Factors influencing patients’ willingness to share their digital health data for primary and secondary use: a theory- and evidence-based overview of reviews

Sabrina Fesl, Caroline Lang, Jochen Schmitt, Stefanie Brückner, Stephen Gilbert, Stefanie Deckert, Madlen Scheibe

Submitted to: Journal of Medical Internet Research
on: August 13, 2024

Table of Contents

Factors influencing patients’ willingness to share their digital health data for primary and secondary use: a theory- and evidence-based overview of reviews

Sabrina Fesl[1]; Caroline Lang[1]; Jochen Schmitt[1]; Stefanie Brückner[2]; Stephen Gilbert[2]; Stefanie Deckert[1*]; Madlen Scheibe[1*]

[1]Center for Evidence-Based Healthcare, Faculty of Medicine and University Hospital Carl Gustav Carus, TUD Dresden University of Technology Dresden DE
[2]Else Kröner Fresenius Center for Digital Health, TUD Dresden University of Technology Dresden DE
[*]these authors contributed equally

Corresponding Author:
Sabrina Fesl
Center for Evidence-Based Healthcare, Faculty of Medicine and University Hospital Carl Gustav Carus, TUD Dresden University of Technology
Fetscherstraße 74
Dresden
DE

Abstract

Background: Sharing of health data (HD) is currently under intense debate, for example in the context of the European Health Data Space (EHDS). Although HD sharing holds great potential, the corresponding determinants of patients are still uncertain. Hearing the patients’ voice is therefore crucial to better understand their needs and increase motivation for HD sharing, which is essential for the beneficial utilization of HD with their healthcare providers (known as Primary Use (PU)) and for purposes other than patient care like research (known as Secondary Use (SU)).

Objective: We conducted an overview of reviews to provide a meta-level synthesis on the research question “Which factors influence patients’ willingness to share their digital health data for primary and secondary use?”.

Methods: This overview has been registered before starting the review (PROSPERO reference CRD42023429302). An electronic literature search was performed in June 2023 using MEDLINE, Embase and Scopus, complemented by additional searches. We included systematic reviews (SRs), published between 2013 and 2023, that focused on determinants influencing patients’ willingness for HD sharing. All initial records were screened in a multi-stage process. After pretesting, the data extraction and quality assessment with R-AMSTAR2 were carried out by one reviewer and verified for accuracy and completeness by a second reviewer. Factors were clustered and categorized following a combined deductive-inductive thematic coding process. As a theoretical basis for category development, available theories on HD sharing and technology acceptance were considered.

Results: A total of 11 SRs was included, published between 2014 and 2021, incorporating 321 papers with heterogeneous study designs, mostly quantitative (158/321, 49.2%) and qualitative (108/321, 33.6%). A total of 41 influencing factors compiled into 15 main categories were identified. For PU, 22 factors were found as facilitators, nine as barriers and four could not be clearly assigned. For SU, 13 factors turned out as facilitators, six as barriers and six were inconsistent. The most important facilitators investigated were higher education status as well as trust, confidentiality and transparency on data sharing approaches, both for PU and SU, and higher income for PU only. The most important barriers determined were existing privacy and security concerns and concerns on data processing, both for PU and SU. The R-AMSTAR2 overall confidence rating indicated critically low quality for all included SRs.

Conclusions: The review identified modifiable and non-modifiable facilitators and barriers as relevant. If policymakers, healthcare providers or researchers aim to increase the willingness of patients towards HD sharing they should focus on modifiable factors such as expected individual usefulness, public benefit or privacy and security concerns. Due to the critically low quality of all included SRs more high-quality SRs are needed to enable the derivation of reliable, evidence-based recommendations and to develop a holistic framework for practice. Clinical Trial: PROSPERO: CRD42023429302, registered on

04/06/2023; https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=429302

(JMIR Preprints 13/08/2024:65349)
DOI: https://doi.org/10.2196/preprints.65349

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**
Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.
No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**
Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v
Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http

Original Manuscript

Cover Page

Factors influencing patients’ willingness to share their digital health data for primary and secondary use: a theory- and evidence-based overview of reviews

Sabrina Fesl[1], Caroline Lang[1], Jochen Schmitt[1], Stefanie Brückner[2], Stephen Gilbert[2], Stefanie Deckert[1*], Madlen Scheibe[1*]
1 Center for Evidence-Based Healthcare, Faculty of Medicine and University Hospital Carl Gustav Carus, TUD Dresden University of Technology, Fetscherstraße 74, 01307 Dresden, Saxony, Germany
2 Else Kröner Fresenius Center for Digital Health, TUD Dresden University of Technology, Fetscherstraße 74, 01307 Dresden, Saxony, Germany
* shared last authorship

Corresponding author:
Sabrina Fesl
Fetscherstraße 74
01307 Dresden
Germany
Phone: +49 (0) 351 458 2651
Fax: +49 (0) 351 458 7238
Email: sabrina.fesl@ukdd.de

Abstract

Background

Sharing of health data (HD) is currently under intense debate, for example in the context of the European Health Data Space (EHDS). Although HD sharing holds great potential, the corresponding determinants of patients are still uncertain. Hearing the patients’ voice is therefore crucial to better understand their needs and increase motivation for HD sharing, which is essential for the beneficial utilization of HD with their healthcare providers (known as Primary Use (PU)) and for purposes other than patient care like research (known as Secondary Use (SU)).

Objective

We conducted an overview of reviews to provide a meta-level synthesis on the research question *“Which factors influence patients’ willingness to share their digital health data for primary and secondary use?”.*

Methods

This overview has been registered before starting the review (PROSPERO reference CRD42023429302). An electronic literature search was performed in June 2023 using MEDLINE, Embase and Scopus, complemented by additional searches. We included systematic reviews (SRs), published between 2013 and 2023, that focused on determinants influencing patients’ willingness for HD sharing. All initial records were screened in a multi-stage process. After pretesting, the data extraction and quality assessment with R-AMSTAR2 were carried out by one reviewer and verified for accuracy and completeness by a second reviewer. Factors were clustered and categorized following a combined deductive-inductive thematic coding process. As a theoretical basis for category development, available theories on HD sharing and technology acceptance were considered.

Results

A total of 11 SRs was included, published between 2014 and 2021, incorporating 321 papers with heterogeneous study designs, mostly quantitative (158/321, 49.2%) and qualitative (108/321, 33.6%). A total of 41 influencing factors compiled into 15 main categories were identified. For PU, 22 factors were found as facilitators, nine as barriers and four could not be clearly assigned. For SU, 13 factors turned out as facilitators, six as barriers and six were inconsistent. The most important facilitators investigated were higher education status as well as trust, confidentiality and transparency on data sharing approaches, both for PU and SU, and higher income for PU only. The most important barriers determined were existing privacy and security concerns and concerns on data processing, both for PU and SU. The R-AMSTAR2 overall confidence rating indicated critically low quality for all included SRs.

Conclusions

The review identified modifiable and non-modifiable facilitators and barriers as relevant. If policymakers, healthcare providers or researchers aim to increase the willingness of patients towards HD sharing they should focus on modifiable factors such as expected individual usefulness, public benefit or privacy and security concerns. Due to the critically low quality of all included SRs more high-quality SRs are needed to enable the derivation of reliable, evidence-based recommendations and to develop a holistic framework for practice.

Trial registration

PROSPERO: CRD42023429302, registered on 04/06/2023; https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=429302

Key words

Electronic Health Records; Personal Health Record; Patient Portals; Health Data; Medical Records; Health Information Exchange; Patient Participation; Informed Consent; Medical Informatics; Technology Acceptance Model; Theory

Introduction

Background

Worldwide, a large amount of various types of health data (HD) is generated, especially in medical healthcare as a result of regular treatment by healthcare providers. According to the EU-General Data Protection Regulation, HD is defined as “all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject.” [1].

At the European level, the European Commission plans to create a *European Health Data Space (EHDS)* by 2025. The EHDS aims to promote better data access and exchange by developing an interoperable infrastructure. This includes HD generated in interactions with healthcare providers, such as electronic health records (EHRs), genomic data or data from patient registries on the one hand, and individually gathered health and certain types of wellness data from smartphones and wearables on the other hand [2].

These HD can be used for two purposes: For primary use (PU) and for secondary use (SU). *Primary use of HD* means the utilization of personal HD for the direct delivery of medical care to patients, for example by sharing personal HD with healthcare providers [3]. As part of the planned EHDS, important care and treatment information, like diagnoses, therapeutic measures, treatment reports and medication plans will be transparently accessible to the patients through their personal health record (PHR) between European countries [4]. This has various implications for the delivery of medical care. Overall, it can support individuals and healthcare professionals in receiving or providing care, for example when moving between EU-Member States. Furthermore, it can ensure efficient inter- and intrasectoral patient healthcare, avoid over-, under- and misuse of health services or ensure diagnostic findings and, therefore, improve patient safety and care quality [5-8].

Secondary use of HD means the utilization of pseudonymized/anonymized HD for purposes other than direct patient care. This includes activities such as research, both commercial and non-commercial, public health monitoring or healthcare policy development [3]. It can help to understand patient’s health, optimizing treatment strategies, and force medical research [9-11].

However, amidst the promise of this digital revolution lies a critical point: the willingness of patients to share their HD for PU and SU. Understanding the factors influencing their decisions in this regard is paramount to realize the full potential of digital health initiatives.

Theories in the field of data sharing and technology acceptance models also deal with this issue. They present potential predictors for patients’ willingness of HD sharing and can serve as a theoretical basis for mapping the available evidence. The most common are the *Unified Theory of Acceptance and Use of Technology (UTAUT)* model [12, 13] and its follow-up, the *UTAUT2* model [14]. Both include, amongst others, age, gender, experience, facilitating conditions and social influence as possible determinants. They combine other theories like *Rogers' Innovation Diffusion Theory (IDT)* [15, 16], the *Theory of reasoned action (TRA)* [17], the *Theory of planned behavior (TPB)* [18], the *Motivational Model (MM*) [19] as well as the *Technology Acceptance Model (TAM)* [20-22] which was expanded to *TAM2* [23], where the variables of perceived usefulness and ease of use are central. While these theories mainly focus on facilitators, other models are noteworthy that address potential barriers like privacy and security concerns, such as the *User Resistance Model (URM*) [24-27] and the *Dual Factor Model of IT Usage,* which bridges the *URM* with the *UTAUT* [28, 29], the *Concerns for Information Privacy (CFIP)* instrument [30-36] and the *Internet Users´ Information Privacy Concerns* (IUIPC) construct [37, 38] which was then combined to the *Internet Privacy Concerns (IPC)* model [39] and restructured to create the

Health Information Privacy Concern scale [40].

Prior work

Patient and public opinion on the sharing of HD for SU, such as research, has been explored in several reviews [41-44]. Howe et al. thematically analyzed studies and concluded four key themes: (1) benefits of data sharing, (2) fears and harms of data sharing, (3) data sharing processes, in particular the role of consent, and (4) the participants-research relationship. However, literature on attitudes toward the sharing of HD remains scant [41]. A narrative review described findings on the UK publics attitudes towards using, sharing and linking of sectoral public administrative data for research purposes [45]. This review identified lacking work focused on obtaining input from relevant demographics and communities in relation to specific data types or research areas [45]. Furthermore, the literature review by Esmaeilzadeh & Sambasivan aimed to identify factors that encourage patients to support health information exchange (HIE) efforts on the pros and cons of HIE from a patient’s perspective. The authors found seven main aspects, including perceived benefits and concerns as well as patient characteristics and preferences regarding features [46]. A recent review focused on how to implement practical consent by including the patient perspective in digital health consent [47], and another review focused on consent procedures for the reuse of routinely recorded HD in scientific research [48]. An overview of reviews has been published summarizing the findings on patient portals (PPs). Van Mens et al. used the Clinical Adoption Framework to illustrate the relation between determinant and outcome categories from 19 SRs retrieved by early 2018, means the authors also included the net benefits of its use. Methodological limitation was the inadvertent inclusion of duplicate primary studies, which could potentially bias the overall conclusions [49].

Rationale of this overview of reviews

Due to the large number of SRs on this topic with partly thematic and methodological limitations previously mentioned, an overview is needed to provide a comprehensive picture of the existing knowledge [50]. To the best of our knowledge, a theory- and evidence-based international meta-level synthesis on patients’ intentions regarding HD sharing with their corresponding facilitators and barriers is lacking, giving the opportunity for our work. This will identify predictors that impact HD sharing behaviour and consequently pave the way for the development of informed consent procedures, customized interventions, and ethical guidelines that prioritize optimal and personalized treatment, force patient autonomy and ensure data protection.

Objective

The research question examined in our overview is: *“Which factors influence patients’ willingness to share their digital health data for primary use and secondary use?”.*

Methods

We conducted an overview of reviews to provide a meta-level synthesis on the aforementioned research question. The corresponding protocol has been published in PROSPERO with the reference number CRD42023429302 before starting the overview and was kept up to date. Methods and results are reported following the Preferred Reporting Items for Overviews of Reviews (PRIOR) statement [51] (see Multimedia Appendix 1).

Inclusion and exclusion criteria

Our inclusion and exclusion criteria were selected using the “Population - Concept/Construct - Context (PCC)” scheme proposed by Aromataris [50] (see Textboxes 1 and 2).

Textbox 1. Inclusion criteria.

Review inclusion criteria.

Population
- Adult patients (at least 18 years), defined as all individuals who have been and/or are in contact with the healthcare system in the past and/or in the present

Concept/Construct
- Any factors that influence patients’ willingness to share their digital HD for PU and SU
- Influencing factors including views, attitudes, opinions, perspectives, thoughts, awareness or acceptance of HD sharing reported by patients

Context
- Sharing of digital HD for PU and SU, defined as legally protected HD sharing of data that is generated in the course of inpatient and outpatient treatment by healthcare providers and is recorded and stored electronically

Types of reviews
- SRs applying a comprehensive, reproducible search strategy and providing critical appraisal of study quality

Further criteria
- SRs that are peer-reviewed and available in a full-text format
- SRs published between January 1, 2013 and May 31, 2023
- No language restrictions

Textbox 2. Exclusion criteria.

Review exclusion criteria.

Population
- Patients under 18 years of age

Concept/Construct
- Opinions from groups other than patients such as healthcare providers or experts
- Technical methods for analyzing, sharing and linking HD like Artificial intelligence, Blockchain only
- Solely containing the design of consent forms
- Solely containing legal or ethical frameworks

Context
- Sharing of digital HD, collected solely by patients themselves, for example through wearables
- Sharing of digital HD, collected solely in the course of clinical trials

Types of reviews
- Expert reviews, scoping reviews
- SRs without a comprehensive, reproducible search strategy and not providing critical appraisal of study quality

Further criteria
- SRs that are not peer-reviewed and not available in full-text format

- SRs published before January 1, 2013

Search strategy

We followed a sensitive search approach with the aim of identifying as many relevant records as possible [52]. Electronic database search was conducted in June 2023 using MEDLINE and Embase (both via Ovid) and Scopus (via Elsevier), complemented by additional searches of Google Scholar in order to retrieve potentially eligible studies. Additionally, the reference lists of the included SRs (backward citation tracking) and the papers citing these included SRs (forward citation tracking) were searched in MEDLINE via Ovid. The search strings for all three databases are shown in Multimedia Appendix 2. They included free text terms and synonyms as well as corresponding Medical Subject Heading (MeSH) terms containing the construct of willingness (eg, motivation), covering the context of healthcare provider-related data (eg, medical record) and referring to HD sharing (eg, exchange) for PU and SU (eg, research). Moreover, the publication type was selected for SRs only. All single components were linked using the Boolean operator AND. For the population criteria of adult patients the humans filter was set. The timeframe was restricted to SR published between January 1, 2013 and May 31, 2023.

Study selection

All SRs retrieved from the electronic searches were imported to EndNote X9 (Clarivate Analytics, Boston, USA) for duplicate removal and uploaded to Rayyan [53] for the selection process.

The process started with an independent title-abstract screening by three project team members (SF, CL, MS) of a randomly selected 5%-subset of records found in an initial search query. The interrater agreement was calculated using Fleiss kappa (κ) [54] and was initially moderate (κ = 0.49). After establishing a more precise common understanding of the inclusion and exclusion criteria, an additional randomly selected 5%-subset of hits finally yielded substantial strength of agreement of κ = 0.76. Based on this, one reviewer (SF) screened titles and abstracts and excluded ineligible records. After title-abstract screening, two reviewers (SF, CL) independently reviewed the full text of the remaining hits based on the set inclusion and exclusion criteria mentioned in Textboxes 1 and 2. Interrater agreement, assessed by Cohen´s kappa (κ) [54], was 0.82, indicating almost perfect agreement.

Data extraction and analysis

A standardized data extraction sheet (Microsoft Excel) was developed. Relevant data were extracted according to the established PCC-scheme. The Excel sheet contains the following information: (1) citation details, (2) review type defined by the authors, (3) search strategy details, (4) publication date range and data collection range if available, (5) number, types and country of origin of studies included in each review, (6) method(s) of evidence analysis/synthesis and (7) critical appraisal tool(s) used, (8) objective(s), (9) setting/context, (10) participants details and (11) reported relevant predictors. Data extraction was carried out by one reviewer (SF) and verified for accuracy and completeness by a second reviewer (CL). Any disagreements that arose between both reviewers were resolved through discussion or with the assistance of a third reviewer (MS, SD). All results presented in tabular form are shown in Multimedia Appendix 3.

Quality Assessment

The revised measurement tool for the assessment of multiple SRs (R-AMSTAR2) was used to assess the methodological quality of included SRs and to identify critical deficiencies reducing overall confidence (see Multimedia Appendix 4). It consists of 16 items covering various aspects, including study selection, data extraction, and risk of bias (RoB) assessment. AMSTAR2 provides a standardized tool for assessing the transparency and rigor of SR methods, contributing to the reliability and validity of evidence synthesis that include randomized or non-randomized studies of healthcare interventions [55]. There is no comparable checklist for the focus of our work, which led us to undertake several modifications. Item 9, which asked for the use of a satisfactory technique for assessing the RoB on primary study level included in the review has been adapted to the context of our research question. We aimed to identify predicting factors on a qualitative level, which will not be provided by randomized controlled trials (RCT). Therefore, this item was adapted to better reflect the specifics of assessing RoB for qualitative research. The domains confounding and selection bias were replaced by an examination of whether an adequate quality assessment tool was used for the respective study design and at the individual study level. The number of critical and non-critical items were counted and a median and interquartile range (IQR) per review on the critical items were calculated.

The critical appraisal was pilot-tested on two SRs and then fully carried out by one reviewer (SF) and verified for accuracy and completeness by a second reviewer (CL). Any disagreements were resolved by discussion or with the assistance of a third reviewer (MS, SD) until consensus was reached.

Data synthesis

To synthesize the results, relevant predictors in terms of influencing patients' willingness to share their digital HD were categorized into cohesive themes and presented in a tabular synthesis. The categorized factors were then clustered into main categories. A deductive-inductive approach was used to derive the factors and main categories for PU and SU. As a theoretical basis for deductive development of corresponding factors and categories, existing theories and models on HD sharing and technology acceptance were considered as described in the introduction section. This deductive basis provided ten factors named costs of data sharing engagement [14], age [12-14], gender [12-14], privacy and security concerns not specified [30-39], health status [12, 13], motivation / interest [12, 13, 19], altruism [12, 13, 17, 18], social responsibility [12, 13, 17, 18], expected usefulness not specified [20-23] and expected ease of use not specified [20-23]. This led to eight main categories named sociodemographic factors [12-14], privacy and security concerns [30-39], facilitating conditions [12-14], user resistance reasons [12, 13, 24-29], social influence [12-14], expected usefulness [20-23], expected ease of use [20-23] and previous experience with the healthcare-system [12-16, 23]. In a second step, the inductive thematic coding process revealed additional or adapted categories as influencing factors. The procedure and assignment were discussed within the review team. Finally, the direction of influence was provided based on reporting of the included SRs results and labelled as facilitator, barrier, or inconsistent for factors which cannot be clearly assigned. The factors were described as consistent predictors for HD sharing in terms of PU and SU if all review results indicated the same direction. Conversely, if at least one SR had a conflicting statement, the factor was considered as inconsistent. We included all appropriate findings and weighted it equally, regardless of the study type and study quality, to obtain the maximum amount of valuable evidence.

Papers included in more than one included SR were only counted once in this overview to avoid bias by double counting.

Results

Search results

Figure 1 illustrates the selection process. The initial search yielded 4,352 hits, complemented by a hand search that yielded further 35 potentially relevant records. A total of 3,199 of the 4,387 records remained after duplicate removal, of which 90 were sought for retrieval, eight were not retrieved [56-63], leaving 82 records eligible for full-text screening. Due to missing critical appraisal of study quality, 40% (33/82) of the hits were excluded. A share of 18% (15/82) were reviews without a systematic literature search and 13% (11/82) were solely aimed at a population that did not meet our inclusion criteria, such as healthcare providers or IT-staff. A further 10% (8/82) focused on a concept/construct that did not meet our inclusion criteria, such as the description of ethical principles or legal frameworks only.

A reference list of the excluded SRs by exclusion criteria can be found in Multimedia Appendix 5. Finally, 11 SRs were included in our overview.

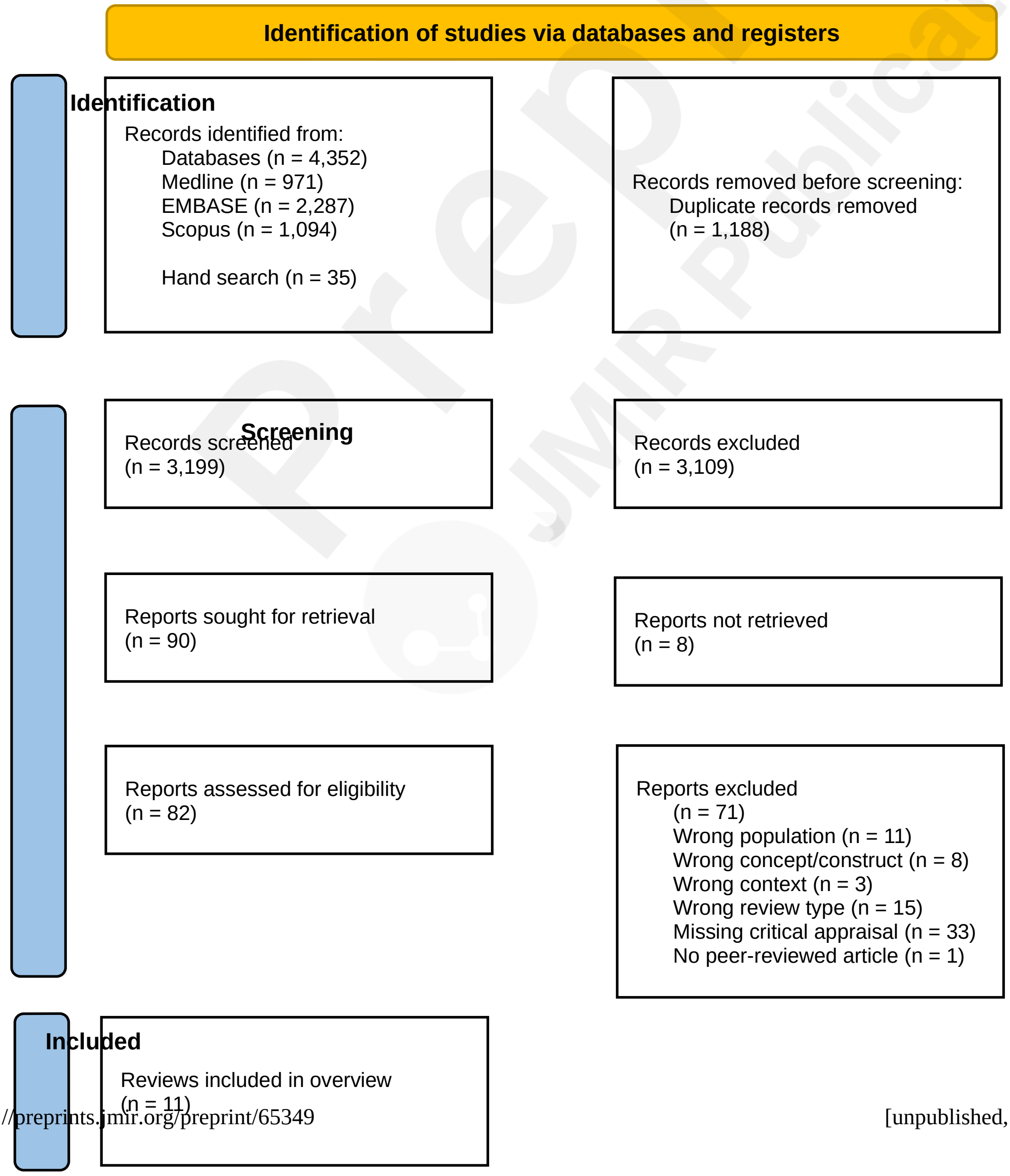


Figure 1. PRISMA flow chart depicting the selection process.

Reviews characteristics

The included 11 SRs [64-74] were published between 2014 and 2021 and based on a total of 321 papers (mean 25; min. 16 and max. 104). A share of 17.1% papers (66/387) were either single or multiple duplicates in several SRs. A reference list of overlaps with the number of duplicates and associated SRs is provided in Multimedia Appendix 6.

Differentiating by the purpose of data sharing, six SRs [64, 66, 67, 70, 71, 73] included studies with regard to PU, four SRs [65, 68, 69, 74] addressed the topic of SU and one covered both topics, PU and SU [72].

Overall, the SRs were heterogeneous in participant details (eg, general public and different kinds of patients), setting (eg, inpatient and outpatient setting) and research context (eg, tethered and untethered EHRs).

Population

Seven of the 11 SRs included a mix of the general population and patients with different types of disease [66, 68-70, 72-74], such as those with metabolic, rheumatic, renal, cardiac, pulmonary, neurological, psychiatric, musculoskeletal, rare or genetic diseases. Two SRs were restricted to patients with different types of diabetes (with co-morbidities) [66, 71]. Five SRs provided information on the total sample size of the primary studies included [64, 68, 69, 73, 74], with sample sizes ranging from 97 [64] to 216,149 participants [69].

Setting

This overview encompasses different types of healthcare technologies as well as different types of healthcare settings. Hutchings et al. included health administrative data in general [68, 69]. While Amante et al. [66] and Dendere et al. [67] focused on PPs only, O´Connor et al. considered both, PHRs and PPs [73]. All other review authors focused on different types of medical records [64, 65, 70-72, 74]. The review by Moon et al. was the most comprehensive in terms of platforms and settings covered. The authors looked at electronic personal health information, PHRs and integrated EHRs in what they termed clinical primary care, hospital-affiliated clinics, hospital outpatient clinics, general practices, and ambulatory care sites [72]. Others were limited to clinical settings [66], hospital inpatient settings [67] or primary care [70, 71].

The characteristics of the included SRs are summarized in Table 1. None of the SRs performed a meta-analysis due to widespread heterogeneity in terms of study designs, outcomes, population groups and various measures reported.

Table 1. Characteristics on purpose, objective(s), population(s), setting/context, data collection and quality assessment of the included SRs.

Reference of SRs	Purpose	Objective(s)	Population(s)	Setting/Context	Data collection	Quality assessment
Abd-alrazaq et al., 2019 [64]	PU[a]	• influencing factors for intention to use PHRs[b]	general public and patients with different conditions	tethered PHRs, connected with EMRs[c]	no. of databases: 42 no. of papers: 104 (97 studies) publications date range:	Mixed Methods Appraisal Tool (MMAT)

		- analyzing initial use rate of PHRs	(eg, diabetes, HIV, rheumatic diseases)		2006 - 2018	
Aitken et al., 2016 [65]	SU[d]	- evaluating key issues of patients' responses in data sharing and data linkage for research	patients, lay persons and the general public	PCHRs[e], other existing medical data or health material	no. of databases: 5 no. of papers: 25 (36 studies) publications date range: 2002 - 2014	Critical Appraisal Skills Programme (CASP)
Amante et al., 2014 [66]	PU	- characteristics of PP[f] users - barriers and facilitators of PP enrollment and utilization	patients with diabetes	clinically integrated PP	no. of databases: 2 no. of papers/studies: 16 publications date range: 2007 - 2016	Mixed Methods Appraisal Tool (MMAT)
Dendere et al., 2019 [67]	PU	- identification of influencing factors and best practices for successful implementation of EMRs	patients with different conditions (eg, cancer, HIV, cardiac diseases)	electronic PP tethered to EMRs in hospital inpatient setting	no. of databases: 3 no. of papers: 58 (555 studies) publications date range: 2005 - 2018	Assessing the Methodological Quality of Systematic Reviews (AMSTAR2) & Quality Assessment Tool for Studies with Diverse Designs (QATSDD)
Hutchings (a) et al., 2020 [68]	SU	- patients' concerns on privacy, trust, and transparency for health administrative and clinical trial data reuse	general public and patients with different conditions (eg, mental health illnesses, hypertension)	health administrative data	no. of databases: 8 no. of papers/studies: 35 publications date range: 1997 - 2020	QualSyst-Criteria (acc. to Kmet et al.)
Hutchings (b) et al., 2021 [69]	SU	- revealing attitudes on consent and the use of health administrative data for research	general public and patients with different conditions (eg, mental health illnesses, hypertension)	health administrative data	no. of databases: 8 no. of papers/studies: 47 publications date range: 1998 - 2020	QualSyst-Criteria (acc. to Kmet et al.)
Mold (a) et al., 2015 [70]	PU	- information on patients' attributes and variations concerning	users and non-users of online record access and remote	online health record access and transactional services in	no. of databases: 10 no. of papers/studies: 17 publications date range: 2003 - 2012	Risk of bias (RoB)

		access and use of EHRs[g]	contact services, including patients	primary care		
Mold (b) et al., 2018 [71]	PU	• characteristics of CMR[h] users • challenges, barriers, and impacting system features on CMR use	users and non-users of CMRs, including adults with type 2 diabetes (combined with hypertension) and their caregivers	CMRs in primary care	no. of databases: 9 no. of papers: 28 (37 studies) publications date range: 2004 - 2015	Mixed Methods Appraisal Tool (MMAT)
Moon et al., 2017 [72]	PU & SU	• information about patient´s data sharing preferences • influencing factors associated with HIE[i]	patients and the general public	HIE of ePHIs[j], PHRs and integrated EHRs in clinics primary care, hospital affiliated clinics, hospital outpatient clinics, general practices and ambulatory care sites	no. of databases: 2 no. of papers: 18 (16 studies) publications date range: 2009 - 2015	Olsen and St. George's (2004) Cross-sectional study design and data analysis framework & Kuper, Lingard, and Levinson (2008) Critically appraising qualitative research strategy
O' Connor et al., 2016 [73]	PU	• assessing factors, including barriers and facilitators, affecting engagement and enrollment in DHI[k]	patients and healthy individuals	PHRs or PP in primary, secondary or tertiary care, the home or workplace	no. of databases: 6 no. of papers/studies: 19 publications date range: 2005 - 2015	Enhancing transparency in reporting the synthesis of qualitative research (ENTREQ)
Stockdale et al., 2019 [74]	SU	• patients' views on data sharing for research • patients' preferences on consent model	general public and patients with different conditions (eg, cancer, multiple sclerosis)	data from electronic hospital records and electronic general practice records	no. of databases: 3 no. of papers/studies: 20 publications date range: 2006 - 2016	Mixed Methods Appraisal Tool (MMAT)

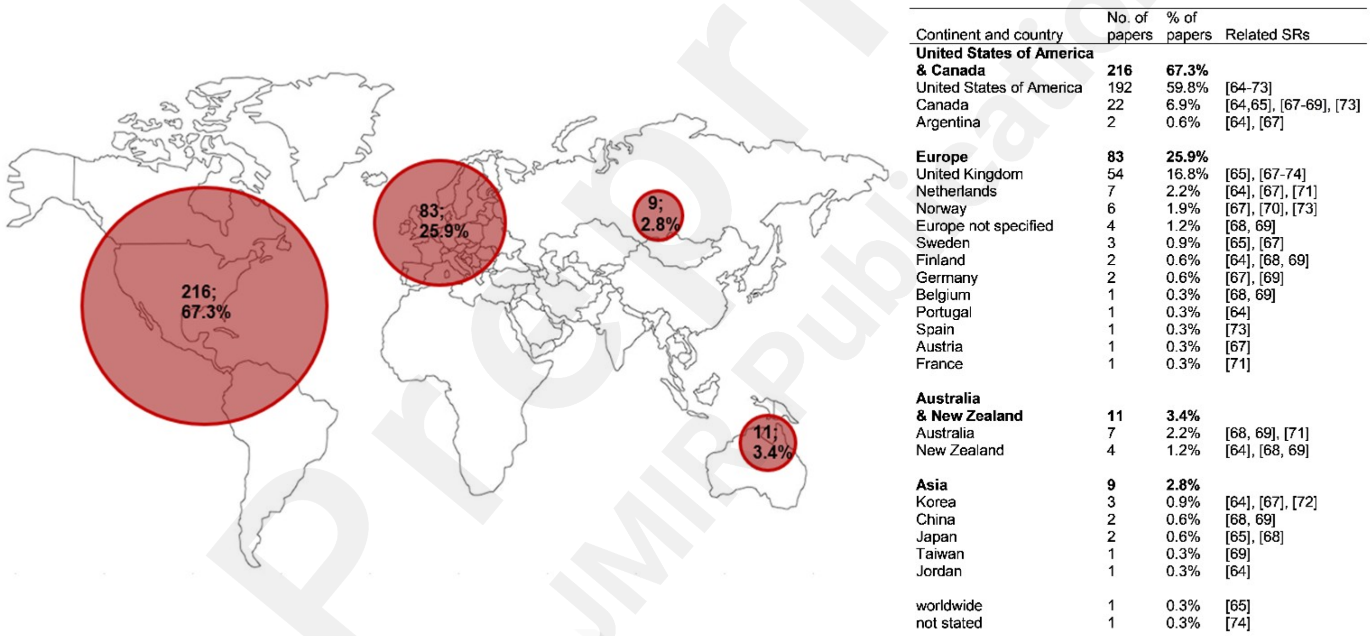
[a] PU: primary use
[b] PHR: personal health record.
[c] EMR: electronic medical record.
[d] SU: secondary use

[e] PCHR: personally controlled health record.
[f] PP: patient portal.
[g] EHR: electronic health record.
[h] CMR: computerized medical record.
[i] HIE: health information exchange.
[j] ePHI: electronic personal health information.
[k] DHI: digital health intervention.

Description of included papers

Countries

The total of 321 individual papers were spread across four continents, where the research was conducted (Figure 2). The majority came from the United States of America and Canada with a share of 67.3% (216/321) [64-73], followed by Europe with a share of 25.9% (83/321) [64, 65, 67-74], Australia and New Zealand with 3.4% (11/321) [64, 68, 69, 71], and Asia with 2.8% (9/321) [64, 65, 67-69, 72]. One paper included in SR [74] stated no country and one [65] indicated countries worldwide.



Continent and country	No. of papers	% of papers	Related SRs
United States of America & Canada	**216**	**67.3%**	
United States of America	192	59.8%	[64-73]
Canada	22	6.9%	[64,65], [67-69], [73]
Argentina	2	0.6%	[64], [67]
Europe	**83**	**25.9%**	
United Kingdom	54	16.8%	[65], [67-74]
Netherlands	7	2.2%	[64], [67], [71]
Norway	6	1.9%	[67], [70], [73]
Europe not specified	4	1.2%	[68, 69]
Sweden	3	0.9%	[65], [67]
Finland	2	0.6%	[64], [68, 69]
Germany	2	0.6%	[67], [69]
Belgium	1	0.3%	[68, 69]
Portugal	1	0.3%	[64]
Spain	1	0.3%	[73]
Austria	1	0.3%	[67]
France	1	0.3%	[71]
Australia & New Zealand	**11**	**3.4%**	
Australia	7	2.2%	[68, 69], [71]
New Zealand	4	1.2%	[64], [68, 69]
Asia	**9**	**2.8%**	
Korea	3	0.9%	[64], [67], [72]
China	2	0.6%	[68, 69]
Japan	2	0.6%	[65], [68]
Taiwan	1	0.3%	[69]
Jordan	1	0.3%	[64]
worldwide	1	0.3%	[65]
not stated	1	0.3%	[74]

Figure 2. World map and number of papers by continent and country with related SRs.

Study designs

The research methodology varied from quantitative study designs (observational and interventional study types) and qualitative study designs. Quantitative design dominated with 49.2% (158/321), followed by qualitative methods with 33.6% (108/321), mixed-methods design with 12.5% (40/321) and 5.0% (16/321) were reviews.

Table 2 summarizes the characteristics in terms of included research designs and provides information on data analysis and (theory-based) synthesis.

Table 2. Characteristics on research designs of included papers, applied data analysis and synthesis.

Reference of SRs	Included research designs	Data analysis and synthesis	Theory-based synthesis
Abd-alrazaq et al., 2019 [64]	Methods: • quantitative (90) • qualitative (10)	narratively; categorization of factors with framework method	yes

	• mixed-methods (4) Designs: • cross-sectional • cohort • case-control		
Aitken et al., 2016 [65]	Methods: • qualitative (16) • mixed-methods (6) • literature/policy/ systematic review (3) Designs: • focus groups • interviews • deliberative events • dialogue workshops • surveys	narratively; deductive-inductive thematic synthesis	no
Amante et al., 2014 [66]	Methods: • quantitative (9) • mixed-methods (4) • qualitative (3) Designs: • RCT[a] • cross-sectional • cohort • focus groups	quantitative results: mathematical statistics qualitative results: categorization of factors	no
Dendere et al., 2019 [67]	Methods: • qualitative (19) • quantitative (18) • reviews (12) • mixed-methods (9) Designs: • surveys • focus groups • interviews • quasi-experimental	narratively; categorization of themes	no
Hutchings (a) et al., 2020 [68]	Methods: • qualitative (28) • mixed-methods (7) Designs: • face-to-face interviews and/or focus groups • surveys • deliberative events + surveys/ + focus groups + interviews • citizens jury model • cohort + RCT • other	quantitative results: descriptive statistics qualitative results: meta aggregative approach with framework method	no

Hutchings (b) et al., 2021 [69]	Methods: - quantitative (31) - qualitative (8) - mixed-methods (8) Designs: - face-to-face/telephone/ questionnaire-based interviews - focus groups (+ interviews) - surveys (+ focus groups) - deliberative events + surveys - citizens jury model - (cohort +) RCT - other	quantitative results: descriptive statistics qualitative results: meta aggregative approach with framework method	no
Mold (a) et al., 2015 [70]	Methods: - quantitative (16) - mixed-methods (1) Designs: - RCT (with qualitative element) - cohort - cluster RCT - quasi experimental trial, non-randomized	quantitative results: mathematical statistics qualitative results: narratively	no
Mold (b) et al., 2018 [71]	Methods: - quantitative (15) - qualitative (11) - mixed-methods (1) - interpretative review (1) Designs: - audits - retrospective, prospective and longitudinal cohort - quasi-experimental design - focus groups/interviews - RCT - surveys	quantitative results: descriptive and mathematical statistics qualitative results: categorization of themes with framework method	no
Moon et al., 2017 [72]	Methods: - quantitative (13) - qualitative (5) Designs: - surveys - interviews	narratively; clustering of factors	yes, authors created their own framework
O' Connor et al., 2016 [73]	Methods: - qualitative (15) - mixed methods (4) Designs: - mixed interventions	content analyzing methods	yes, authors created their own framework

	• interviews • focus groups • participant observations • documentary evidence • surveys		
Stockdale et al., 2019 [74]	Methods: • qualitative (10) • quantitative (7) • mixed-methods (3) Designs: • focus groups • interviews • surveys • workshops • other	quantitative results: descriptive statistics qualitative results: narratively; content analyzing methods	yes

[a] RCT: randomized controlled trial.

Factors influencing patients’ willingness to share their digital health data for primary and secondary use

Overview

The deductive-inductive thematic coding process revealed 41 factors compiled into 15 main categories influencing patients’ willingness towards HD sharing indicating the direction of influence. As a result, 39% (16/41) of the influencing factors were related to PU only, a share of 15% (6/41) was related to SU only and 46% (19/41) of the factors were with regard to both PU and SU.

A share of 24% (10/41) of the influencing factors and 53% (8/15) of the main categories were deductively derived as described in the methods section. Consequently, a share of 76% (31/41) of the influencing factors and 47% of the main categories (7/15) were inductively formed based on the evidence found.

Primary Use

Concerning patients’ willingness to share their digital HD for PU a total of 35 factors were identified. 22 factors were identified as facilitators, nine factors were found as barriers and the results were inconsistent for four factors. Detailed results on the facilitators, barriers and inconsistent factors with underlying models/theories are presented in Table 3. Figure 3 summarizes all influencing factors on data sharing for PU.

Table 3. Main categories and influencing factors on data sharing for PU with corresponding direction of influence and category development with underlying models/theories

main category influencing factor with number of appearance in included SRs	influencing factor with number of appearance in included SRs	direction of influencing factor: facilitator/barrier/inconsistent with corresponding SR references	relation	category development with underlying models/theories
Socioeconomic factors (n=10)				**inductively**
	education (n=7)	(+) higher educational level [64], [66], [68,69], [71, 72], [74]	PU[a] & SU[b]	inductively
	socioeconomic factors	(+) higher socioeconomic status [64],	PU & SU	inductively

	not specified (n=4)	[70]		
	health insurance status (n=4)	(+) existing/commercial health insurance status [66], [69-71]	PU & SU	inductively
	residential area (n=3)	(+) living in wealthier neighborhood [64], [69], [71]	PU & SU	inductively
	income (n=5)	(+) higher income [64], [66,67], [71, 72]	PU	inductively
	employment status (n=3)	(+) (full-time) employed [64], [71, 72]	PU	inductively
	patient costs of data sharing engagement (n=1)	(-) high costs for participation [73]	PU	deductively from UTAUT2 [14][c]
Sociodemographic factors (n=9)				**deductively from UTAUT2 [14]/UTAUT [12, 13]**
	age (n=8)	(+/-) inconsistent direction of influencing factor [66-72], [74]	PU & SU	deductively from UTAUT2 [14]/ UTAUT [12, 13]
	gender (n=8)	(+/-) inconsistent direction of influencing factor [64], [66-72]	PU & SU	deductively from UTAUT2 [14]/ UTAUT [12, 13]
	ethnicity (n=8)	(+/-) inconsistent direction of influencing factor [64], [66, 67], [69-72], [74]	PU & SU	inductively
	family situation (n=2)	(+) married, children in household, caregivers presence [64], [72]	PU	inductively
Privacy and security concerns (n=9)				**deductively from CFIP[d] [30-36]/IUIPC[e] [37, 38]/IPC[f] [39]**
	privacy and security concerns not specified (n= 8)	(-) existing privacy and security concerns in general [64-68], [72-74]	PU & SU	deductively from CFIP [30-36]/ IUIPC [37, 38]/ IPC [39]
	concerns on data processing (n=5)	(-) existing privacy and security concerns on data processing [65], [68, 69], [72], [74]	PU & SU	inductively
	concerns on data access (n=2)	(-) existing privacy and security concerns on data access [68], [74]	PU & SU	inductively
Health conditions (n=8)				**inductively**
	health status (n=8)	(+/-) inconsistent direction of influencing factor [64], [66-72]	PU & SU	deductively from adapted UTAUT [12, 13]
	utilization of healthcare services (n=2)	(+) regular/higher utilization of healthcare services [66], [72]	PU	inductively
Personality traits (n=7)				**inductively**

	motivation/interest (n=2)	(-) lack of motivation to understand or improve health/no interest for changes [66], [73]	PU	deductively from UTAUT [12, 13]/ MM[g] [19]
Knowledge and understanding (n=6)				**inductively**
	technical/digital literacy (n=4)	(+) higher degree of technical/digital literacy [66], [68, 69], [73]	PU & SU	inductively
	health literacy (n=4)	(+) higher health literacy level [66], [69], [71], [73]	PU & SU	inductively
	awareness of PHR[h] (-features) (n=3)	(-) lack of awareness on PHR (-features) [64], [66], [71]	PU	inductively
Facilitating conditions (n=5)				**deductively from UTAUT2 [14]/UTAUT [12, 13]**
	trust, confidentiality and transparency (n=5)	(+) assurance of trust, confidentiality and transparency [65], [68, 69], [72], [74]	PU & SU	inductively
	autonomy and control (n=3)	(+) assurance of autonomy and control [65], [69], [72]	PU & SU	inductively
User resistance reasons (n=5)				**deductively from dual factor model of IT usage [28, 29]/ URM[i] [24-27]/ UTAUT [12, 13]**
	concerns being discriminated/ stigmatized (n=4)	(-) existing concerns being discriminated/stigmatized [65], [69], [72], [74]	PU & SU	inductively
Technological conditions (n=4)				**inductively**
	computer/internet access (n=3)	(+) available computer/internet access [64], [66], [73]	PU	inductively
	internet use (n=2)	(+) internet use [64], [72]	PU & SU	inductively
Social influence (n=4)				**deductively from UTAUT2 [14]/UTAUT [12, 13]**
	family and peers (n=3)	(+) recommendation/support by family and peers [66], [69], [73]	PU & SU	inductively
	healthcare professionals (n=3)	(+) recommendation/encouraging behaviour by healthcare professionals [66, 67], [73]	PU	inductively
Expected usefulness (n=4)				**deductively from TAM2[j] [23]/ TAM [20-22]**
	expected usefulness	(+) expected usefulness in general	PU & SU	deductively from

	not specified (n=3)	[64, 65], [67]		TAM2 [23]/TAM [20-22]
	information, organization and documentation (n=2)	(+) improved own information, organization and documentation [67], [72]	PU	inductively
	communication (n=2)	(+) improved communication [67], [72]	PU	inductively
	medical care (n=1)	(+) better medical care [72]	PU	inductively
Expected ease of use (n=4)				**deductively from TAM2 [23]/ TAM [20-22]**
	expected ease of use not specified (n=4)	(+) expected usability of EHR[k] [64], [66, 67], [73]	PU	deductively from TAM2 [23]/TAM [20-22]
Previous experience with healthcare-system (n=3)				**deductively from UTAUT2 [14]/UTAUT [12, 13]/TAM2 [23]/IDT[l] [15, 16]**
	technical aspects (n=3)	(-) negative digital/data sharing experience [66], [71], [73]	PU	inductively
	personal aspects (n=2)	(+) current dissatisfaction and negative experience on traditional healthcare [66], [73]	PU	inductively
Lifestyle aspects (n=2)				**inductively**
	lifestyle aspects not specified (n=2)	(-) busy lifestyle [66], [73]	PU	inductively

[a] PU: primary use.
[b] SU: secondary use.
[c] UTAUT/UTAUT2: Unified Theory of Acceptance and Use of Technology.
[d] CFIP: Concern for Information Privacy.
[e] IUIPC: Internet Users' Information Privacy Concerns.
[f] IPC: Internet Privacy Concerns.
[g] MM: Motivational Model.
[h] PHR: personal health record.
[i] URM: User Resistance Model.
[j] TAM/TAM2: Technology Acceptance Model.
[k] EHR: electronic health record.
[l] IDT: Innovation Diffusion Theory.

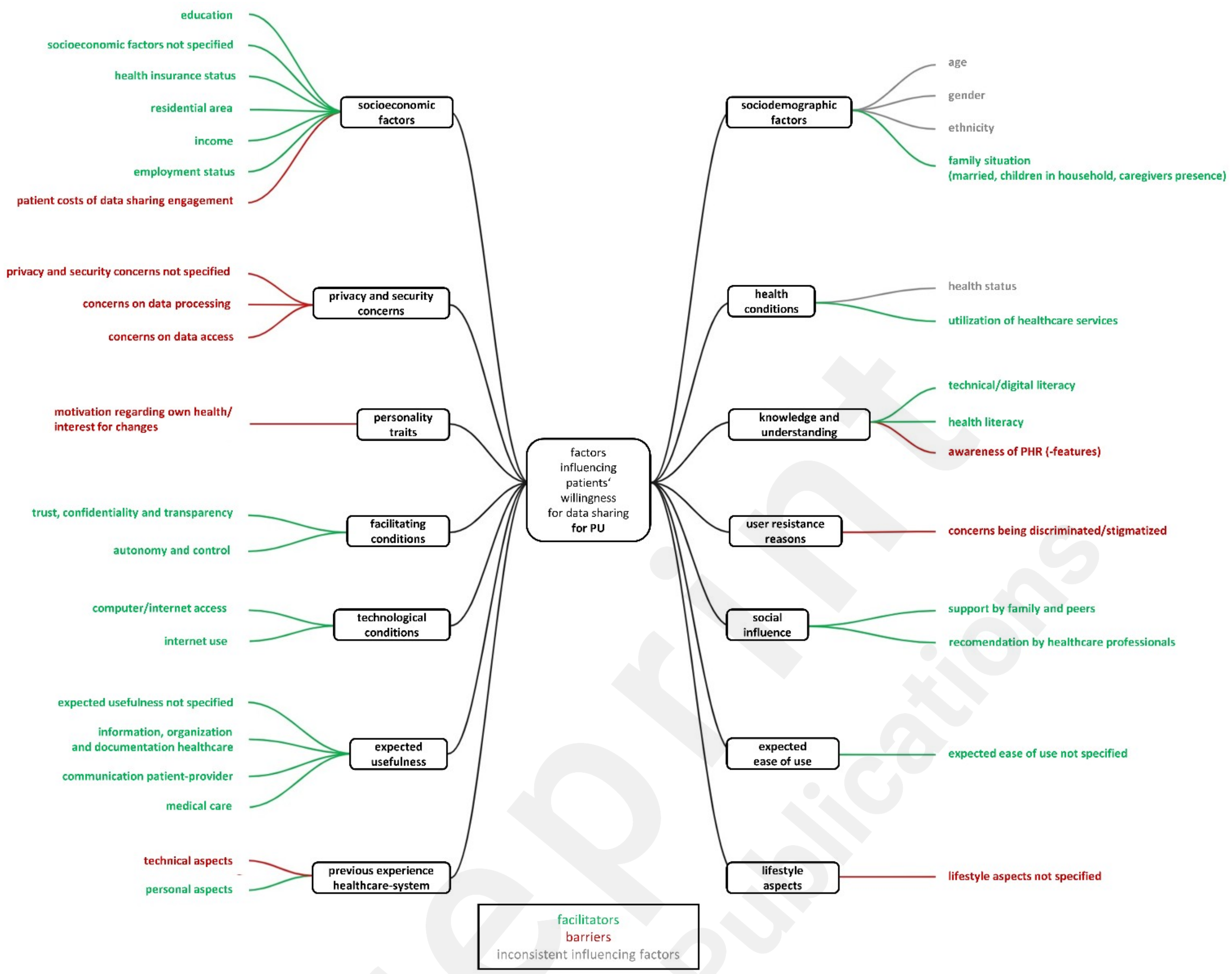


Figure 3. Evidence map on main categories and influencing factors regarding data sharing for PU

Secondary Use

Concerning patients' willingness to share their digital HD for SU a total of 25 factors were identified. 13 factors were identified as facilitators, six factors were found as barriers and the results were inconsistent for six factors. Detailed results on the facilitators, barriers and inconsistent factors with underlying models/theories are presented in Table 4. Figure 4 summarizes all influencing factors on data sharing for SU.

Table 4. Main categories and influencing factors on data sharing for SU with corresponding direction of influence and category development with underlying models/theories

main category influencing factor with number of appearance in included SRs	influencing factor with number of appearance in included SRs	direction of influencing factor: facilitator/barrier/inconsistent with corresponding SR references	relation	category development with underlying models/theories
Socioeconomic factors (n=10)				**inductively**
	education (n=7)	(+) higher educational level [64], [66], [68,69], [71, 72], [74]	PU[a] & SU[b]	inductively
	socioeconomic	(+/-) inconsistent direction of	PU & SU	inductively

	factors not specified (n=4)	influencing factor [69], [74]		
	health insurance status (n=4)	(+) existing/commercial health insurance status [66], [69-71]	PU & SU	inductively
	residential area (n=3)	(+) living in wealthier neighborhood [64], [69], [71]	PU & SU	inductively
Sociodemographic factors (n=9)				**deductively from UTAUT2[c] [14]/UTAUT [12, 13]**
	age (n=8)	(+/-) inconsistent direction of influencing factor [66-72], [74]	PU & SU	deductively from UTAUT2 [14]/UTAUT [12, 13]
	gender (n=8)	(+/-) inconsistent direction of influencing factor [64], [66-72]	PU & SU	deductively from UTAUT2 [14]/UTAUT [12, 13]
	ethnicity (n=8)	(+/-) inconsistent direction of influencing factor [64], [66, 67], [69-72], [74]	PU & SU	inductively
Privacy and security concerns (n=9)				**deductively from CFIP[d] [30-36]/IUIPC[e] [37, 38]/IPC[f] [39]**
	privacy and security concerns not specified (n= 8)	(-) existing privacy and security concerns in general [64-68], [72-74]	PU & SU	deductively from CFIP [30-36]/IUIPC [37, 38]/IPC [39]
	concerns on data processing (n=5)	(-) existing privacy and security concerns on data processing [65], [68, 69], [72], [74]	PU & SU	inductively
	concerns on data access (n=2)	(-) existing privacy and security concerns on data access [68], [74]	PU & SU	inductively
Health conditions (n=8)				**inductively**
	health status (n=8)	(+/-) inconsistent direction of influencing factor [64], [66-72]	PU & SU	deductively from adapted UTAUT [12, 13]
Personality traits (n=7)				**inductively**
	social responsibility (n=4)	(+) high degree of social responsibility [65], [68, 69], [74]	SU	deductively from UTAUT [12, 13]/TPB[g] [18]/TRA[h] [17]
	altruism (n=2)	(+) positive altruistic attitude [68], [74]	SU	deductively from UTAUT [12, 13]/TPB [18]/TRA [17]

Knowledge and understanding (n=6)				**inductively**
	technical/digital literacy (n=4)	(+) higher degree of technical/digital literacy [66], [68, 69], [73]	PU & SU	inductively
	health literacy (n=4)	(+) higher health literacy level [66], [69], [71], [73]	PU & SU	inductively
Facilitating conditions (n=5)				**deductively from UTAUT2 [14]/UTAUT [12, 13]**
	trust, confidentiality and transparency (n=5)	(+) assurance of trust, confidentiality and transparency [65], [68, 69], [72], [74]	PU & SU	inductively
	autonomy and control (n=3)	(+) assurance of autonomy and control [65], [69], [72]	PU & SU	inductively
	consent management (n=3)	(+/-) inconsistent direction of influencing factor [65], [69], [74]	SU	inductively
User resistance reasons (n=5)				**deductively from dual factor model of IT usage [28, 29]/URM[i] [24-27]/UTAUT [12, 13]**
	concerns being discriminated/ stigmatized (n=4)	(-) existing concerns being discriminated/stigmatized [65], [69], [72], [74]	PU & SU	inductively
	concerns regarding commercial use (n=4)	(-) existing concerns regarding commercial use [65], [68, 69], [74]	SU	inductively
	concerns being overstrained (n=1)	(-) existing concerns being overstrained [69]	SU	inductively
Technological conditions (n=4)				**inductively**
	internet use (n=2)	(+) internet use [64], [72]	PU & SU	inductively
Social influence (n=4)				**deductively from UTAUT2 [14]/UTAUT [12, 13]**
	family and peers (n=3)	(+) recommendation/support by family and peers [66], [69], [73]	PU & SU	inductively
Expected usefulness (n=4)				**deductively from TAM2[j] [23] /TAM [20-22]**
	expected usefulness not specified (n=3)	(+) expected usefulness in general [64, 65], [67]	PU & SU	deductively from TAM2 [23]/TAM [20-22]
Expected public				**inductively**

benefit (n=3)				
	expected public benefit not specified (n=3)	(+) expected public benefit on healthcare [65], [69], [72]	SU	inductively

[a] PU: primary use.
[b] SU: secondary use.
[c] UTAUT/UTAUT2: Unified Theory of Acceptance and Use of Technology.
[d] CFIP: Concern for Information Privacy.
[e] IUIPC: Internet Users' Information Privacy Concerns.
[f] IPC: Internet Privacy Concerns.
[g] TPB: Theory of Planned Behavior.
[h] TRA: Theory of Reasoned Action.
[i] URM: User Resistance Model.
[j] TAM/TAM2: Technology Acceptance Model.

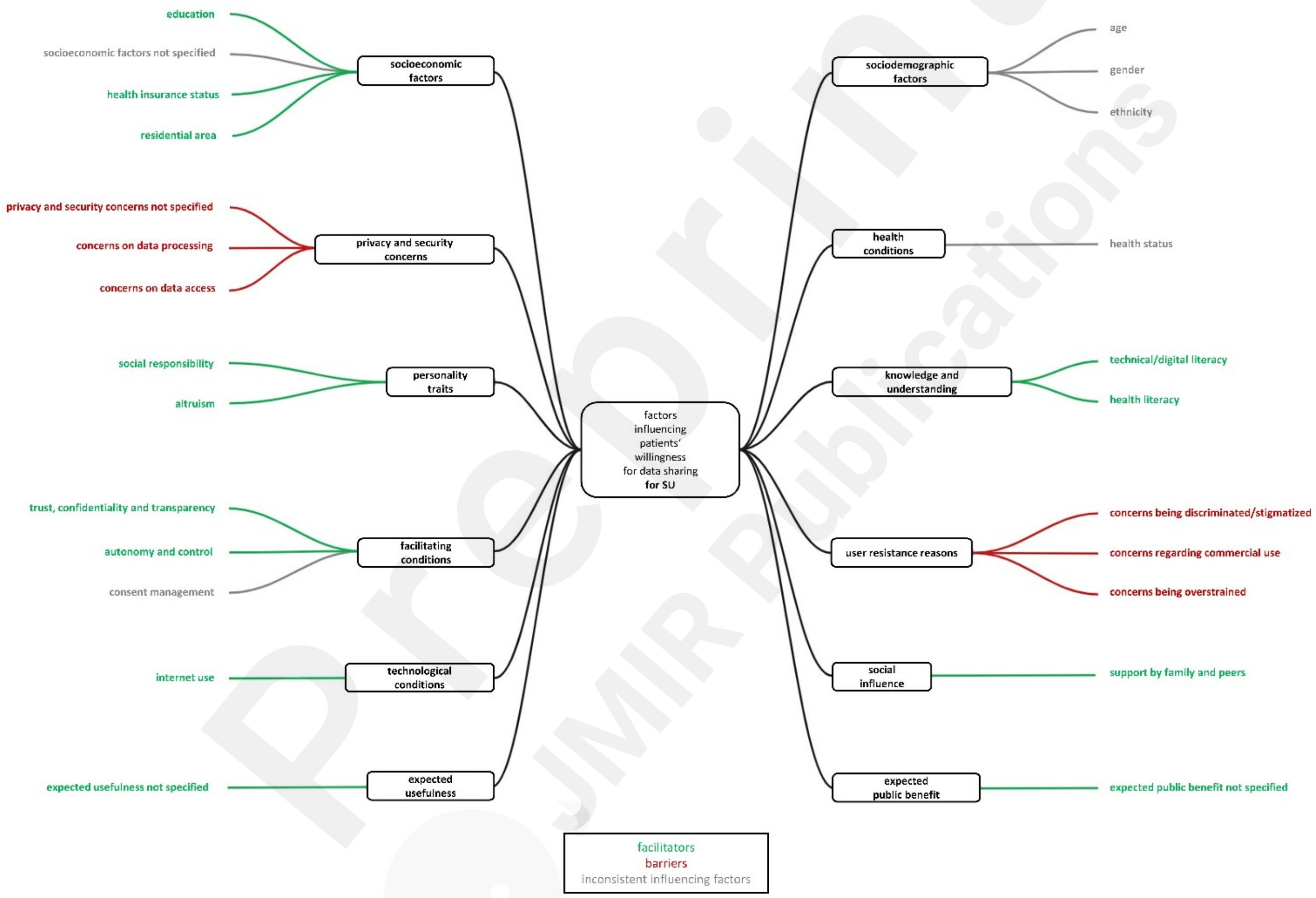


Figure 4: Evidence map on main categories and influencing factors regarding data sharing for SU

Additionally, Multimedia Appendix 7 contains more detailed information on the main categories and individual influencing factors for data sharing in the context of PU and SU.

Results of quality assessment

In summary, the overall confidence rating showed that all included SRs were of critically low quality [55]. Therefore, strong doubts about the validity and reliability of the above-mentioned findings must be admitted. Herewith a brief narrative summary is provided on the number of critical items, where the overall median was 3 (IQR: 2-4). Six SRs [65-67, 71-73] did not include an explicit statement that the review methods were established prior to the review with a written protocol, for example published PROSPERO registration (item 2). With regard to the question if the review authors did use a comprehensive literature search strategy (item 4), it can be stated that only one SR [64] scored with yes, while the other SRs scored partially yes only. None of the SRs provided a complete list of potentially relevant studies that were excluded during the full-text-eligibility screening (item 7). Three of the SRs that included non-randomized intervention studies [64, 65, 73] did not use a satisfactory technique to assess RoB at the level of the individual studies included (adjusted item 9b). As no meta-analysis were performed within the included SRs, item 11 on appropriate methods for statistical combination of the results and item 15 on investigated publication bias were not applicable. Only one SR [64] considered RoB of individual studies when interpreting and discussing the results (item 13). The detailed results of the quality assessment by the R-AMSTAR2-checklist are presented in Multimedia Appendix 4.

Discussion

Discussion on principal findings

The aim of our overview was to summarize and qualitatively assess the current evidence on factors influencing patients’ willingness to share HD for PU and SU. Overall, 41 factors were identified which were compiled into 15 main categories. While a total of 35 factors were identified as influencing factors for PU, a total of 25 factors were found regarding SU.

A comparison of the respective influencing factors shows that PU considerations are more individualized, focusing on direct patient care and personal motivations. In contrast, SU considerations emphasizes broader societal benefits, altruism, and include a wider range of user resistance factors. More specifically, it has been shown that assurance of trust, confidentiality and transparency as well as autonomy and control over data are facilitators for PU and SU. At the same time existing concerns about data processing and data access has been identified as barriers for PU and SU. However, for SU the factor of consent management has been found to be important, reflecting an additional layer of data governance concerns.

On user resistance reasons it has to be stated that for PU and SU concerns about being discriminated/stigmatized were shown as barrier. For SU, further barriers were concerns regarding commercial use and concerns being overstrained, indicating a broader spectrum of resistance factors.

In view of previous experiences with the healthcare-system, technical aspects of digital data sharing and personal aspects of traditional healthcare are relevant for PU while none of these factors were identified for SU.

Focusing socioeconomic and sociodemographic factors, our overview revealed that for PU a wider range of socioeconomic factors act as influencing factors. While education, unspecified socioeconomic factors, health insurance status and residential area were associated for PU and SU, the factors income, employment status, and patient costs of data sharing engagement has been found as specifically relevant for PU.

Altogether, the findings of our overview are highly important to the design and development of digital health policy and digital health initiatives. For this purpose, those factors that can be influenced and that we have identified as consistent predictors have greatest implications and potential impact and therefore need to be discussed in more detail. Factors were labelled as consistent predictors for HD sharing in terms of PU and SU if all results indicated the same direction, regardless of how many primary studies and which study designs the results were based on. Sociodemographic and socioeconomic factors were studied the most in the sourced SRs, but these cannot be modified directly. However we validated other relevant and influenceable factors. These included, amongst others, individual usefulness and ease of use, which are the two central variables of the TAM, as well as privacy and security concerns, which are addressed in several theories such as the URM or CFIP.

Our review found that expected usefulness and expected public benefit were consistent facilitators for patients' willingness to share their HD for PU and SU, which underlines that perceived value is considered as the strongest predictor of EHR adoption and the associated potential of data sharing [75]. Therefore, we believe it is crucial to clearly communicate the benefits of PU and SU to patients, especially to regular or frequent users of healthcare services, who would benefit the most. Naturally, this is often related to chronic conditions and older adults, although the factors of health status and age were not consistent in the results of our overview, while other studies confirmed that lower age and having chronic conditions were positively associated with PP access [76, 77]. It is necessary to discuss, that an age classification was mostly not settled with numbers [66-72, 74]. In particular, recommendations and encouragement from healthcare professionals [66, 67, 73], the promise of increased convenience [72], and "open, honest digital interaction" [73] can have a positive impact on PHR adoption. Healthcare providers play a key role as change agents in patients' willingness to use EHRs [22] and other studies suggested that physicians encouragement increases their use [78, 79]. This confirms our findings on recommendation and encouraging behavior from healthcare professionals as consistent facilitator. Consequently, they should be empowered in their role as multipliers to inform patients about the benefits and risks of HD sharing for PU and SU. At the same time, extensive public relations work is also needed to explain the high added value of HD sharing on the one hand and the low risks on the other, ensured by measures making HD sharing as safe as technically possible.

The lack of awareness of EHR (-features) among patients and present concerns of being overstrained were found as consistent barriers to EHR adoption and HD sharing in our overview and were also concluded elsewhere [80-83]. Another review confirmed low participant knowledge of specific use of routinely collected patient data and low understanding in terms of medical research [74] as cause of anxiety or feelings of being overwhelmed [69], but increasing the level of understanding can significantly support the participation in data sharing for PU and SU [84]. Therefore, we recommend target group-orientated and easily understandable information, for example through trustworthy patient organizations, health insurance companies and public campaigns. The planned purpose, the data protection guidelines followed and the option for giving or withdrawing consent respectively opting out of HD sharing should transparently made available in simple language. Providing easy-to-understand information would also help patients with lower levels of socioeconomic status, lacking health literacy or technical/digital literacy to be better informed and to take informed decisions.

This overview demonstrates, that people with lower levels of socioeconomic status or health literacy deserve special attention. These groups should be specifically targeted, for example, by providing modular support [85] in order to understand the available digital health information [86, 87]. Also providing patients with limited technical knowledge with a customized training prior to using a PP can significantly improve participation in HD sharing for PU [88]. Furthermore, technical assistance ranked first as HIE adoption promoters [89]. Focusing SU, a lack of understanding between the terms of anonymization and identifiable data showed a negative influence on data sharing for SU [68]. Public education on national privacy laws and regulations can be helpful here [68, 69].

Expected ease of use was also found as a consistent facilitator on data sharing for PU in our overview. Usability ranked on the third position as HIE adoption promoters [89], usability elements might be crucial to increase adherence to PP [90]. Usability benchmarking is a powerful approach for improving usability by evaluating and comparing the strength and weaknesses of systems like PP [91]. User-friendliness can be achieved by the involvement of end users through a human-centered design process [92] by “an approach to interactive systems development that aims to make systems usable and useful by focusing on the users, their needs and requirements, and by applying human factors or ergonomics and usability knowledge and techniques.” [93]. Although, in our overview age showed heterogeneous results, one possible reason for a lower willingness of HD sharing in older adults could be that EHRs are not sufficiently designed to meet their needs [94, 95].

The last essential aspect to be discussed are the privacy and security concerns. They were also frequently studied and found as consistent barriers on data sharing for PU and SU equally, whereas more negative statements were raised by the participants on SU of data and a lower socioeconomic status correlated with higher concerns about privacy [74]. In this context, the assurance of autonomy and control as well as trust, confidentiality and transparency act as consistent facilitators. Broad public support for HD sharing for research was shown, but this was linked to three combined core conditions: safeguarded privacy and security, established trust and ensured transparency [45]. Perceived healthcare quality was associated with lower privacy concerns, possible benefits of HIE and positively framed arguments can mitigate them [33, 96]. Assumptions were made, that societal benefits may overweigh privacy concerns [68] and benefits to the population like an increased understanding and better treatment of diseases may outweigh potential risks and concerns with positive influence on HIE [72].

Discussion on reviews characteristics

Our overview includes various types of healthcare technologies, such as EHRs and PPs in both inpatient and outpatient treatment, as the healthcare technology landscape is not “one-size-fits-all”. Different functionalities and features that capture individual needs and preferences are most likely to influence the decision to use a PHR [97]. The most common type worldwide, tethered PHRs, also known as PPs, give patients no or only partial control over their medical records within a particular healthcare network [98, 99]. In contrast, untethered PHRs enable patient access, control and a comprehensive health management by the patients is given [64]. Untethered PHRs allow users to manually enter and manage their health information and provide greater autonomy. Assurance of autonomy and individual control over one´s data have been found to facilitate HD sharing [65]. Inconsistent or missing reporting of features respectively functionalities make it difficult to specifically assign and compare factors. Subsequently, throughout our analysis, we reported themes across different EHRs and PPs together.

Most of the SRs focused only on factors influencing the intention to use an EHR, while others also included the initial use [64, 66, 73], but none focused on long-term use. According to [64], factors that influence intention to use do not necessarily influence actual use as well, and vice versa. As the success of health technologies and the follow-up effectiveness of various outcomes depend on ongoing utilization [100, 101], it would be interesting to conduct longitudinal studies and SRs on active use over time.

The type of HD to be shared for PU and SU varied across individual SRs, and in some cases, were not specified in detail or considered in a differentiated manner. In addition, the distinction between data collected for administrative purposes and electronic documentation in EHRs was less clear [68]. Willingness to share one´s HD may also be strongly influenced by the type of data involved. Lower willingness to consent to the access to medical records for research were found for sensitive topics, such as sexual orientation, sexual or sexually transmitted diseases, infectious diseases, reproductive issues, contraception or female genital disorders, urinary disorders, mental health, disability and genetics [69]. Moreover, Moon et al. demonstrated that the willingness to share non-sensitive digital HD was higher, but mental health, drug/alcohol use and sexually transmitted diseases were considered as particularly sensitive [72]. This may explain the inconsistent findings on preferred consent models and highlights the importance of personal granular control over access, limited data set, restriction of specific information and choice in the context of HD sharing [72].

This overview deliberately aimed to provide an international perspective on the topic of influencing factors on HD sharing. The majority of primary research, 60%, was conducted in America. Some findings may not be generalizable to other countries (eg, Europe), due to different legal regulations in healthcare, health systems and health funding models. In the European context, only Hutchings et al. compared several countries in their two SRs [68, 69]. Different consent preferences were found across European countries [69, 102, 103]. Current evidence shows, that the Nordic countries can be considered as frontrunners in digital health with a HD collection and linkage as source of complete, reliable, and representative health information, for SU like public health policy in each country, which is also used by research institutions and regulatory authorities worldwide [104, 105]. While in Finland, the adoption rate of the nationwide online PP has already exceeded 89% in 2020, in other countries, patients' awareness of the importance of HD sharing in healthcare is an ongoing concern [62, 80, 81, 104, 106, 107]. In Germany, for example, one third of the population is not aware of the existence of an EHR [108]. Only about 1.7% of those with statutory health insurance currently use the EHR service [109], although, on the other hand, an actual study showed surprising willingness, openness and trust in the use of HD [110].

We defined patients as all individuals who have been and/or are in contact with the healthcare system in the past and/or in the present, meaning lay persons, the general public and sick people equally. Most SRs included a mix of healthy individuals and patients with very diverse types of diseases [65, 68-70, 72-74]. This may explain the inconsistent evidence regarding the factor health status. Additionally, some information about health status were based on self-reporting, which could also have caused potential bias.

The majority of the included SRs (7/11) did not follow a theory-based approach to evidence synthesis. This severely limits the comparability and synthesis of results when conducting meta-syntheses.

Strengths & Limitations

To the best of our knowledge, our work is the first to provide an international theory- and evidence-based overview on factors influencing patients' willingness to share their digital HD for PU and SU, independent of study design, type of HD, and type of healthcare technology with qualitatively assessing the evidence. The separation of the factors in terms of data sharing for PU and SU enables the reader to selectively spot the findings of interest.

To summarize a maximally comprehensive body of literature, we have used a broad variety of possibly appropriate search terms and followed a sensitive search approach with the aim of identifying as many relevant records as possible. The consideration and exclusion of overlaps and duplicate papers included in multiple SRs ensures unbiased reporting of results. The authors used the quality appraisal of the results to critically reflect on the reliability of the results.

We categorized the available evidence by taking existing technology acceptance and data sharing models into account to provide a broader understanding of the contribution to digital

HD sharing [111] and address the common criticism that health informatics research is often not grounded in theory [112-114]. As the literature postulates, that healthcare technologies have unique characteristics, these models have less explanatory power for healthcare settings [115, 116] and we therefore followed a deductive-inductive approach for our thematic coding process to derive influencing factors and main categories.

We only extracted the views of patients on sharing their digital HD for PU and SU according to our research question although some SRs included also opinions of another stakeholders. The literature highlights the relevance of patient involvement. For example, an essential part of the British National Health Service modernization agenda is to provide healthcare that is responsive to the individual needs of patients, especially those with long-term conditions [117]. Patient participation is also emphasized at various points in the German health data usage act [118].

Implications for future research

This overview includes publications from three major databases. Further updated reviews could build on our search, extending it to include additional databases and possibly also gray literature. In addition, the views of healthcare professionals (eg, physicians, nurses), who could influence care and improve health outcomes [119] and, as described, act as multipliers in getting patients involved for HD sharing, are also particularly relevant for future research. The availability of only low-quality evidence strongly highlights the need for more high-quality SRs to provide reliable recommendations for practice. Future research could broaden our evidence map to a holistic framework model to verify which of the 41 factors are especially relevant, to what extent, and whether all required variables have been captured. Further research could also investigate the subsequent effects of the HD sharing in terms of clinical or patient-reported outcomes, such as patient satisfaction, behavior, and empowerment. For a comprehensive picture, it is also essential to examine the factors influencing the long-term use of healthcare technologies, whereas the majority of currently available evidence have focused on factors influencing the intention to use or the initial use.

Conclusion

Our overview provides a theory-based meta-level synthesis on the factors that influence patients' willingness to share HD for PU and SU. We identified 41 factors across 15 categories, with 35 factors affecting PU and 25 affecting SU, that relevant stakeholders should consider when developing and implementing HD sharing policies.

Socioeconomic and sociodemographic factors, as well as privacy and security concerns, were particularly prevalent in our 11 included SRs, while some key factors from common technology acceptance models, such as expected usefulness and expected ease of use, were less common. With 25 factors consistently identified as facilitators and 11 factors consistently identified as barriers, our overview has shown that influencing patients' willingness to share their HD is a complex challenge. However, if policymakers, healthcare providers or researchers want to increase patients' willingness to share their HD, then they should focus on modifiable factors. While socioeconomic and sociodemographic factors remain largely unmodifiable, such as expected individual usefulness, public benefit, privacy and security concerns, concerns about being discriminated/stigmatized or trust, confidentiality and transparency emerged as influenceable predictors.

The findings of our overview are highly relevant to the design and development of target-group specific digital health policies and HD sharing approaches. It is essential to involve future user groups in the development process of HD sharing approaches right from the start. This ensures a high level of user-friendliness and acceptance and subsequently a higher willingness to use them. Additionally, healthcare professionals play a key role as change agents in patients' willingness to share their HD. They should be empowered in their function as multipliers to inform patients about the benefits and risks of HD sharing for PU and SU. In all of these measures, it is also important to transparently communicate the differences between the two HD sharing options - PU and SU.

The low methodological quality of the included SRs emphasizes the need for high-quality SRs to derive reliable, evidence-based recommendations and to develop a holistic framework model for practice. Moreover, further research is needed to explore long-term use and clinical outcomes of HD sharing.

Acknowledgments

The authors would like to thank the German Federal Ministry of Education and Research for funding the PATH project (Personal Mastery of Health and Wellness Data, grant number 16KISA100K) and making this overview of reviews possible.

Authors' Contributions

SF, CL, SD and MS were responsible for the study design of the review. JS, SG and SB provided input to the conceptualization of the review and the study design. SF and SD conducted the literature search. SF and CL conducted the study selection process, quality assessment, and data extraction. SD and MS were involved in the consensus process during study selection, data extraction, and quality assessment. SF, MS, CL and SD analyzed the extracted data and derived points for discussion and implications. SF drafted the manuscript with the support of CL, SD and MS. All authors critically revised the manuscript for intellectual important content and approved the final version of the manuscript. MS and SG obtained funding for the project. SG is responsible for the overall project leadership.

Conflicts of Interest

Unrelated to this study, JS reports institutional grants for investigator-initiated research from the German GBA, BMG, BMBF, EU, Federal State of Saxony, Novartis, Sanofi, ALK, and Pfizer. He also participated in advisory board meetings as a paid consultant for Sanofi, Lilly, and ALK. JS is a member of the Expert Council on Health and Care at the Federal Ministry of Health and a member of the government commission for modern and needs-based hospital care of the current German Coalition.

SG declares a nonfinancial interest as an Advisory Group member of the EY-coordinated “Study on Regulatory Governance and Innovation in the Field of Medical Devices” conducted on behalf of the DG SANTE of the European Commission. S.G. declares the following competing financial interests: he has or has had consulting relationships with DG SANTE of the European Commission, Una Health GmbH, Lindus Health Ltd., Flo Ltd, ICURA ApS, Rock Health Inc., Thymia Ltd., FORUM Institut fuer Management GmbH, High-Tech Gruenderfonds Management GmbH, and Ada Health GmbH and holds share options in Ada Health GmbH.

Multimedia Appendix 1

PRIOR checklist.

Multimedia Appendix 2

Search strategy.

Multimedia Appendix 3

Full data extraction table.

Multimedia Appendix 4

Final R-AMSTAR2 checklist results.

Multimedia Appendix 5

List of excluded reviews by exclusion criteria.

Multimedia Appendix 6

Reference list of overlaps and duplicate papers.

Multimedia Appendix 7

Detailed table of main categories and influencing factors with direction and explanation.

References

1. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. European Commission. 2011. URL: https://www.eumonitor.eu/9353000/1/j9vvik7m1c3gyxp/vioaz2lmfc58 [accessed 2024-07-03]
2. Saelaert M, Mathieu L, Van Hoof W, Devleesschauwer B. Expanding citizen engagement in the secondary use of health data: an opportunity for national health data access bodies to realise the intentions of the European Health Data Space. Archives of Public Health. 2023 2023/09/12;81(1):168. doi: 10.1186/s13690-023-01182-4.
3. Proposal for a regulation of the European Parliament and of the Council on the European Health. European Commission. 2022. URL: https://www.european-health-data-space.com/European_Health_Data_Space_Article_2_(Proposal_3.5.2022).html [accessed 2024-07-03]
4. Raab R, Küderle A, Zakreuskaya A, Stern AD, Klucken J, Kaissis G, et al. Federated electronic health records for the European Health Data Space. Lancet Digit Health. 2023 Nov;5(11):e840-e7. PMID: 37741765. doi: 10.1016/s2589-7500(23)00156-5.
5. Adane K, Gizachew M, Kendie S. The role of medical data in efficient patient care delivery: a review. Risk Manag Healthc Policy. 2019;12:67-73. PMID: 31114410. doi: 10.2147/rmhp.S179259.
6. Zhang J, Ashrafian H, Delaney B, Darzi A. Impact of primary to secondary care data sharing on care quality in NHS England hospitals. npj Digital Medicine. 2023 2023/08/14;6(1):144. doi: 10.1038/s41746-023-00891-y.
7. Ammenwerth E, Schnell-Inderst P, Hoerbst A. The impact of electronic patient portals on patient care: a systematic review of controlled trials. J Med Internet Res. 2012 Nov 26;14(6):e162. PMID: 23183044. doi: 10.2196/jmir.2238.
8. Baumann LA, Baker J, Elshaug AG. The impact of electronic health record systems on clinical documentation times: A systematic review. Health Policy. 2018 Aug;122(8):827-36. PMID: 29895467. doi: 10.1016/j.healthpol.2018.05.014.
9. Adibuzzaman M, DeLaurentis P, Hill J, Benneyworth BD. Big data in healthcare - the promises, challenges and opportunities from a research perspective: A case study with a model database. AMIA Annu Symp Proc. 2017;2017:384-92. PMID: 29854102.
10. Rowhani-Farid A, Barnett AG. Has open data arrived at the British Medical Journal (BMJ)? An observational study. BMJ Open. 2016;6(10):e011784. doi: 10.1136/bmjopen-2016-011784.
11. National Academy of M, The Learning Health System S. In: Carman KL, Grossmann C, Zirkle M, Adams I, Siddiqi S, Ahmed M, et al., editors. Health Data Sharing to Support Better Outcomes: Building a Foundation of Stakeholder Trust. Washington (DC): National Academies Press (US); 2021.
12. Venkatesh V, Morris MG, Davis GB, Davis FD. User Acceptance of Information Technology: Toward a Unified View. MIS Quarterly. 2003;27(3):425-78. doi: 10.2307/30036540.
13. Yousef CC, Salgado TM, Farooq A, Burnett K, McClelland LE, Thomas A, et al. Predicting Patients' Intention to Use a Personal Health Record Using an Adapted Unified Theory of Acceptance and Use of Technology Model: Secondary Data Analysis. JMIR Med Inform. 2021 Aug 17;9(8):e30214. PMID: 34304150. doi: 10.2196/30214.
14. Venkatesh V, Thong JYL, Xu X. Consumer Acceptance and Use of Information Technology: Extending the Unified Theory of Acceptance and Use of Technology. MIS Quarterly. 2012;36(1):157-78. doi: 10.2307/41410412.
15. Rogers EM. Diffusion of Innovations, 5th Edition: Free Press; 2003. ISBN: 9780743258234.
16. Emani S, Yamin CK, Peters E, Karson AS, Lipsitz SR, Wald JS, et al. Patient perceptions of a personal health record: a test of the diffusion of innovation model. J Med Internet Res. 2012 Nov

5;14(6):e150. PMID: 23128775. doi: 10.2196/jmir.2278.
17. Ajzen I, Fishbein M. Understanding attitudes and predicting social behavior. Publisher: Prentice-Hall Englewood Cliffs. 1980. ISBN: 9780139364358.
18. Ajzen I. The theory of planned behavior. Organizational Behavior and Human Decision Processes. 1991 1991/12/01/;50(2):179-211. doi: https://doi.org/10.1016/0749-5978(91)90020-T.
19. Davis FD, Bagozzi RP, Warshaw PR. User Acceptance of Computer Technology: A Comparison of Two Theoretical Models. Management Science. 1989;35(8):982-1003. doi: https://doi.org/10.1287/mnsc.35.8.982
20. Davis FD. A Technology Acceptance Model for Empirically Testing New End-User Information Systems: theory and results. 1985. URL: https://dspace.mit.edu/handle/1721.1/15192. [accessed 2024-05-30]
21. Razmak J, Bélanger C. Using the technology acceptance model to predict patient attitude toward personal health records in regional communities. Information Technology & People. 2018 02/13;31:00-. doi: 10.1108/ITP-07-2016-0160.
22. Noblin A, Wan T, Fottler M. Intention to use a personal health record: A theoretical analysis using the technology acceptance model. Int J of Healthcare Technology and Management. 2013 01/01;14:73-89. doi: 10.1504/IJHTM.2013.055085.
23. Venkatesh V, Davis F. A Theoretical Extension of the Technology Acceptance Model: Four Longitudinal Field Studies. Management Science. 2000 02/01;46:186-204. doi: 10.1287/mnsc.46.2.186.11926.
24. Kim H-W, Kankanhalli A. Investigating User Resistance to Information Systems Implementation: A Status Quo Bias Perspective. MIS Quarterly. 2009 09/01;33:567-82. doi: 10.2307/20650309.
25. Samhan B, Joshi KD, editors. Resistance of Healthcare Information Technologies; Literature Review, Analysis, and Gaps. 2015 48th Hawaii International Conference on System Sciences; 2015 5-8 Jan. 2015. doi: 10.1109/HICSS.2015.362
26. Ngafeeson M. Understanding User Resistance to Information Technology in Healthcare: The Nature and Role of Perceived Threats. Transactions of the International Conference on Health Information Technology Advancement. 2015;56.
27. Samhan B, Joshi KD. Switching to Electronic Health Record Systems: A Replication of the User Resistance Model. AIS Trans Replication Res. 2019 /;5:11. doi: 10.17705/1atrr.00043
28. Samhan B. Why Do People Resist Patient Portal Systems?: An Application of the Dual Factor Model of IT Usage. International Journal of Healthcare Information Systems and Informatics. 2017 10/01;12:68-86. doi: 10.4018/IJHISI.2017100105.
29. Samhan B. Patients' Resistance towards Health Information Technology A Perspective of the Dual Factor Model of IT Usage. Hawaii International Conference on System Sciences. 2017.
30. Smith HJ, Milberg SJ, Burke SJ. Information Privacy: Measuring Individuals' Concerns about Organizational Practices. MIS Quarterly. 1996;20(2):167-96. doi: 10.2307/249477.
31. Harborth D, Pape S. German Translation of the Concerns for Information Privacy (CFIP) Construct. SSRN Electronic Journal. 2018 01/29. doi: 10.2139/ssrn.3112207.
32. Dinev T, Albano V, Xu H, D'Atri A, Hart P. Individuals' Attitudes Towards Electronic Health Records: A Privacy Calculus Perspective. 2016. p. 19-50. doi: 10.1007/978-3-319-23294-2_2
33. Angst CM, Agarwal R. Adoption of Electronic Health Records in the Presence of Privacy Concerns: The Elaboration Likelihood Model and Individual Persuasion. MIS Q. 2009;33:339-70. doi: https://doi.org/10.2307/20650295
34. Angst C, Agarwal R. Overcoming Personal Barriers to Adoption when Technology Enables Information to be Available to Others. SSRN Electronic Journal. 2006 06/01. doi:

10.2139/ssrn.922075.
35. Hwang H-G, Han H-E, Kuo K, Liu C-F. The Differing Privacy Concerns Regarding Exchanging Electronic Medical Records of Internet Users in Taiwan. Journal of medical systems. 2012 04/20;36:3783-93. doi: 10.1007/s10916-012-9851-1.
36. Li T, Slee T. The Effects of Information Privacy Concerns on Digitizing Personal Health Records. Journal of the Association for Information Science and Technology. 2014 08/01;65. doi: 10.1002/asi.23068.
37. Malhotra N, Kim S, Agarwal J. Internet Users' Information Privacy Concerns (IUIPC): The Construct, the Scale, and a Causal Model. Information Systems Research. 2004 12/01;15:336-55. doi: 10.1287/isre.1040.0032.
38. Kordzadeh N, Warren J, Seifi A. Antecedents of privacy calculus components in virtual health communities. International Journal of Information Management. 2016 2016/10/01/;36(5):724-34. doi: https://doi.org/10.1016/j.ijinfomgt.2016.04.015.
39. Hong W, Thong J. Internet Privacy Concerns: An Integrated Conceptualization and Four Empirical Studies. MIS Quarterly. 2013 03/01;37:275-98. doi: 10.25300/MISQ/2013/37.1.12.
40. Fox G, Connolly R. Mobile health technology adoption across generations: Narrowing the digital divide. Information Systems Journal. 2018;28(6):995-1019. doi: https://doi.org/10.1111/isj.12179.
41. Howe N, Giles E, Newbury-Birch D, McColl E. Systematic review of participants' attitudes towards data sharing: a thematic synthesis. J Health Serv Res Policy. 2018 Apr;23(2):123-33. PMID: 29653503. doi: 10.1177/1355819617751555.
42. Hill EM, Turner EL, Martin RM, Donovan JL. "Let's get the best quality research we can": public awareness and acceptance of consent to use existing data in health research: a systematic review and qualitative study. BMC Med Res Methodol. 2013 Jun 4;13:72. PMID: 23734773. doi: 10.1186/1471-2288-13-72.
43. Jackie S, Stacy C, Belinda F, Rebecca B, Lucy C, Annette B-M. “Public attitudes to sharing government data with private industry: a systematic scoping review”. medRxiv. 2022:2022.06.07.22276084. doi: 10.1101/2022.06.07.22276084.
44. Hermansen A, Regier DA, Pollard S. Developing Data Sharing Models for Health Research with Real-World Data: A Scoping Review of Patient and Public Preferences. J Med Syst. 2022 Oct 22;46(12):86. PMID: 36271208. doi: 10.1007/s10916-022-01875-3.
45. Waind E. Trust, security and public interest: striking the balance A narrative review of previous literature on public attitudes towards the sharing, linking and use of administrative data for research. Int J Popul Data Sci. 2020 Dec 11;5(3):1368. PMID: 34036179. doi: 10.23889/ijpds.v5i3.1368.
46. Esmaeilzadeh P, Sambasivan M. Patients' support for health information exchange: a literature review and classification of key factors. BMC Med Inform Decis Mak. 2017 Apr 4;17(1):33. PMID: 28376785. doi: 10.1186/s12911-017-0436-2.
47. Kassam I, Ilkina D, Kemp J, Roble H, Carter-Langford A, Shen N. Patient Perspectives and Preferences for Consent in the Digital Health Context: State-of-the-art Literature Review. J Med Internet Res. 2023 2023/2/10;25:e42507. doi: 10.2196/42507.
48. de Man Y, Wieland-Jorna Y, Torensma B, de Wit K, Francke AL, Oosterveld-Vlug MG, et al. Opt-In and Opt-Out Consent Procedures for the Reuse of Routinely Recorded Health Data in Scientific Research and Their Consequences for Consent Rate and Consent Bias: Systematic Review. Journal of Medical Internet Research. 2023;25:e42131. doi: https://dx.doi.org/10.2196/42131.
49. van Mens HJT, Duijm RD, Nienhuis R, de Keizer NF, Cornet R. Determinants and outcomes of patient access to medical records: Systematic review of systematic reviews. Int J Med Inform. 2019

Sep;129:226-33. PMID: 31445260. doi: 10.1016/j.ijmedinf.2019.05.014.
50. Aromataris E, Fernandez R, Godfrey CM, Holly C, Khalil H, Tungpunkom P. Summarizing systematic reviews: methodological development, conduct and reporting of an umbrella review approach. Int J Evid Based Healthc. 2015 Sep;13(3):132-40. PMID: 26360830. doi: 10.1097/xeb.0000000000000055.
51. Gates M, Gates A, Pieper D, Fernandes RM, Tricco AC, Moher D, et al. Reporting guideline for overviews of reviews of healthcare interventions: development of the PRIOR statement. BMJ. 2022;378:e070849. doi: 10.1136/bmj-2022-070849.
52. Nordhausen T, Hirt J. Navigieren im Dschungel – Empfehlungen zur Auswahl der Fachdatenbanken für eine systematische Literaturrecherche / Navigating in the jungle – recommendations for selecting databases for systematic literature searching. 2020 09/02;20:Doc08. doi: 10.3205/mbi000465.
53. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan—a web and mobile app for systematic reviews. Systematic Reviews. 2016 2016/12/05;5(1):210. doi: 10.1186/s13643-016-0384-4.
54. Fleiss JL. Statistical Methods for Rates and Proportions. Second Edition: Wiley, John and Sons, Incorporated, New York, N.Y.. 1981.
55. Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. Bmj. 2017 Sep 21;358:j4008. PMID: 28935701. doi: 10.1136/bmj.j4008.
56. Cresswell K, Sheikh A. Organizational issues in the implementation and adoption of health information technology innovations: an interpretative review. Int J Med Inform. 2013 May;82(5):e73-86. PMID: 23146626. doi: 10.1016/j.ijmedinf.2012.10.007.
57. Fisher-Grace K, Turk MT, Anthony MK, Chia LR. Use of Personal Health Records to Support Diabetes Self-management: An Integrative Review. Comput Inform Nurs. 2021 Jun;39(6):298-305. PMID: 33315699. doi: 10.1097/cin.0000000000000682.
58. Goldzweig CL, Orshansky G, Paige NM, Towfigh AA, Haggstrom DA, Miake-Lye I, et al. Electronic patient portals: evidence on health outcomes, satisfaction, efficiency, and attitudes: a systematic review. Ann Intern Med. 2013 Nov 19;159(10):677-87. PMID: 24247673. doi: 10.7326/0003-4819-159-10-201311190-00006.
59. Kallmerten PS, Chia LR, Jakub K, Turk MT. Patient Portal Use by Adults With Heart Failure: An Integrative Review. Computers, informatics, nursing: CIN. 2021;39(8):418-31. doi: https://dx.doi.org/10.1097/CIN.0000000000000733.
60. Nguyen L, Bellucci E, Nguyen LT. Electronic health records implementation: an evaluation of information system impact and contingency factors. Int J Med Inform. 2014 Nov;83(11):779-96. PMID: 25085286. doi: 10.1016/j.ijmedinf.2014.06.011.
61. Rudin RS, Motala A, Goldzweig CL, Shekelle PG. Usage and effect of health information exchange: A systematic review. Annals of Internal Medicine. 2014;161(11):803-11. doi: https://dx.doi.org/10.7326/M14-0877.
62. Thompson MJ, Reilly JD, Valdez RS. Work system barriers to patient, provider, and caregiver use of personal health records: A systematic review. Appl Ergon. 2016 May;54:218-42. PMID: 26851482. doi: 10.1016/j.apergo.2015.10.010.
63. Zhang T, Shen N, Booth R, LaChance J, Jackson B, Strudwick G. Supporting the use of patient portals in mental health settings: a scoping review. Inform Health Soc Care. 2022 Jan 2;47(1):62-79. PMID: 34032528. doi: 10.1080/17538157.2021.1929998.
64. Abd-alrazaq AA, Bewick BM, Farragher T, Gardner P. Factors that affect the use of electronic personal health records among patients: A systematic review. International Journal of Medical

Informatics. 2019;126:164-75. doi: 10.1016/j.ijmedinf.2019.03.014.
65. Aitken M, de St Jorre J, Pagliari C, Jepson R, Cunningham-Burley S. Public responses to the sharing and linkage of health data for research purposes: a systematic review and thematic synthesis of qualitative studies. BMC Med Ethics. 2016 Nov 10;17(1):73. PMID: 27832780. doi: 10.1186/s12910-016-0153-x.
66. Amante DJ, Hogan TP, Pagoto SL, English TM. A systematic review of electronic portal usage among patients with diabetes. Diabetes technology & therapeutics. 2014;16(11):784-93. doi: https://dx.doi.org/10.1089/dia.2014.0078.
67. Dendere R, Slade C, Burton-Jones A, Sullivan C, Staib A, Janda M. Patient Portals Facilitating Engagement With Inpatient Electronic Medical Records: A Systematic Review. Journal of medical Internet research. 2019;21(4):e12779. doi: https://dx.doi.org/10.2196/12779.
68. Hutchings E, Loomes M, Butow P, Boyle FM. A systematic literature review of health consumer attitudes towards secondary use and sharing of health administrative and clinical trial data: a focus on privacy, trust, and transparency. Syst Rev. 2020 Oct 9;9(1):235. PMID: 33036664. doi: 10.1186/s13643-020-01481-9.
69. Hutchings E, Loomes M, Butow P, Boyle FM. A systematic literature review of attitudes towards secondary use and sharing of health administrative and clinical trial data: a focus on consent. Syst Rev. 2021 May 4;10(1):132. PMID: 33941282. doi: 10.1186/s13643-021-01663-z.
70. Mold F, De Lusignan S, Sheikh A, Majeed A, Wyatt JC, Quinn T, et al. Patients' online access to their electronic health records and linked online services: A systematic review in primary care. British Journal of General Practice. 2015;65(632):e141-e51. doi: 10.3399/bjgp15X683941.
71. Mold F, Raleigh M, Alharbi NS, de Lusignan S. The Impact of Patient Online Access to Computerized Medical Records and Services on Type 2 Diabetes: Systematic Review. J Med Internet Res. 2018 Jul 6;20(7):e235. PMID: 29980499. doi: 10.2196/jmir.7858.
72. Moon LA. Factors influencing health data sharing preferences of consumers: A critical review. Health Policy and Technology. 2017 2017/06/01/;6(2):169-87. doi: https://doi.org/10.1016/j.hlpt.2017.01.001.
73. O'Connor S, Hanlon P, O'Donnell CA, Garcia S, Glanville J, Mair FS. Understanding factors affecting patient and public engagement and recruitment to digital health interventions: a systematic review of qualitative studies. BMC medical informatics and decision making. 2016;16(1):120. doi: https://dx.doi.org/10.1186/s12911-016-0359-3.
74. Stockdale J, Cassell J, Ford E. Giving something back: A systematic review and ethical enquiry into public views on the use of patient data for research in the United Kingdom and the Republic of Ireland. Wellcome Open Research. 2019;3(6). doi: 10.12688/wellcomeopenres.13531.2.
75. Andrews L, Gajanayake R, Sahama T. The Australian general public's perceptions of having a personally controlled electronic health record (PCEHR). Int J Med Inform. 2014 Dec;83(12):889-900. PMID: 25200198. doi: 10.1016/j.ijmedinf.2014.08.002.
76. Sun R, Burke LE, Saul MI, Korytkowski MT, Li D, Sereika SM. Use of a Patient Portal for Engaging Patients with Type 2 Diabetes: Patterns and Prediction. Diabetes Technol Ther. 2019 Oct;21(10):546-56. PMID: 31335206. doi: 10.1089/dia.2019.0074.
77. Wright JA, Volkman JE, Leveille SG, Amante DJ. Predictors of Online Patient Portal Use Among a Diverse Sample of Emerging Adults: Cross-sectional Survey. JMIR Form Res. 2022 Feb 15;6(2):e33356. PMID: 35166686. doi: 10.2196/33356.
78. Sun R, Korytkowski MT, Sereika SM, Saul MI, Li D, Burke LE. Patient Portal Use in Diabetes Management: Literature Review. JMIR Diabetes. 2018 Nov 6;3(4):e11199. PMID: 30401665. doi: 10.2196/11199.
79. Powell KR. Patient-Perceived Facilitators of and Barriers to Electronic Portal Use: A

Systematic Review. Computers, informatics, nursing : CIN. 2017;35(11):565-73. doi: https://dx.doi.org/10.1097/CIN.0000000000000377.
80. Tulu B, Trudel J, Strong DM, Johnson SA, Sundaresan D, Garber L. Patient Portals: An Underused Resource for Improving Patient Engagement. Chest. 2016 Jan;149(1):272-7. PMID: 26066707. doi: 10.1378/chest.14-2559.
81. Huygens MW, Vermeulen J, Friele RD, van Schayck OC, de Jong JD, de Witte LP. Internet Services for Communicating With the General Practice: Barely Noticed and Used by Patients. Interact J Med Res. 2015 Nov 24;4(4):e21. PMID: 26601596. doi: 10.2196/ijmr.4245.
82. Dhanireddy S, Walker J, Reisch L, Oster N, Delbanco T, Elmore JG. The urban underserved: attitudes towards gaining full access to electronic medical records. Health Expect. 2014 Oct;17(5):724-32. PMID: 22738155. doi: 10.1111/j.1369-7625.2012.00799.x.
83. Ross SE, Lin CT. The effects of promoting patient access to medical records: a review. J Am Med Inform Assoc. 2003 Mar-Apr;10(2):129-38. PMID: 12595402. doi: 10.1197/jamia.m1147.
84. Gajanayake R, Sahama T, Iannella R. E-health in Australia and elsewhere: a comparison and lessons for the near future. Stud Health Technol Inform. 2013;188:26-32. PMID: 23823284.
85. Sakaguchi-Tang DK, Bosold AL, Choi YK, Turner AM. Patient Portal Use and Experience Among Older Adults: Systematic Review. JMIR Med Inform. 2017 Oct 16;5(4):e38. PMID: 29038093. doi: 10.2196/medinform.8092.
86. Van Kasteren Y, Maeder A, Williams PA, Damarell R. Consumer Perspectives on MyHealth Record: A Review. Stud Health Technol Inform. 2017;239:146-52. PMID: 28756450.
87. Hassol A, Walker JM, Kidder D, Rokita K, Young D, Pierdon S, et al. Patient experiences and attitudes about access to a patient electronic health care record and linked web messaging. J Am Med Inform Assoc. 2004 Nov-Dec;11(6):505-13. PMID: 15299001. doi: 10.1197/jamia.M1593.
88. Kruse CS, Argueta DA, Lopez L, Nair A. Patient and provider attitudes toward the use of patient portals for the management of chronic disease: a systematic review. J Med Internet Res. 2015 Feb 20;17(2):e40. PMID: 25707035. doi: 10.2196/jmir.3703.
89. Wu H, LaRue EM. Linking the health data system in the U.S.: Challenges to the benefits. International Journal of Nursing Sciences. 2017;4(4):410-7. doi: https://dx.doi.org/10.1016/j.ijnss.2017.09.006.
90. Portz JD, Bayliss EA, Bull S, Boxer RS, Bekelman DB, Gleason K, et al. Using the Technology Acceptance Model to Explore User Experience, Intent to Use, and Use Behavior of a Patient Portal Among Older Adults With Multiple Chronic Conditions: Descriptive Qualitative Study. J Med Internet Res. 2019 Apr 8;21(4):e11604. PMID: 30958272. doi: 10.2196/11604.
91. Kujala S, Simola S, Wang B, Soone H, Hagström J, Bärkås A, et al. Benchmarking usability of patient portals in Estonia, Finland, Norway, and Sweden. Int J Med Inform. 2024 Jan;181:105302. PMID: 38011806. doi: 10.1016/j.ijmedinf.2023.105302.
92. Maguire M. Methods to support human-centred design. International Journal of Human-Computer Studies. 2001 2001/10/01/;55(4):587-634. doi: https://doi.org/10.1006/ijhc.2001.0503.
93. International Organization for Standardization. ISO 9241-210:2019 Ergonomics of human-system interaction. Part 210: Human-centred design for interactive systems. Second Edition. 2019.
94. Witteman HO. Capsule commentary on Ancker et al., Rapid growth in use of personal health records in New York, 2012-2013. J Gen Intern Med. 2014 Jun;29(6):893. PMID: 24643527. doi: 10.1007/s11606-014-2822-0.
95. Smith SG, O'Conor R, Aitken W, Curtis LM, Wolf MS, Goel MS. Disparities in registration and use of an online patient portal among older adults: findings from the LitCog cohort. J Am Med Inform Assoc. 2015 Jul;22(4):888-95. PMID: 25914099. doi: 10.1093/jamia/ocv025.
96. Shen N, Bernier T, Sequeira L, Strauss J, Silver MP, Carter-Langford A, et al. Understanding the

patient privacy perspective on health information exchange: A systematic review. Int J Med Inform. 2019 May;125:1-12. PMID: 30914173. doi: 10.1016/j.ijmedinf.2019.01.014.
97. Roehrs A, da Costa CA, Righi RD, de Oliveira KS. Personal Health Records: A Systematic Literature Review. Journal of medical Internet research. 2017;19(1):e13. doi: https://dx.doi.org/10.2196/jmir.5876.
98. Vydra TP, Cuaresma E, Kretovics M, Bose-Brill S. Diffusion and Use of Tethered Personal Health Records in Primary Care. Perspect Health Inf Manag. 2015;12(Spring):1c. PMID: 26755897.
99. Garets D, Davis M. Electronic Medical Records vs. Electronic Health Records: Yes, There Is a Difference. Chinese Hospitals. 2006.
100. Gebauer L, Söllner M, Leimeister JM. Towards understanding the formation of continuous it use. Thirty Fourth International Conference on Information Systems, Milan: 2013.
101. Bhattacherjee A. Understanding Information Systems Continuance: An Expectation-Confirmation Model. MIS Quarterly. 2001;25(3):351-70. doi: 10.2307/3250921.
102. Patil S, Lu H, Saunders CL, Potoglou D, Robinson N. Public preferences for electronic health data storage, access, and sharing - evidence from a pan-European survey. J Am Med Inform Assoc. 2016 Nov;23(6):1096-106. PMID: 27107445. doi: 10.1093/jamia/ocw012.
103. Stallmann C, Swart E, Robra BP, March S. Linking primary study data with administrative and claims data in a German cohort study on work, age, health and work participation: is there a consent bias? Public Health. 2017 2017/09/01/;150:9-16. doi: https://doi.org/10.1016/j.puhe.2017.05.001.
104. Jormanainen V. Over 89% Adoption Rate of the Nationwide Online Patient Portal in Finland. Stud Health Technol Inform. 2022 May 25;294:589-93. PMID: 35612157. doi: 10.3233/shti220537.
105. Hägglund M, Moll J, Åhlfeldt RM, Scandurra I. Timing It Right - Patients' Online Access to Their Record Notes in Sweden. Stud Health Technol Inform. 2018;247:336-40. PMID: 29677978.
106. Powell KR. Patient-Perceived Facilitators of and Barriers to Electronic Portal Use: A Systematic Review. CIN: Computers, Informatics, Nursing. 2017;35(11). PMID: 28723832. doi: 10.1097/CIN.0000000000000377
107. Osborn CY, Mayberry LS, Wallston KA, Johnson KB, Elasy TA. Understanding patient portal use: implications for medication management. J Med Internet Res. 2013 Jul 3;15(7):e133. PMID: 23823974. doi: 10.2196/jmir.2589.
108. Vielen Bürgern ist E-Akte nicht bekannt. Pharmazeutische Zeitung. 2023. URL: https://www.pharmazeutische-zeitung.de/vielen-buergern-ist-e-akte-nicht-bekannt-138993/ [accessed 2024-05-28]
109. TI-Dashboard - Digitalisierung in der Übersicht. Gematik. 2023. URL: https://www.gematik.de/telematikinfrastruktur/ti-dashboard [accessed 2024-05-28]
110. Weisband YS, A.; Thun, S; Balicer, R.,. GIHF-AI Study 2023: Trust in the Use of Health Data. 2024. URL: https://gihf-ai.eu/en/study/gihf-ai-study-2023-trust-in-the-use-of-health-data/ [accessed 2024-07-01]
111. Sartain SA, Stressing S, Prieto J. Patients' views on the effectiveness of patient-held records: a systematic review and thematic synthesis of qualitative studies. Health expectations : an international journal of public participation in health care and health policy. 2015;18(6):2666-77. doi: https://dx.doi.org/10.1111/hex.12240.
112. Scott PJ, Georgiou A, Hyppönen H, Craven CK, Rigby M, Brender McNair J. Theoretical Foundations for Evidence-Based Health Informatics: Why? How? Stud Health Technol Inform. 2016;228:614-8. PMID: 27577457.
113. Gray K, Sockolow P. Conceptual Models in Health Informatics Research: A Literature Review and Suggestions for Development. JMIR Med Inform. 2016 Feb 24;4(1):e7. PMID: 26912288. doi:

10.2196/medinform.5021.

114. Scott PJ, Brown AW, Friedman CP, Wyatt JC, Georgiou A, Eisenstein EL, editors. Improving the science of health informatics by using validated instruments and outcome measures. Medical Informatics Europe; 2014.

115. Smith T, Grant G, Ramirez A. Investigating the Influence of Psychological Ownership and Resistance on Usage Intention among Physicians. 47th Hawaii International Conference on System Sciences. 2014.

116. Holden RJ, Karsh B-T. A theoretical model of health information technology usage behaviour with implications for patient safety. Behav Inf Technol. 2009;28(1):21–38. doi: 10.1080/01449290601138245.

117. Tattersall RL. The expert patient: a new approach to chronic disease management for the twenty-first century. Clin Med (Lond). 2002 May-Jun;2(3):227-9. PMID: 12108472. doi: 10.7861/clinmedicine.2-3-227.

118. Gesetz zur verbesserten Nutzung von Gesundheitsdaten. Bundesministerium fuer Gesundheit. 2024. URL: https://www.recht.bund.de/eli/bund/bgbl-1/2024/102 [accessed 2024-07-03]

119. Ammenwerth E, Hoerbst A, Lannig S, Mueller G, Siebert U, Schnell-Inderst P. Effects of Adult Patient Portals on Patient Empowerment and Health-Related Outcomes: A Systematic Review. Studies in health technology and informatics. 2019;264:1106-10. doi: https://dx.doi.org/10.3233/SHTI190397.

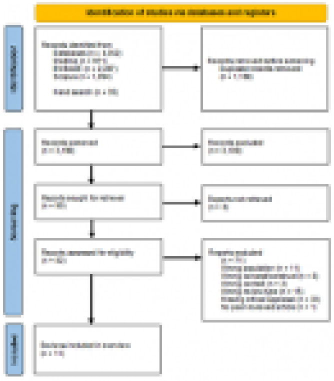
Abbreviations

CFIP	Concerns for Information Privacy
CMR	computerized medical record
EHDS	European Health Data Space
EHR	electronic health record
HD	health data
HIE	health information exchange
IDT	Innovation Diffusion Theory
IPC	Internet Privacy Concerns
IUIPC	Internet Users’ Information Privacy Concerns
MeSH	Medical Subject Heading
MM	Motivational Model
PCC	Population - Concept/Construct - Context
PHR	personal health record
PP	patient portal
PRIOR	Preferred Reporting Items for Overviews of Reviews
PU	primary use
R-AMSTAR	Revised Measurement Tool for the Assessment of Multiple Systematic Reviews
RCT	randomized controlled trial
RoB	Risk of Bias
SR	systematic review
SU	secondary use
TAM	Technology Acceptance Model
TPB	Theory of Planned Behavior
TRA	Theory of Reasoned Action
URM	User Resistance Model
UTAUT	Unified Theory of Acceptance and Use of Technology

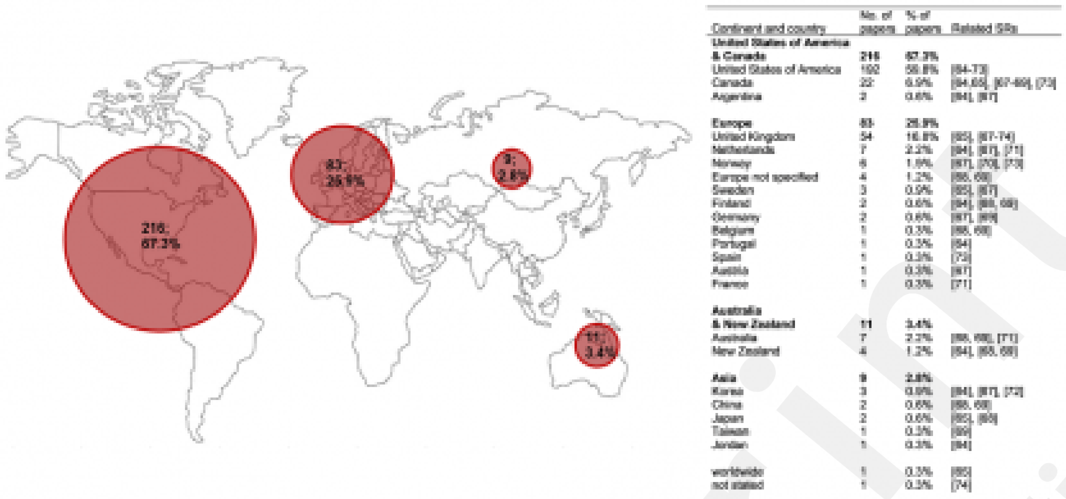
Supplementary Files

Figures

PRISMA flow chart depicting the selection process.

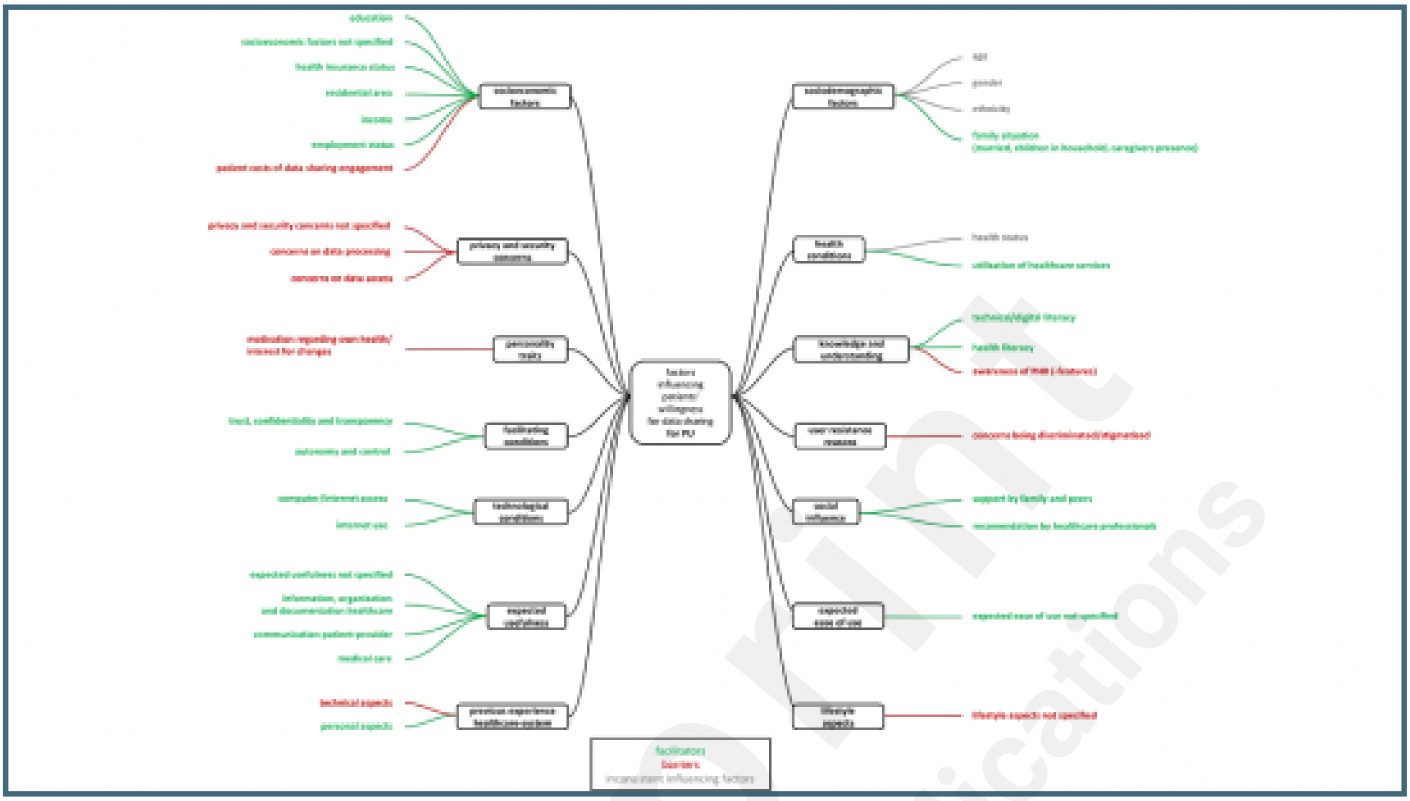


World map and number of papers by continent and country with related SRs.

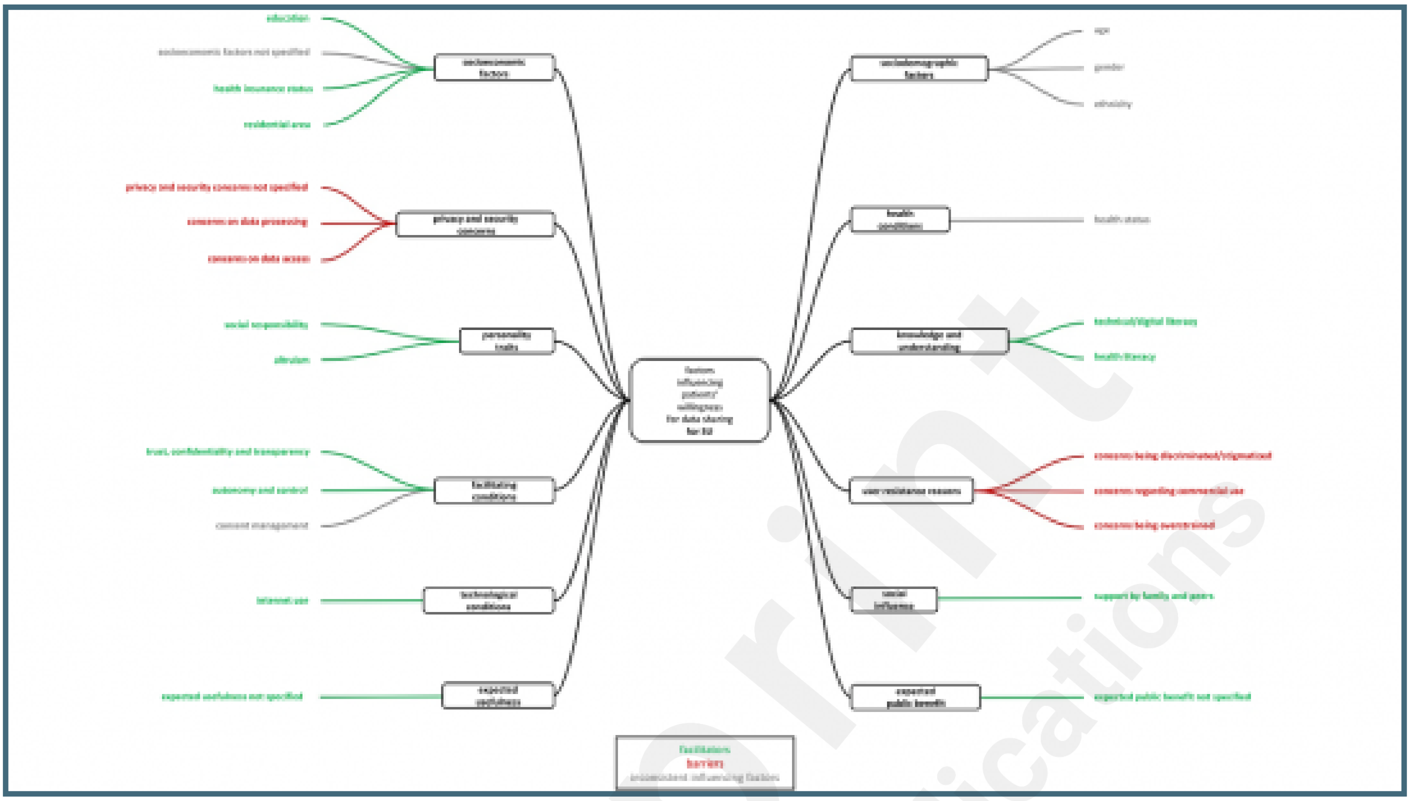


Continent and country	No. of papers	% of papers	Related SRs
United States of America & Canada	**216**	**67.3%**	
United States of America	192	59.8%	[64-73]
Canada	22	6.9%	[64,65], [67-69], [73]
Argentina	2	0.6%	[64], [67]
Europe	**83**	**25.9%**	
United Kingdom	54	16.8%	[65], [67-74]
Netherlands	7	2.2%	[64], [67], [71]
Norway	6	1.9%	[67], [70], [73]
Europe not specified	4	1.2%	[68, 69]
Sweden	3	0.9%	[65], [67]
Finland	2	0.6%	[64], [68, 69]
Germany	2	0.6%	[67], [69]
Belgium	1	0.3%	[68, 69]
Portugal	1	0.3%	[64]
Spain	1	0.3%	[73]
Austria	1	0.3%	[67]
France	1	0.3%	[71]
Australia & New Zealand	**11**	**3.4%**	
Australia	7	2.2%	[68, 69], [71]
New Zealand	4	1.2%	[64], [68, 69]
Asia	**9**	**2.8%**	
Korea	3	0.9%	[64], [67], [72]
China	2	0.6%	[68, 69]
Japan	2	0.6%	[65], [69]
Taiwan	1	0.3%	[69]
Jordan	1	0.3%	[64]
worldwide	1	0.3%	[65]
not stated	1	0.3%	[74]

Evidence map on main categories and influencing factors regarding data sharing for PU.



Evidence map on main categories and influencing factors regarding data sharing for SU.



Multimedia Appendixes

PRIOR checklist.
URL: http://asset.jmir.pub/assets/4bd1313d1290b8e82ee256187b53e8a6.pdf

Search strategy.
URL: http://asset.jmir.pub/assets/778fa02edb6262bf5a12cac9de2d7b61.xlsx

Full data extraction table.
URL: http://asset.jmir.pub/assets/a46aa3c9dadeec9e2f2e042c3416879a.xlsx

Final R-AMSTAR2 checklist results.
URL: http://asset.jmir.pub/assets/0a377f9a27b1a883ede956937bb618e9.xlsx

Please Select A Types

List of excluded reviews by exclusion criteria.
URL: http://asset.jmir.pub/assets/03b2daf80066d0d1fc0d1b6a6c4db648.pdf

Multimedia Appendixes

Reference list of overlaps and duplicate papers.
URL: http://asset.jmir.pub/assets/1de747f83b02f922f72dbba3b8f38a2b.pdf

Detailed table of main categories and influencing factors with direction and explanation.
URL: http://asset.jmir.pub/assets/0c7a22f6497453ef068e51148865f105.xlsx