 3. The oblique rotation OBEAQUAMAX showed that saturation weights revealed several possible associations between items and factors. Items 3 and 7 were associated with both factors 1 and 3 based on the saturation weights close or superior to 0.30. Communalities were all acceptable.

Table 4. Interitem polychoric correlation matrix.

Item	1	2	3	4	5	6	7
1	—[a]	—	—	—	—	—	—
2	0.33	—	—	—	—	—	—
3	0.00	0.46	—	—	—	—	—
4	0.06	0.64	0.52	—	—	—	—
5	0.45	–0.02	–0.10	–0.06	—	—	—
6	0.06	0.19	0.34	0.12	–0.02	—	—
7	0.13	–0.11	–0.13	–0.15	0.21	0.20	—

[a]Dashes correspond to the absence of a correlation between items.

Figure 1. Distribution of the median simulated eigenvalues according to the number of factors and application of the parallel analysis. 7 variables, iterations, 848 observations.

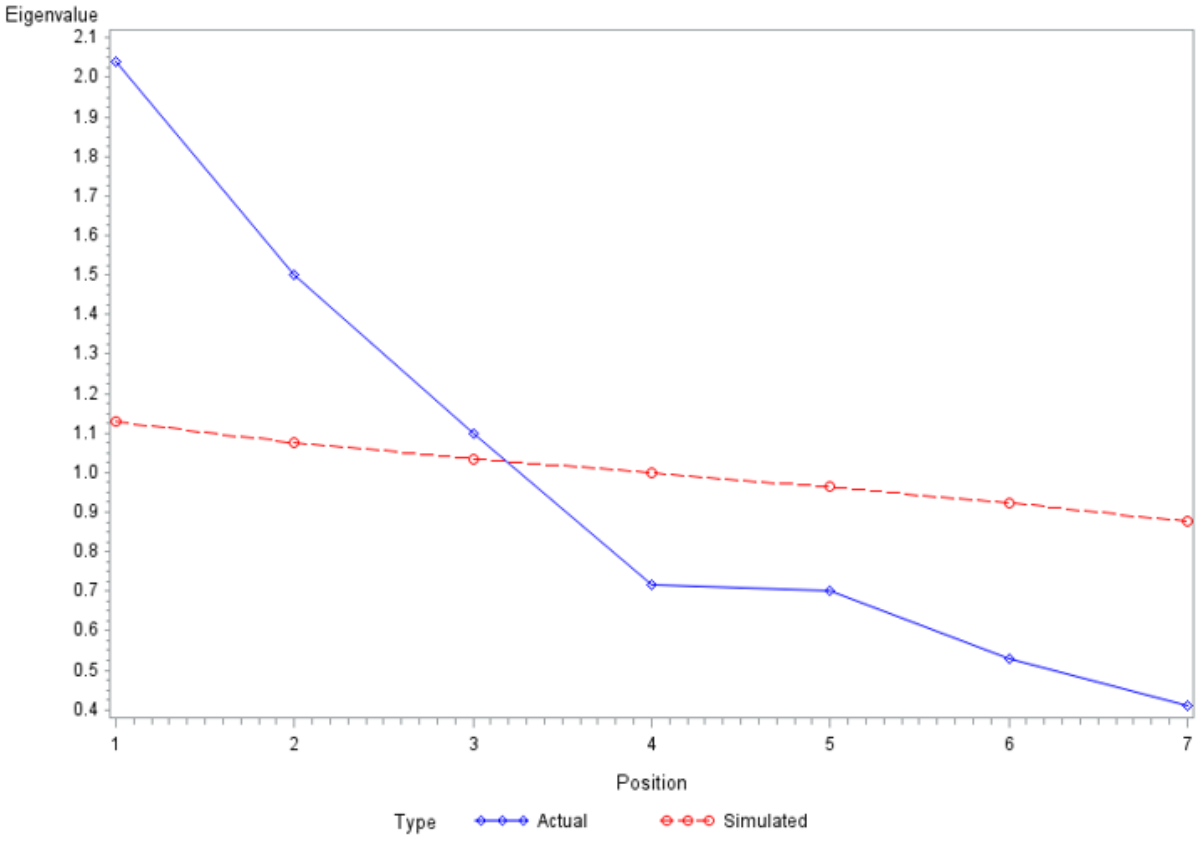

Table 5. Matrices of the saturation weights with oblique rotations and item communalities.

Item	OBLIMIN			OBEAQUAMAX			Communality
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3	
1	0.19	0.69	–0.02	0.19	0.67	0.01	0.46
2	0.78	0.23	–0.01	0.74	0.21	0.13	0.63
3	0.60	–0.14	0.25	0.50	–0.15	0.37	0.47
4	0.76	0.01	–0.03	0.72	–0.01	0.12	0.57
5	–0.08	0.56	0.03	–0.07	0.57	–0.01	0.34
6	0.17	–0.05	0.49	0.03	–0.04	0.53	0.28
7	–0.23	0.20	0.33	-0.30	0.21	0.29	0.21

Table 6 shows the interfactor correlations according to the OBLIMIN and OBEAQUAMAX rotations. Correlations were low but factor 1 was negatively correlated with factor 2, and factor 3 was positively correlated with the other 2 factors.

In view of these results, the relationships between the items and the factors were interpreted as follows. Factor 1 was associated with items relating to "reliable" information about vaccination (government sites), with the label "understanding and trust official information about vaccination provided by institutional websites." Factor 2 was associated with items related to information about vaccination of which 1 should be relatively "unreliable" (social media) with the label "understanding and trust information about vaccines as provided by social media." Finally, factor 3 was associated with items related to the application of knowledge on vaccination consulted on the web (label of factor 3).

Finally, we also performed a CFA to confirm these 3 dimensions (Table 7).

In the CFA the criterion values were as follows: root-mean-square error of approximation 0.12 (90% CI 0.11-1.14), comparative fit index 0.80, and standardized root-mean-square error 0.08.

Table 6. Interfactor correlation matrices (OBLIMIN and OBEAQUAMAX).

Factor	OBLIMIN			OBEAQUAMAX		
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3
1	1	—[a]	—	1	—	—
2	–0.08	1	—	–0.09	1	—
3	0.11	0.18	1	0.19	0.16	1

[a]Dashes correspond to the absence of a correlation between items and factors.

Table 7. Weights of the relationships item-factors of the final model by confirmatory factor analysis.

Item	Model 1		
	Factor 1	Factor 2	Factor 3
1	—[a]	0.87	—
2	0.56	—	—
3	0.43	—	—
4	0.51	—	—
5	—	0.23	—
6	—	—	0.83
7	—	—	0.15

[a]Dashes correspond to the absence of a correlation between items and factors.

Convergent and Discriminant Validity

The mean DVL score of the baseline sample of 848 participants was 19.5 (SD 2.8). Participants scored between 14 and 21 points (ie, in the medium DVL range). The median was 20.

Table 8 shows the sociodemographic characteristics of the sample according to the DVL level. The score was dichotomized into <20 (low DVL score) and ≥20 (high DVL score).

Participants with a low DVL level were significantly older (30.8 years vs 29 years; *P*=.03). Those working or studying in the

field of health were significantly more numerous in the group with a higher score (*P*=.01). Those who did not receive regular flu vaccinations were significantly more likely to be in the low score group (*P*=.01). Among online sources for vaccine-related information, government websites were more used by those with a higher DVL (*P*=.03). Those with a score less than 20 considered the use of the internet for vaccine-related information less important than others, with the means being 3.4 (SD 1.1) and 4.0 (0.9), respectively.

Table 8. Sociodemographic characteristics of the baseline sample by DVL[a] level (n=848).[b]

Sociodemographics	Low DVL (score <20)	High DVL (score ≥20)	*P* value
Age (years), mean (SD)	30.8 (12.9)	29.0 (11.7)	.03
Age c ategories (n=397)			.04
18-34	298/397 (75.1)	355/438 (81.1)	
≥35	99/397 (24.9)	83/438 (18.9)	
Gender (n=404)			.24
Female	303/404 (75)	317/444 (71.4)	
Male	101/404 (25)	127/444 (28.6)	
Studying or working in the field of health (n=357)			.01
No	192/357 (53.8)	174/406 (42.9)	
Yes	165/357 (46.2)	232/406 (57.1)	
Having children (n=404)			.38
No	314/404 (77.7)	356/444 (80.2)	
Yes	90/404 (22.3)	88/444 (19.8)	
Vaccinated against flu (n=404)			.01
No	283/404 (70)	274/444 (61.7)	
Yes	121/404 (30)	170/444 (38.3)	
Online sources for vaccine-related information (n=338)			.03
Online journals	30/338 (8.9)	26/390 (6.7)	
Government websites	73/338 (21.6)	111/390 (28.5)	
Health institutions websites	185/338 (54.7)	210/390 (53.8)	
Social media	19/338 (5.6)	13/390 (3.3)	
Forums	7/338 (2.1)	1/390 (0.3)	
Video Platforms	5/338 (1.5)	11/390 (2.8)	
Other	19/338 (5.6)	18/390 (4.6)	
Importance of the use of the internet for vaccine-related information seeking (n=338), mean (SD)	3.4 (1.1)[c]	4.0 (0.9)[d]	<.001

[a]DVL: digital vaccine literacy.

[b]Values are presented as n/N (%) unless indicated otherwise.

[c]N=338.

[d]N=390.

Discussion

The DVL Scale: Dimensions, Items, and Answer Options

We conceived a scale measuring DVL and assessed its psychometric proprieties among a sample of French adults. The scale was composed of 7 items covering the overarching construct of DVL, which includes 3 subdimensions. The first subdimension (items 2 and 4) refers to understanding and trusting official information about vaccination provided by institutional websites. The second subdimension (items 1 and 5) refers to understanding and trusting information about vaccines as provided by social media. The underlying assumption for these 2 dimensions is that government websites provide valid information while social media provide fake news [31]. In this line, in our sample, the most accessed sources were health institutions and government websites, while social media and forums were less consulted.

The third subdimension (items 3, 6, and 7) refers to the appraisal of vaccine information online in terms of evaluation of the

information and its application for decision making. Two items (3 and 7) are actually included in both subdimensions 1 and 2. For the item "I can detect fake news," this ambivalence can be explained by the fact that recognizing fake news is a reflection of both the understanding/trust of official information (subdimension 1) and the appraisal and practical application of found information (subdimension 3). The possible explanation is that those who recognize fake news are more inclined to government websites and are more cautious in interpreting vaccine-related information. The inclusion of the item "I think the information I find online may influence my decision to get vaccinated" in both subdimensions 1 and 3 can be interpreted as the fact that trusting official information might correspond to a higher capacity to make correct evidence-based decisions about vaccination. This overlap of factors infers an interrelation of items, which can suggest that the scale is coherent and congruent.

Some recommendations must be considered when using the DVL scale. There are 4 response options (*disagree*, *rather disagree*, *rather agree*, and *agree*) that are used to obtain a score. However, even if it does not contribute to the calculation of the score, the fifth response option (I do not know, I do not look for vaccine-related information) provides useful information. First, this option respects the opinion of those not feeling concerned without forcing or biasing their answer. Second, it is really interesting to measure the percentage of those who do not feel concerned by seeking vaccine-related information online. In this study, one-half of the participants used the option "I do not know, I do not look for vaccine-related information" for the item on understanding information found on social media, and more than one-third for the item on trust in social media. These results confirm the fact that social media are more rarely used than government websites for this type of information. Thus, we suggest to calculate the score by considering as missing values all cases including 1 response option "I do not know, I do not look for vaccine-related information", and to complete this information with the percentage of those using this same option. These data are complementary in measuring DVL.

The DVL Scores of the Study Sample

Having a low DVL score (<20) can be interpreted as a relevant alarm in relation to the extensive use of the internet for vaccine-related contents, especially in France [15]. As is the case with health literacy, low DVL scores are associated with a higher risk of adopting an unhealthy behavior [32]; in this case this refers to the decision of *not to get vaccinated*. Not being able to navigate information on the internet could increase the chance of having a negative perception about vaccines [33]. Lower scores in the scale would also correspond to the incapacity to recognize fake news and trust in unofficial information provided by social media. There are many who consult the internet regarding vaccination and it is important to know their levels of DVL to help them navigate online information.

DVL scores were significantly different by age (participants with a low DVL score were significantly older), studying or working in the field of health (those working or studying in the field of health were significantly more numerous in the group with a high score), and being vaccinated against flu (those who did not regularly get vaccinated against influenza were significantly more numerous in the group with a low score). These results are in line with previous literature concerning general health literacy: scores of health literacy are higher in younger adults [34], health care professionals [35], and those vaccinated against flu [36].

Comparison with results from other studies is not possible because DVL has never been measured before.

Strengths and Limitations

This study is the very first to develop and validate a standardized instrument for assessing general DVL in people. It responds to the urgent need for similar scales to tackle vaccine-related misinformation [37], especially in relation to the COVID-19 pandemic. Measuring the DVL of individuals consulting the internet for information on COVID-19–related vaccination could inform health institutions, communication experts, and health care providers to plan and implement strategies to overcome gaps in DVL and promote vaccination [38]. Furthermore, analyses performed in this study are robust and based on an in-depth knowledge of psychometrics techniques. In particular, the use of the bifactorial model is justified by the fact that it considers correlations between items based on the general factor and the relations between the general factor. Items are not limited by the group factors. This model is largely applied in cognitive and psychological sciences [39].

This study is not without limitations. Items were defined a priori based on existing scales but limited to 7. A larger number of items might have provided a more exhaustive coverage of DVL factors. The population under study was not representative of French adults given that it comprised a high number of women (2971/3738, 79.48%), students (3498/3783, 93.58%), and young people (29.2 years) [40], compared with the general population [41]. However, the sample was large enough to assess the relevance of the scale. Low ICC values in some separated items might be explained by an inaccurate phrasing. The ICCs of 3 items were low, which corresponds to a low reliability. Future instruments might be based on our scale, but we propose more precise wording according to the population of interest in a specific context (eg, cultural or sociodemographic characteristics).

Conclusions

The DVL scale is the first instrument providing information on the way individuals understand, trust, and appraise vaccine-related information on the internet through 2 channels, namely, social media and government websites. The DVL scale has good psychometric properties in terms of content validity, dimensionality, and convergent and discriminant validity. Results show that the scale can be easily administered with well-grounded outcomes. It is a screening instrument contributing to detect people who need to be supported in navigating vaccine-related information online. It can be used in questionnaires to identify profiles of web users who could be influenced by anti-vax movements, for instance. Providing the instructions to look for online information and to understand

its content is the key to spreading good vaccine-related information and promoting vaccination in general [42]. The scale can be used to measure DVL in the French population and translated validated versions could be proposed internationally.

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Data Availability Statement

All data generated or analyzed during this study are included in this published article. The full data set is available upon request from the CONFINS cohort team.

Authors' Contributions

IM conceived the study and wrote and revised the manuscript. JLGC conceived the study, supervised analyses, and revised the manuscript. EP and AP analyzed the data. SS, NT, and CT conceived and designed the study cohort. Also see the “Acknowledgments” section.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Original items of the DVL scale (French). DVL scale: Digital Vaccine Literacy scale.
[DOCX File , 15 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Comparison of responses to the 7 DVL items according to sociodemographic characteristics (n=848). DVL: digital vaccine literacy.
[DOCX File , 21 KB-Multimedia Appendix 2]

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Abbreviations

CFA: confirmatory factor analysis
CNIL: Commission Nationale de l'Informatique et des Libertés
COSMIN: Consensus-Based Standards for the Selection of Health Measurement Instruments
CPP: Comité de Protection des Personnes
DVL: digital vaccine literacy
EFA: exploratory factor analysis
EU GDPR: European Union General Data Protection Regulation
ICC: intraclass correlation coefficient

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Original Paper

Predicting Publication of Clinical Trials Using Structured and Unstructured Data: Model Development and Validation Study

Siyang Wang[1*], MSc; Simon Šuster[1*], PhD; Timothy Baldwin[1,2], PhD; Karin Verspoor[3], PhD

[1]School of Computing and Information Systems, University of Melbourne, Melbourne, Australia

[2]Mohamed bin Zayed University of Artificial Intelligence, Abu Dhabi, United Arab Emirates

[3]School of Computing Technologies, RMIT University, Melbourne, Australia

[*]these authors contributed equally

Corresponding Author:
Simon Šuster, PhD
School of Computing and Information Systems
University of Melbourne
Parkville
Melbourne, 3000
Australia
Phone: 61 40834491
Email: simon.suster@unimelb.edu.au

Abstract

Background: Publication of registered clinical trials is a critical step in the timely dissemination of trial findings. However, a significant proportion of completed clinical trials are never published, motivating the need to analyze the factors behind success or failure to publish. This could inform study design, help regulatory decision-making, and improve resource allocation. It could also enhance our understanding of bias in the publication of trials and publication trends based on the research direction or strength of the findings. Although the publication of clinical trials has been addressed in several descriptive studies at an aggregate level, there is a lack of research on the predictive analysis of a trial's publishability given an individual (planned) clinical trial description.

Objective: We aimed to conduct a study that combined structured and unstructured features relevant to publication status in a single predictive approach. Established natural language processing techniques as well as recent pretrained language models enabled us to incorporate information from the textual descriptions of clinical trials into a machine learning approach. We were particularly interested in whether and which textual features could improve the classification accuracy for publication outcomes.

Methods: In this study, we used metadata from ClinicalTrials.gov (a registry of clinical trials) and MEDLINE (a database of academic journal articles) to build a data set of clinical trials (N=76,950) that contained the description of a registered trial and its publication outcome (27,702/76,950, 36% published and 49,248/76,950, 64% unpublished). This is the largest data set of its kind, which we released as part of this work. The publication outcome in the data set was identified from MEDLINE based on clinical trial identifiers. We carried out a descriptive analysis and predicted the publication outcome using 2 approaches: a neural network with a large domain-specific language model and a random forest classifier using a weighted bag-of-words representation of text.

Results: First, our analysis of the newly created data set corroborates several findings from the existing literature regarding attributes associated with a higher publication rate. Second, a crucial observation from our predictive modeling was that the addition of textual features (eg, eligibility criteria) offers consistent improvements over using only structured data (F_1-score=0.62-0.64 vs F_1-score=0.61 without textual features). Both pretrained language models and more basic word-based representations provide high-utility text representations, with no significant empirical difference between the two.

Conclusions: Different factors affect the publication of a registered clinical trial. Our approach to predictive modeling combines heterogeneous features, both structured and unstructured. We show that methods from natural language processing can provide effective textual features to enable more accurate prediction of publication success, which has not been explored for this task previously.

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KEYWORDS

clinical trials; study characteristics; machine learning; natural language processing; pretrained language models; publication success

Introduction

Background

Rigorously conducted randomized controlled trials provide the highest level of scientific evidence, enabling medical practitioners to provide better care for patients and ultimately improving public health. Available, findable, and accessible clinical research results are necessary for the successful transfer of findings into evidence-based practice and further research [1]. In recent years, improved clinical trial registration has meant that more trials than ever are now discoverable and searchable according to a variety of metadata. However, registration does not offer detailed information about important aspects of the study execution and results, such as specification of outcomes and pointers to all resulting publications [2]. Scientific publications resulting from completed clinical trials offer a means of disseminating the findings comprehensively, which is essential for supporting subsequent clinical trials, increasing possibilities for research collaboration, and advancing medical practice and research [3]. In addition to research results, detailed information about the study methods provided in publications is also critical to appraising the validity, reliability, and applicability of clinical evidence in clinical practice [4].

Despite the importance of publication, many clinical trials are never published. Estimates of the publication rate of trials vary depending on the medical area and length of the follow-up period. Broadly, publication rates are in the range of 52% to 77% [5-8]. On the basis of a shorter follow-up period of 30 months from clinical trial completion, the rates tend to be lower, at approximately 11% to 46% [3,6,9]. When results are not published, are substantially delayed, or are published selectively based on the direction or strength of the findings, the ability of health care professionals and consumers to make informed decisions based on the full body of current evidence is impeded [10,11]. Such gaps in the evidence base can lead to the use of ineffective or harmful interventions and potentially waste scarce health care resources. In a study by Eyding et al [12] on the treatment of depression, it was found that, when unpublished studies were included in a meta-analysis, the antidepressant reboxetine had more adverse effects but no better efficacy than placebo for treatment of major depression, a different finding from that when only published studies were included. Additional ethical concerns have also been raised by some researchers [7,13], highlighting that, in the case of nonpublication, the trial participants are still exposed to the risks of participation but without the societal benefits resulting from the dissemination of study results.

In this work, we explore the factors affecting publication of the outcomes of individual clinical trials through the tool of predictive modeling of clinical trial–publication outcomes based on a large data set of clinical trials and associated literature. The adoption of this approach provides a mechanism for both predicting the publication outcome of a given trial and identifying the key factors driving those outcomes.

Existing Work and Contributions

Publication Outcome Studies

Many studies have addressed the publication rates of clinical trials and the factors influencing them. However, previous studies used different statistical analysis methods to examine the association between study characteristics and the publication outcome of a clinical trial. The available studies either analyzed a small number of clinical trials (in the order of hundreds) [3,7,14] or included only clinical trials with specific populations (eg, children or patients with cancer [5,15,16]). Conversely, in our work, we focused on approaching the modeling of publication outcomes *through a predictive lens*, although we also provided a descriptive analysis to better characterize the data set that we developed. Our analysis examined factors that may affect the publication outcome without any constraints regarding the population or medical specialty and, therefore, was more general.

A number of studies have focused on analyzing and remedying the quality of linkage between ClinicalTrials.gov and PubMed [17-22]. The presence of incomplete links may hamper efforts to measure publication and outcome reporting biases and identify relevant trials for systematic reviews. As a result of this, semiautomated methods that rank articles using natural language processing (NLP) techniques and allow humans to scan the top-ranked documents are valuable in supporting the effective identification of clinical trial publications [17,18].

Factors Affecting Publication

A variety of factors have been identified as influencing publication outcome, which can be summarized as follows: (1) large clinical trials and those with noncommercial funding are more likely to be published [8,13,23]; (2) industry-funded clinical trials are less likely to appear as publications [7]; (3) the likelihood of publication is associated with the direction and significance of study findings [11,24], although whether to assign this publication bias to rejection by journals or the lack of time and interest by the investigators has been disputed [7]; (4) place of conduct of the research may affect the odds of publication [23]; (5) some fields have higher publication rates, for example, neurology and psychiatry [13] (this may in certain cases be related to the existence of subareas, eg, vascular neurology, with niche journals allowing for easier dissemination [25]); and (6) lack of time and resources by the authors, and even disagreement between coauthors, have been mentioned as potential factors in the literature [26] but are not captured directly in the description of clinical trials and, therefore, are difficult to quantify.

Completion Status and Drug Approval Studies

Although we are not aware of any work that analyzes publishability within a predictive framework, several related

problems have been treated as classification problems [27-29]. One such task is predicting the completion of a clinical trial. Noncompletion can be seen as similar to nonpublication in terms of undesired consequences. A clinical trial that is not completed typically still involves significant financial resources, so it would make sense to ensure that decision makers are aware of the likelihood of termination or nonpublication in the early stages of a clinical trial, potentially allowing for changes in the study design. Admittedly, having such predictive power would mean that the decision makers are shouldered with the additional responsibility of considering the potential for nonpublication and have the ability to interpret the output of such predictive models. Care would also need to be taken on an ongoing basis to mitigate potential biases in the model and its use [30,31].

Another task related to publication outcome prediction is whether a drug intervention studied in a clinical trial will result in the approval of the drug. Machine learning (ML) over structured data has been explored in this context [32-34], relying on features pertaining to drug and trial characteristics as well as those covering commercial figures relating to indication. Lo et al [33] proposed a large data set consisting of approval outcomes of >6000 drug-indication pairs across almost 16,000 phase-2 trials. Although this represents the largest data collection for applying supervised ML to drug approval, our task was more general (concerning clinical trials without needing to identify drug-indication pairs), allowing us to include an even larger number of clinical trials paired with publication outcomes.

In contrast to descriptive studies on publication status, studies on trial completion and drug approval do include textual inputs from trial descriptions in the modeling, which leads to better sensitivity and specificity than using structured features alone [27,35]. These studies generally use relatively simple methods to represent text. Elkin and Zhu [27] included word-embedding features [36,37] in predicting trial completion but only used static word representations rather than more advanced contextualized word representations derived from pretrained language models [38,39]. In drug approval prediction, features constructed over unstructured input data have been studied by Feijoo et al [35], who focused on predicting drug transitions across clinical trial phases. The authors used simple pattern matching to develop an eligibility criteria complexity metric defined in terms of the number of inclusion and exclusion criteria. Although these criteria were shown to be useful (a higher number of criteria has been connected with a higher risk of trial failure), their representation is still rather rudimentary. In our work, we included the eligibility criteria using state-of-the-art NLP techniques that can capture the meaning of the eligibility criteria.

Contributions

We constructed and made available a new data set that provides publication outcomes for trials registered in ClinicalTrials.gov. It is the largest data set of its kind to date.

Predicting the publication status of a clinical trial using numerical, categorical, and textual input features in a single ML model leads to a classification performance of an area under the curve (AUC) of >0.7. We found that textual descriptions of registered trials are an important source of information and are effectively represented using NLP techniques.

We identified a lack of studies investigating publishability within a *predictive* framework. Thus, we confirmed several factors known from *descriptive* studies to influence the publication outcome and identified *new* ones from textual descriptions of clinical trials (eg, eligibility criteria). Our work lays the foundation for a technology that would support trial planning and decision-making by providing, for a given trial, the prominent features that lead to a particular publication outcome. How such technology can best benefit trial developers in increasing the value of their prospective study should be a subject of future research.

Methods

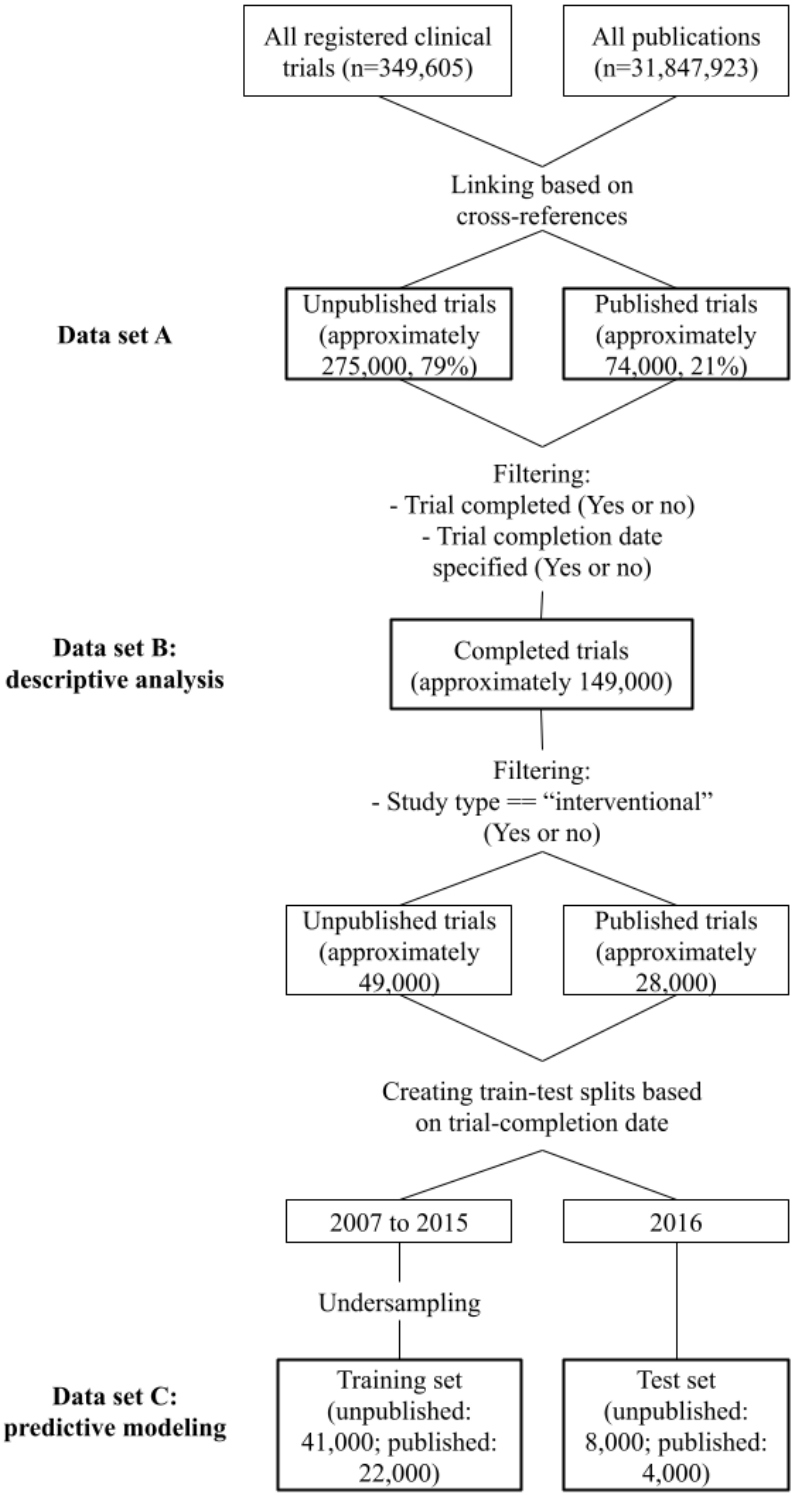
Constructing a Data Set Automatically

We used 2 primary resources in our work: the largest available registry of clinical trials, ClinicalTrials.gov, and MEDLINE, a bibliographic database of academic journal articles. For both data sources, we used the data dumps in XML available as of the start of our study in August 2020 [40,41]. To find out which clinical trials were actually published, we adopted a 2-step procedure and took the union over clinical trial-publication links found at each step. The first step recognized all PubMed article IDs directly listed in the registry of clinical trials. However, as some clinical trials lacked this information, we also looked for clinical trial–related information within the publications themselves (second step). We located that information in MEDLINE inside the databank list, from which we retrieved the clinical trial identifier provided that the databank name equaled “clinicaltrials.gov.” To consider a trial published, we required that there be at least one publication associated with it in MEDLINE. If a trial had more than one associated publication, additional pairs were created for each publication.

The final result was a map between clinical trial IDs and PubMed article ID values (*trial-publication map*). In our data set, the number of clinical trials that had an associated publication was 74,394, and there were approximately 275,000 clinical trials without publication, totaling approximately 349,000 trials (data set A). We illustrate the data creation procedure in Figure 1. We made the mapping openly available to promote further work on this topic.

The complete list of data fields and model features used in our work is shown in Table S1 in Multimedia Appendix 1 [42]. Although most of the features were obtained directly from the trial file, information such as the number of research sites and the number of primary or secondary outcomes was not explicitly stated. Therefore, we added those features as they pertain to clinical trial design and may contain an important signal for the prediction of publication status.

Figure 1. Data set construction.



The data set used in our descriptive analysis and predictive modeling (*data set B*) was based on selecting the instances that satisfied a few additional criteria. Specifically, we filtered out data instances that did not satisfy the following two conditions: (1) the study had both started and been *completed*, with known start and end dates and without "anticipated" status (as the information about a clinical trial may be updated several times after registration, such as updating the enrollment field, which indicates the planned number of participants, the information remains stable after completion, thus increasing the representativeness); and (2) the *completion date* of the study was later than 2006 (to remove older studies whose information was less complete) but earlier than 3 years before our data collection (to allow time for publication, similarly to Jones et al [7] and Ross et al [3]).

Performing these steps reduced the size of the data considerably. The resulting data set was used to obtain the descriptive statistics.

In addition, we constrained the type of study to be *interventional* to obtain the data set used in predictive modeling (*data set C*). We decided to exclude observational studies as they are less common and are characterized by several features that are different from those of interventional studies.

To emulate the real-world scenario of predicting publishability of future trials, we partitioned the data such that the completion dates of all trials in the test set postdated those in the training data set. This also made the task more challenging as we could expect previously unseen interventions in the test set. Finally, we removed all features from each trial record that would not have been known at the time of registration of the trial, such as the trial duration and results. Although including them would simplify the prediction, it would also make the task less realistic. By comparison, we note that, in the related ML task of the drug approval prediction work by Lo et al [33], the authors assumed that the same information about clinical trials *is* accessible. As these features are found to be strong predictors of drug approval, the predictive performance is likely to suffer in the more realistic scenario of this information not being available.

As the number of unpublished clinical trials in data set C was much larger than that of published clinical trials, we randomly undersampled the unpublished trials for our publication prediction experiments. We performed the undersampling by stratifying per completion year, keeping roughly equal percentages of positive and negative labels in each year. Note that we performed this step for the training set only, preserving the real-world label bias in the test set, again to make the task as faithful to reality as possible.

Manually Constructed Test Set

The aforementioned data construction approach provided a large-scale data set that allowed us to analyze and predict the publication status at scale using ML models. However, some links between clinical trials and publications may be incomplete, as we mentioned in the *Existing Work and Contributions* section. Therefore, we gathered data from 3 previously published studies [3,18,20] that included manual publication status annotations (see Table 1 for the statistics). Although the scale of these annotations was smaller than in our automatically constructed data set, because of human effort, it was less likely that the publication of a clinical trial would go unnoticed. We used this data set as an additional test set and also made it publicly available with the permission of the original authors [43].

Table 1. Data from previously published studies. A total of 5 studies were included in more than one original work but received the same annotation. Owing to this, the size of the resulting test set was less than the sum of the sizes of the individual data sets.

	Size	Proportion of positive labels (“published”) out of all
Ross et al [3]	630	0.54
Zarin et al [20]	148	0.23
Dunn et al [18]	199	0.45
Combined	972	0.48

Modeling Approach

To study factors associated with publication status and learn to predict whether a clinical trial is likely going to be published, we created 3 types of features for our models: numerical, categorical (both can be seen as structured inputs), and textual features. The textual features encode a wealth of information that augments the structured information and have the potential to improve predictive modeling, but they are also potentially much noisier. An example of textual fields that can be indicative of publication status are the inclusion and exclusion criteria. A possible link between eligibility criteria, sample size, significant effect, and publication status has been pointed out by Elkin and Zhu [27]. NLP techniques allowed us to extract and represent this information in a predictive model as well as highlight which textual features are important.

As a simple baseline, we used a k-nearest neighbor classifier that only used numerical and categorical features (with no text-based features). At test time, the classifier predicts the predominant label among k training instances that are closest to the test instance in terms of Euclidean distance. Through a random search over various values of k, we settled on k=460.

We trained and evaluated 2 different models that incorporated textual features: a random forest (RF) classifier and a neural network (NN).

For RF, a standard approach to include textual inputs is to convert them into numeric word vectors, extracting both unigrams and bigrams. These terms are weighted using term frequency-inverse document frequency (Schütze et al [44]), whereby the frequency of a term in a document is divided by the proportion of documents that that term appears in within the data set to down-weight common terms. We thresholded the vocabulary by selecting the 20,000 most frequent terms. We used the one-hot encoding method to represent categorical features and included numeric features without additional adaptation. We report other RF details in Multimedia Appendix 2.

In the NN, the categorical features are embedded using a weight matrix that is randomly initialized and updated during training. The textual inputs (examples are included in Table 2) are embedded using pretrained language models that output context-dependent token activations [39], as explained in more detail next.

Table 2. Examples of selected textual features from clinical trial metadata.

Feature name and identifier	Textual excerpt
Brief title	
NCT01309919	Bleeding Patterns and Complications After Postpartum IUD Placement: a Pilot Study
NCT00230971	Study Comparing Tigecycline Versus Ceftriaxone Sodium Plus Metronidazole in Complicated Intra-abdominal Infection (cIAI)
NCT01364948	Effect of Coconut Oil Application in Reducing Water Loss From Skin of Premature Babies in First Week of Life (TEWL) (TopOilTewl)
Brief summary	
NCT01309919	The purpose of the study is to determine the feasibility of placing the levonorgestrel-releasing intrauterine system (LNG - IUS, Mirena®) post-delivery. The investigators will gain information about complications at the time of placement; the investigators will also examine the expulsion rate, side effects, bleeding patterns and subject satisfaction at various time periods after insertion.
NCT00230971	This is a study of the safety and efficacy of tigecycline to ceftriaxone sodium plus metronidazole in hospitalised subjects with cIAI. Subjects will be followed for efficacy through the test-of-cure assessment. Safety evaluations will occur through the treatment and post-treatment periods and continue through resolution or stability of the adverse event(s).
NCT01364948	The skin of newborn infants is immature and ineffective as a barrier. Preterm skin exhibits even more vulnerability to the environment due to poor self regulatory heat mechanisms, paucity of fatty tissue and its thinness. Most preterm babies lose up to 13\% of their weight as water loss from their skin during the first week of life. Many strategies have been utilised by neonatologists to decrease this water loss. Oil application on the skin can act as a non permeable barrier and can help in reducing water loss from the skin. Edible coconut oil, often used for traditional massage of babies by Indian communities, is culturally acceptable and Hence the investigators decided to undertake this study to objectively assess the reduction in water loss from skin after oil application
Inclusion criteria	
NCT01309919	Age 18 years or older, speak either English or Spanish, desire to use an IUD as their postpartum contraception (IUD arm), do NOT desire an IUD as their contraception (Diary Only arm), plan to deliver at Baystate Medical Center
NCT00230971	Clinical diagnosis of complicated intra-abdominal infection that requires surgery within 24 hours. Fever plus other symptoms such as nausea, vomiting, abdominal pain.\\
NCT01364948	All preterm babies born at the study center with birth weight 1500gms were eligible for inclusion in the study.
Participant condition	
NCT01309919	Postpartum period
NCT00230971	Appendicitis, cholecystitis, diverticulitis, intra-abdominal abscess, intra-abdominal infection, and peritonitis
NCT01364948	Trans Epidermal Water Loss (TEWL)
Keywords	
NCT01309919	Intrauterine device, Mirena, levonorgestrel intrauterine system, postpartum contraception
NCT00230971	Intra-abdominal infections, abscess
NCT01364948	Preterm, VLBW, coconut oil application, transepidermal water loss, weight gain

We evaluated the RF and NN classifiers that used textual features compared with those without, in which only structured features were used.

We opted for 2 different encoders: Bidirectional Encoder Representations from Transformers (BERT) [39], pretrained on general-domain English corpora, and BERT for scientific texts (SciBERT) [38], pretrained on the biomedical domain. We used the same idea as Adhikari et al [45], who took the hidden layer output at the sentence-level classification level as the representation of the document. In addition, we used the hidden outputs of the 3 last layers [46] as inputs to the top dense layers of our classifier. To refine the model's representational capacity, we included 2 additional sources of information: positional and segmental. For the first one, a trainable positional embedding [47], which is unique to each token, is added to the token vector to endow the model with a sense of word order. For the second one, a trainable segment embedding helps the encoder discriminate between the multiple, independent textual fields (Table S1 in Multimedia Appendix 1) that are passed to the model as one long string of text. We found the interchangeable segment scheme illustrated in Figure S1 in Multimedia Appendix 1 to work best. Another variation represents each text field with a different segment embedding but works less well, although the difference is small. In addition, an alternative scheme for positional embeddings in which the embedding index is restarted with each text field yields similar results. We took inspiration for that from Herzig et al [48], who used positional embeddings in the context of table parsing to enhance input structuring.

A limitation of the original BERT architecture is that it can only accept sequences of up to 512 tokens. Therefore, we needed to truncate the textual inputs exceeding this limit. We started by

selecting the first n=512/*T* tokens of each field (*T* being the total number of textual fields to encode). As some textual fields can be shorter, we progressively raised *n* across all fields until we reached the maximum number of tokens. Finally, the parameters of the encoder were fine-tuned jointly with the remaining NN parameters on our publication outcome prediction data set, minimizing the cross-entropy loss during training.

In addition to adopting the standard BERT model in the NN, we looked at 2 adaptations of the training regime: a special case when the encoder parameters are left unchanged during training (named "frozen" in the table of results) and a model that receives cased text as input ("cased"; ie, text that has not been previously lowercased), the latter being the most common practice. Finally, for RF, we tested an adaptation that, instead of the term frequency-inverse document frequency encoder, uses language model representations previously induced in the text. These representations were kept fixed throughout the training and testing phases.

Evaluation Details

We evaluated the predictive performance using the F_1-score measure (F_1 = 2 × [P × R / (P + R)]), which is the harmonic mean of precision (P = TP / [TP + FP]; the proportion of trials predicted as published out of all predictions, where TP are true positives and FP are false positives) and recall (R = TP / [TP + FN]; the proportion of trials predicted as published out of all published trials, where FN are false negatives). We also reported the area under the receiver operating characteristic curve (itself indicative of the trade-off between recall and false-positive rate at various thresholds over the predicted probabilities), which was useful in summarizing the classifier's ability to distinguish between classes via a single figure of merit.

Results

Descriptive Analysis

Overview

To obtain a clear idea of the *publication rate* in our data set, we plotted the number of published and unpublished studies per year, as shown in Multimedia Appendix 3. We observed that the number of registered trials was monotonically increasing (with >20,000 trials registered in 2016), but the number of published trials increased less strongly. For trials with an earlier completion year, the publication rate was approximately 45%, whereas, for later trials, it decreased by approximately 10%. For comparison, existing studies on publication rates reported highly variable publication percentages, up to 77% in Huiskens et al [6] and as low as 11% in Chen et al [9] depending on the medical area and length of follow-up considered.

Furthermore, we examined the *time needed to publish*. Analyzing only the published studies, we found a median time to publish of 27 months. We show the distribution of publication times in Figure 2. For a smaller number of trials, it can take much longer to publish, as seen by the long tail on the right of the plot. The previous studies generally reported shorter times of approximately 19 to 23 months [3,9,16].

An additional way of analyzing publication time is to plot the probability that a study will go unpublished for an interval longer than some time *t*. We borrowed here a tool from survival analysis, the Kaplan-Meier plot. By analogy, the survival time in our case represents the time that a clinical trial remains unpublished, and the relevant event is the publication. Some individuals (clinical trials) may be lost to follow-up (right censoring), which is also considered by the method. We see in Figure 3 that, when given a very short period (eg, a few months after completion), the chance is still high that the trial will not be published. When given more time, the probability of nonpublication drops, although it remains fairly high even for very long intervals (at 80 months, it is still >70%).

Figure 2. The distribution of publication times in months.

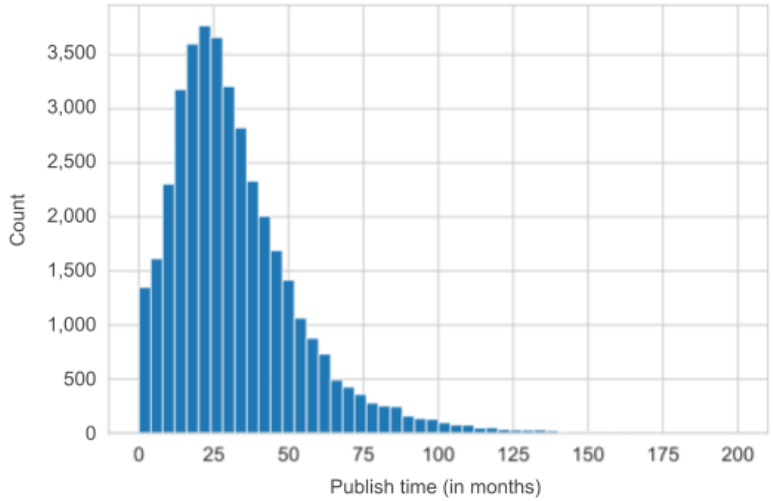
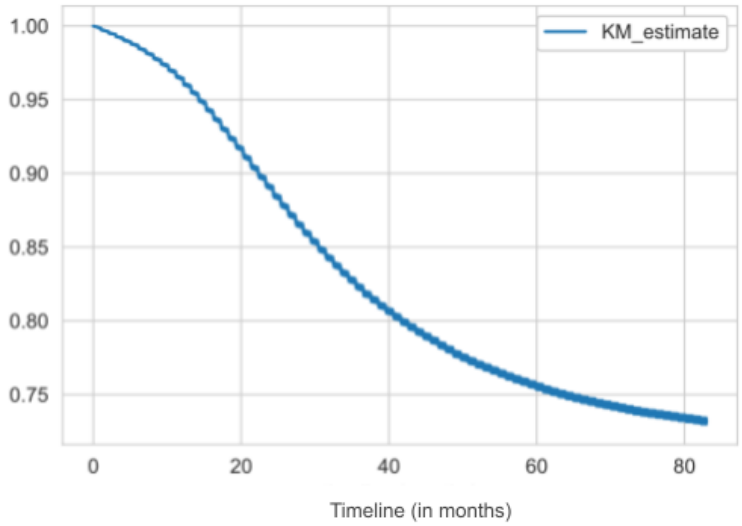


Figure 3. A Kaplan-Meier (KM) plot representing the probability (y-axis) that a trial will go unpublished for longer than the number of months shown on the x-axis.



Association Between Publication Outcome and Categorical Features

To analyze the relationship between a feature and the publication outcome, we applied the chi-square test (in line with the related literature [8,9,14,16,23,49,50]) but, because of its sensitivity to the sample size [51,52], we also carried out the Cramér *V* association test for discrete variables. In this analysis, we followed the related work and focused on categorical features only. In the *Predictive Performance* section, we analyze the importance of all feature types in predictive performance. The results for all categorical features are shown in Table 3. The features with the highest values of *V* include the overall status (eg, a value such as "Suspended" may be indicative of future publication), whether the results were reported, enrollment type (anticipated vs actual), and the phase of the trial (when calculating the odds ratio over different phases of the trial, we found that trials in phase 3 were 2 times more likely to be published than trials in other phases). By contrast, some features such as the type of observational study (retrospective, prospective, or cross-sectional) and the class of funding agency (US National Institutes of Health, other US Federal agencies, industry, or other) can hardly be associated with publication status. The latter example is particularly surprising as most previous works have reported that the source of funding is a strong indicator of publication status [8,23,50], with the exception of Gandhi et al [14].

Table 3. Strength of association between categorical features extracted directly from structured metadata associated with clinical trials and publication status. For the definition of each feature, see Table S1 in Multimedia Appendix 1.

Feature name	Chi-square *P* value	Cramér V
overall_status	.001	0.26
were_results_reported	.001	0.157
enrollment_type	.001	0.153
Phase	.001	0.126
plan_to_share_ipd	.001	0.095
intervention_type_behavioral	.001	0.06
has_dmc	.001	0.056
intervention_model	.001	0.053
intervention_type_diagnostic_test	.001	0.047
has_single_facility	.001	0.044
intervention_type_device	.001	0.039
Country	.001	0.035
study_type	.001	0.034
Allocation	.001	0.026
primary_purpose	.001	0.025
is_fda_regulated_device	.001	0.023
Masking	.001	0.022
intervention_type_dietary_supplement	.001	0.021
intervention_type_biological	.001	0.019
Gender	.001	0.018
intervention_type_combination_product	.001	0.017
intervention_type_other	.001	0.016
intervention_type_radiation	.001	0.013
sampling_method	.001	0.013
intervention_type_drug	.001	0.012
intervention_type_procedure	.001	0.012
observational_model	.002	0.012
is_us_export	.13	0.011
responsible_party_type	.001	0.011
intervention_type_genetic	.001	0.01
healthy_volunteers	.001	0.009
is_fda_regulated_drug	.001	0.009
observational_prospective	.14	0.006
agency_class	.32	0.002

Predictive Performance

Overview

The main results of our predictive models for data set C are shown in Table 4. Interestingly, the k-nearest neighbor baseline already set a high bar for the use of structured inputs. We see that the best performance on the test set was achieved with the models that used textual information. The 2 evaluation metrics show slightly different trends (ie, when looking at F_1-score, the neural models using BERT-based representations performed better than the RF classifier using the bag-of-words representation); however, according to AUC, the RF classifier outperformed different variants of the neural model. Judging by the improvement obtained when including the textual features in both models, the NN model makes more effective use of these features. We found that the difference between the NN model using only structured features and the NN model using SciBERT-encoded text features was statistically significant at

P<.001 (statistic value: 778.4), measured with the McNemar test for binary classification tasks [53]. Although it had a considerably lower performance compared with the RF classifier when including only the structured features, the performance difference between the 2 models vanished when including the textual features. For the neural model, choosing a BERT model with a better domain fit (ie, SciBERT) appears to boost F_1-score, but the differences are too small to make a judgment in the case of AUC. We include the precision-recall curves in Figures 4 and 5, calculated using the predictions of the model that tested best in terms of F_1-score (ie, NN with structured and SciBERT textual features).

Table 4. Results for publication prediction[a].

Method	Input	Validation		Test	
		F_1-score	AUC[b]	F_1-score	AUC
K-nearest neighbor	Structured	0.592	N/A[c]	0.611	N/A
RF[d]	Structured	0.64	0.701	0.614	0.704
RF	Structured+text (TF-IDF[e])	0.656	0.721	0.623	0.719
RF	Structured+text (SciBERT[f])	0.65	0.709	0.63	0.711
NN[g]	Structured	0.611	0.672	0.607	0.612
NN	Structured+text (frozen SciBERT)	0.642	0.689	0.63	0.696
NN	Structured+text (SciBERT)	0.648	0.708	0.641	0.7
NN	Structured+text (cased SciBERT)	0.641	0.697	0.637	0.701
NN	Structured+text (BERT[h])	0.64	0.699	0.633	0.7

[a]All models use categorical and numerical features ("structured"). When textual features are added, this is marked with "+ text." As the k-nearest neighbor classifier does not output probabilities, we cannot calculate the area under the curve.

[b]AUC: area under the curve.

[c]N/A: not applicable.

[d]RF: random forest.

[e]TF-IDF: term frequency-inverse document frequency.

[f]SciBERT: Bidirectional Encoder Representations from Transformers model for scientific texts.

[g]NN: neural network.

[h]BERT: Bidirectional Encoder Representations from Transformers.

Figure 4. Precision-recall curve for the positive class (publication) using the neural network model with structured and textual features from a Bidirectional Encoder Representations from Transformers model for scientific texts. AP: average precision.

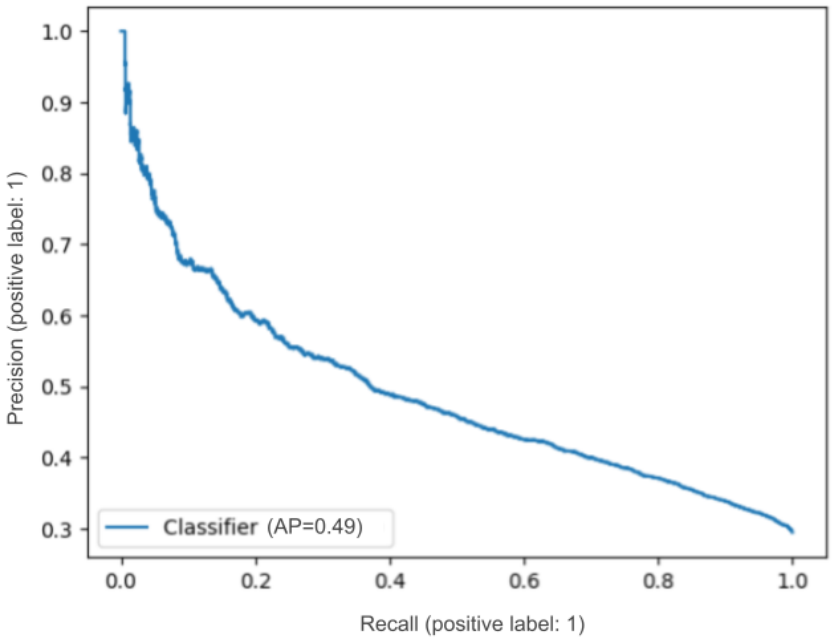
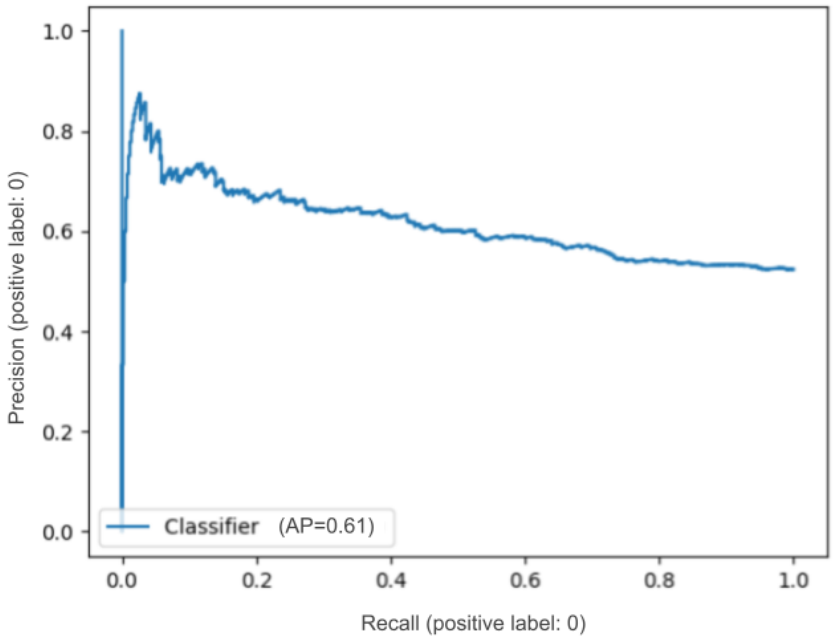


Figure 5. Precision-recall curve for the negative class (nonpublication) using the neural network model with structured and textual features from a Bidirectional Encoder Representations from Transformers model for scientific texts. AP: average precision.



Factors Affecting Publication

To determine which features play a key role in prediction, we used a feature permutation technique to obtain the features ranked by their respective drop in performance. We performed this analysis using RF only because of faster inference times. The classifier is trained once; then, at test time, a corrupted representation of a feature is obtained by shuffling its possible feature values in the test set. After that, the model is applied to the test set, and the drop in accuracy is calculated compared with the performance on the noncorrupted data set. We only corrupted one feature at a time and repeated the process for all features. The entire process was performed 5 times using different random seeds for shuffling, after which the reported scores were averaged.

The results, organized according to feature type, are shown in Table 5. The most significant numerical feature is the number of enrolled participants, with a possible explanation being that it may affect the reliability of the results (thus ultimately increasing the odds of publication). Similarly, a larger number of facilities has been linked to higher publication rates [8]. The number of outcomes indicates the size and complexity of the study, which may in turn also affect publishability. For textual inputs, the narrative describing the trial (the detailed description and brief summary) as well as the eligibility criteria are the strongest features. We observed that some textual features contained overlapping information. For example, the brief title could be subsumed into the official title. The same word often occurred in different inputs, and this redundancy can be a strong indicator for predicting publication status. For example, when we measured the importance of the words in RF using the impurity criterion of our RF implementation [9], we found that the presence of *randomized* (occurring in both the official title and detailed description) was a strong discriminator between published and unpublished studies.

In the case of categorical inputs, we found similar features to be important, as mentioned in the *Descriptive Analysis* section, including the country of the main institution (“country”) and whether the study had a data monitoring committee (“has dmc”). However, some features that were found to be important in our descriptive analysis and in the prior work were less important in the predictive approach (eg, the phase of investigation [“phase”], the allocation of participants to trial arms [“allocation”], and the method used to assign an intervention to participants [“intervention model”]).

Table 5. The drop in accuracy after permuting the values of a feature as measured with random forest using term frequency-inverse document frequency representation of text. The values for each feature type are ranked in decreasing order, so the most important features are mentioned first.

Feature type and feature	Drop in accuracy
Numerical	
number_of_facilities	0.007364
outcome_counts_secondary	0.004911
outcome_counts_others	0.004068
outcome_counts_primary	0.003702
number_study_directors	0.003518
number_study_chairs	0.003359
minimum_age	0.003235
number_principal_investigators	0.003157
maximum_age	0.002719
number_of_arms	0.000985
Textual	
detailed_description	0.010193
brief_summary	0.008551
criteria_Exclusion	0.008313
criteria_Inclusion	0.004971
official_title	0.003428
brief_title	0.001433
Source	0.001342
responsible_party_keywords	0.001064
participant_condition	0.00064
Categorical	
has_single_facility	0.004591
intervention_type_Behavioral	0.004211
primary_purpose	0.003914
Country	0.003804
intervention_type_Biological	0.003643
is_fda_regulated_device	0.003376
is_us_export	0.003333
intervention_type_Diagnostic_Test	0.003322
intervention_type_Combination_Product	0.003322
intervention_type_Genetic	0.003322
is_fda_regulated_drug	0.003321
intervention_type_Procedure	0.003205
has_dmc	0.003185
intervention_type_Other	0.003144
intervention_type_Radiation	0.003144
intervention_type_Device	0.003078
Gender	0.003012
responsible_party_type	0.002925
intervention_type_Dietary_Supplement	0.002873

Feature type and feature	Drop in accuracy
plan_to_share_ipd	0.002819
healthy_volunteers	0.002607
intervention_type_Drug	0.00227
agency_class	0.001854
Phase	0.001426
Allocation	0.001347
intervention_model	0.00131

Performance on the Manually Verified Test Set

As an additional experiment, we took the model that achieved the highest F_1-score on the automatically constructed data set (NN with structured+text [SciBERT] input features) and applied it to the test set built from the manually verified publication links introduced in the *Manually Constructed Test Set* section. We measured an F_1-score of 55.9 and area under the receiver operating characteristic curve of 58.6. To better understand this drop in performance with respect to automatically obtained test sets, we calculated a confusion matrix, which revealed that the model too eagerly predicted "publication" (ie, it was more likely to commit a type-1 error [a false positive, 272/972, 28% of the time] than a type-2 error [a false negative, 146/972, 15% of the time]). As the test data consisted of 3 subsets, there might be important individual variations in the performance that we need to consider. Indeed, splitting the results according to each subset (Table 6), we noticed that the subset from Zarin et al [20] showed lower performance than the subsets from Ross et al [3] and Dunn et al [18], both with similar performance. Our explanation is that these subsets contain varying proportions of positive labels, which, if different from those seen during training, will negatively affect the test performance. Specifically, the Zarin et al [20] subset has only 23% (34/148) of positive labels compared with approximately 50% (410/824, 49.8%) in the remaining subsets. Understandably, the model that was trained on roughly equal portions of positive and negative instances overpredicted the positive class on the Zarin et al [20] subset, and almost all modeling mistakes in this case were due to false positives (78/87, 90% compared with 9/87, 10% of false negatives). We found that this negative effect vanished when the model was retrained with a similar ratio of positive to negative instances. We used the nonbalanced version of our training data set (data set C in Figure 1).

Table 6. Data statistics and performance on the subsets of the manually verified test set.

	Ross et al [3]	Zarin et al [20]	Zarin et al [20] with nonbalanced training set	Dunn et al [18]
Percentage positive[a]	54	23	23	45
F_1-score	58.4	43.4	58.2	55.0
AUROC[b]	62.3	52.6	53.5	60.4

[a]*Percentage positive* represents the percentage of instances bearing the positive label (*published*) out of all instances.

[b]AUROC: area under the receiver operating characteristic curve.

Discussion

Limitations

Although our work established at scale the various attributes associated with a higher publication rate and the positive impact of including textual descriptions of clinical trials in a predictive framework, a few additional considerations are necessary.

The qualitative performance of an ML model is sensitive to the quality of the underlying data that are used for training and testing, and predicting publication success is no different. When constructing our data set, we noticed that incorrect information existed in the trial registration entries (eg, the estimated completion year may be set to 2099). In addition, the current status of the study (eg, ongoing, completed, or terminated) may not be always up to date, and this is similar for other registered information. Incompleteness and incorrect information in ClinicalTrials.gov have been examined in the literature [7,54-56], but the precise extent of this is unknown and difficult to estimate, and it would require substantial manual effort to reveal it. We see noise as an integral part of learning from large data collections, similar to the related work (*Existing Work and Contributions* section) that uses structured resources such as ClinicalTrials.gov [27-29,32-34] and to the work on learning under distant supervision [57-59]. As our classifiers used a very large number of training instances and each instance is represented using multiple features, the effect of occasional noise is deemed small.

Another potential source of noise in our automatically constructed data set could stem from the linkage between clinical trials and their publications, which is established automatically and, hence, prone to incorrect or missed links. The data set was also limited to studies that were publicly available and indexed in public resources. Although conference abstracts and other gray literature resources may provide additional context on trial outcomes, they are not typically considered to be formal publications and require ad hoc strategies for collection that are

beyond the scope of our study. Overall, the results presented reflect the most realistic scenario possible based on accessible resources.

Finally, a more general limitation in the modeling of publication outcomes is that it is difficult to capture and quantify the influence of factors that are not available in trial registries but would otherwise be useful, particularly for understanding nonpublication, for example, whether investigators did not have enough time to publish and instead focused on other tasks, whether there were changing interests or disagreements between coauthors, whether researchers believed that a journal was unlikely to accept their work, and whether financial problems or other contractual issues prevented publication [15,60-62]. Although such information is obtainable from study authors in principle, it would be extremely difficult to carry out such information acquisition at scale, and it is not currently available in public resources.

Impact

In this study, we sought to simulate a real-world situation in which a prospective estimate is desired regarding the publication outcome of a clinical trial. To this end, we carried out a set of experiments on the newly created data set that linked clinical trial records from the period of 2007 to 2016 with their publications, if they existed, with a follow-up period of 4 years. The resulting data set represents the largest such collection available to date. We have shown how a combination of heterogeneous features—including text features derived from the clinical trial registry record—can lead to a classification performance of >0.7 AUC; this means that, if one randomly selects a case that is positive (ie, a trial that will eventually lead to publication), there is at least a 70% chance that the case is also classified as such. This technology has strong potential to be used in trial design. It can provide a prospective estimate of publishability in the early stages of a clinical trial when the properties of the study design and environment are already known, more broadly giving an indication of the viability of the trial. The tool could reveal to trial developers the different areas suggestive of lowered publication chances (and, by extension, of a reduced value of their study) before wasting resources unnecessarily. In future work, we will explore the incorporation of this model into a system that can effortlessly and in a human-friendly way provide, for a given trial, the prominent features that lead to a particular outcome, as well as indicate the reliability of the classifier's decision, to support trial planning and decision-making.

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Data Availability

We have made the data set publicly available [63].

Authors' Contributions

SW collected the data, conceived and designed the analysis, and performed the analysis. SŠ conceived and designed the analysis, contributed to conceptualization, and wrote the paper. TB conceived and designed the analysis, contributed to conceptualization, wrote the paper, and supervised. KV contributed to conceptualization and wrote the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Text-representation scheme.
[PNG File , 98 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Experimental details.
[DOCX File , 13 KB-Multimedia Appendix 2]

Multimedia Appendix 3

The distribution of published and unpublished trials per year of completion.
[PNG File , 33 KB-Multimedia Appendix 3]

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Abbreviations

AUC: area under the curve
BERT: Bidirectional Encoder Representations from Transformers
ML: machine learning
NLP: natural language processing
NN: neural network
RF: random forest
SciBERT: Bidirectional Encoder Representations from Transformers model for scientific texts

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Original Paper

Web-Based Short Video Intervention and Short Message Comparison of Repeat Blood Donation Behavior Based on an Extended Theory of Planned Behavior: Prospective Randomized Controlled Trial Study

Qiuyue Hu, MD; Wei Hu, MD; Wenjuan Han, MD; Lingling Pan, MPH

Blood Center of Zhejiang Province, Hangzhou, China

Corresponding Author:
Lingling Pan, MPH
Blood Center of Zhejiang Province
789 Jianye Road, Binjiang District
Hangzhou, 310052
China
Phone: 86 13588809060
Email: panbbs@163.com

Abstract

Background: Although blood is an indispensable and important resource for clinical treatment, an imbalance between supply and demand may occur as the population ages and diversifies. Studies indicate that repeat blood donors are safe blood sources because of their voluntary blood donation education and frequent blood screening. However, the high rate of reduction in the number of first-time voluntary blood donors and low rate of repeated blood donation are common problems worldwide.

Objective: This study aimed to evaluate the effect of an intervention in nonregular blood donors using web-based videos and SMS text messages, in which the former was guided by the extended theory of planned behavior, to discover effective intervention methods to improve repeat blood donation rates among nonregular blood donors.

Methods: A total of 692 nonregular blood donors in Zhejiang province were randomly divided into intervention and control groups. The control group received regular, short reminder messages for a 6-month period, whereas the intervention group received web-based videos on the WeChat platform. The intervention group was guided by an extended theory of planned behavior, which included 9 factors: the respondents' attitude, subjective behavioral norms, perceived behavioral control, the willingness to donate blood, outcome expectations, self-identity, blood donation–related anxiety, cognition of the blood donation environment, and previous blood donation experience. The intervention group was divided into 2 stages: those with an intervention at 3 months and those with a follow-up 3 months later. After 6 months, the redonation rate was evaluated for the 2 groups, and the scale in the intervention group was determined both before and after the intervention. A *t* test, chi-square test, logistic stepwise regression, and ANOVA were performed.

Results: The intervention group's redonation rate was 16.14%, which was significantly higher than the control group's redonation rate of 5.16%; $P<.001$. Men who were aged 31 to 45 years and had donated blood twice had a higher redonation rate after the web-based video intervention than after the SMS text messages; $P<.05$. The repeat donors' improved blood donation anxiety ($P=.01$), outcome expectations ($P=.008$), and cognition of the blood donation environment ($P=.005$) after the intervention were significantly higher than those of the nonrepeat donors.

Conclusions: The web-based short video intervention based on the extended theory of planned behavior can effectively improve redonation rates. Outcome expectations, blood donation anxiety, and cognition of the blood donation environment can directly influence irregular blood donors to redonate blood.

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KEYWORDS

extended theory of planned behavior; repeated blood donation intervention; randomized controlled trial; mobile phone

Introduction

Background

Although blood is an indispensable and important resource for clinical treatment, an imbalance between supply and demand may occur as the population ages and diversifies [1]. Studies indicate that repeat blood donors are safe blood sources because of their voluntary blood donation education and frequent blood screening [2-4]. However, the high rate of reduction in the number of first-time voluntary blood donors and the low rate of repeated blood donation among are common problems worldwide. The rate of repeated blood donation in Zhejiang province from 2006 to 2015 was 30.8%, which was lower than the global rate of 50% and fell within the average range of 24.3% to 38.8% in China [5]. Hence, a common challenge—in Zhejiang province as well as nationally and internationally—involves the question of how the rate of repeat blood donations can be increased while ensuring an ample blood supply and safety. Current research on the evaluation, prediction, and behavioral intervention of repeated blood donation behavior is in its infancy. Furthermore, the relationship between personal, psychological, and socioenvironmental factors, among others, and repeated blood donation behavior has been clarified, nor has an authoritative evaluation system been developed to index repeated blood donation intentions [6-8]. The literature has primarily focused on changing blood donation knowledge, attitude, and willingness through education [9,10]. Most methods involve traditional SMS text messages, phone calls, and brochures [11] and lack robustness in methodological reporting [12] and intervention studies on repeated blood donation behavior. Few studies have addressed prospective randomized controlled trials of repeated blood donation intervention.

Objectives

The theory of planned behavior is the most widely used theory to explain behavioral motivation and has consistently demonstrated the ability to predict blood donation intention and behavior [13-17]. This theory posits that human behavior is determined by 3 aspects: the first factor is the consequences of a behavior and the evaluation of these results, which can generate positive or negative attitudes toward the behavior. The second factor comes from the normative expectations of others and the motivation to follow these expectations, namely normative beliefs, which lead to social pressure and subjective norms. The resources and opportunities required for this behavior, as well as their ease of access, are the control beliefs that lead to the third factor, that is, perceived behavioral control. Although a majority of studies have confirmed that the theory of planned behavior can effectively predict behavioral intentions and can significantly improve the explanatory and predictive power of behavioral research, such works also have various shortcomings, such as the omission of socioenvironmental factors and insignificant intervention effects [18,19]. Ajzen [20] observed that if a factor was found to enhance the prediction of an intention or behavior, the theory of planned behavior can extend the factor, forming an extended theory of planned behavior (ETPB). Therefore, this study's initial stage first considers a literature review and a Delphi expert consultation based on the theory of planned behavior's 4 dimensions: attitude, subjective behavioral norms, perceived behavioral control, and willingness. It also explores the expected outcome, self-identity, and blood donation anxiety and environment and ultimately forms an ETPB; further research is incorporated to form a repeat blood donation intention–assessment scale with this theory as the overall guiding framework (Textbox 1).

The "Statistical Report on Internet Development in China" indicates that as of December 2020, China's short videos reached an audience of 873 million people or 88.3% of all netizens [21]. The widespread popularity of these short videos suggests that people generally accept and enjoy them. Currently, videos are widely used in behavioral health interventions, such as patient education for different diseases and patient family care [22-28], but few studies have examined their application in blood donation environments. On the basis of the previous research results on the factors influencing repeated blood donation as guided by the ETPB [28-30], this study designed short videos based on the ETPB; these short videos were presented on the web to nonregular blood donors as repeated blood donation interventions. An exploratory, prospective, randomized, and controlled experiment was conducted to analyze the changes in intermediary variables before and after the intervention period. The results from repeated blood donation behavior were compared with those from the SMS control group to not only analyze the intervention effect but also provide a reference for empirical research in determining the next intervention strategy to ensure repeat blood donation behavior.

Textbox 1. The influencing factor scale of repeated blood donation based on the extended theory of planned behavior.

Factors and the corresponding items

1. Attitude
   a. I think donating blood can save lives.
   b. I think donating blood is a kind of blood storage protection for me and my family.
   c. I feel that giving blood demonstrates my courage.
   d. I think many people in the hospital need blood transfusions and need me to donate blood.
2. Subjective behavioral norms
   a. Most of the people who are important to me think I should donate blood or donate again.
   b. Most of the people who are important to me will support and encourage me to donate again.
   c. Most people I know will evaluate me based on whether I donate blood or donate again.
   d. I think donating blood is about everyone.
3. Perceived behavioral control
   a. The standardized process of voluntary blood donation will not be infected with diseases.
   b. I will pay attention to information on voluntary blood donations (such as those presented on the television, internet, newspapers, or magazines) and will actively acquire knowledge about voluntary blood donation.
   c. Each voluntary blood donation of 200-400 mL is in the normal range and will not damage the body.
   d. I will take the initiative to donate blood because my family, friends, or colleagues donate blood.
   e. I will encourage my family, friends, or colleagues to voluntarily donate blood.
   f. It is my decision to donate blood or continue to donate blood again.
   g. I can meet the necessary conditions, such as good health or a convenient time, among others, to increase the number of blood donations.
   h. If the blood donation experience will be positive, I will donate blood or donate blood again.
   i. If my family can prioritize transfusions as necessary after I donate blood, I will donate blood or donate blood again.
   j. I am confident I will overcome the factors that may prevent me from donating or continuing to donate blood.
   k. The preferential blood donation policy affirmed and encouraged me.
   l. in the next year, I plan to donate blood (or donate again).
4. Blood donation willingness
   a. I believe that I will be able to donate blood or donate blood again within the next year.
   b. Blood donation souvenirs or awards will motivate me to donate blood or donate blood again.
   c. In the next year, I will definitely donate blood (or donate again).
5. Outcome expectations
   a. If I donate blood again, more patients will be treated.
   b. If I donate blood again, I can set a good example for others.
   c. If I donate blood again, I will gain more recognition and respect.
   d. Voluntarily donating blood at regular intervals (6 months or more) is good for your health.
   e. If you do not donate blood, or do not continue to donate blood, you are likely to regret it in the future.
6. Self-identity
   a. I am the type of person who will donate blood (or continue to donate blood).
   b. I believe it is appropriate in every way for someone like me to donate blood (or donate blood again).
   c. Donating blood is a way of realizing one’s self-worth.
7. Donation anxiety
   a. I am concerned that my physical condition does not meet the blood donation requirements.

b. Dissatisfaction with the blood donation experience, whether when I have donated blood or heard from others, causes me to worry about donating blood.

c. If I am asked to donate blood or donate blood again, I will feel distressed and anxious.

8. Cognition of the blood donation environment

a. The blood donation environment looks clean and comfortable.

b. The blood donation environment looks safe.

c. The blood collection staff at the donation site are highly skilled.

d. The blood donation site's hours of operation are convenient for me.

e. The blood donation site's staff were friendly.

f. The blood donation site's location was convenient for me.

g. I have seen promotional materials for blood donation in the media.

9. Previous blood donation experience

a. Have you ever felt unbearable pain when donating blood?

b. Have you ever experienced dizziness, weakness, or a mild headache during or after donating blood?

c. Have you ever felt nervous when donating blood?

Methods

Research Design

This was a prospective, single-blind, randomized study. SMS text messages from the Zhejiang provincial blood management information system were sent to eligible, nonregular blood donors, inviting them to participate in the study. The text messages included an invitation letter and a research link. Blood donors who were willing to participate could click the link to obtain detailed information, such as the research objective and content, notice of informed consent, and the research group's contact information. Participants were randomly assigned to either a web-based intervention group or a SMS control group. As blood donors in China have a minimum interval of 6 months between donations, the study's SMS control group received a regular reminder SMS within the 6-month interval. The web-based intervention group was analyzed across 2 phases: the intervention period, or the first 3 months, and the follow-up period, or the next 3 months. A baseline survey was conducted using the scale before the intervention and reassessed using the same scale at the end of the intervention period. This scale's outcome measures were the 9 ETPB factors: attitude, subjective behavioral norms, perceived behavioral control, willingness, outcome expectations, self-identity, blood donation anxiety, the blood donation environment, and previous blood donation experience. At the end of the 3-month follow-up period, blood donation results of the intervention and control groups were tracked using the Zhejiang provincial blood management information system. We hypothesized that the blood donors who received the web-based intervention would donate again more often than those in the SMS control group, as mediated by increases in the 9 ETPB factors. The study protocol was approved by the ethics review committee of the Zhejiang provincial blood center.

Study Participants, Exclusion and Inclusion Criteria, and the Recruitment Method

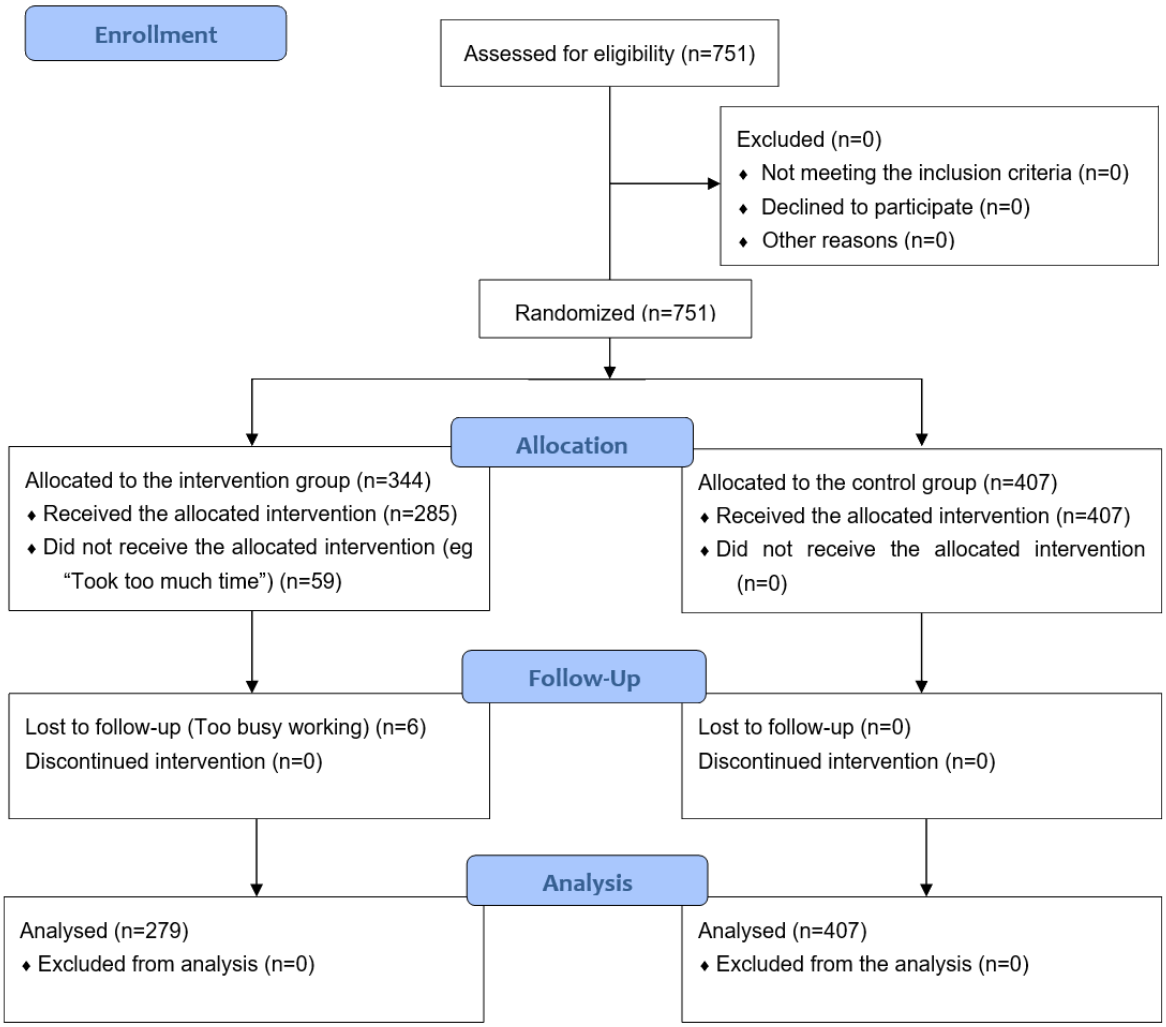
According to the World Health Organization's definition, regular blood donors are those who donated blood >3 times and at least once in recent year [31]. This study examines nonregular blood donors; for the convenience of observation, the inclusion criteria were blood donors aged 18 to 55 years, with current physical conditions meeting the requirements for blood donation, and who meet at least one of the following conditions: (1) donated whole blood in 2019 and did not donate again in 2020, consistent with the category of "*lost donor*" or "*those who donated blood at least once in the past 24 months but did not donate blood in the past 12 months*" [32]; or (2) whole-blood donors with fewer than 3 blood donations and who have not donated blood in the last 6 months, including first-time blood donors who had not donated blood in the past. Respondents were excluded if (1) their current physical condition did not meet the blood donation requirements and (2) they were "regular" blood donors or had donated blood at least 3 times and at least once in recent year.

According to the Zhejiang province's blood donation statistics in 2017 based on the Zhejiang blood information system, approximately 5% of blood donors had repeatedly donated blood within 6 months after meeting the blood donation interval requirement in Zhejiang province, or specifically, the control group's repeat blood donation rate was 5%. This study assumes that the intervention could consequently increase the repeat blood donation rate by at least 10% [33]. To detect a minimum 10% difference between the control and intervention groups, the repeat blood donation rate of the latter group was expected to be 15%. The target sample size of each group was calculated to be 141 (α=.05, β=.8). The estimated loss to follow-up rate was 25%; thus, the minimum sample size of each group was 176.

From March 9 to 15, 2021, an invitation was texted to all the research participants who met the inclusion criteria. All the 751

respondents who agreed to the invitation were coded by a computer and randomly divided into the web-based intervention (344 people) and SMS control groups (407 people; Figure 1).

Figure 1. Flow diagram.



Measurement

Web-Based Intervention Methods

Two outcome indicators were used for the web-based intervention: (1) the 3-month period from March 15 to June 15, 2021, was the intervention period, and the changes in the 9 influencing factors before and after the intervention were measured using the same scale and (2) from June 15 to September 15, 2021, the 3-month follow-up period after the intervention period ended, included an investigation of whether the participants donated blood again.

Baseline Measurement and Postintervention Reassessment

On the basis of the previous research results, this study adopted the "Repeated Blood Donation Influencing Factors Scale Based on ETPB" (or the "ETPB scale" hereafter) [30], which consists of 9 factors and 44 items. The responses were measured on a 5-point Likert scale and ranged from "strongly disagree" to "strongly agree." On March 15, 2021, the ETPB scale was sent to the web-based intervention group to collect the participants' baseline data. On June 15, the day the intervention ended, the same scale was sent again to measure the postintervention results.

Short Videos Based on the ETPB Elements and Short Videos Regularly Sent on the Web

The primary web-based intervention method involved sending weekly short videos, which were designed based on the ETPB elements, and timely web-based responses to questions from blood donors. This study used smartphones as the carrier because they are characterized as convenient, low cost, and unlimited by time and space, with positive effects, strong communication ability, and high acceptance [34-37]. Moreover, WeChat was chosen because it is easy to operate and free to use and because China's mainstream social media platform is the most widely used instant messaging tool [38,39]. This study's web-based intervention WeChat group was equivalent to a small internet-based community. The respondents could view this study's videos in real time, which facilitates the reception and reading of information and reduces disturbances to daily life while being highly interactive. The group could publicly respond to various frequently asked questions, such as those regarding blood donation locations and policies and how

long after vaccination one can donate blood, and eliminate similar doubts among other blood donors.

This study adopted group announcements, real-time communication, and group agency methods in WeChat groups after sending videos. The respondents click a button to complete a group chat after watching a video to let the researchers know that they have watched it. The short videos used in this study were between 45 seconds and 2 minutes in length. Studies have indicated that periodic reminders can encourage the occurrence and persistence of healthy patient behaviors [40-42]. Table 1 displays this study's short video content and the arrangement of the web-based intervention group.

Table 1. Web-based intervention videos' content and distribution schedule.

Intervention factor	Corresponding short video content	Description	Implementation date
Attitude	1. Why donate blood?	Letting blood donors understand the practical significance of donating blood to save others and promoting change in blood donation attitudes, from opposition and indifference to approval and understanding	Week 1
Self-identity	1. College students' blood donation stories 2. The blood donor family's donation story	Self-identity is an important part of self-awareness and the core self-regulatory system in self-awareness. In the human social environment, the process of becoming a qualified social member is inseparable from the growing maturity of self-awareness. This study uses college students' blood donation and family blood donation experiences to stimulate blood donors' self-identity regarding blood donation	Week 2
Cognition of blood donation environment	1. The blood donation environment (such as the most beautiful and digital blood donation site)	Sending a video depicting the most esthetic, state-of-the-art blood donation environment to convey the concepts of safety, hygiene, cleanliness, warmth, and convenience	Week 3
Blood donation anxiety	1. Responses regarding blood donation misconceptions 2. Why is there a charge for donating blood? 3. Blood donation knowledge	In providing relief to potential donors by eliminating misunderstandings, this study adopts a face-to-face attitude, with open and candid communication and response methods to reduce or alleviate the blood donors' anxiety	Week 4
Subjective behavioral norms	1. Stories of regular blood donor representatives 2. Volunteer service	Addressing blood donors' perceived normative expectations set by others and their motivation to follow those expectations; the video demonstrates that donating blood, as a part of service and selfless dedication to others, can bring spiritual satisfaction and joy and relieve the external pressure that blood donors experience	Weeks 5 and 6
Outcome expectations	1. Blood donation care policy 2. Blood donors get direct fee waived after transfusion 3. One blood recipient's college car accident story and a Rh-negative recipient's story	Sending videos of real cases where blood recipients have had their lives saved because of blood transfusions and communicating that timely blood transfusions can avoid the negative consequence of patient death; furthermore, post–blood donation results can include social honors and other care policies that can be enjoyed after donation	Weeks 7 and 8
Previous blood donation experience	1. Precautions taken for donating blood 2. The donation process 3. From one blood vessel to another, 3 topics: the blood source, detection, and blood preparation and supply	Sending videos to reshape the blood donors' scientific concept of blood donation and view such experiences as adverse reactions in previous blood donation experiences from a scientific perspective	Weeks 9 and 10
Perceived behavioral control	1. Reach out to donate blood 2. People who have donated blood many times show up 3. The first blood donation experience	By addressing the blood donor's awareness of whether they can donate blood again, the video enhanced the blood donor's confidence in their ability to donate blood again	Week 11
Blood donation willingness	1. Call for blood donations	The final week's video reinforces the significance of blood donation as conveyed in the discussion of the first factor. This will hopefully spur recipients to action and change blood donors' awareness and influence them to donate blood again	Week 12

Method for the SMS Control Group

In the SMS control group, only regular interval reminder messages were sent during the 6-month period. The content primarily thanked the blood donors for their selfless dedication, warmly reminded them that they have met the minimum required donation interval, and invited them to donate blood again. No other intervention methods were used, such as communication through the telephone or internet. The respondents promised

not to watch blood donation–related videos or read similar material during the study.

Statistical Methods

As SPSS (version 23.0; IBM Corp) software was used to organize the data, the measurement data were expressed as "mean (SD); x [s])," and the count data were expressed as a percentage (%). Furthermore, this study's statistical analysis was conducted through a chi-square test, 2 independent sample *t* tests, an ANOVA, and a logistic stepwise regression, among other methods. The results were statistically significant ($P<.05$).

Ethics Approval

This study was approved by the Regional Ethics Committee of the Blood Center of Zhejiang Province (approval number 2019-019). This study was conducted with the framework of randomized controlled trial, which was in full compliance with the CONSORT guidelines. In terms of content, it has no clinical trials, no human trials, no human samples, no medical records and other information, no human blood samples, pathological phenomena, disease etiology and pathogenesis, no disease prevention, diagnosis, treatment and rehabilitation information, and will not have any adverse effects on the human body. As this study was an observational study, we did not register in the Chinese Clinical Trial Registry. No personal privacy or medical information that can identify the blood donors and commercial interests will be disclosed.

Results

Overview

The average age of the participants in this study was 30.47 (SD 9.76) years, approximately 70.4% (487/692) of the participants were male, and the frequency of blood donation was mostly once (481/692, 69.5%) and twice (173/692, 25%). Responses of "*never*" and "*three or more times*" were included only in the intervention group. At the end of 6 months, the intervention group's blood donation rate was 16.1% and that of the SMS control group was 5.2%. The chi-square test ($c^2_1=23.1$; $P<.001$) results indicated that the difference in repeated donation rates between the groups was statistically significant (Table 2).

Table 2. Participants' demographic and donation information collected during the intervention period[a].

Items	Web-based intervention group (n=285), n (%)	SMS group (n=407), n (%)
Sex		
Male	198 (69.5)	289 (71)
Female	87 (30.5)	118 (29)
Intersex	0 (0)	0 (0)
Age (years)		
18-25	159 (55.8)	98 (24.1)
26-30	48 (16.8)	71 (17.4)
31-35	27 (9.5)	70 (17.2)
36-40	17 (6)	70 (17.2)
41-45	14 (4.9)	84 (20.6)
46-55	20 (7)	14 (3.4)
Number of previous blood donations		
0 time	24 (8.4)	0 (0)
1 time	130 (45.6)	351 (86.2)
2 times	117 (41.1)	56 (13.8)
≥3 times	14 (4.9)	0 (0)
Number of people who donated blood again within 6 months of observation period	46 (16.1)	21 (5.2)

[a]Chi-square test of the blood donation rate for the intervention and control groups during the observation period; $c^2_1=23.1$; $P<.001$.

Comparative Analysis of the 2 Groups

According to whether the participants in the web-based intervention and SMS control groups donated blood again during the study period, they were divided into the "redonating" and "nonredonating" groups, respectively. The results revealed that male blood donors who were aged 31 to 45 years and had donated twice in the past exhibited significant differences in their response to the text messages and web-based intervention, and the redonation rate was higher among such participants in the web-based intervention group (Table 3).

Table 3. Comparative analysis of repeat and nonrepeat donors in the SMS control and web-based intervention groups during the observation period.

Items	SMS group		Web-based intervention group		Chi-square (*df*)	*P* value
	Repeat donation (n=21), n (%)	Nonrepeat donation (n=386), n (%)	Repeat donation (n=46), n (%)	Nonrepeat donation (n=239), n (%)		
Sex						
Male	13 (62)	276 (71.5)	36 (78)	162 (67.8)	24.3 (1)	<.001
Female	8 (38)	110 (28.5)	10 (22)	77 (32.2)	1.4 (1)	.24
Intersex	0 (0)	0 (0)	0 (0)	0 (0)	N/A[a]	N/A
Age (years)						
18-25	5 (24)	80 (20.7)	17 (37)	142 (59.4)	1.6 (1)	.21
26-30	7 (33)	64 (16.6)	10 (22)	38 (15.9)	2.8 (1)	.09
31-35	3 (14)	68 (17.6)	6 (13)	21 (8.8)	5.6 (1)	.02
36-40	1 (5)	67 (17.4)	4 (9)	13 (5.4)	8.3 (1)	.004
41-45	5 (24)	68 (17.6)	7 (15)	7 (2.9)	14.9 (1)	<.001
46-55	0 (0)	39 (10.1)	2 (4)	18 (7.5)	1.6 (1)	.22
Blood donation times						
0 time	0	0	0	24 (10.0)	N/A	N/A
1 time	17 (81)	334 (86.5)	12 (26)	118 (49.4)	3.2 (1)	.07
2 times	4 (19)	52 (13.5)	30 (65)	87 (36.4)	8.2 (1)	.004
≥3 times	0 (0)	0 (0)	4 (9)	11 (4.6)	N/A	N/A

[a]N/A: not applicable.

Results of the Theory of Planned Behavior Scale Comparison in the Web-Based Intervention Group Before and After the Intervention

After the intervention and verification of the respondents' information, it was determined that 279 people completed both the baseline and postintervention surveys. The statistical results presented in Table 4 indicate the clear effects of the web-based intervention. The 9 factors—specifically, participants' attitude, subjective behavioral norms, perceived behavioral control, blood donation willingness, expectation of the results, self-identity, blood donation anxiety, cognition of the blood donation environment, and previous blood donation experience—were significantly improved.

Table 4. Comparison of the survey results of the theory of planned behavior scale before and after intervention in the web-based intervention group.

Factor	Before, mean (SD)	After, mean (SD)	*t* test (*df*)	*P* value	Improved, mean (SD)	95% CI
Attitude	17.36 (2.338)	18.19 (2.234)	4.770 (278)	<.001	0.84 (2.292)	0.49-1.18
Subjective behavioral norms	14.9 (2.898)	16.22 (2.974)	5.940 (278)	<.001	1.32 (2.91)	0.88-1.76
Perceived behavioral control	51.82 (5.772)	54.44 (6.165)	5.858 (278)	<.001	2.62 (5.848)	1.74-3.50
Blood donation willingness	20.79 (3.114)	22.04 (3.168)	5.697 (278)	<.001	1.25 (2.859)	0.81-1.68
Outcome expectations	12.99 (1.71)	13.66 (1.535)	5.732 (278)	<.001	0.66 (1.507)	0.43-0.89
Self-identity	16.2 (3.274)	17.55 (6.138)	2.755 (278)	.007	1.35 (6.348)	0.38-2.31
Blood donation anxiety	12.46 (1.941)	13.27 (1.802)	6.234 (278)	<.001	0.82 (1.717)	0.56-1.08
Cognition of the blood donation environment	27.25 (4.464)	29.82 (4.138)	9.128 (278)	<.001	2.57 (3.686)	2.02-3.13
Previous blood donation experience	10.82 (2.646)	11.25 (2.855)	2.613 (278)	.01	0.22 (2.745)	0.2-0.63
Total	184.56 (21.124)	196.19 (21.986)	8.931 (278)	<.001	11.64 (17.039)	9.07-14.21

Comparison of Variables Before and After the Intervention for Blood Donors With Different Blood Donation Times in the Web-Based Intervention Group

The respondents in the web-based intervention group were further divided into groups based on the number of times they had donated blood in the past: none, once, twice, or ≥3 times. Statistically significant differences were observed between the groups in the factors blood donation anxiety, cognition of the blood donation environment, and previous blood donation experience. The willingness to donate, blood donation anxiety, and cognition of the blood donation environment improved the

most in the group with 2 donations, and the difference between the groups was statistically significant. In terms of cognitive improvement regarding the respondents' past blood donation experiences, the group with 1 donation showed greater improvement than the other groups, with a statistically significant difference between the groups (Table 5).

Table 5. Comparison of variable changes in blood donors with different blood donation times after the web-based intervention.

Factor	0 time, mean (SD)	1 time, mean (SD)	2 times, mean (SD)	≥3 times, mean (SD)	*F* test (*df*)	*P* value
Attitude	0.63 (2.018)	0.69 (2.303)	0.98 (2.201)	−0.40 (3.376)	1.673 (282)	.17
Subjective behavioral norms	1.21 (3.464)	1.04 (3.002)	1.63 (2.705)	0.20 (4.873)	1.358 (282)	.26
Perceived behavioral control	3.17 (5.239)	2.46 (5.203)	3.04 (4.800)	−1.07 (11.835)	2.484 (282)	.06
Blood donation willingness	0.33 (3.046)	0.89 (3.148)	1.57 (2.595)	−0.40 (4.469)	2.845 (282)	.04
Outcome expectations	0.42 (1.613)	0.45 (1.576)	0.71 (1.527)	0.27 (1.668)	0.822 (282)	.48
Self-identity	−0.67 (2.729)	0.00 (4.334)	0.01 (3.121)	0.40 (2.501)	0.315 (282)	.82
Blood donation anxiety	−0.46 (2.126)	0.66 (1.749)	1.00 (1.698)	−0.13 (1.685)	5.637 (282)	.001
Cognition of the blood donation environment	1.25 (3.904)	1.17 (3.657)	3.16 (3.626)	1.73 (4.284)	6.166 (282)	<.001
Previous blood donation experience	−1.54 (3.189)	0.34 (3.087)	−0.17 (2.857)	−0.33 (2.870)	2.796 (282)	.04
Total	4.33 (13.786)	7.7 (18.078)	11.93 (14.852)	0.27 (26.980)	3.210 (282)	.02

Postintervention Variable Comparison of Repeat and Nonrepeat Donors in the Web-Based Intervention Group

According to whether they donated blood again after the intervention in the subsequent 6-month period, the respondents in the web-based intervention group were divided into 2 groups, and the differences in the changes in the 9 variables were compared and analyzed. Table 6 reveals that the blood donors who chose to donate blood again after the intervention exhibited a greater improvement in the "outcome expectation" and "blood donation anxiety" variables; compared with nonrepeat donors, the difference was statistically significant.

Furthermore, with the blood donation result again as the dependent variable, age, gender, blood donation frequency, and the 9 intermediary variables were included as independent variables. A logistic stepwise regression indicated that improvements to the "outcome expectations" and "blood donation environment" factors can increase the possibility that nonregular blood donors will donate again, with statistical significance (Table 7).

Table 6. Analysis of the degree of change in variables among the repeat and nonrepeat donors in the web-based intervention group after the intervention.

Factor	Nonrepeat donors, mean (SD)	Repeat donors, mean (SD)	*t* test (*df*)	*P* value
Attitude	18.19 (2.096)	18.34 (2.854)	0.441 (283)	.66
Subjective behavioral norms	16.36 (2.971)	16.24 (3.226)	−0.25 (283)	.80
Perceived behavioral control	54.19 (5.543)	54.85 (7.430)	0.693 (283)	.49
Blood donation willingness	21.88 (3.184)	22.35 (3.466)	0.889 (283)	.38
Outcome expectations	13.45 (1.679)	14.04 (1.264)	2.739 (283)	.008
Self-identity	15.22 (3.391)	16.11 (3.295)	1.626 (283)	.11
Blood donation anxiety	13.06 (1.898)	13.70 (1.412)	2.603 (283)	.01
Cognition of the blood donation environment	30.18 (4.333)	29.52 (3.650)	−1.082 (283)	.28
Previous blood donation experience	13.32 (3.493)	14.26 (3.022)	1.701 (283)	.09
Total	195.86 (20.573)	199.41 (20.824)	1.068 (283)	.29

Table 7. Results of the logistic stepwise regression analysis of the web-based intervention group after the intervention.

	B	SE	Chi-square (df)	*P* value	Exp (B)	95% CI
Outcome expectations	0.560	0.174	10.3 (1)	.001	1.751	1.244-2.465
Blood donation environment	0.165	0.059	7.8 (1)	.005	0.848	0.754-0.952
Constant	−3.886	1.871	4.3 (1)	.04	0.021	N/A[a]

[a]N/A: not applicable.

Discussion

Principal Findings

This study aimed to not only address the possible influencing factors of blood donor losses after an initial blood donation but also discover theoretical intervention strategies given these factors to improve repeat donation rates. This study first provided data on interventions for nonregular blood donors based on the ETPB, which was important in providing reasons for continuous blood donation and future intervention directions; the results then indicated the effects of 2 different intervention methods: web-based videos and SMS text messages.

There are 3 factors that have a significant influence on repeated blood donation behavior: outcome expectations, blood donation anxiety, and blood donation environment. The first step in planning blood donation interventions involves having knowledge regarding the preventive factors in blood donation [43]. This study applied an ETPB to a prospective randomized controlled trial of an intervention in repeat blood donation behavior and received positive results. After the intervention, participants' attitudes, subjective behavioral norms, perceived behavioral control, blood donation willingness, self-identity, blood donation anxiety, outcome expectations, cognition of the blood donation environment, and cognition of the previous blood donation experience all significantly improved, with positive changes.

However, improvements in such perceptions as attitudes were not always reflected in the respondents' actions [44-46], and actual blood donors were far fewer than self-reported blood donors. Therefore, what factors have a significant impact on repeated blood donation behavior? This study further observed that 3 factors—outcome expectations, blood donation anxiety, and cognition of the blood donation environment–significantly differed between those who chose to donate blood again after the web-based video intervention and those who did not donate blood again after the intervention. Clearly, these 3 factors significantly impacted repeat blood donation behaviors.

First, outcome expectations can be divided into positive outcome expectations and negative outcome expectations. Similar to other studies, negative outcome expectations, such as anticipatory regret, have been shown to predict blood donation behavior [47-49]. Simultaneously, studies have demonstrated that in promoting healthy behaviors, the persuasion effect to avoid loss will be better than that to obtain gains [50]. This study adopted a negative outcome expectation, and 2 videos of negative outcome expectation were presented. One was about college students in a car accident who required substantial blood transfusions during surgery. The video indicated that if everyone actively donated blood, the blood supply would be sufficient to avoid any negative consequences, including amputations. The other one was about a Rh-negative mother in childbirth who urgently needed a transfusion. If everyone actively donated blood, an adequate supply of blood would ensure a smooth delivery, and the mother would avoid the negative consequences of stillbirth or infant death. These videos aroused donors' empathy, generated positive emotions, and psychologically matched the act of donating blood with the individual in need of help, prompting people to donate blood again. In support of the suggestion that the transfusion story videos should be promoted more in the future, these videos also helped people realize that repeatedly donating blood could avoid loss of life for the recipients because of insufficient blood supply; the viewers could avoid regret and be encouraged to donate blood again.

Second, this study verified that blood donation anxiety was an important factor affecting repeat donation behaviors; blood donation anxiety can prevent repeat donations. Other studies have shown that blood donation anxiety was critical in blood donors' decision to donate blood again [51]. The main reasons for not donating blood were concerns about safety and fear of donation [52,53]. Previous studies have revealed the fear of donating blood, needles in particular, and the belief that blood donation will adversely affect one's health are primary anxiety factors [54-56]. Hence, this study's short video of blood donation anxiety factors was aimed at explaining the above major anxiety factors in a straightforward manner and refuting the common fears and misunderstandings in donating blood. The video also details the entire donation process and the practices of blood donation testing, blood donation preparation, and delivery of the donated blood to the hospital, thereby reducing misunderstandings, alleviating blood donors' fears, and enhancing safety as well as confidence in the blood supply.

Third, the research discovered the connections between these environmental factors and blood donation behavior. A good blood donation environment may promote repeated blood donation behavior. Therefore, the possibility of irregular blood donors' repeat donations can be increased by improving the blood donation environment and providing a warm and comfortable blood donation environment, mitigating blood donation anxiety and strengthening outcome expectations. This is an important finding in research on repeat blood donors after expanding the theory of planned behavior in this study, and it offers significance and guidance for blood collection and supply institutions in implementing their own interventions for nonregular blood donors in subsequent steps.

In addition, the study also found that men aged 31 to 45 years and had donated blood twice in the past and irregular blood

donors who had donated twice in the past were more likely to donate blood again after the web-based intervention than after the SMS text message. This may be related to the fact that those who have donated blood twice have had a certain donation experience and a particular foundation in blood donation knowledge, including the process, experience, and perceptions. The group with ≥3 donations had the most experience in donating blood; with a similar "ceiling effect" [57], there was limited room for cognitive improvement. Therefore, those who had donated twice in the past were the most likely to become regular donors. Blood donors aged over 31 years generally had steady employment and were more mature. After receiving the relevant video interventions, they exhibited a higher action-based conversion rate after a cognitive change.

Web-based video interventions were effective. A major issue for blood donation workers involves the question of how to not only best convey information on coping with the obstacles to blood donation but also choose the best intervention method. This study combines the currently most effective web-based short video methods for dissemination with guidance from an ETPB to conduct an exploratory study of behavioral interventions. The study's results—specifically, that the web-based short video intervention method was more effective than SMS text messages for nonregular blood donors—were consistent with the research findings that video can effectively improve patients' knowledge, self-efficacy, satisfaction, and self-management levels in other areas, such as diabetes, heart disease, and patient family care [22-28,58].

However, this study differs from the findings of Karacaoğlu and Öncü [59]. Karacaoğlu and Öncü [59] began with first understanding new blood donors' fears and concerns and compared 6-minute educational videos with the brochures in use at that time; the videos addressed how to handle stress and anxiety among those experiencing the blood donation procedure for the first time. Considering the increase in knowledge and decrease in anxiety as outcome indicators after the intervention, the results revealed no difference between the brochure and video intervention groups. In the study by Masser et al [11], the video content was relatively simple, with only a video providing content from a precaution manual on the process before, during, and after blood donation. In contrast to these studies, this study first provided a short video with rich content, which was theoretically guided, driven by influencing factors, and provided on the web; measured the degree of psychological change from the intervention; and then tracked blood donation behavior rather than blood donation intention as an outcome variable, which more intuitively reflects the overall situation from the change of consciousness to the occurrence of behavior. The study also found that when those viewing the web-based video intervention chose to donate blood again, most of them uploaded photos of the time when they donated blood again to the WeChat group. This also played a role in donors' taking the initiative by example and encouraged undecided blood donors to donate blood again.

Conclusions

In conclusion, this study developed and verified an ETPB-driven web-based video intervention method to promote nonregular blood donors to donate again. The method addressed the individual donors' psychological and environmental factors, with remarkable results that can be popularized and applied in nonregular blood donor interventions to consequently improve repeat blood donation rates. Among the factors presented in this study, blood donation anxiety, result expectation, and improvements to the blood donation environment can positively impact repeat blood donation behaviors; hence, these are recommended as directions of focus in subsequent key interventions.

However, this study also has some limitations. First, this was an exploratory study, and its video sequence and frequency corresponding to the influencing factors were the first attempt and exploration, with no comparative study of other sequences. Second, the web-based intervention was based on the WeChat social media platform. Although group announcements and tasks were available to urge participants to click and watch the videos, no exact, effective means were used to understand more specific information, such as a particular viewing time. The respondents in the SMS group promised not to watch videos or other blood donation recruitment material during the study period, but these were limited by the respondents' self-awareness. As we could not discern whether they actually accessed intervention videos, errors may exist in that some respondents could have still accessed such videos. Third, this study used multiple comparisons, which may have caused a type 1 error. Fourth, this study has only been conducted for 6 months, and a longer follow-up period is needed for more comprehensive results. Fifth, the data collected in this study were Chinese, and the results may be different from those of other countries with different regions and cultures.

In subsequent research, we will continue to track these respondents' repeat donation behaviors after 1 and 1.5 years to further improve this study. Simultaneously, using the 9 variables discovered in this study—especially outcome expectations, blood donation anxiety, and cognition of the blood donation environment—specific improvement measures were designed and applied to a larger number of nonregular blood donors to observe the results of repeat blood donations. Further research will be conducted on the web-based video intervention method driven by the ETPB created in this study and focusing on factors such as video length, playback order, and sending frequency to further improve the web-based video intervention method.

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Authors' Contributions

All the authors contributed to the preparation and editing of the manuscript. QH and W Hu designed the study, collected the data, and drafted the manuscript. W Han and LP analyzed the data. QH, W Hu, W Han, and LP contributed to data interpretation and critical revisions of the manuscript. All authors approved the final version of the paper.

Conflicts of Interest

None declared.

Editorial notice: This randomized study was not registered because, as explained by the authors, it is observational in nature. The editor granted an exception from ICMJE rules mandating registration of randomized trials because the risk of bias appears low. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness.

Multimedia Appendix 1

CONSORT-eHEALTH checklist (V 1.6.1).
[DOC File , 197 KB-Multimedia Appendix 1]

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Abbreviations

ETPB: extended theory of planned behavior

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