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Synthesizing and Translating Evidence on Patient Portals:

A Protocol for an Umbrella Review with Stakeholder Engagement

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Abstract

Introduction

Over the last two decades, patient portals have emerged as a noticeable eHealth strategy. Patient portals provide patients with secure online access to their personal health information (e.g., summaries of doctor visits and lab results), sometimes with functions of secure messaging and medication refill. Reported benefits of portals include enhanced patient engagement and improved health outcomes. To date, research on patient portals including systematic reviews has been rapidly increasing, making it difficult to form a coherent view on the current state of

evidence. Our umbrella review (or a review of reviews) aims to provide a meta-level synthesis to make sense of the evidence on patient portals from published systematic reviews.

Methods

We will employ the Joanna Briggs Institute umbrella review method with four methodological extensions. The search strategy encompasses multiple databases (e.g., MEDLINE, CINAHL) without date- or language restrictions. The inclusion criterion is specific to various kinds of systematic reviews focused on patient portal.

Analysis

Two independent researchers will screen titles/abstracts and then full-text articles against the inclusion/exclusion criteria. Methodological quality of included reviews will be assessed and data will be extracted from the final selection of reviews. A narrative meta-level synthesis will be structured around the type of reviews (quantitative or qualitative); target population characteristics; and type of outcome. We will use the Clinical Adoption Meta-Model as an organizing framework.

Ethics and Dissemination

As part of this review, we will create a guidance and roadmap and gather feedback from a small group of eHealth stakeholders using a Delphi-like process. The evidence and feedback summary will be disseminated among relevant stakeholders. We will also present at conferences and publish the final report. The umbrella review does not require ethical approval. For a Delphi component, appropriate guidance/approvals will be sought from our respective institutional Ethics Review boards.

Article Summary

Strengths and limitations of this study

- This umbrella review (review) aims to produce a meta-level synthesis of the current state of evidence on patient portals
- The meta-level synthesis will summarize published quantitative and qualitative reviews into a coherent evidence-base on patient portals guided by an eHealth maturity model
- This review will include initial feedback from eHealth stakeholders to ensure the relevance and uptake of the evidence
- This review will be limited by the quality of and information provided in the published systematic reviews

INTRODUCTION

During the past two decades, many western countries have introduced eHealth strategies and programs to support patients through a variety of electronic health technologies such as the patient portal.[1-3] For example, the Patient Portals & e-Views project funded by Canada Health Infoway was designed at the jurisdictional level to enable patients to assume an active role in their own health.[4] In England, the National Health Service Patient Online program allows patients to securely communicate with their health providers, schedule appointments, and view their GP record.[2] The US Office of National Coordinator for Health Information Technology has introduced the Patient Engagement Playbook as a web-based resource guide for health care providers and administrators to engage patients in their health and care through such technologies as patient portals linked to an electronic health record.[5]

Patient portal is a secure interface that provides patients with 24-hour online access to their personal health information such as recent doctor visits, discharge summaries, medications, allergies, immunizations, and lab results.[6,7] Some portals also enable patients to communicate with their care providers through secure email/text messaging as well as to schedule

appointments and request medication refills online. Patient portals, also known as tethered personal health records, are maintained by healthcare organizations.

Organizations responsible for consumer-focused eHealth technologies tout the benefits of patient portals including improved communication with care providers, better access to health information and services, higher satisfaction level and quality of care, and increased motivation and confidence in managing one's health.[4,5,8] For example, results from a patient survey (n=1000) during a six-month Canadian pilot project on the implementation of the "Citizen Health Information Portal," suggested improved patient care and provider–patient relationships.[9] Similarly, empirical studies have identified the benefits of patient portals.[10-15] However, other studies cautioned about barriers to the use of patient portals among different user groups. Factors influencing utilization of portals among patients include health literacy, technological proficiency, educational level, and socioeconomic status.[16-18] Provider-specific factors include concerns about workload and personal attitudes and perceptions influencing adoption of portals among health providers.[19] Despite these mixed responses, promised benefits of portals such as an enhanced patient engagement and improved health outcomes seem to generate growing interest in this technology among various stakeholders.

Alongside policy conducive to the implementation and uptake of eHealth such as the US Meaningful Use legislation,[20] research on the introduction, use and impact of electronic patient portals has been rapidly increasing. In addition to hundreds of original research articles, multiple systematic reviews on patient portals have been published in the past decade. These reviews are focused on diabetes care,[21] pediatric population,[22] impact,[23] patient and provider attitudes,[19] facilitators and barriers,[24] and technical development.[25] Thus, the evidence on patient portal is dispersed across many publications. Moreover, the empirical evidence on portals

is mixed. For instance, studies have reported varying results as to whether patient portals utilization results in a decrease, increase, or no difference in the number of patient visits.[26-28] These accumulating disparate findings have made it difficult for those involved with, or affected by, patient portals to form a coherent view on the current state of evidence on the introduction, use and effects of these technologies.

With the volume of systematic reviews on eHealth technologies rapidly growing, a higher or meta-level synthesis is required to make sense of the evidence from published reviews in a given domain such as patient portals. The need for a systematic review of reviews on the topic of patient portal is confirmed by our preliminary literature search, which identified only one meta-level review explicitly referring to patient portals.[29] However, this integrative review by Jilka et al.[29] is based on ten reviews published prior to 2015 and specifically focused on patient-accessible electronic health records among adult populations. Thus, reviews on patient portals were a subset of articles on patient access to electronic record. In light of these limitations, there is a necessity for a current and more comprehensive systematic review of reviews addressing the increasing utilization of patient portals. To address this knowledge gap, we will conduct an umbrella review synthesizing present-day evidence on patient portals.

Our decision for selecting an umbrella review approach for this systematic review of reviews was made following a scan of published higher-level reviews and relevant methodological literature.[30,31] The literature scan revealed a disunity of terminology for labeling higher-level reviews: umbrella review, overview, meta-review, review of systematic reviews, review of reviews, and so on. *Meta-reviews* tend to focus on systematic reviews (SRs) of randomized controlled trials (RCTs) and often include statistical meta-analyses.[e.g., 32-35] *Reviews of SRs* and *overviews of reviews* tend to focus on quantitative SRs not exclusive to

RCTs. Some authors reserve the term *overviews* for syntheses of Cochrane SRs only.[36] In contrast, *umbrella reviews* (UR) and *reviews of reviews* are usually more inclusive of different types of SRs. In particular, UR "focuses on broad condition or problem for which there are competing interventions and highlights reviews that address these interventions and their results" [37, p. 95] to integrate evidence from multiple quantitative and qualitative SRs into one handy document.[38] In fact, the Joanna Briggs Institute (JBI) claims that their UR methodology is "the first to consider reviews that report other than quantitative evidence."[39, p. 132] As our review will include reviews of quantitative and/or qualitative primary studies, the research team decided to adopt, with extensions, the JBI UR method.[40]

We anticipate that our contribution will be threefold. Our first contribution is substantive: This UR will consolidate the current state of knowledge about patient portals. Given the rapidly rising volume of systematic review literature to date, the UR method is the next logical step to synthesize the review literature on portals in a more timely and efficient manner. Our second contribution is methodological: We aim to apply a novel approach to appraising evidence that supplements GRADE criteria modified by the Evidence-Based Practice Centers Program[41,42] with a vote count (described below). Our third contribution relates to a knowledge-translation component incorporated in our study. Specifically, the evidence produced in our UR will be used in a Delphi-like process designed to generate initial feedback from the relevant eHealth community (described below). This step aims to develop actionable guidance and a roadmap for policy makers, health providers, and researchers to inform successful introduction and use of patient portals. This stakeholder engagement is particularly important in a Canadian context where some jurisdictions are actively embarking on the implementation of patient portals.

REVIEW METHODOLOGY

Our review of reviews will draw on the Joanna Briggs Institute (JBI) Umbrella Review (UR) methodology with some extensions to enhance the relevance of the evidence produced to eHealth stakeholders. This protocol adheres to the PRISMA-P guidelines[43] and has been submitted to PROSPERO[1] on May 22, 2018.

Objective and questions

The objective of this umbrella review is to summarize the current state of evidence on patient portals based on published systematic literature reviews and to provide guidance and a roadmap for those involved with this eHealth technology. Ultimately, our findings will be of interest not only to eHealth managers/directors, health providers, and researchers, but to patients and families affected by the introduction of patient portals. The questions addressed in this umbrella review are:

(a) What are the characteristics of the patient portals being introduced and used in different settings?

(b) What are the effects of patient portals on the organization, delivery and outcomes of care including provider and patient experiences?

(c) What are the factors that influence the introduction, use and effects of patient portals?

(d) How can we make this evidence actionable? (This is a question for a Delphi component and for the development of guidance and a roadmap for knowledge translation)

Conceptual framework

We will use the Clinical Adoption Meta-Model (CAMM)[44] as a framework to organize and make sense of the UR findings. The CAMM is a maturity model used to understand, describe and explain the introduction, use and effects of eHealth systems over time. It is a temporal model with five dimensions of availability, use, clinical/health behaviour, outcomes, and time. In this

[1] http://www.crd.york.ac.uk/PROSPERO/

review, availability refers to the ability of users to access the patient portal. System use refers to user interaction and experience with the portal. Clinical/health behavior refers to changes in user behaviors from interacting with the portal. Outcomes refers to effects of portal use, which can be at the patient, provider, organization or population level. Time refers to the transition periods across the four dimensions.

UR method

The JBI UR method is intended to provide an overall examination of a body of information that is available for a given topic.[40] Key features of the JBI UR is that it:

(a) compiles evidence from multiple research syntheses that may be quantitative and/or qualitative in nature;

(b) includes reviews based on empirical studies rather than theoretical speculations or opinion (even if the review itself is titled *theoretical* or *critical*);

(c) summarizes evidence from existing reviews without any re-synthesis of the primary studies;

(d) publishes a protocol prior to conducting the meta-review;

(e) requires at least two researchers to conduct the meta-review;

(f) uses a standard JBI critical appraisal checklist to assess the methodological quality of the included reviews;

(g) uses the principles of Grading of Recommendations Assessment, Development and Evaluation (GRADE) to assess the overall strengths of the evidence [45]; and

(h) uses a set of predefined tables to present the quantitative and qualitative findings, and the overall summary of the quantitative and qualitative evidence.

In this review, we will extend the JBI UR method in four ways. First, we will apply the CAMM[44] to organize and make sense of the review findings. Second, we will reconcile the

primary studies across the reviews to eliminate duplicates (described below). Third, we will apply both the GRADE criteria modified by the Evidence-Based Practice Centers Program[41,42] and vote counting[46] as ways to determine the strength of evidence in the reviews. Fourth, we will add a Delphi component with a group of eHealth stakeholders to confirm the evidence to serve as guidance and a roadmap. This approach is consistent with the emerging effort to maximize knowledge translation through a partnership model by involving stakeholders in the review process.[47]

Our systematic review of reviews will reflect methodological recommendations outlined by Pollock et al.[30] and Smith et al.[31] Of note is that these recommendations reinforce those presented in the JBI UR methodology.[39,40] Particular attention will be paid to what Pollock and colleagues[30] identified as eight methodological challenges affecting the quality of reviews of reviews: 1) overlap between reviews (studies appearing in more than one review); 2) outdated reviews; 3) "systematic reviews" that do not meet expected methodological standards; 4) assessment of methodological quality of reviews; 5) quality of reporting within reviews; 6) applying GRADE; 7) potential for publication bias; and 8) summarising key findings in brief accessible format suitable for informing decision making. Each of these areas will be addressed either below or in the final review report, as appropriate.

Search strategy

An academic librarian developed a comprehensive search strategy and assisted with searchers. Two search terms, a) *patient portal* and b) *systematic reviews*, were used in combination and adapted according to the databases, MeSH terms and Boolean rules, and other library best practices to maximize the retrieval of relevant citations. For example, synonyms for patient portal included patient web portal and tethered personal health record. Multiple search

terms for systematic reviews are listed in the following section. We searched multiple databases on April 20, 2018: Ovid MEDLINE, Embase, CINAHL Plus with Full Text, Web of Science Core Collection, Scopus, the Cochrane Database of Systematic Reviews, PROSPERO registry, the JBI Database of Systematic Reviews and Implementation Reports, and Proquest Dissertations & Theses. A MEDLINE search strategy is included as an online supplement.

We searched for reviews published in any language (however, only English key terms were used) and without any date restrictions. Patient portals appeared in the 1990s, and the policy attention fueled their development and use in the 2000th. Incidentally, during this time, various kinds of systematic reviews and overviews of systematic reviews started to flourish. Thus, we anticipate that the bulk of retrieved citations will fall within the last decade. Due to the recent emergence of patient portals, the issue of outdated reviews (i.e., Pollock et al.'s[30] challenge #2) will likely be irrelevant in our UR. We are planning to supplement the above searches by examining the reference lists of all included reviews for additional studies. We will also search the first 100 citations in Google Scholar for missed reviews. The searches will be re-run during an analysis stage to identify reviews published since the initial search.

Inclusion criteria

The overarching inclusion criterion is systematic reviews focused on patient portal as the topic. The types of reviews may include systematic review, meta-analysis, narrative review, descriptive review, scoping review, qualitative review, theoretical review, realist review, critical review, literature review, mixed methods reviews, qualitative evidence synthesis, rapid review, review of reviews, overview, and umbrella review.[37,38] To be included, these reviews must be based on empirical studies, even if the purpose of the review itself is theoretical or critical. We

will include reviews regardless of the year of publication. We will take note about the quantity and the language of non-English reviews.

We will use the PICOS/PICo framework to provide explicit criteria on the types of population (P), intervention (I), comparison (C), outcome (O), study design (S) and context (Co) for inclusion[48] as described below.

- Population – patients regardless of demographic and disease characteristics, and also health providers, consumers, researchers, educators, policy and/or decision makers, and the public
- Intervention/exposure – patient portal; patient web portal; tethered personal health record
- Comparison – intervention vs. a non-exposed control group, pre vs. post, user vs. non-user, and single cohorts only, as well as qualitative reviews not mentioning any comparison
- Outcome – any types of effects including attitudes/behaviors, utilization, care processes, economic value, health outcomes or policies
- Study design – any types of systematic reviews such as meta-analysis, narrative review, descriptive review, scoping review, qualitative review, theoretical review, realist review, critical review, literature review, mixed methods reviews, qualitative evidence synthesis, rapid review, review of reviews, overview, and umbrella review. Reviews can include any kind of empirical primary studies: experimental, quasi-experimental, observational, mixed, and qualitative designs.
- Context – any organizational and practice settings in high-resource countries (e.g., the US, UK, Canada, Netherlands)

Exclusion criteria

- Reviews with multiple eHealth technologies where portal is just one of many technologies examined
- Reviews that include standalone (i.e., not tethered) personal health records controlled by patients (this topic will be addressed in a separate UR)
- Reviews addressing low- and medium-resource countries (this topic will be addressed in a separate UR)
- Reviews in languages other than English will be counted but not read and evaluated
- Reviews not based on primary empirical studies
- *Systematic* reviews that do not describe (at a minimum) the search strategy, inclusion criteria, and quality assessment methods. This inclusion/exclusion decision will happen at the stage of full-text screening or quality evaluation, and will address Pollock et al.'s[30] challenge #3.
- *Scoping* reviews that do not describe (at a minimum) the search strategy and inclusion criteria. Quality assessment is not expected in scoping reviews. This inclusion/exclusion decision will happen at the stage of full-text screening or quality evaluation.

Review selection

Citations retrieved via searchers of electronic databases will be imported to Covidence©[2], a Cochrane-supported software designed for conducting systematic reviews. Two independent researchers will proceed through a series of steps: a) screening the titles and abstracts against the inclusion criteria; and b) screening the full-text articles that met the initial screening step, against the inclusion criteria. Excluded articles and the reasons for exclusion will be logged.

[2] https://www.covidence.org/home

Discrepancies will be resolved by consensus between the two researchers and/or by a third researcher.

Methodological quality assessment

Typically, the methodology for conducting review of reviews presupposes that the quality of included reviews rather than the quality of primary studies is assessed. The purpose of quality assessment is to assess methodological quality, risk of bias, and reporting quality.

Our UR will include reviews of diverse designs. Assessing different types of reviews requires a recognition of the best-practice recommendations for each design. The quality of systematic reviews included thus far will be accessed in the following manner:

Step one. The research team will compare six critical appraisal instruments: 1) the AMSTAR tool by Shea et al.[49] with 11 quality criteria; 2) the AMSTAR 2 tool[50] with 16 items; 3) the ROBIS by Whiting et al.[51] with three phases to assess risk of bias in reviews; 4) the McMaster 10 criteria quality assessment tool[52]; 5) the JBI critical appraisal checklist for systematic reviews[40]; and 6) the ENTREQ framework for reporting the synthesis of qualitative research.[53] One instrument will be selected.

We anticipate that the JBI critical appraisal checklist for systematic reviews might be suitable because a) it is part of the JBI UR method; b) it evaluates both quantitative and qualitative reviews; and c) it is based on principles common across accepted quality assessment tools. There are 11 questions in the JBI checklist each with a possible response of Yes, No or Unclear. For example, Q5 asks “were the criteria for appraising studies appropriate?” and requires that the included review provided details of the appraisal in either the methods section, an appendix, or an online supplementary file. By tallying all Yes responses, a review can have a score range of 0 to 11, with 11 being the highest quality.

Step two. Based on a selected tool, the research team will develop a rubric explicating how to interpret each of the tool's criteria for this specific review. In addition, we will determine the cut-off score for eliminating low quality reviews.

Step three. Using the agreed-upon rubric, one researcher (FL) will asses the quality of all included reviews, whereas the second and third researchers (MA, OP) will each assess 25% of reviews selected randomly. Any discrepancies will be discussed by all three researchers and resolved by consensus.

For reviews of primary qualitative studies, risk of bias assessment designed for reviews of randomized and non-randomized intervention studies is not applicable. When assessing the quality of reviews of qualitative studies, for example trustworthiness, in addition to using the JBI checklist, we might consult other sources such as the CASP-Qualitative tool.[54,55] Scoping reviews will be assessed against the JBI methodology for Scoping Reviews.[56]

This step-wise process aims to address the issue of the absence of a universally-accepted quality assessment instrument and the ensuing attempts by reviewers to mitigate this challenge by recognizing the subjective component in applying quality assessment tools[57] and by modifying existing tools.[58] By paying close attention to the process of quality assessment, we are aiming to address Pollock et al.'s[30] challenges #4 and #5.

Data Extraction

We will use a standardised, pre-piloted form to extract data from the included reviews. We define quantitative studies as those where the results contain numerical values and/or statistical significance. We define qualitative studies as those where the results are reported in descriptive forms. Extracted information will include:

A. Characteristics of included reviews: Review reference (author-year-country), Date of search (years that the review covers), Objective of review, Types of studies / designs included in review, Number of included studies, and Country of included studies

B. Setting focus of the review; Study population and participant demographics and baseline characteristics (Participants included in review; Number of participants included in review; Target condition being addressed in the review); Interventions included in review (Name or brief description; i.e., portal features); Comparisons included in review if applicable; Suggested mechanisms of interventions included in review; Outcomes included in review; Statistical data from quantitative studies reported in review such as Effect size, Confidence intervals, and Positive and negative predictive values is applicable; Major themes from qualitative studies reported in review; Study limitations reported in review

One researcher (FL) will extract all data independently. Two other researchers (MA, OP) will each extract data from 25% of randomly selected reviews. All three researchers will compare the outputs for consistency and resolve discrepancies through discussion. Missing data might be requested from review authors if necessary.

Data synthesis

We anticipate that there will be no meta-analyses among our reviews (due to the lack of RCTs on the topic). In addition, we anticipate a significant heterogeneity of included reviews both in terms of designs and statistical tests (if any) they used. Therefore, we will provide a meta-level narrative, or descriptive, synthesis of the findings from the included reviews, structured around a) the type of reviews—quantitative or qualitative; b) target population characteristics, as appropriate; and c) type of outcome. The CAMM will be used as an

overarching organizing framework to arrange the findings temporally based on the implementation stage of patient portal in health organizations.

In the process of data synthesis, we will determine whether any subgroup description is warranted. That is, whether and how different types of participants (e.g., by age, disease, ethnicity, socioeconomic status); different portal features (e.g., self-scheduling of appointments, direct messaging, access to test results); different contexts (e.g., country, acute or primary care sector, provider or patient perspectives); or different types of reviews (e.g., systematic vs. scoping; quantitative vs. qualitative) require separate presentation and exploration. This is a qualitative synthesis and while subgroup descriptions may be undertaken, it is not possible to specify the groups in advance.

One researcher (FL) will conduct the synthesis, which will be checked by the other two researchers (MA, OP). Discrepancies will be discussed to reach consensus among the three researchers.

Eliminating duplicates

Following the JBI UR method, our review does not involve retrieving the primary studies. Nevertheless, we intend to remove duplicates based on the information in the reviews included in our review. This is a preparatory step for rating the evidence.

Rating the evidence

For quantitative findings, we will first apply the vote counting method described by Lau et al.[46] to quantify the evidence for each outcome. To do so, we will tally the number of positive/neutral/negative results for each outcome based on the significant differences reported in the study. An outcome will be considered positive if >50% of the results are positive and statistically significant. Next, we will apply the GRADE method to determine the strength of

evidence for each outcome. The GRADE method will follow the updated Guidance from the US Evidence-Based Practice Centre[41] as used by Gibbons et al.[42] in their evidence review of consumer eHealth technology. Specifically, we will assign a score to each outcome according to the five domains: study limitations, directness, consistency, precision and reporting bias. Then, an overall grade—high, moderate, low or insufficient—will be assigned to reflect the level of confidence that the estimated effect of the outcome is close to the true effect.[41]

Confidence in findings from qualitative research syntheses will be ascertained by combing the ConQual approach developed by the JBI[59] and GRADE-CerQual approach[60].

The steps of eliminating duplicates and rating the evidence aim to address Pollock et al.'s[30] challenges #1, #6 and #7.

Delphi component

As part of the synthesis, we will create a guidance and roadmap output to be used in a Delphi-like process to gather initial feedback from selected eHealth stakeholders. A guidance will consist of a set of propositions on how a healthcare organization may achieve the optimal effects based on the evidence available, when implementing a patient portal. A roadmap will consist of a visual model based on CAMM,[44] taking into account the above-mentioned propositions in terms of their perceived feasibilities, priorities and interdependencies.

Our Delphi component will be based on the technique used by other researchers to solicit stakeholder feedback in eHealth studies.[61,62] Specifically, we will invite a purposive sample of senior eHealth practitioners from the regional eHealth community to provide up to three rounds of asynchronous feedback related to presented evidence (i.e., our review findings) through a secure web-based survey. Examples of survey questions are:

(a) Do the guidance and roadmap documents provide any new information that you were not aware of earlier?

(b) Do the guidance and roadmap documents make sense to you? If yes, in what ways? If not, why not?

(c) Are the two documents helpful to your plans to introduce patient portals in your organization? If yes, in what ways? If not, why not?

(d) What are the implications of the two documents to your organization's plans to implement patient portal?

Feedback from this small group of eHealth stakeholders will be incorporated into the final review output including the guidance and roadmap documents for subsequent knowledge translation effort with the larger eHealth community.

ETHICS AND DISSEMINATION

The UR does not require approval of ethics boards. For a Delphi component, appropriate guidance/approvals will be sought from institutional Ethics Review boards at the University of Victoria and University of Alberta.

Based on the synthesized evidence, we will create the guidance and roadmap output to be used to gather feedback from selected Canadian eHealth stakeholders using a Delphi survey process, as explained above. The evidence and stakeholder feedback will be disseminated among the larger eHealth community. Ultimately, our findings will be of interest not only to eHealth managers/directors, health providers, and researchers, but also to patients and families affected by the introduction of patient portals. We will also present at conferences and publish the final report in a peer-review, preferably open access journal.

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AUTHORS' CONTRUBUTIONS

MA and FL developed the intellectual idea for the review. FL led the development of the study design and methods and analysis. MA and OP provided suggestions on study methods. OP collaborated with a librarian to develop the search strategy and procured a Covidence© seat. OP and FL drafted the protocol and its various components. MA contributed to the intellectual development of the protocol, commenting on drafts. FL, MA, and OP all helped to resolve disagreement and reach consensus.

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COMPETING INTERESTS STATEMENT

None

Synthesizing and Translating Evidence on Patient Portals:
A Protocol for an Umbrella Review with Stakeholder Engagement

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Supplementary File
MEDLINE Search Strategy

Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

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1 patient portals/

2 ((patient* or consumer*) adj2 portal*).ti,ab,kf.

3 (portal hypertension or portal vein* or portal venous or ((proton or carbon) adj2 portal*)).mp.

4 2 not 3

5 1 or 4

6 (exp "Health Records, Personal"/ or "Patient Access to Records"/) and (electronic or online or internet or web or portal* or tethered).mp.

7 ((tethered adj3 record*) or eclinician or mychart).ti,ab,kf.

8 1 or 5 or 6 or 7

9 meta-analysis.pt.

10 (meta-anal$ or metaanal$).mp.

11 ((quantitativ$ adj3 review$1) or (quantitativ$ adj3 overview$)).mp.

12 ((systematic$ adj3 review$) or (systematic adj3 overview$)).mp.

13 ((methodologic adj3 review$1) or (methodologic adj3 overview$)).mp.

14 (integrat$ adj5 research).mp.

15 (quantitativ$ adj3 synthes$).mp.

16 ((qualitiative* adj3 (review* or overview)) or (meta-synthes* or metasynthes*)).mp.

17 or/9-16

18 review.pt. or (review$ or overview$).mp.

19 (medline or medlars or pubmed or index medicus or embase or cochrane).mp.

20 (scisearch or web of science or psycinfo or psychinfo or cinahl or cinhal).mp.

21 (excerpta medica or psychlit or psyclit or current contents or science citation index or sciences citation index or scopus).mp.

22	(hand search$ or manual search$).mp.
23	((electronic adj3 database$) or (bibliographic adj3 database$) or periodical index$).mp.
24	(pooling or pooled or mantel haenszel).mp.
25	(peto or der simonian or dersimonian or fixed effect$).mp.
26	((combine$ or combining) adj5 (data or trial or trials or studies or study or result or results)).mp.
27	or/19-26
28	18 and 27
29	17 or 28
30	(hta$ or health technology assessment$ or biomedical technology assessment$).mp.
31	technology assessment, biomedical/ or biomedical technology assessment/
32	30 or 31
33	29 or 32
34	8 and 33

Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-P reporting guidelines, and cite them as:

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		Reporting Item	Page Number
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	7
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	24
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important	n/a

		protocol amendments	
Sources	#5a	Indicate sources of financial or other support for the review	24
Sponsor	#5b	Provide name for the review funder and / or sponsor	n/a
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a
Rationale	#6	Describe the rationale for the review in the context of what is already known	3,4,5
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7,11
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	10,11,12
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	9,10
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	10
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	12
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	12
Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	14,15
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	15

Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	15
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	13,14
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	n/a
	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	n/a
	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	n/a
	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	15,16
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	16
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	16,17

BMJ Open

Synthesizing Evidence on Patient Portals: A Protocol for an Umbrella Review

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Synthesizing Evidence on Patient Portals:

A Protocol for an Umbrella Review

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Abstract

Introduction

Over the last two decades, patient portals have emerged as a noticeable eHealth strategy. To date, research on patient portals has been rapidly increasing. Our umbrella review aims to provide a meta-level synthesis to make sense of the evidence on patient portals from published systematic reviews.

Methods

We will employ a modified version of the Joanna Briggs Institute (JBI) umbrella review method. The search strategy encompasses multiple databases. The inclusion criterion is specific to systematic reviews focused on patient portal.

Patients or public were not involved in this work.

Analysis

Two researchers will independently screen titles/abstracts and then full-text articles against the inclusion/exclusion criteria. Methodological quality of included reviews will be assessed and data will be extracted from the final selection of reviews. These reviews will be categorized into quantitative, qualitative, and/or mixed-synthesis groups based on information about the design of primary studies provided in the reviews. Correspondingly, we will create quantitative, qualitative, and/or mixed-synthesis Excel data-extraction tables. Within each table, data will be extracted with the reference to primary studies as reported in the reviews, and will be synthesized into themes and then a smaller number of findings/outcomes. Modified GRADE and CERQual tools will be applied to assess the strength of evidence at the level of each finding/outcome. The output of our umbrella review will consist of Summary of Findings tables and Evidence Profile tables. A narrative meta-level synthesis will be provided. We will use the Clinical Adoption Meta-Model as an organizing framework.

Ethics and Dissemination

As an outcome of this review, we will create a guidance and roadmap to be used in a future Delphi study to gather feedback from Canadian eHealth stakeholders. We will also present at conferences and publish the final report. The umbrella review does not require ethical approval.

PROSPERO registration number CRD42018096657

Article Summary

Strengths and limitations of this study

- Through the application of GRADE and CERQual, this work provides an evaluation of the strength of the quantitative evidence and confidence in the qualitative evidence
- We apply Sandelowski et al.'s conception of logic (i.e., aggregation and configuration) underlying included reviews as an early step in umbrella reviews, to determine the approach to data analysis and synthesis that preserves the integrity of findings reported in included reviews
- Our umbrella review offers a recommended, but seldom-used approach to managing overlaps in included reviews underpinned by the logic of aggregation, namely, elimination of duplicates at the level of primary studies
- While selected elements of the JBI Umbrella Review method will be used, we are not adhering to this method as a whole. Our methodological modifications of the JBI approach include: a) extracting data at *the level of primary studies* as reported within reviews underpinned by the logic of aggregation; and b) using CERQual tool developed by the Cochrane GRADE group
- Only systematic reviews published in English will be included

INTRODUCTION

During the past two decades, many western countries have introduced eHealth strategies and programs to support patients through a variety of electronic health technologies such as the patient portal.[1-3] For example, the Patient Portals & e-Views project funded by Canada Health Infoway was designed at the jurisdictional level to enable patients to assume an active role in their own health.[4] In England, the National Health Service Patient Online program allows patients to securely communicate with their health providers, schedule appointments, and view

their GP record.[2] The US Office of National Coordinator for Health Information Technology has introduced the Patient Engagement Playbook as a web-based resource guide for health care providers and administrators to engage patients in their health and care through such technologies as patient portals linked to an electronic health record.[5]

Patient portal is a secure interface that provides patients with 24-hour online access to their personal health information such as recent doctor visits, discharge summaries, medications, allergies, immunizations, and lab results.[6,7] Some portals also enable patients to communicate with their care providers through secure email/text messaging as well as to schedule appointments and request medication refills online. Patient portals, also known as tethered personal health records, are maintained by healthcare organizations.

Organizations responsible for consumer-focused eHealth technologies tout the benefits of patient portals including improved communication with care providers, better access to health information and services, higher satisfaction level and quality of care, and increased motivation and confidence in managing one's health.[4,5,8] For example, results from a patient survey (n=1000) during a six-month Canadian pilot project on the implementation of the "Citizen Health Information Portal," suggested improved patient care and provider–patient relationships.[9] Similarly, empirical studies have identified the benefits of patient portals.[10-15] However, other studies cautioned about barriers to the use of patient portals among different user groups. Factors influencing utilization of portals among patients include health literacy, technological proficiency, educational level, and socioeconomic status.[16-18] Provider-specific factors include concerns about workload and personal attitudes and perceptions influencing adoption of portals among health providers.[19] Despite these mixed responses, promised

benefits of portals such as an enhanced patient engagement and improved health outcomes seem to generate growing interest in this technology among various stakeholders.

Alongside policy conducive to the implementation and uptake of eHealth such as the US Meaningful Use legislation,[20] research on the introduction, use and impact of electronic patient portals has been rapidly increasing. In addition to hundreds of original research articles, multiple systematic reviews on patient portals have been published in the past decade. These reviews are focused on diabetes care,[21] pediatric population,[22] impact,[23] patient and provider attitudes,[19] facilitators and barriers,[24] and technical development.[25] Thus, the evidence on patient portal is dispersed across many publications. Moreover, the empirical evidence on portals is mixed. For instance, studies have reported varying results as to whether patient portals utilization results in a decrease, increase, or no difference in the number of patient visits.[26-28] These accumulating disparate findings have made it difficult for those involved with, or affected by, patient portals to form a coherent view on the current state of evidence on the introduction, use and effects of these technologies.

With the volume of systematic reviews on eHealth technologies rapidly growing, a higher or meta-level synthesis is required to make sense of the evidence from published reviews in a given domain such as patient portals. The need for a systematic review of reviews on the topic of patient portal is confirmed by our preliminary literature search, which identified one meta-level review explicitly referring to patient portals.[29] However, this integrative review by Jilka et al.[29] is based on ten reviews published prior to 2015 and specifically focused on patient-accessible electronic health records among adult populations. Thus, reviews on patient portals were a subset of articles on patient access to electronic record. In light of these limitations, there is a necessity for a current and more comprehensive systematic review of reviews addressing the

increasing utilization of patient portals. To address this knowledge gap, we will conduct an umbrella review synthesizing present-day evidence on patient portals.

Our decision for selecting an umbrella review approach for this systematic review of reviews was made following a scan of published higher-level reviews and relevant methodological literature.[30,31] The literature scan revealed a disunity of terminology for labeling higher-level reviews: umbrella review, overview, meta-review, review of systematic reviews, review of reviews, and so on. *Meta-review* label is often applied to systematic reviews (SRs) of published meta-analyses, or reviews that employ statistical analyses of data pooled from randomized controlled trials (RCTs) or observational intervention studies; meta-reviews themselves may or may not employ statistical analyses.[e.g., 32-35] *Reviews of SRs* and *overviews of reviews* tend to focus on quantitative SRs not exclusive to meta-analyses of RCTs. Some authors reserve the term *overviews* for syntheses of Cochrane SRs only.[36] In contrast, *umbrella reviews* and *reviews of reviews* are usually more inclusive of different types of SRs. In particular, umbrella review "focuses on broad condition or problem for which there are competing interventions and highlights reviews that address these interventions and their results" [37, p. 95] to integrate evidence from multiple SRs based on primary studies of various designs into one handy document.[38] In fact, the Joanna Briggs Institute (JBI) claims that their umbrella review methodology is "the first to consider reviews that report other than quantitative evidence."[39, p. 132] Our review will include reviews of quantitative, qualitative, and mixed-method primary studies, and thus the JBI approach to umbrella reviews offers a useful guidance.[40] However, we adopt selected elements of this approach while modifying other elements of the JBI method. Our methodological decisions are explained below.

We anticipate that our substantive and methodological contribution will be manifold. This umbrella review will consolidate aspects of the current state of knowledge about patient portals. Given the rapidly rising volume of systematic review literature to date, the umbrella review method is the next logical step to synthesize the review literature on portals in a more timely and efficient manner. Moreover, we aim to apply a novel approach to appraising quantitative evidence that supplements GRADE criteria modified by the Evidence-Based Practice Centers Program[41,42] with a vote count (described below). Further, we demonstrate the usefulness of Sandelowski et al.'s[43] conception of the logic of aggregation or configuration underpinning included reviews (addressed in more detail below). Next, we offer an approach to managing overlaps in reviews by eliminating duplicates at the level of primary studies. Further, as far as we know, our application of CERQual criteria[44] to evaluate qualitative evidence will be the first attempt to use this tool in the context of umbrella reviews. Additionally, the application of GRADE and CERQual to rate the quality of eHealth evidence will contribute to the health informatics discipline in terms of both growing the evidence base and providing guidance on evidence review methods.

REVIEW METHODOLOGY

Umbrella reviews, or overviews of reviews of qualitative, quantitative and mixed-method studies is a growing genre in health sciences,[36,45] and several protocols have been recently published.[46-48] In 2016, Pollock et al.[49] identified as many as 52 guidance documents produced by 19 research groups on how to conduct overviews of reviews. The most consistent recommendations are that umbrella reviews include published systematic reviews with the aim to synthesize findings from included reviews; that these systematic reviews are retrieved through comprehensive searches using more than one databases; and that the methodological quality of

reviews is assessed. The most consistent challenge that these guidance documents point out is that overviews are limited by the methods, reporting, and coverage of their included systematic reviews. Further, Pollock et al.[49] found that the guidance documents present limited and inconsistent recommendations in respect to procedures for evaluating confidence in evidence, managing overlap among reviews, and analyzing and synthesizing data from systematic reviews that include primary studies of various designs. Moreover, Pollock et al.[49] indicated that the guidance documents do not address several important logistical challenges (e.g., the extent of turning to primary studies vs. remaining at the level of included systematic reviews). Indeed, this diversity or absence of guidance is reflected in the methodological variation observed in recently published umbrella reviews.[50-52]

Our survey of several published protocols for umbrella review identified a protocol by Rouleau et al.[47] that illustrates how researchers conducting a review of mixed-synthesis reviews grapple with some challenges listed above (e.g., evaluating quality of evidence, managing overlaps, synthesizing data from mixed-synthesis reviews). Rouleau et al.'s protocol[47] is also distinct for its recognition of a) the element of emergence in umbrella reviews (i.e., an open-ended nature of the data extraction process that makes it counterproductive to pre-select all phenomena of interest at the outset), and b) the importance of both inductive and deductive analysis when using a pre-selected theoretical framework. We anticipate that these challenges and insights will be applicable for our work.

Our umbrella review will use a modified version of the JBI Umbrella Review methodology as defined earlier, and more details are provided below. This protocol adheres to the PRISMA-P guidelines[53] and has been registered in PROSPERO[1] (CRD42018096657).

[1] http://www.crd.york.ac.uk/PROSPERO/

Objective and questions

The objective of this umbrella review is to summarize the aspects of the current state of evidence on patient portals reported in published systematic reviews. Based on this summary, our future step is to provide guidance and a roadmap for stakeholders involved with this eHealth technology, specifically in Canada. Our findings will be of interest not only to eHealth managers/directors, health providers, and researchers, but to patients and families affected by the introduction of patient portals. The questions addressed in this umbrella review are:

(a) What are the characteristics of the patient portals being introduced and used in different settings?

(b) What is the impact of patient portals on clinical outcomes of care?

(c) What are the system-related, health provider-related, and patient-related factors that influence the introduction, use and impact of patient portals?

Conceptual framework

We will use the Clinical Adoption Meta-Model (CAMM)[54] as a framework to organize and make sense of the umbrella review findings. The CAMM is a maturity model used to understand, describe and explain the introduction, use and effects of eHealth systems over time. It is a temporal model with five dimensions of availability, use, clinical/health behaviour, outcomes, and time. In this review, availability refers to the ability of users to access the patient portal. System use refers to user interaction and experience with the portal. Clinical/health behavior refers to changes in user behaviors from interacting with the portal. Outcomes refers to effects of portal use, which can be at the patient, provider, organization or population level. Time refers to the transition periods across the four dimensions.

Modifications to the JBI umbrella review method

Umbrella review method is intended to provide an overall examination of a body of information that is available for a given topic.[40] We have adopted selected key features of the JBI approach to umbrella reviews:

(a) compiling evidence from multiple research syntheses that may be quantitative and/or qualitative in nature;

(b) including reviews based on empirical studies rather than theoretical speculations or opinion (even if the review itself is titled *theoretical* or *critical*);

(c) summarizing evidence from existing reviews without retrieving and reanalyzing primary studies;

(d) publishing a protocol prior to conducting the umbrella review;

(e) including at least two researchers to conduct the umbrella review;

(f) using a standard JBI critical appraisal checklist to assess the methodological quality of the included reviews;

(g) applying an established tool to assess the overall strength of the evidence; and

(h) presenting a summary of findings table and an evidence profile table.

The following five features are unique to our review and constitute a modification of the JBI approach to umbrella reviews. First, we will use Sandelowski et al.'s[43] classification of reviews (i.e., the logic of aggregation or configuration underpinning systematic reviews[2]) as a guidance for data analysis and synthesis (explained below). Second, although we will summarize data from included reviews without retrieving and reanalyzing primary studies, our Excel data-

[2] To prevent any possible confusion, we would like to emphasize that Sandelowski et al.'s ideas presented in this 2012 article, differ from both her earlier conceptions of aggregation and the JBI's terminology used in the context of mixed-method reviews. Importantly, the logics of aggregation and configuration are not tied exclusively to any one side of the qualitative/quantitative binary. E.g., narrative qualitative meta-synthesis can be based on the logic of aggregation.

extraction tables will list the primary studies referenced in each review that aggregates primary quantitative, qualitative, and/or mixed findings, as a support for relevant pieces of data. This step will enable us to reconcile the primary studies across the reviews to eliminate duplicates (described below). In addition, this step is a prerequisite for the application of GRADE and CERQual criteria at the level of individual outcome/finding. Third, we will apply both the GRADE criteria modified by the Evidence-Based Practice Centers Program[41,42] and vote counting[55] as ways to determine the strength of evidence synthesized from aggregative reviews that include quantitative primary studies. Fourth, we will apply the CERQual criteria to determine the confidence in the evidence synthesized from aggregative reviews that include qualitative primary studies. Fifth, we will apply the CAMM[54] to organize and make sense of the umbrella review findings.

Our systematic review of reviews will reflect methodological recommendations outlined by Pollock et al.[30] and Smith et al.[31] Of note is that these recommendations reinforce those presented in the JBI approach to umbrella reviews.[39,40] Particular attention will be paid to what Pollock et al.[30] identified as eight methodological challenges affecting the quality of reviews of reviews: 1) overlap between reviews (studies appearing in more than one review); 2) outdated reviews; 3) "systematic reviews" that do not meet expected methodological standards; 4) assessment of methodological quality of reviews; 5) quality of reporting within reviews; 6) applying GRADE; 7) potential for publication bias; and 8) summarising key findings in brief accessible format suitable for informing decision making. Each of these areas will be addressed either below or in the final review report, as appropriate.

Search strategy

An academic librarian developed a search strategy and assisted with searchers. Two search terms, a) *patient portal* and b) *systematic reviews*, were used in combination and adapted according to the databases, MeSH terms and Boolean rules, and other library best practices to maximize the retrieval of relevant citations. For example, synonyms for patient portal included patient web portal and tethered personal health record. Multiple search terms for systematic reviews are listed in the following section. We searched multiple databases on April 20, 2018: Ovid MEDLINE, Embase, CINAHL Plus with Full Text, Web of Science Core Collection, Scopus, the Cochrane Database of Systematic Reviews, PROSPERO registry, the JBI Database of Systematic Reviews and Implementation Reports, and Proquest Dissertations & Theses. A MEDLINE search strategy is included as an online supplement.

A preliminary scan of retrieved citations (after eliminating duplicates) identified approximately 40 citations meeting inclusion criteria at a glance. We anticipate that after a rigorous application of the inclusion/exclusion criteria and a methodological quality appraisal, we will have a smaller, manageable number of reviews. A preliminary scan also revealed two other important feature of systematic reviews candidates for inclusion in our umbrella review: 1) the majority of systematic reviews synthesize quantitative, qualitative, and/or mixed-method primary studies within each review; and 2) none of a few purely quantitative systematic reviews performs meta-analyses with statistical pooling of findings. Thus, systematic reviews candidates for inclusion all appear to synthesize their findings narratively.

We restricted our searches to reviews published since the year 1990 in English. Patient portals appeared in the 1990s, and the policy attention fueled their development and use in the 2000th. Incidentally, during this time, various kinds of systematic reviews and overviews of

systematic reviews started to flourish. In our preliminary searches, the bulk of retrieved citations fell within the last decade. Due to the recent emergence of patient portals, the issue of outdated reviews (i.e., Pollock et al.'s[30] challenge #2) will likely be irrelevant in our umbrella review. We are planning to supplement the above searches by examining the reference lists of all included reviews for additional studies. We will also search the first 100 citations in Google Scholar for missed reviews. The searches will be re-run during an analysis stage to identify reviews published since the initial search. In addition, at that time we will expand our search to systematic reviews published in grey literature such as reports commissioned by governmental agencies and non-governmental organizations, and retrieved from Google search.

Inclusion criteria

The overarching inclusion criterion is systematic reviews focused on patient portal as the topic. The types of reviews may include systematic review, meta-analysis, narrative review, descriptive review, qualitative review, theoretical review, realist review, critical review, literature review, mixed methods reviews, qualitative evidence synthesis, review of reviews, overview, and umbrella review.[37,38] To be included, these reviews must synthesize findings from empirical studies (i.e., the review authors must indicate that their review synthesizes primary research studies; if in included aggregative reviews we come across an occasional non-empirical primary source or a SR, we will delete this primary source). Because scoping reviews tend to include broader, non-empirical literature, they will be excluded. Inclusion will be limited to reviews published in English since 1990.

We will use the PICOS/PICo framework to provide explicit criteria on the types of population (P), intervention (I), comparison (C), outcome (O), study design (S) and context (Co) for inclusion[56] as described below.

- Population – patients regardless of demographic and disease characteristics, and also health providers, consumers, researchers, educators, policy and/or decision makers, and the public
- Intervention/exposure – patient portal; patient web portal; tethered personal health record
- Comparison – primary studies in included systematic reviews can be intervention vs. a non-exposed control group, pre vs. post, user vs. non-user, and single cohorts only, as well as qualitative designs not mentioning any comparison
- Outcome – any types of effects including attitudes/behaviors, utilization, facilitators and barriers, care processes, economic value, health outcomes or policies
- Study design – any types of systematic reviews summarizing empirical studies (e.g., meta-analysis, narrative review, descriptive review, qualitative review, theoretical review, realist review, critical review, literature review, mixed methods reviews, qualitative evidence synthesis, review of reviews, overview, and umbrella review). Reviews can include empirical primary studies of any design: experimental, quasi-experimental, cross-sectional surveys, mixed, and qualitative designs.
- Context – any organizational and practice settings in countries including but not limited to the US, UK, Canada, or Netherlands, except those locations explicitly labeled in systematic reviews as low- or medium-resource countries

Exclusion criteria

- Reviews with multiple eHealth technologies where portal is just one of many technologies examined
- Reviews that include standalone (i.e., not tethered) personal health records controlled by patients (this topic will be addressed in a separate umbrella review)

- Reviews that explicitly identify in the title or abstract their focus on low- and medium-resource countries (this is a topic for a separate umbrella review)
- Reviews in languages other than English
- Reviews not based on primary empirical studies, e.g., scoping reviews
- Reviews that do not provide a complete list of included primary studies
- *Systematic* reviews that do not describe (at a minimum) the search strategy and explicit inclusion criteria. This inclusion/exclusion decision will happen at the stage of full-text screening or quality evaluation, and will address Pollock et al.'s[30] challenge #3.

Review selection

Citations retrieved via searchers of electronic databases will be imported to Covidence©[3], a Cochrane-supported software designed for conducting systematic reviews. Two researchers will independently proceed through a series of steps: a) screening the titles and abstracts against the inclusion criteria; and b) screening the full-text articles that met the initial screening step, against the inclusion criteria. Excluded articles and the reasons for exclusion will be logged. Discrepancies will be resolved by consensus between the two researchers and/or by a third researcher.

Methodological quality assessment

Typically, the methodology for conducting review of reviews presupposes that the quality of included reviews rather than the quality of primary studies be assessed. The purpose of quality assessment is to assess methodological quality, risk of bias, and reporting quality.

As a preliminary scan of retrieved citations revealed, candidates for inclusion in our umbrella review are mostly mixed-syntheses reviews that narratively aggregate findings of

[3] https://www.covidence.org/home

quantitative, qualitative, and/or mixed-method primary studies within each review. To assess the quality of systematic reviews included after screening the full text, we will apply the JBI critical appraisal checklist for systematic reviews[40].

While several critical appraisal instruments exist[40, 57-61] and they are based on common principles, the JBI checklist is the only tool designed for evaluating both quantitative and qualitative reviews. There are 11 questions in the JBI checklist each with a possible response of Yes, No or Unclear. For example, Q5 asks "were the criteria for appraising studies appropriate?" and requires that the included review provided details of the appraisal in either the methods section, an appendix, or an online supplementary file. By tallying all Yes responses, a review can have a score range of 0 to 11, with 11 being the highest quality.

We will develop a rubric explicating how to interpret each of the tool's criteria for this specific review. In addition, we will determine the cut-off score for eliminating low quality reviews. Using the agreed-upon rubric, one researcher (FL) will asses the quality of all included reviews, whereas the second and third researchers (MA, OP) will each assess at least 30% of reviews selected randomly. Any discrepancies will be discussed by all three researchers and resolved by consensus.

Overall, our team's approach to assessing methodological quality of reviews recognizes the issue of the absence of a universally-accepted quality assessment instrument and the ensuing attempts by reviewers to mitigate this challenge by acknowledging the subjective component in applying quality assessment tools[62] and by modifying existing tools.[63] By paying close attention to the process of quality assessment, we are aiming to address Pollock et al.'s[30] challenges #4 and #5.

PATIENT AND PUBLIC INVOLVEMENT

Patients and public were not involved at this stage. Patient groups will be included in a future Delphi study.

Data Analysis

Prior to data extraction, we will separate included systematic reviews into distinctive groups based on design of primary studies comprising those reviews (i.e., purely quantitative, purely qualitative, or mixed synthesis). For the purely quantitative reviews, we will ascertain their approaches to data synthesis, for instance, meta-analysis with statistical pooling of findings or narrative synthesis. For qualitative and mixed-synthesis reviews, we anticipate some kind of narrative synthesis reported by the authors of those reviews. As explained above, our preliminary scan of reviews candidates for inclusion has shown that the majority of reviews are mixed syntheses while a smaller number of reviews synthesize quantitative primary studies; and that all reviews employ narrative synthesis. This grouping has implications for our subsequent analysis and synthesis.

As the next analytical move, we will apply Sandelowski et al.'s[43] ideas about the type of logic—aggregation or configuration—that can underpin review syntheses (irrespective of the design of primary studies comprising those reviews). The logic of aggregation is evident when a review simply amasses findings of primary studies of various designs in an additive manner. In other words, aggregation is merging thematically-similar findings into a pooled summary.[43, p. 323] In contrast, the logic of configuration is evident when a review develops a synthesis exceeding any specific findings of primary studies. In other words, configuration is meshing thematically-diverse findings into a theory or model.[43, p. 323] A significance of this move is that narrative aggregative syntheses can be disaggregated into the level of primary studies (for our Excel data-extraction tables) without detracting from the integrity of systematic review

findings. On the other hand, syntheses underpinned by the logic of configuration should not be pulled apart into their component findings, as this can detract from the integrity of a theory or model.[43, p. 323]

Based on the above groupings, we will determine what Excel data-extraction tables are necessary in our umbrella review. Examples of data-extraction tables are quantitative, qualitative, and/or mixed-synthesis. Narrative aggregative systematic reviews included in these tables will be analyzed at the level of primary studies. If necessary, we will separately extract any theories reported in reviews underpinned by the logic of configuration.

As mentioned earlier, this analytical process will enable us to achieve three important goals: 1) not to retrieve and reanalyze primary studies while at the same time tracking their findings; 2) to manage overlaps in reviews by removing duplicate primary studies from each table so that they do not contribute the same finding more than once; and 3) to apply GRADE and CERQual at the level of individual outcome/finding from the included reviews.

Eliminating duplicates

Duplicates are identified as an important issue in umbrella reviews, and metrics for calculating the degree of an overlap have been suggested.[64] As described above, our approach to managing an overlap among included reviews is to filter out duplicate primary studies so that they only appear once. The goal of removing duplicates is "to preclude the double counting that overstates the evidence."[64, p. 374]

On the other hand, we will aim to avoid an overestimation of the degree of overlap.[64] This happens when different reviews include the same primary studies, but extract non-overlapping data from those primary studies. Our Excel data-extraction tables will list both the primary studies and the finding from these studies reported in reviews, so that we will only

eliminate fully overlapping findings originating from the same primary study and reported in different reviews.

Data extraction

Excel data-extraction tables described above will be initially piloted by at least two reviewers. Extracted information will include:

A. Characteristics of included reviews: Review reference (author-year-country), Date of search (years that the review covers), Objective of review, Types of studies / designs included in review, Number of included studies, and Country of included studies
B. Setting focus of the review; Study population and participant demographics and baseline characteristics (Participants included in review; Number of participants included in review; Target condition being addressed in the review); Interventions included in review (a thorough description of the features of the patient portal); Comparisons included in review if applicable; Suggested mechanisms of interventions included in review; Outcomes included in review; Statistical data from quantitative studies reported in review such as Effect size, Confidence intervals, and Positive and negative predictive values if applicable; Themes from qualitative studies reported in review; Study limitations reported in review

Items in group B will be extracted line by line from the reviews' Findings/Results sections and recorded in the relevant Excel tables by the primary studies from which these findings originate, as reported in the reviews. One researcher (FL) will extract all data independently. Two other researchers (MA, OP) will each crosscheck at least 30% of the extracted data against review articles. All three researchers will compare the outputs for consistency and resolve discrepancies through discussion.

Data synthesis

If applicable, statistical meta-analysis and subgroup analysis will be preformed depending on the homogeneity in the scope of the intervention, population, or outcomes, using the information provided in included reviews of RCTs and observational intervention studies.[65]

Within each data extraction table, data will be synthesized into descriptive themes, then analytical themes,[66] and then higher-order domains (or evidence findings), and the final Summary of Findings tables will be presented. We will use the Clinical Adoption Meta-Model as an organizing framework to narratively report the findings based on the temporal implementation stage of patient portal in health organizations. Within each implementation stage, a narrative can be structured around the type of evidence, selected population characteristics, and type of outcome.

One researcher (FL) will conduct the synthesis, which will be checked by the other two researchers (MA, OP). Discrepancies will be discussed to reach consensus among the three researchers.

Rating the evidence

We will apply modified GRADE and CERQual tools to assess the strength of the quantitative evidence and the confidence in the qualitative evidence, respectively, at the level of each individual finding. The output of this process will be Evidence Profile tables.

For quantitative findings, we will apply the GRADE method to determine the strength of evidence for each outcome. The GRADE method will follow the updated Guidance from the US Evidence-Based Practice Centre[41] as used by Gibbons et al.[42] in their evidence review of consumer eHealth technology. Specifically, we will assign a score to each outcome according to the five domains: study limitations, directness, consistency, precision and reporting bias. Then,

an overall grade—high, moderate, low or insufficient—will be assigned to reflect the level of confidence that the estimated effect of the outcome is close to the true effect.[41] We will supplement the GRADE method with vote counting[55,67] to quantify the evidence for each outcome. This will be done by tallying the number of positive/neutral/negative results for each outcome based on the significant differences reported in the reviews. An outcome will be considered positive if at least 50% of the results are positive and statistically significant. While vote counting does not show the magnitude of effect, it can reveal the overall direction of the effect for a given outcome. We will also record the sample size of each primary study if mentioned in the reviews and use this information alongside the vote count to make sense of the outcome qualitatively.

For qualitative findings, we will apply GRADE-CERQual criteria to determine the confidence in evidence for each outcome.[68-73] We will assign a score to each outcome according to the four domains: methodological limitations, coherence, relevance, and adequacy. Then, an overall grade—high, moderate, low, or very low confidence—will be assigned to reflect the level of confidence that the estimated effect of the outcome is close to the true effect.[68-73]

The steps of eliminating duplicates and rating the evidence aim to address Pollock et al.'s[30] challenges #1, #6 and #7.

ETHICS AND DISSEMINATION

The umbrella review does not require approval of ethics boards.

A future Delphi study

As an output of this review, we will create a guidance and roadmap to be used in a future Delphi study[74,75] to gather feedback from Canadian eHealth stakeholders (numbers and roles of

stakeholders to be decided). A guidance will consist of a set of suggested actions on how a healthcare organization may achieve the optimal effects based on the evidence available and our personal field experiences, when implementing a patient portal. A roadmap will visually represent suggested actions based on CAMM[54] stages.

Our findings will be of interest not only to eHealth managers/directors, health providers, and researchers, but also to patients and families affected by the introduction of patient portals. We will also present at conferences and publish the final report in a peer reviewed, preferably open access journal.

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AUTHORS' CONTRUBUTIONS

MA and FL developed the intellectual idea for the review. FL led the development of the major aspects of study design, methods and analysis. MA and OP provided suggestions on study methods. OP and MA developed approaches to dealing with qualitative and mixed-synthesis aspects. OP collaborated with a librarian to develop the search strategy and procured a Covidence© seat. OP and FL drafted the protocol and its various components. MA contributed to the intellectual development of the protocol, commenting on drafts. FL, MA, and OP all helped to resolve disagreement and reach consensus. OP revised the protocol with inputs from FL and MA.

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COMPETING INTERESTS STATEMENT

None

Synthesizing and Translating Evidence on Patient Portals:
A Protocol for an Umbrella Review with Stakeholder Engagement

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[1]University of Alberta, [2]University of Victoria

Supplementary File
MEDLINE Search Strategy

Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

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1 patient portals/

2 ((patient* or consumer*) adj2 portal*).ti,ab,kf.

3 (portal hypertension or portal vein* or portal venous or ((proton or carbon) adj2 portal*)).mp.

4 2 not 3

5 1 or 4

6 (exp "Health Records, Personal"/ or "Patient Access to Records"/) and (electronic or online or internet or web or portal* or tethered).mp.

7 ((tethered adj3 record*) or eclinician or mychart).ti,ab,kf.

8 1 or 5 or 6 or 7

9 meta-analysis.pt.

10 (meta-anal$ or metaanal$).mp.

11 ((quantitativ$ adj3 review$1) or (quantitativ$ adj3 overview$)).mp.

12 ((systematic$ adj3 review$) or (systematic adj3 overview$)).mp.

13 ((methodologic adj3 review$1) or (methodologic adj3 overview$)).mp.

14 (integrat$ adj5 research).mp.

15 (quantitativ$ adj3 synthes$).mp.

16 ((qualitiative* adj3 (review* or overview)) or (meta-synthes* or metasynthes*)).mp.

17 or/9-16

18 review.pt. or (review$ or overview$).mp.

19 (medline or medlars or pubmed or index medicus or embase or cochrane).mp.

20 (scisearch or web of science or psycinfo or psychinfo or cinahl or cinhal).mp.

21 (excerpta medica or psychlit or psyclit or current contents or science citation index or sciences citation index or scopus).mp.

22	(hand search$ or manual search$).mp.
23	((electronic adj3 database$) or (bibliographic adj3 database$) or periodical index$).mp.
24	(pooling or pooled or mantel haenszel).mp.
25	(peto or der simonian or dersimonian or fixed effect$).mp.
26	((combine$ or combining) adj5 (data or trial or trials or studies or study or result or results)).mp.
27	or/19-26
28	18 and 27
29	17 or 28
30	(hta$ or health technology assessment$ or biomedical technology assessment$).mp.
31	technology assessment, biomedical/ or biomedical technology assessment/
32	30 or 31
33	29 or 32
34	8 and 33

Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-P reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	7
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	24
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important	n/a

		protocol amendments	
Sources	#5a	Indicate sources of financial or other support for the review	24
Sponsor	#5b	Provide name for the review funder and / or sponsor	n/a
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a
Rationale	#6	Describe the rationale for the review in the context of what is already known	3,4,5
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7,11
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	10,11,12
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	9,10
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	10
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	12
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	12
Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	14,15
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	15

Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	15
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	13,14
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	n/a
	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	n/a
	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	n/a
	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	15,16
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	16
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	16,17

BMJ Open

Synthesizing Evidence on Patient Portals: A Protocol for an Umbrella Review

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Synthesizing Evidence on Patient Portals:

A Protocol for an Umbrella Review

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Keywords: patient portal; tethered Personal Health Record (PHR); umbrella review; review evidence

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Abstract

Introduction

Over the last two decades, patient portals have emerged as a noticeable eHealth strategy. To date, research on patient portals has been rapidly increasing. Our umbrella review aims to provide a meta-level synthesis to make sense of the evidence on patient portals from published systematic reviews.

Methods

We will employ a modified version of the Joanna Briggs Institute (JBI) umbrella review method. The search strategy encompasses multiple databases. The inclusion criterion is specific to systematic reviews focused on patient portal.

Patients or public were not involved in this work.

Analysis

Two researchers will independently screen titles/abstracts and then full-text articles against the inclusion/exclusion criteria. Methodological quality of included reviews will be assessed and data will be extracted from the final selection of reviews. These reviews will be categorized into quantitative, qualitative, and/or mixed-synthesis groups based on information about the design of primary studies provided in the reviews. Correspondingly, we will create quantitative, qualitative, and/or mixed-synthesis Excel data-extraction tables. Within each table, data will be extracted with the reference to primary studies as reported in the reviews, and will be synthesized into themes and then a smaller number of findings/outcomes. Modified GRADE and CERQual tools will be applied to assess the strength of evidence at the level of each finding/outcome. The output of our umbrella review will consist of Summary of Findings tables and Evidence Profile tables. A narrative meta-level synthesis will be provided. We will use the Clinical Adoption Meta-Model as an organizing framework.

Ethics and Dissemination

As an outcome of this review, we will create a guidance and roadmap to be used in a future Delphi study to gather feedback from Canadian eHealth stakeholders. We will also present at conferences and publish the final report. The umbrella review does not require ethical approval.

PROSPERO registration number CRD42018096657

Article Summary

Strengths and limitations of this study

- Through the application of GRADE and CERQual, this work provides an evaluation of the strength of the quantitative evidence and confidence in the qualitative evidence
- We apply Sandelowski et al.'s conception of logic (i.e., aggregation and configuration) underlying included reviews as an early step in umbrella reviews, to determine the approach to data analysis and synthesis that preserves the integrity of findings reported in included reviews
- Our umbrella review offers a recommended, but seldom-used approach to managing overlaps in included reviews underpinned by the logic of aggregation, namely, elimination of duplicates at the level of primary studies
- While selected elements of the JBI Umbrella Review method will be used, we are not adhering to this method as a whole. Our methodological modifications of the JBI approach include: a) extracting data at *the level of primary studies* as reported within reviews underpinned by the logic of aggregation; and b) using CERQual tool developed by the Cochrane GRADE group
- Only systematic reviews published in English will be included

INTRODUCTION

During the past two decades, many western countries have introduced eHealth strategies and programs to support patients through a variety of electronic health technologies such as the patient portal.[1-3] For example, the Patient Portals & e-Views project funded by Canada Health Infoway was designed at the jurisdictional level to enable patients to assume an active role in their own health.[4] In England, the National Health Service Patient Online program allows patients to securely communicate with their health providers, schedule appointments, and view

their GP record.[2] The US Office of National Coordinator for Health Information Technology has introduced the Patient Engagement Playbook as a web-based resource guide for health care providers and administrators to engage patients in their health and care through such technologies as patient portals linked to an electronic health record.[5]

Patient portals are a secure interface that provide patients with 24-hour online access to their personal health information such as recent doctor visits, discharge summaries, medications, allergies, immunizations, and lab results.[6,7] Some portals also enable patients to communicate with their care providers through secure email/text messaging as well as to schedule appointments and request medication refills online. Patient portals, also known as tethered personal health records, are maintained by healthcare organizations.

Organizations responsible for consumer-focused eHealth technologies tout the benefits of patient portals including improved communication with care providers, better access to health information and services, higher satisfaction level and quality of care, and increased motivation and confidence in managing one's health.[4,5,8] For example, results from a patient survey (n=1000) during a six-month Canadian pilot project on the implementation of the "Citizen Health Information Portal," suggested improved patient care and provider–patient relationships.[9] Similarly, empirical studies have identified the benefits of patient portals.[10-15] However, other studies cautioned about barriers to the use of patient portals among different user groups. Factors influencing utilization of portals among patients include health literacy, technological proficiency, educational level, and socioeconomic status.[16-18] Provider-specific factors include concerns about workload and personal attitudes and perceptions influencing adoption of portals among health providers.[19] Despite these mixed responses, promised

benefits of portals such as an enhanced patient engagement and improved health outcomes seem to generate growing interest in this technology among various stakeholders.

Alongside policy conducive to the implementation and uptake of eHealth such as the US Meaningful Use legislation,[20] research on the introduction, use and impact of electronic patient portals has been rapidly increasing. In addition to hundreds of original research articles, multiple systematic reviews on patient portals have been published in the past decade. These reviews are focused on diabetes care,[21] pediatric population,[22] impact,[23] patient and provider attitudes,[19] facilitators and barriers,[24] and technical development.[25] Thus, the evidence on patient portals is dispersed across many publications. Moreover, the empirical evidence on portals is mixed. For instance, studies have reported varying results as to whether utilization of patient portals results in a decrease, increase, or no difference in the number of patient visits.[26-28] These accumulating disparate findings have made it difficult for those involved with, or affected by, patient portals to form a coherent view on the current state of evidence on the introduction, use and effects of these technologies.

With the volume of systematic reviews on eHealth technologies rapidly growing, a higher or meta-level synthesis is required to make sense of the evidence from published reviews in a given domain such as patient portals. The need for a systematic review of reviews on the topic of patient portals is confirmed by our preliminary literature search, which identified one meta-level review explicitly referring to patient portals.[29] However, this integrative review by Jilka et al.[29] is based on ten reviews published prior to 2015 and specifically focused on patient-accessible electronic health records among adult populations. Thus, reviews on patient portals were a subset of articles on patient access to electronic records. In light of these limitations, there is a necessity for a current and more comprehensive systematic review of reviews addressing the

increasing utilization of patient portals. To address this knowledge gap, we will conduct an umbrella review synthesizing present-day evidence on patient portals.

Our decision for selecting an umbrella review approach for this systematic review of reviews was made following a scan of published higher-level reviews and relevant methodological literature.[30,31] The literature scan revealed a disunity of terminology for labeling higher-level reviews: umbrella review, overview, meta-review, review of systematic reviews, review of reviews, and so on. *Meta-review* label is often applied to systematic reviews (SRs) of published meta-analyses, or reviews that employ statistical analyses of data pooled from randomized controlled trials (RCTs) or observational intervention studies; meta-reviews themselves may or may not employ statistical analyses.[e.g., 32-35] *Reviews of SRs* and *overviews of reviews* tend to focus on quantitative SRs not exclusive to meta-analyses of RCTs. Some authors reserve the term *overviews* for syntheses of Cochrane SRs only.[36] In contrast, *umbrella reviews* and *reviews of reviews* are usually more inclusive of different types of SRs. In particular, an umbrella review "focuses on broad condition or problem for which there are competing interventions and highlights reviews that address these interventions and their results" [37, p. 95] to integrate evidence from multiple SRs based on primary studies of various designs into one handy document.[38] In fact, the Joanna Briggs Institute (JBI) claims that their umbrella review methodology is "the first to consider reviews that report other than quantitative evidence."[39, p. 132] Our review will include reviews of quantitative, qualitative, and mixed-method primary studies, and thus the JBI approach to umbrella reviews offers a useful guidance.[40] However, we adopt selected elements of this approach while modifying other elements of the JBI method. Our methodological decisions are explained below.

We anticipate that our substantive and methodological contribution will be manifold. This umbrella review will consolidate aspects of the current state of knowledge about patient portals. Given the rapidly rising volume of systematic review literature to date, the umbrella review method is the next logical step to synthesize the review literature on portals in a more timely and efficient manner. Moreover, we aim to apply a novel approach to appraising quantitative evidence that supplements GRADE criteria modified by the Evidence-Based Practice Centers Program[41,42] with a vote count (described below). Further, we demonstrate the usefulness of Sandelowski et al.'s[43] conception of the logic of aggregation or configuration underpinning included reviews (addressed in more detail below). Next, we offer an approach to managing overlaps in reviews by eliminating duplicates at the level of primary studies. Further, as far as we know, our application of CERQual criteria[44] to evaluate qualitative evidence will be the first attempt to use this tool in the context of umbrella reviews. Additionally, the application of GRADE and CERQual to rate the quality of eHealth evidence will contribute to the health informatics discipline in terms of both growing the evidence base and providing guidance on evidence review methods.

REVIEW METHODOLOGY

Umbrella reviews, or overviews of reviews of qualitative, quantitative and mixed-method studies is a growing genre in health sciences,[36,45] and several protocols have been recently published.[46-48] In 2016, Pollock et al.[49] identified as many as 52 guidance documents produced by 19 research groups on how to conduct overviews of reviews. The most consistent recommendations are that umbrella reviews include published systematic reviews with the aim to synthesize findings from included reviews; that these systematic reviews are retrieved through comprehensive searches using more than one database; and that the methodological quality of

reviews is assessed. The most consistent challenge that these guidance documents point out is that overviews are limited by the methods, reporting, and coverage of their included systematic reviews. Further, Pollock et al.[49] found that the guidance documents present limited and inconsistent recommendations in respect to procedures for evaluating confidence in evidence, managing overlap among reviews, and analyzing and synthesizing data from systematic reviews that include primary studies of various designs. Moreover, Pollock et al.[49] indicated that the guidance documents do not address several important logistical challenges (e.g., the extent of turning to primary studies vs. remaining at the level of included systematic reviews). Indeed, this diversity or absence of guidance is reflected in the methodological variation observed in recently published umbrella reviews.[50-52]

Our survey of several published protocols for umbrella reviews identified a protocol by Rouleau et al.[47] that illustrates how researchers conducting a review of mixed-synthesis reviews grapple with some challenges listed above (e.g., evaluating quality of evidence, managing overlaps, synthesizing data from mixed-synthesis reviews). Rouleau et al.'s protocol[47] is also distinct for its recognition of a) the element of emergence in umbrella reviews (i.e., an open-ended nature of the data extraction process that makes it counterproductive to pre-select all phenomena of interest at the outset), and b) the importance of both inductive and deductive analysis when using a pre-selected theoretical framework. We anticipate that these challenges and insights will be applicable for our work.

Our umbrella review will use a modified version of the JBI Umbrella Review methodology as defined earlier, and more details are provided below. This protocol adheres to the PRISMA-P guidelines[53] and has been registered in PROSPERO[1] (CRD42018096657).

[1] http://www.crd.york.ac.uk/PROSPERO/

Objective and questions

The objective of this umbrella review is to summarize the aspects of the current state of evidence on patient portals reported in published systematic reviews. Based on this summary, our future step is to provide guidance and a roadmap for stakeholders involved with this eHealth technology, specifically in Canada. Our findings will be of interest not only to eHealth managers/directors, health providers, and researchers, but to patients and families affected by the introduction of patient portals. The questions addressed in this umbrella review are:

(a) What are the characteristics of the patient portals being introduced and used in different settings?

(b) What is the impact of patient portals on clinical outcomes of care?

(c) What are the system-related, health provider-related, and patient-related factors that influence the introduction, use and impact of patient portals?

Conceptual framework

We will use the Clinical Adoption Meta-Model (CAMM)[54] as a framework to organize and make sense of the umbrella review findings. The CAMM is a maturity model used to understand, describe and explain the introduction, use and effects of eHealth systems over time. It is a temporal model with five dimensions of availability, use, clinical/health behaviour, outcomes, and time. In this review, availability refers to the ability of users to access the patient portal. System use refers to user interaction and experience with the portal. Clinical/health behavior refers to changes in user behaviors from interacting with the portal. Outcomes refers to effects of portal use, which can be at the patient, provider, organization or population level. Time refers to the transition periods across the four dimensions.

Modifications to the JBI umbrella review method

Umbrella review method is intended to provide an overall examination of a body of information that is available for a given topic.[40] We have adopted selected key features of the JBI approach to umbrella reviews:

(a) compiling evidence from multiple research syntheses that may be quantitative and/or qualitative in nature;

(b) including reviews based on empirical studies rather than theoretical speculations or opinion (even if the review itself is titled *theoretical* or *critical*);

(c) summarizing evidence from existing reviews without retrieving and reanalyzing primary studies;

(d) publishing a protocol prior to conducting the umbrella review;

(e) including at least two researchers to conduct the umbrella review;

(f) using a standard JBI critical appraisal checklist to assess the methodological quality of the included reviews;

(g) applying an established tool to assess the overall strength of the evidence; and

(h) presenting a summary of findings table and an evidence profile table.

The following five features are unique to our review and constitute a modification of the JBI approach to umbrella reviews. First, we will use Sandelowski et al.'s[43] classification of reviews (i.e., the logic of aggregation or configuration underpinning systematic reviews[2]) as a guidance for data analysis and synthesis (explained below). Second, although we will summarize data from included reviews without retrieving and reanalyzing primary studies, our Excel data-

[2] To prevent any possible confusion, we would like to emphasize that Sandelowski et al.'s ideas presented in this 2012 article, differ from both her earlier conceptions of aggregation and the JBI's terminology used in the context of mixed-method reviews. Importantly, the logics of aggregation and configuration are not tied exclusively to any one side of the qualitative/quantitative binary. E.g., narrative qualitative meta-synthesis can be based on the logic of aggregation.

extraction tables will list the primary studies referenced in each review that aggregates primary quantitative, qualitative, and/or mixed findings, as a support for relevant pieces of data. This step will enable us to reconcile the primary studies across the reviews to eliminate duplicates (described below). In addition, this step is a prerequisite for the application of GRADE and CERQual criteria at the level of individual outcome/finding. Third, we will apply both the GRADE criteria modified by the Evidence-Based Practice Centers Program[41,42] and vote counting[55] as ways to determine the strength of evidence synthesized from aggregative reviews that include quantitative primary studies. Fourth, we will apply the CERQual criteria to determine the confidence in the evidence synthesized from aggregative reviews that include qualitative primary studies. Fifth, we will apply the CAMM[54] to organize and make sense of the umbrella review findings.

Our systematic review of reviews will reflect methodological recommendations outlined by Pollock et al.[30] and Smith et al.[31] Of note is that these recommendations reinforce those presented in the JBI approach to umbrella reviews.[39,40] Particular attention will be paid to what Pollock et al.[30] identified as eight methodological challenges affecting the quality of reviews of reviews: 1) overlap between reviews (studies appearing in more than one review); 2) outdated reviews; 3) "systematic reviews" that do not meet expected methodological standards; 4) assessment of methodological quality of reviews; 5) quality of reporting within reviews; 6) applying GRADE; 7) potential for publication bias; and 8) summarising key findings in brief accessible format suitable for informing decision making. Each of these areas will be addressed either below or in the final review report, as appropriate.

Search strategy

An academic librarian developed a search strategy and assisted with searches. Two search terms, a) *patient portal* and b) *systematic reviews*, were used in combination and adapted according to the databases, MeSH terms and Boolean rules, and other library best practices to maximize the retrieval of relevant citations. For example, synonyms for patient portal included patient web portal and tethered personal health record. Multiple search terms for systematic reviews are listed in the following section. We searched multiple databases on April 20, 2018: Ovid MEDLINE, Embase, CINAHL Plus with Full Text, Web of Science Core Collection, Scopus, the Cochrane Database of Systematic Reviews, PROSPERO registry, the JBI Database of Systematic Reviews and Implementation Reports, and Proquest Dissertations & Theses. A MEDLINE search strategy is included as an online supplement.

A preliminary scan of retrieved citations (after eliminating duplicates) identified approximately 40 citations meeting inclusion criteria at a glance. We anticipate that after a rigorous application of the inclusion/exclusion criteria and a methodological quality appraisal, we will have a smaller, manageable number of reviews. A preliminary scan also revealed two other important feature of systematic reviews candidates for inclusion in our umbrella review: 1) the majority of systematic reviews synthesize quantitative, qualitative, and/or mixed-method primary studies within each review; and 2) none of a few purely quantitative systematic reviews perform meta-analyses with statistical pooling of findings. Thus, systematic reviews candidates for inclusion all appear to synthesize their findings narratively.

We restricted our searches to reviews published since the year 1990 in English. Patient portals appeared in the 1990s, and the policy attention fueled their development and use in the 2000s. Incidentally, during this time, various kinds of systematic reviews and overviews of systematic reviews started to flourish. In our preliminary searches, the bulk of retrieved citations

fell within the last decade. Due to the recent emergence of patient portals, the issue of outdated reviews (i.e., Pollock et al.'s[30] challenge #2) will likely be irrelevant in our umbrella review. We are planning to supplement the above searches by examining the reference lists of all included reviews for additional studies. We will also search the first 100 citations in Google Scholar for missed reviews. The searches will be re-run during an analysis stage to identify reviews published since the initial search. In addition, at that time we will expand our search to systematic reviews published in grey literature such as reports commissioned by governmental agencies and non-governmental organizations, and retrieved from a Google search.

Inclusion criteria

The overarching inclusion criterion is systematic reviews focused on patient portals as the topic. The types of reviews may include systematic reviews, meta-analysis, narrative reviews, descriptive reviews, qualitative reviews, theoretical reviews, realist reviews, critical reviews, literature reviews, mixed methods reviews, qualitative evidence synthesis, review of reviews, overviews, and umbrella reviews.[37,38] To be included, these reviews must synthesize findings from empirical studies (i.e., the review authors must indicate that their review synthesizes primary research studies; if in included aggregative reviews we come across an occasional non-empirical primary source or a SR, we will delete this primary source). Because scoping reviews tend to include broader, non-empirical literature, they will be excluded. Inclusion will be limited to reviews published in English since 1990.

We will use the PICOS/PICo framework to provide explicit criteria on the types of population (P), intervention (I), comparison (C), outcome (O), study design (S) and context (Co) for inclusion[56] as described below.

- Population – patients regardless of demographic and disease characteristics, and also health providers, consumers, researchers, educators, policy and/or decision makers, and the public
- Intervention/exposure – patient portal; patient web portal; tethered personal health record
- Comparison – primary studies in included systematic reviews can be intervention vs. a non-exposed control group, pre vs. post, user vs. non-user, and single cohorts only, as well as qualitative designs not mentioning any comparison
- Outcome – any types of effects including attitudes/behaviors, utilization, facilitators and barriers, care processes, economic value, health outcomes or policies
- Study design – any types of systematic reviews summarizing empirical studies (e.g., meta-analysis, narrative review, descriptive review, qualitative review, theoretical review, realist review, critical review, literature review, mixed methods reviews, qualitative evidence synthesis, review of reviews, overview, and umbrella review). Reviews can include empirical primary studies of any design: experimental, quasi-experimental, cross-sectional surveys, mixed, and qualitative designs.
- Context – any organizational and practice settings in countries including but not limited to the US, UK, Canada, or Netherlands, except those locations explicitly labeled in systematic reviews as low- or medium-resource countries

Exclusion criteria

- Reviews with multiple eHealth technologies where portals are just one of many technologies examined
- Reviews that include standalone (i.e., not tethered) personal health records controlled by patients (this topic will be addressed in a separate umbrella review)

- Reviews that explicitly identify in the title or abstract their focus on low- and medium-resource countries (this is a topic for a separate umbrella review)
- Reviews in languages other than English
- Reviews not based on primary empirical studies, e.g., scoping reviews
- Reviews that do not provide a complete list of included primary studies
- *Systematic* reviews that do not describe (at a minimum) the search strategy and explicit inclusion criteria. This inclusion/exclusion decision will happen at the stage of full-text screening or quality evaluation, and will address Pollock et al.'s[30] challenge #3.

Review selection

Citations retrieved via searches of electronic databases will be imported to Covidence©[3], a Cochrane-supported software designed for conducting systematic reviews. Two researchers will independently proceed through a series of steps: a) screening the titles and abstracts against the inclusion criteria; and b) screening the full-text articles that met the initial screening step, against the inclusion criteria. Excluded articles and the reasons for exclusion will be logged. Discrepancies will be resolved by consensus between the two researchers and/or by a third researcher.

Methodological quality assessment

Typically, the methodology for conducting review of reviews presupposes that the quality of included reviews rather than the quality of primary studies be assessed. The purpose of quality assessment is to assess methodological quality, risk of bias, and reporting quality.

As a preliminary scan of retrieved citations revealed, candidates for inclusion in our umbrella review are mostly mixed-syntheses reviews that narratively aggregate findings of

[3] https://www.covidence.org/home

quantitative, qualitative, and/or mixed-method primary studies within each review. To assess the quality of systematic reviews included after screening the full text, we will apply the JBI critical appraisal checklist for systematic reviews[40].

While several critical appraisal instruments exist[40, 57-61] and they are based on common principles, the JBI checklist is the only tool designed for evaluating both quantitative and qualitative reviews. There are 11 questions in the JBI checklist each with a possible response of Yes, No or Unclear. For example, Q5 asks "were the criteria for appraising studies appropriate?" and requires that the included review provided details of the appraisal in either the methods section, an appendix, or an online supplementary file. By tallying all Yes responses, a review can have a score range of 0 to 11, with 11 being the highest quality.

We will develop a rubric explicating how to interpret each of the tool's criteria for this specific review. In addition, we will determine the cut-off score for eliminating low quality reviews. Using the agreed-upon rubric, one researcher (FL) will assess the quality of all included reviews, whereas the second and third researchers (MA, OP) will each assess at least 30% of reviews selected randomly. Any discrepancies will be discussed by all three researchers and resolved by consensus.

Overall, our team's approach to assessing methodological quality of reviews recognizes the issue of the absence of a universally-accepted quality assessment instrument and the ensuing attempts by reviewers to mitigate this challenge by acknowledging the subjective component in applying quality assessment tools[62] and by modifying existing tools.[63] By paying close attention to the process of quality assessment, we are aiming to address Pollock et al.'s[30] challenges #4 and #5.

PATIENT AND PUBLIC INVOLVEMENT

Patients and public were not involved at this stage. Patient groups will be included in a future Delphi study.

Data Analysis

Prior to data extraction, we will separate included systematic reviews into distinctive groups based on design of primary studies comprising those reviews (i.e., purely quantitative, purely qualitative, or mixed synthesis). For the purely quantitative reviews, we will ascertain their approaches to data synthesis, for instance, meta-analysis with statistical pooling of findings or narrative synthesis. For qualitative and mixed-synthesis reviews, we anticipate some kind of narrative synthesis reported by the authors of those reviews. As explained above, our preliminary scan of review papers that were candidates for inclusion has shown that the majority of reviews are mixed syntheses while a smaller number of reviews synthesize quantitative primary studies; and that all reviews employ narrative synthesis. This grouping has implications for our subsequent analysis and synthesis.

As the next analytical move, we will apply Sandelowski et al.'s[43] ideas about the type of logic—aggregation or configuration—that can underpin review syntheses (irrespective of the design of primary studies comprising those reviews). The logic of aggregation is evident when a review simply amasses findings of primary studies of various designs in an additive manner. In other words, aggregation is merging thematically-similar findings into a pooled summary.[43, p. 323] In contrast, the logic of configuration is evident when a review develops a synthesis exceeding any specific findings of primary studies. In other words, configuration is meshing thematically-diverse findings into a theory or model.[43, p. 323] A significance of this move is that narrative aggregative syntheses can be disaggregated into the level of primary studies (for our Excel data-extraction tables) without detracting from the integrity of systematic review

findings. On the other hand, syntheses underpinned by the logic of configuration should not be pulled apart into their component findings, as this can detract from the integrity of a theory or model.[43, p. 323]

Based on the above groupings, we will determine what Excel data-extraction tables are necessary in our umbrella review. Examples of data-extraction tables are quantitative, qualitative, and/or mixed-synthesis. Narrative aggregative systematic reviews included in these tables will be analyzed at the level of primary studies. If necessary, we will separately extract any theories reported in reviews underpinned by the logic of configuration.

As mentioned earlier, this analytical process will enable us to achieve three important goals: 1) not to retrieve and reanalyze primary studies while at the same time tracking their findings; 2) to manage overlaps in reviews by removing duplicate primary studies from each table so that they do not contribute the same finding more than once; and 3) to apply GRADE and CERQual at the level of individual outcome/finding from the included reviews.

Eliminating duplicates

Duplicates are identified as an important issue in umbrella reviews, and metrics for calculating the degree of an overlap have been suggested.[64] As described above, our approach to managing an overlap among included reviews is to filter out duplicate primary studies so that they only appear once. The goal of removing duplicates is "to preclude the double counting that overstates the evidence."[64, p. 374]

On the other hand, we will aim to avoid an overestimation of the degree of overlap.[64] This happens when different reviews include the same primary studies, but extract non-overlapping data from those primary studies. Our Excel data-extraction tables will list both the primary studies and the finding from these studies reported in reviews, so that we will only

eliminate fully overlapping findings originating from the same primary study and reported in different reviews.

Data extraction

Excel data-extraction tables described above will be initially piloted by at least two reviewers. Extracted information will include:

A. Characteristics of included reviews: Review reference (author-year-country), Date of search (years that the review covers), Objective of review, Types of studies / designs included in review, Number of included studies, and Country of included studies
B. Setting focus of the review; Study population and participant demographics and baseline characteristics (Participants included in review; Number of participants included in review; Target condition being addressed in the review); Interventions included in review (a thorough description of the features of the patient portal); Comparisons included in review if applicable; Suggested mechanisms of interventions included in review; Outcomes included in review; Statistical data from quantitative studies reported in review such as Effect size, Confidence intervals, and Positive and negative predictive values if applicable; Themes from qualitative studies reported in review; Study limitations reported in review

Items in group B will be extracted line by line from the reviews' Findings/Results sections and recorded in the relevant Excel tables by the primary studies from which these findings originate, as reported in the reviews. One researcher (FL) will extract all data independently. Two other researchers (MA, OP) will each crosscheck at least 30% of the extracted data against review articles. All three researchers will compare the outputs for consistency and resolve discrepancies through discussion.

Data synthesis

If applicable, statistical meta-analysis and subgroup analysis will be performed depending on the homogeneity in the scope of the intervention, population, or outcomes, using the information provided in included reviews of RCTs and observational intervention studies.[65]

Within each data extraction table, data will be synthesized into descriptive themes, then analytical themes,[66] and then higher-order domains (or evidence findings), and the final Summary of Findings tables will be presented. We will use the Clinical Adoption Meta-Model as an organizing framework to narratively report the findings based on the temporal implementation stage of patient portal in health organizations. Within each implementation stage, a narrative can be structured around the type of evidence, selected population characteristics, and type of outcome.

One researcher (FL) will conduct the synthesis, which will be checked by the other two researchers (MA, OP). Discrepancies will be discussed to reach consensus among the three researchers.

Rating the evidence

We will apply modified GRADE and CERQual tools to assess the strength of the quantitative evidence and the confidence in the qualitative evidence, respectively, at the level of each individual finding. The output of this process will be Evidence Profile tables.

For quantitative findings, we will apply the GRADE method to determine the strength of evidence for each outcome. The GRADE method will follow the updated Guidance from the US Evidence-Based Practice Centre[41] as used by Gibbons et al.[42] in their evidence review of consumer eHealth technology. Specifically, we will assign a score to each outcome according to the five domains: study limitations, directness, consistency, precision and reporting bias. Then,

an overall grade—high, moderate, low or insufficient—will be assigned to reflect the level of confidence that the estimated effect of the outcome is close to the true effect.[41] We will supplement the GRADE method with vote counting[55,67] to quantify the evidence for each outcome. This will be done by tallying the number of positive/neutral/negative results for each outcome based on the significant differences reported in the reviews. An outcome will be considered positive if at least 50% of the results are positive and statistically significant. While vote counting does not show the magnitude of effect, it can reveal the overall direction of the effect for a given outcome. We will also record the sample size of each primary study if mentioned in the reviews and use this information alongside the vote count to make sense of the outcome qualitatively.

For qualitative findings, we will apply GRADE-CERQual criteria to determine the confidence in evidence for each outcome.[68-73] We will assign a score to each outcome according to the four domains: methodological limitations, coherence, relevance, and adequacy. Then, an overall grade—high, moderate, low, or very low confidence—will be assigned to reflect the level of confidence that the estimated effect of the outcome is close to the true effect.[68-73]

The steps of eliminating duplicates and rating the evidence aim to address Pollock et al.'s[30] challenges #1, #6 and #7.

ETHICS AND DISSEMINATION

The umbrella review does not require approval of ethics boards.

A future Delphi study

As an output of this review, we will create a guidance and roadmap to be used in a future Delphi study[74,75] to gather feedback from Canadian eHealth stakeholders (number and roles of

stakeholders to be decided). A guidance will consist of a set of suggested actions on how a healthcare organization may achieve the optimal effects based on the evidence available and our personal field experiences, when implementing a patient portal. A roadmap will visually represent suggested actions based on CAMM[54] stages.

Our findings will be of interest not only to eHealth managers/directors, health providers, and researchers, but also to patients and families affected by the introduction of patient portals. We will also present at conferences and publish the final report in a peer reviewed, preferably open access journal.

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AUTHORS' CONTRUBUTIONS

MA and FL developed the intellectual idea for the review. FL led the development of the major aspects of study design, methods and analysis. MA and OP provided suggestions on study methods. OP and MA developed approaches to dealing with qualitative and mixed-synthesis aspects. OP collaborated with a librarian to develop the search strategy and procured a Covidence© seat. OP and FL drafted the protocol and its various components. MA contributed to the intellectual development of the protocol, commenting on drafts. FL, MA, and OP all helped to resolve disagreement and reach consensus. OP revised the protocol with inputs from FL and MA.

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COMPETING INTERESTS STATEMENT

None

Synthesizing and Translating Evidence on Patient Portals:
A Protocol for an Umbrella Review with Stakeholder Engagement

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Supplementary File
MEDLINE Search Strategy

Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

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1 patient portals/

2 ((patient* or consumer*) adj2 portal*).ti,ab,kf.

3 (portal hypertension or portal vein* or portal venous or ((proton or carbon) adj2 portal*)).mp.

4 2 not 3

5 1 or 4

6 (exp "Health Records, Personal"/ or "Patient Access to Records"/) and (electronic or online or internet or web or portal* or tethered).mp.

7 ((tethered adj3 record*) or eclinician or mychart).ti,ab,kf.

8 1 or 5 or 6 or 7

9 meta-analysis.pt.

10 (meta-anal$ or metaanal$).mp.

11 ((quantitativ$ adj3 review$1) or (quantitativ$ adj3 overview$)).mp.

12 ((systematic$ adj3 review$) or (systematic adj3 overview$)).mp.

13 ((methodologic adj3 review$1) or (methodologic adj3 overview$)).mp.

14 (integrat$ adj5 research).mp.

15 (quantitativ$ adj3 synthes$).mp.

16 ((qualitiative* adj3 (review* or overview)) or (meta-synthes* or metasynthes*)).mp.

17 or/9-16

18 review.pt. or (review$ or overview$).mp.

19 (medline or medlars or pubmed or index medicus or embase or cochrane).mp.

20 (scisearch or web of science or psycinfo or psychinfo or cinahl or cinhal).mp.

21 (excerpta medica or psychlit or psyclit or current contents or science citation index or sciences citation index or scopus).mp.

22	(hand search$ or manual search$).mp.
23	((electronic adj3 database$) or (bibliographic adj3 database$) or periodical index$).mp.
24	(pooling or pooled or mantel haenszel).mp.
25	(peto or der simonian or dersimonian or fixed effect$).mp.
26	((combine$ or combining) adj5 (data or trial or trials or studies or study or result or results)).mp.
27	or/19-26
28	18 and 27
29	17 or 28
30	(hta$ or health technology assessment$ or biomedical technology assessment$).mp.
31	technology assessment, biomedical/ or biomedical technology assessment/
32	30 or 31
33	29 or 32
34	8 and 33

Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-P reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	7
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	24
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important	n/a

		protocol amendments	
Sources	#5a	Indicate sources of financial or other support for the review	24
Sponsor	#5b	Provide name for the review funder and / or sponsor	n/a
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a
Rationale	#6	Describe the rationale for the review in the context of what is already known	3,4,5
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7,11
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	10,11,12
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	9,10
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	10
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	12
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	12
Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	14,15
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	15

Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	15
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	13,14
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	n/a
	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	n/a
	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	n/a
	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	15,16
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	16
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	16,17