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# Toward an interprofessional shared decision making support tool for primary care patients with complex care needs: a participatory systematic mixed studies review protocol

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## Abstract

INTRODUCTION

Patients with complex care needs suffer from combinations of multiple chronic conditions, mental health problems, drug interactions and social vulnerability, which can lead to health care services overuse, underuse or misuse. Typically, these patients, their families, their caregivers, and their practitioners (hereafter stakeholders), face interprofessional and patient-practitioner interactional issues related to stakeholders' personal uncertainty regarding possible options (decisional conflict). Gaps in knowledge, values clarification and social support in situations where options need to be deliberated (decisional needs) hamper effective decision support interventions. This review aims to: (a) identify decisional needs of patients with complex care needs, from the perspective of stakeholders; (b) build a taxonomy of these decisional needs; (c) prioritize decisional needs; and (d) design a decision support tool to help address stakeholders' decisional conflicts.

METHODS AND ANALYSIS

This theory-driven review will be based on the Interprofessional Shared Decision Making (IP-SDM) model and the Ottawa Decision Support Framework. Applying a participatory research approach, we will identify potentially relevant studies through a comprehensive literature search; select relevant ones using eligibility criteria inspired from our previous scoping review on patients with complex care needs; appraise quality using the Mixed Methods Appraisal Tool; conduct a 3-step synthesis (sequential exploratory mixed methods design) to build taxonomy of key decisional needs; and design an IP-SDM decision support tool based on these results.

ETHICS AND DISSEMINATION

Our review will produce a working taxonomy of key decisional needs for primary care patients with complex care needs (ontological contribution), allowing our team to design an innovative

IP-SDM support tool for addressing decisional conflict of multiple stakeholders (practical contribution). We will be the first team to adapt the IP-SDM model for patients with complex care needs (theoretical contribution). Knowledge users will facilitate the implementation of the tool, and disseminate the results in the Canadian primary care network.

**Trial registration number:** Our protocol is registered with PROSPERO (registration number CRD42015020558).

**Strengths and limitations of this study**

- Our review will clarify decisional needs of primary care patients with complex care needs to inform the design of an innovative support tool for addressing stakeholders' decisional conflict.
- This work will be conducted with a participatory research approach involving multiple stakeholders', including patients' perspectives.
- Large team governance can be an issue; thus, an executive task force will carry out the review.
- There is a two-way knowledge gap that our systematic review will help to fill: firstly, the majority of intervention studies address simple care needs rather than complex ones; and secondly, current systematic reviews typically focus on one condition and one homogeneous population.
- The studies heterogeneity challenge will be raised by using an innovative mixed methods design 3-step synthesis to build a taxonomy presenting various key decisional needs configuration.

## Introduction

### Rationale for the review

The concept of ‘patients with complex care needs’ refers to people who suffer from combinations of multiple chronic conditions, mental health issues, drug interactions, social vulnerability, and who are associated with health care services overuse, underuse or misuse [1-3]. However, this does not fully capture the complex care needs experience that encompasses individual (patient and practitioner), interpersonal (patient-practitioner or interprofessional), organizational (e.g., resources), and socio-cultural characteristics (e.g., values)[2 4-6]. Typically, patients with complex care needs, their families, their caregivers, and their practitioners (hereafter stakeholders), face interactional issues related to stakeholders’ personal uncertainty or disagreements regarding possible options (decisional conflict). Gaps in knowledge of situations where options need to be deliberated (decisional needs) hamper effective decision support interventions for these patients.

Team members contributed to a pilot project that sought to identify characteristics of patients with complex care needs and possible interventions [7 8]. A case series[7] and a scoping review[8] revealed that interprofessional coordination of care and lack of stakeholders’ agreement are two major issues affecting this population. Stakeholders’ experience decisional conflict usually associated with knowledge, expectations, personal values, social support and a variety of personal, socio-cultural and clinical characteristics. Three individual evaluation tools of complex care needs [9-11] and one study about patient preference in the context of multi-morbidity were identified [12 13]. In the literature, we found no specific decision support tool that can facilitate shared decision making between a patient with complex care needs, their families and caregivers, and a multidisciplinary team (health and social primary care services). Thus, our target population, patients with complex care needs, can benefit from an interprofessional shared decision making tool (decision support tool) that accounts for the knowledge, values and preferences of all stakeholders [14].

### Interprofessional Shared Decision Making (IP-SDM) model

Shared Decision Making (SDM) is a process where one patient and one health professional work together to make a healthcare choice; it is essential for informed consent and patient centred care

[15 16]. Decision aids are a type of decision support tool that fosters shared decision making. As defined by the IPDAS (International Patient Decision Aid Standards)[17] they support a 5-step iterative decision-making process: (a) help patients and professionals identify a decision point and its related options; (b) help them to exchange information about the benefits and limitations of each option; (c) help patients clarify and communicate personal values and preferences; (d) help patients deliberate with diverse professionals about options; and (e) help patients make an informed value-based decision. A Cochrane systematic review of 110 randomized controlled trials provides strong evidence for the effectiveness of SDM and decision support tools [18-21]. Such tools (a) improve decision quality (increase knowledge of options and reduce personal uncertainty and decisional regret); (b) improve patient engagement in healthcare; (c) decrease non-effective healthcare choices (reduce overuse of health services); and (d) have the potential to increase effective healthcare choices. Decision support tools are also effective interventions to improve interactions, patient satisfaction, self-care, and patient-reported outcomes [20 22-27]. In addition, SDM tools have the potential to reduce inequities in health [28]. Therefore, industrialised countries such as Australia[29], UK[30] and USA[31] are currently implementing large SDM initiatives.

SDM is the most effective decision making process when careful deliberation is needed to address uncertainties inherent to evidence-based medicine, and to weigh the risks and benefits of patients' healthcare choices (based on their values and preferences). Many factors may influence the choices individuals make and the roles they attribute to others and to themselves in the context of interprofessional care [32-35], which justifies framing this review with the Interprofessional Shared Decision Making (IP-SDM) model (Figure 1) [36].

The Interprofessional Shared Decision Making (IP-SDM) model extends the SDM beyond the patient-health professional dyad to interprofessional (IP) teams[36 37]. In addition to its interprofessional component, this model proposes to include family members and potential caregiver in a patient-centered process. The IP-SDM also takes into account the environmental complexity in which the SDM takes place (socio-cultural norm, organizational routines, and institutional structure). This model is particularly relevant to help IP teams respond to decisional needs of patients with complex care needs as it helps the stakeholders reach informed value-based decisions [36-38].

## Decisional needs assessment

A decisional need is usually derived from a needs assessment that addresses or focuses on situations where multiple options need to be deliberated. Assessing decisional needs is needed in order to elaborate effective decision support, even more so when an interprofessional team is required to provide decision support to a patient (e.g., IP-SDM tool). Decision support interventions address stakeholders' personal uncertainty (decisional conflict). Indeed, unmet decisional conflict affects the decision quality (e.g., uninformed, not congruent with values and unsupported socially). This in turn may affect behaviour (e.g., uptake and maintenance of the chosen option), lead to negative emotions (e.g., decision regret) and impact health care use (e.g., overuse, underuse and misuse). The Ottawa Decision Support Framework (ODSF) informs the conduct of the decisional needs assessment and thus the design of decision support tools (Figure 2)[39].

The initial step in the IP-SDM tool development is a decisional needs assessment for primary care patients with complex care needs, which answers the following questions: What are the types of decisions stakeholders have to make? Which decisions are most frequent? Which decisions are the most difficult to make and why? What do the stakeholders need to better support regarding the interprofessional shared decision making process (e.g., information, values clarification, social support or else)? What is currently being done? What are the barriers and facilitators for applying this decision support? Several strategies could be mobilized to assess the stakeholders' decisional needs[14 40]. A systematic review is a good first step.

## Review question and objectives

Our overall review question is: What are, from the perspective of stakeholders, the key decisional needs of patients with complex care needs? In line with the Knowledge Translation (KT) cycle [41], the purpose of our systematic review is to provide the needed groundwork to identify decisional needs of patients with complex care needs to inform the design of an IP-SDM decision support tool (KT tool). With a task force and a multidisciplinary team including patients, practitioners, researchers, and knowledge users in community-based primary health care, this review aims to:

(1) Identify decisional needs of patients with complex care needs from the perspective of stakeholders;

(2) Build a taxonomy of these decisional needs;

(3) Prioritize decisional needs;

(4) Design a decision support tool (with a user-centered approach) to help reconcile stakeholders' decisional conflicts.

## Methods

This review will use a multipronged approach. First, we will conduct a theory-driven systematic mixed studies review (including qualitative, quantitative and mixed methods studies) [42]. Mixed studies reviews provide a rich and highly practical understanding of complex health issues [43-48]. Second, we will use an organizational participatory research approach to determine key decisional needs. Finally, we will apply a user-centered design approach to elaborate the prototype of a first decision support tool for patient with complex care needs.

We will thus blend research with action using a number of iterative cycles, thereby producing knowledge that can inform healthcare practices [49-52]. It consists of doing research with patients and practitioners, rather than on them; it is a strategy for organizational change and practice improvement [52-56]. It also supports the idea of producing and designing decision support tools that respond to the needs and perspectives of the knowledge users rather than producing tools that they need to adapt to. Both approaches are complementary and suitable for this review as the pilot project emerged from practice. A multidisciplinary team mixing scientific and practical knowledge is necessary to achieve our objectives. Team members are knowledge users, researchers and collaborators with practical knowledge (practitioners and patient partners). Our knowledge users are the directors and the members (clinicians, patients and managers) of the four Quebec network of Practice Based Research Networks (PBRN) [57] and the Quebec SPOR SUPPORT Unit (SPOR standing for Strategy for Patient Oriented Research). Our end users are the patients, families, caregivers and practitioners. In partnership with knowledge users, we will systematically search, identify, select, appraise, and synthesize qualitative and quantitative evidence. An executive task force will lead the review and mobilize the participatory review team (knowledge users, co-researchers, patient experts, and international experts).

## Information sources and search strategy

Building on our previous work [7 8], the concept map and the search strategy was written and tested in collaboration with specialized librarians. Based on the scoping review [7], we anticipate retrieving about 4500 potentially relevant database records (authors, title, source, abstract) in MEDLINE (Ovid), Embase (Ovid), PsycINFO (Ovid), CINAHL (EBSCOhost) and Social Sciences Citation Index (SSCI). In addition, our librarians will provide guidance in searching the grey literature using Google Scholar, Conference Proceedings Citation Index-Science (CPCI-S) and specialized websites. After the selection stage, other potentially relevant records will be sought by tracking citations of included studies using Scopus, up to saturation (no additional studies found). Our team members and the first authors of included studies will be emailed to request additional records or bibliographies.

**Eligibility criteria and identification of potentially relevant studies**

Eligibility criteria will be inspired from the previous scoping reviews on patients with complex care needs [8] with a focus on interactional and decisional issues. A study will be included if it is a French, English, or Spanish language empirical study about:

(1) Patients with complex care needs (population with at least one of the following characteristics: multiple chronic conditions; mental health issues; drug interactions; social vulnerability; or health care services overuse, underuse and misuse);

(2) Primary health care setting;

(3) Interpersonal relationships (reciprocal interaction of two or more persons, e.g., interprofessional, or professional-patient, patient-family or professional-family);

(4) Decisional needs (factors associated with stakeholders' decisional conflict and affecting the decision making process regarding situations where multiple options are possible).

We expect to identify about 300 potentially relevant studies. We will use EndNote (reference management software) to remove duplicates and store records with indexing terms. For each record, two reviewers will independently assign codes according to our eligibility criteria using specialized software (DistillerSR). For each code, we will measure the agreement between reviewers (kappa) [58 59]. When reviewers disagree, the record will be included in the following selection process.

### Selection of relevant studies (coding full-text documents)

We anticipate including 150 relevant studies as follows. The two reviewers will independently code each full text paper identified in the previous step. As with identification, inter-reviewer agreement will be measured. Disagreements that are not resolved easily will be referred to a third party [60].

### Critical appraisal of included studies

Critical appraisal is a core component of systematic reviews [41 60]. It provides a rationale to break down the synthesis of included studies by level of quality. We will use the Mixed Methods Appraisal Tool (MMAT) [44 61 62], a unique validated tool for critically appraising the quality of qualitative, quantitative and mixed methods studies in systematic mixed studies reviews [63]. Using the 2011 version of the MMAT [64] appraisal form and user-manual, two reviewers will independently appraise included studies. As with selection, inter-reviewer agreement will be measured, and disagreements resolved. In line with the GRADE system, results will be expressed using two categories, weak/conditional or strong (qualitative or quantitative or mixed) evidence.

### Synthesis design

Included studies will be described in a summary table [60 63 65]. Then, guided by a sequential mixed methods design [42 48 66], we will conduct a 3-step synthesis.

Step 1: Objective 1 -Identify decisional needs from the perspectives of multiple stakeholders

For each included study, two reviewers will independently list decisional needs using a deductive/inductive qualitative thematic analysis with specialized software (NVivo 11) [67-70]. For each decisional need (e.g., goal setting), the facilitators (e.g., interpreter) and barriers (e.g., language) influencing the decision will be listed, including stakeholders' information needs (e.g., options list with their potential benefits and harms), values, preferences and sources of support.

Data extraction: A hybrid thematic analysis (deductive/inductive) will be used. All articles will be coded using predefined themes (codebook) derived from the IP-SDM model and the ODSF (framework for decisional needs assessment)[40], as well as themes suggested by the data; thus, creating an inventory of decisional needs and their facilitators and barriers. A comparative analysis will be conducted to explore similarities/differences between patients' and practitioners' perspectives. Consistency and rigor will be ensured via a process of combining interpretations and dialogues [69 71]. Executive task force team members will examine the inventory and written interpretations, and ask the reviewers to explain strengths and limitations of their interpretations (trustworthiness) and to suggest alternative interpretations.

Data synthesis: A summary table of the analysis will be made by systematically noting the following for all decisional needs: label, definition, patients' and practitioners' perspectives, facilitators that simplify patients' decisions, barriers that make decisions difficult with patients, key excerpts of articles broken down by decisional need (illustrative examples), and GRADE. The summary table will be posted on our review blog, and the team will provide feedback. Given the feedback, some of the decisional needs will be revised, and modifications will be discussed. Then, a harmonization of themes will be conducted [72]. For each term, the usage will be confirmed in reference to documents on decision making (distinguishing accurate from improper usage), and accurate usages will be adopted to avoid ambiguity.

### Step 2: Objective 2 – Build a taxonomy of decisional needs

The Configurational Comparative Method (CCM) is a case-based analysis useful for building taxonomies [73 74]. For this review, each included study will be a case. Using CCM, we will determine commonalities in the relationships between decisional needs, their facilitators and barriers. We will use CCM to test relationships between decision-related variables using Boolean algebra. CCM is appropriate for two reasons: the theory-driven approach and the heterogeneity of study designs.

Data extraction: We will use a data extraction form to ensure a systematic process [75]. Then, we will conduct a quantitative content analysis [76]. The codebook will contain categories listed in step-one (deductive coding), and will be tested by two coders using a random sample of 10% of our cases (studies). For each case, the two coders will independently assign text excerpts to codes (variables and values). This will produce a table of raw data. Inter-coder agreement will be measured (kappa). Disagreements that are not resolved easily will be referred to a third party. For each code with less than substantial agreement ($kappa<0.61$) [59], the codebook will be revised (label, definition and key extracts) and an additional random sample of cases (10%) will be coded.

Data synthesis: Data will be discussed by executive task force members, to produce a table of binary variables with cases in rows and variables in columns. Then, we will conduct the CCM [73] [74], group similar cases in sets, and produce a table of configurations of decisional needs (sets in rows, variables in columns). Results will be interpreted by going back and forth between configurations and cases. The configurations will allow us to ‘pose more focused questions’ on the cases [74]. Configurations of decisional needs and interpretations will be reviewed. The configurations of decisional needs will be posted on the blog, and feedback provided by the team. Discrepancies that are not resolved easily will be referred to a third party. The synthesis will produce a comprehensive taxonomy of decisional needs for primary care patients with complex care needs.

Step 3: Objective 3 - Determine key decisional needs

The taxonomy will be discussed in a half-day workshop with team members, and a penultimate taxonomy will be posted on the blog. Then, the importance of decisional needs (taxonomy elements) will be rated by the team with a blog-embedded web-questionnaire and a 5-item Likert scale (from ‘not important at all’ to ‘extremely important’). Discrepancies (e.g., a need with a variety of ratings from low to high importance) that are not resolved easily will be referred to a third party. This will produce a taxonomy of key decisional needs, facilitators and barriers.

The taxonomy will be compared to the qualitative results of a provincial Demonstration Project of the Quebec SPOR SUPPORT Unit funded by CIHR (Canadian Institutes of Health Research), Quebec Ministry of Health and FRQS (Quebec Research Fund). The demonstration project, conducted by co-authors of this review, focuses on primary care patients with complex care needs. In this other project, semi-structured interviews and focus group will be done with patients/relatives, health/social professionals and decision makers to explore their perspectives of decisional needs of patients with complex care needs. The demonstration project and this systematic review will be done concurrently to validate emerging decisional needs. This will give a deeper and broader understanding to better inform the design of an IP-SDM decision support tool.

### Objective 4 - Design an IP-SDM decision support tool

In a second workshop, participants will determine how results can inform the design of an initial version (V1) of the proposed IP-SDM support tool. Note that given the difficulty in assembling all team members at the same time, this workshop will be held twice: once with local team members and once with international experts (online). Having designed V1 of the tool, we will proceed with its diffusion, dissemination and implementation.

Diffusion, our broadest strategy, will involve raising general awareness about our results and the tool through conference presentations and publications based on International Patient Decision Aid Standards (IPDAS)[1]. Dissemination, a more active and targeted strategy, will consist of reaching other Knowledge Users through websites, listservs, and peer networks through the Canadian primary care and SPOR networks. Implementation in clinical settings will be conducted within the Demonstration Project of the Quebec SPOR SUPPORT Unit. This project will begin in 2017, and consists of three sequential phases: the identification of profiles of these patients with complex care needs in administrative databases, an intervention in clinical settings and a pilot pragmatic trial. Our IP-SDM decision support tool will be a component of a case management intervention in the second phase; our review is, thus, timely. In this phase, an ecological content validation will be conducted in six clinical settings [77]. Practitioners, patients and caregivers will be asked to assess V1 (relevance, clarity and representativeness of its elements). Based on results, we will produce a modified version (V2). Then, using a web-application (app) version of V2, usability will be tested [78 79]. The app will be integrated in the case management intervention. After the demonstration project, the four Quebec PBRNs will be the primary settings targeted for scaling up the implementation of the tool. They include 49 clinics, including most of the Quebec family medicine teaching units (FMUs). These academic units include leaders from multiple professions who have the potential to influence practitioners in other primary care settings.

### Discussion and dissemination

Patients with complex care needs are associated with unmet health care needs, overuse, underuse or misuse of health care services, low quality of care, and increased costs of health systems [80-82].

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[1] http://www.ipdas.ohri.ca/

Given the aging population and rising rates of chronic disease, the number of patients with complex care needs is growing [3 83 84]. This review and its ensuing tool has the potential to improve the quality of health care they receive.

This systematic review will identify decisional needs of patients with complex care needs from the perspective of stakeholders (substantive contribution). The result of our analysis will offer a working taxonomy of key decisional needs for primary care patients with complex care needs (ontological contribution). We will be the first team to adapt the IP-SDM model for patients with complex care needs (theoretical contribution). The taxonomy of key decisional needs will help to design an innovative IP-SDM support tool (practical contribution). This tool will frame stakeholders' decisional needs, help them understand options (e.g., watchful waiting) and patients' goals, and find the common ground crucial for improving patient-practitioner and interprofessional interactions, quality of decisions and care [85].

Our systematic review will contribute to bridge two knowledge gaps: on the one hand, the majority of intervention studies address simple care needs rather than complex ones; on the other hand, current systematic reviews typically focus on one condition and one homogeneous population [86-90]. The studies' heterogeneity challenge will be addressed by using an innovative mixed methods design 3-step synthesis to build a taxonomy presenting various key decisional needs' configurations.

Previous studies showed that patients with complex care needs are typically facing interactional issues, which justifies framing this proposal within the IP-SDM model. Strong evidence shows that SDM support tools improve patient-practitioner interactions and decision quality, and reduce ineffective care [20 91-93]. However, we know of no decision support tool that could facilitate shared decision making between patients with complex care needs and multiple professionals. The unique contribution of our review will be to enhance decision support for these patients.

As with all systematic reviews, due to publication bias, our work will be biased toward positive results. This limitation will be reduced by validating the results with the knowledge users and the qualitative results of a provincial Demonstration Project of the Quebec SPOR SUPPORT Unit (semi-structured interviews and focus group will be done with patients with complex care needs, relatives, health/social professionals and decision makers to explore their perspectives of decisional needs of patients with complex care needs).

This review emerged from two Quebec PBRNs' pilot work, addresses an important issue for stakeholders and is a priority of the Quebec Ministry of Health [94]. In line with Canadian Institutes for Health Research (CIHR) priorities[2], patient perspectives will be included in this review given our organizational participatory research and our user-centered design approaches. Results will be disseminated across Quebec PBRNs and the Canadian primary care network. The tool will be used in the Quebec-SPOR SUPPORT Unit's Demonstration Project. Our multidisciplinary team (family medicine, nursing, pharmacology, public health, psychology, and social work) is ideal for achieving our objectives, and for implementing the proposed tool in Quebec and disseminating it across Canada.

## SYSTEMATIC REVIEW STATUS

The review is currently in the protocol and search strategy updating phase. We are testing the search strategy in Ovid MEDLINE (2017/02/06). We expect to complete the selection of relevant studies in 2017 and design the first version of the IP-SDM support tool in 2018.

## ABBREVIATIONS

- CIHR : Canadian Institutes of Health Research
- FRQS: Fond de recherche du Québec – Santé
- IP-SDM: Interprofessional Shared Decision Making
- KT: Knowledge Translation
- ODSF: Ottawa Decision Support Framework
- PBRN: Practice Based Research Network
- SPOR: CIHR Strategy for Patient Oriented Research

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[2] http://www.cihr-irsc.gc.ca/e/193.html

## KEY TERMS

- KNOWLEDGE USERS: The directors and the members (clinicians, patients, managers) of the four Quebec PBRNs and the Quebec SPOR SUPPORT Unit.
- MULTIDISCIPLINARY TEAM: Patients, practitioners, knowledge users and researchers.
- PRIMARY CARE: Community based primary health care.
- STAKEHOLDERS: Patients with complex care needs, families, caregivers and practitioners.

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## AUTHOR CONTRIBUTIONS

PP, FL and MB conceived and designed the review with input from all team members. MB drafted the manuscript. All authors (MB, PP, FL, JH, GG, RES, MEP, BMC, BMD, BPL, CY, DB, GJ, GA, GR, GV, GS, HC, KB, KE, KI, LB, LC, LMT, MC, NQ, PR, RB, RE, SI, SN, TD, TM, VI, VB, WM) read, critically revised, and approved the final manuscript. Team members are (i) knowledge users (BMC, BMD, DB, JH, LMT, RE, SI), (ii) researchers (MB, PP, FL, GG, RES, MEP, BPL, CY, GA, GR, HC, KE, LB, LC, VI.), (iii) collaborators (GJ, GS, GV, KB, KI, MC, NQ, RB, TD) and (iv) international experts (PR, SN, TM, VB, WM).

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## COMPETING INTERESTS

The authors declare no competing interests.

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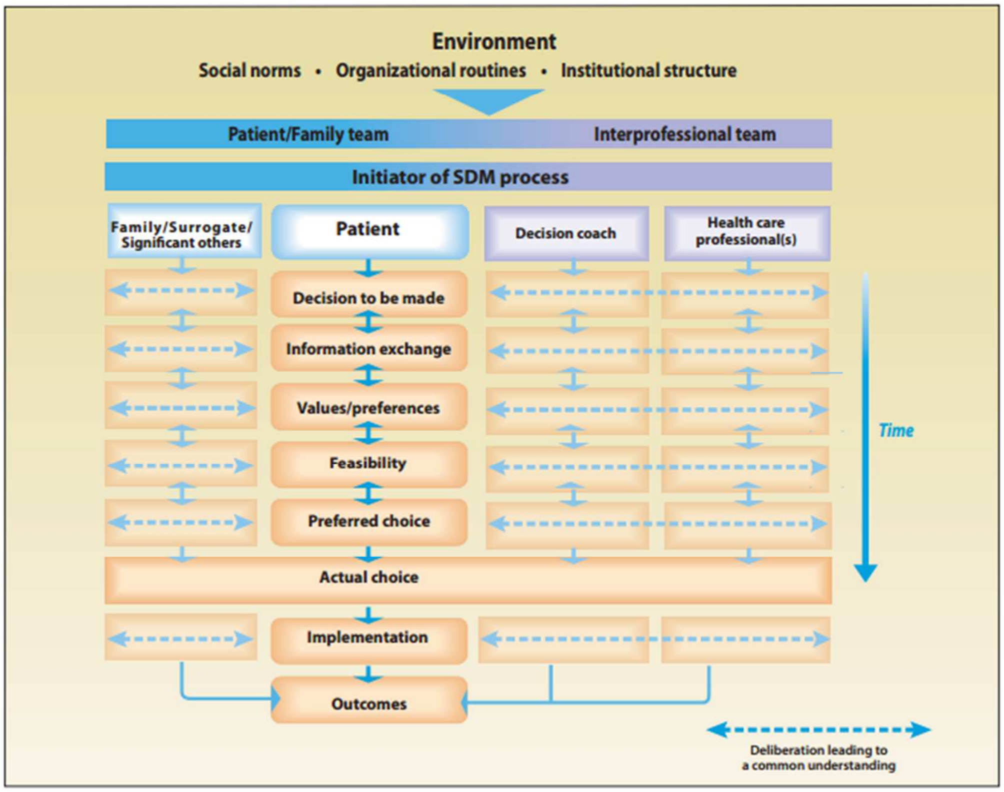
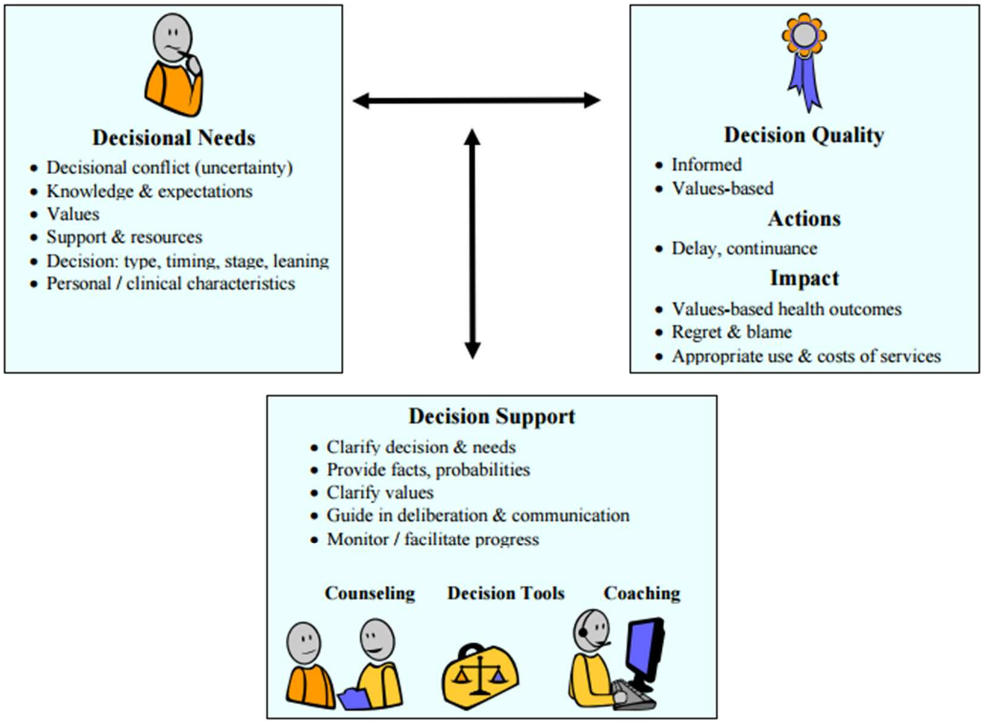
## FIGURES

### Figure 1. The InterProfessional Shared Decision Making (IP-SDM) model



© Légaré F, Stacey D, and IP Team, 2010. Available from www.ohri.ca/decisonaid.

**Figure 2. The Ottawa Decision Support Framework (ODSF)**



AM O'Connor, Ottawa Decision Support Framework to Address Decisional Conflict. © 2006. Available from https://decisionaid.ohri.ca/docs/develop/ODSF.pdf

| Section and topic | Item No | Checklist item - http://www.bmj.com/content/349/bmj.g7647 | Check |
|---|---|---|---|
| **Administrative information** | | | |
| Title: | | | |
| Identification | 1a | Identify the report as a protocol of a systematic review | ✓ |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | ✓ |
| Registration | 2 | If registered, provide the name of the registry (such as PROSPERO) and registration number | ✓ |
| Authors: | | | |
| Contact | 3a | Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author | ✓ |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | ✓ |
| Amendments | 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 protocol amendments | ✓ |
| Support: | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | ✓ |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | ✓ |
| Role of sponsor or funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol | ✓ |
| **Introduction** | | | |
| Rationale | 6 | Describe the rationale for the review in the context of what is already known | ✓ |
| Objectives | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) | ✓ |

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|---|---|---|---|
| **Methods** | | | |
| 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 | ✓ |
| 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 | ✓ |
| 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 | ✓ |
| Study records: | | | |
| Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review | ✓ |
| 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) | ✓ |
| 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 | ✓ |
| 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 | ✓ |
| Outcomes and prioritization | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale | ✓ |
| 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 | ✓ |
| Data synthesis | 15a | Describe criteria under which study data will be quantitatively synthesised | ✓ |

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|---|---|---|---|
| | 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 $I^2$, Kendall's τ) | ✓ |
| | 15c | Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) | |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | |
| Meta-bias(es) | 16 | Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) | ✓ |
| Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (such as GRADE) | ✓ |

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# Decisional needs assessment of patients with complex care needs in primary care: a participatory systematic mixed studies review protocol

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| Secondary Subject Heading: | Patient-centred medicine |
| Keywords: | Patients with complex care needs, Shared decision making, Interprofessional care, PRIMARY CARE |
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# Decisional needs assessment of patients with complex care needs in primary care: a participatory systematic mixed studies review protocol

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## Abstract

INTRODUCTION

Patients with complex care needs (PCCNs) often suffer from combinations of multiple chronic conditions, mental health problems, drug interactions and social vulnerability, which can lead to health care services overuse, underuse or misuse. Typically, PCCNs face interactional issues and unmet decisional needs regarding possible options in a cascade of interrelated decisions involving different stakeholders (themselves, their families, their caregivers, their health care practitioners). Gaps in knowledge, values clarification and social support in situations where options need to be deliberated hamper effective decision support interventions. This review aims to: (1) assess decisional needs of PCCNs from the perspective of stakeholders; (2) build a taxonomy of these decisional needs; and (3) prioritize decisional needs with knowledges users (clinicians, patients and managers).

METHODS AND ANALYSIS

This review will be based on the Interprofessional Shared Decision Making (IP-SDM) model and the Ottawa Decision Support Framework. Applying a participatory research approach, we will identify potentially relevant studies through a comprehensive literature search; select relevant ones using eligibility criteria inspired from our previous scoping review on PCCNs; appraise quality using the Mixed Methods Appraisal Tool; conduct a 3-step synthesis (sequential exploratory mixed methods design) to build taxonomy of key decisional needs; and integrate these results with those of a parallel PCCNs' qualitative decisional need assessment (semi-structured interviews and focus group with stakeholders).

## ETHICS AND DISSEMINATION

This systematic review, together with the qualitative study, will produce a working taxonomy of key decisional needs (ontological contribution), to inform the subsequent user-centered design of an IP-SDM support tool for addressing PCCNs' decisional needs with multiple stakeholders (practical contribution). We will adapt the IP-SDM model, normally dealing with a single decision, for PCCNs who experience cascade of decisions involving different stakeholders (theoretical contribution). Knowledge users will facilitate dissemination of the results in the Canadian primary care network.

**Trial registration number:** Our protocol is registered with PROSPERO (registration number CRD42015020558).

**Strengths and limitations of this study**

- This review will clarify decisional needs of patients with complex care needs (PCCNs) to inform the subsequent user-centered design of an Interprofessional Shared Decision Making (IP-SDM) support tool for addressing PCCNs' decisional needs with multiple stakeholders.
- This work will be conducted with a participatory research approach involving multiple knowledge users', including patients' perspectives.
- Large team governance can be an issue; thus, an executive task force will carry out the review.
- There is a two-way knowledge gap this systematic review will help to fill: firstly, the majority of intervention studies address simple care needs rather than complex ones; and secondly, current systematic reviews typically focus on one condition and one homogeneous population.
- The studies heterogeneity challenge will be raised by using an innovative mixed methods design 3-step synthesis to build a taxonomy presenting various key decisional needs configuration.

## Introduction

### Rationale for the review

Community-based primary health care (hereafter, primary care) plays a key role regarding situations of complex care needs [1-3]. Patients with complex care needs (PCCNs) often suffer from combinations of multiple chronic conditions, mental health problems, drug interactions and social vulnerability, which can lead to health care services overuse, underuse or misuse [1 4 5]. However, this does not fully capture the complex care needs experience that encompasses individual (patient and practitioner), interpersonal (patient-practitioner or interprofessional), organizational (e.g., resources), and socio-cultural characteristics (e.g., values) [4 6-8]. Typically, PCCNs face interactional issues related to personal uncertainty or disagreements regarding possible options (decisional conflict) and unmet decisional needs (e.g., knowledge acquisition, clarification of values and preferences, support, and resources). The complexity of decision-making could be exacerbated by a cascade of interrelated decisions involving different stakeholders (PCCNs, their families, their caregivers, their health care practitioners, etc.). Gaps in knowledge, values clarification and social support in these situations where multiple options need to be deliberated (decisional needs) hamper decision support interventions.

In a quality improvement process, a group of health and social primary care practitioners, patients and researchers from Practice Based Research Networks (PBRNs) identified the necessity to better understand PCCNs' decisional needs. Team members contributed to a pilot project that sought to identify characteristics of PCCNs and possible support interventions [9 10]. A case series[9] and a scoping review[10] revealed that interprofessional coordination of care and lack of stakeholders' agreement are two major issues affecting this population. It is necessary to better understand the decisional needs of PCCNs associated with mismatched knowledge, expectations, personal values, as well as social support related to a variety of personal, socio-cultural and clinical characteristics. Three individual evaluation tools of complex care needs [11-13] and one study about patient preference in the context of multi-morbidity were identified [14 15]. In the literature, we found no tool to facilitate shared decision making between PCCNs, their families and caregivers, and health care providers. Thus, our target population, PCCNs, may benefit from a decisional needs assessment to inform the design of an interprofessional shared decision making tool that accounts for their knowledge, values and preferences[16].

### Interprofessional Shared Decision Making (IP-SDM) model

Shared Decision Making (SDM) is a process where one patient and one health professional work together to make a healthcare choice; it is essential for informed consent and patient centred care [17-22]. Industrialised countries such as Australia[23], UK[24] and USA[25] are currently implementing large SDM initiatives. SDM is an effective decision making process when careful deliberation is needed to address uncertainties inherent to evidence-based medicine, and to weigh the risks and benefits of patients' healthcare choices (based on their values and preferences). Many factors may influence the choices individuals make and the roles they attribute to others and to themselves in the context of interprofessional care [26-29], which justifies framing this review with the Interprofessional Shared Decision Making (IP-SDM) model [30].

The IP-SDM model extends the SDM beyond the patient-health professional dyad to interprofessional (IP) teams [30-32]. In addition to its interprofessional component, this model proposes to include family members and potential caregivers in a patient-centered process (Figure 1). This model aims to stimulate deliberation and reach a common understanding among patients, family/surrogate/significant others, decision coaches, and health care professionals. The IP-SDM model follows a patient-centered step by step process: (1) choose a decision to make and explore related options; (2) exchange information; (3) clarify values and preferences; (4) assess the feasibility of the decision; (5) choose the preferred decision option; (6) implement the decision; (7) assess the outcome. Based on the IP-SDM model interventions have been developed for specific decision-making situations. For example, a study is currently under way to scale up and evaluate the implementation of IP-SDM intervention for frails elderly clients or their caregivers facing a decision about staying at home or moving elsewhere [33 34]. The IP-SDM also takes into account the environmental complexity in which the SDM takes place (socio-cultural norm, organizational routines, and institutional structure). This model is particularly relevant to help IP teams respond to decisional needs of PCCNs as it helps the stakeholders reach informed value-based decisions [30 31 35]. Typically, the IPSDM is used for one decision. We will be the first team to adapt this model for PCCNs who experience complex interrelated decisions involving different stakeholders with various opinions.

## Decisional needs assessment

A decisional need is usually derived from a needs assessment that addresses or focuses on a situation where multiple options need to be deliberated. Assessing decisional needs is needed in order to elaborate effective decision support, even more so when an interprofessional team is required to provide decision support to a patient. A decisional needs assessment is particularly relevant for PCCNs, such as prioritizing a cascade of complex decisions that involve multiple stakeholders. Decision support interventions address stakeholders' decisional needs (decisional conflict, lack of knowledge and information exchange, values, expectation and preferences clarification, support and resource). Indeed, unmet decisional needs affects the decision quality (e.g., uninformed, incongruent with values and unsupported socially). This in turn may affect behaviour (e.g., uptake and maintenance of the chosen option), lead to negative emotions (e.g., decision regret) and impact health care use (e.g., overuse, underuse and misuse). The Ottawa Decision Support Framework (ODSF) informs the conduct of the decisional needs assessment [36 37].

The decisional needs assessment for PCCNs will answers the following questions: What are the types of decisions have to make complex care needs situations? Which decisions are most frequent? Which decisions are the most difficult to make and why? How these decisions are interrelated? Who are the stakeholders involved in the decision? What is needed to better support regarding the interprofessional shared decision making process (e.g., information, values clarification, social support or else)? What is currently being done? What are the barriers and facilitators for applying this decision support? Several strategies could be mobilized to assess decisional needs of a population[16 38]. One of them consists to review the existing information (i.e. previous studies)[16].

## Review question and objectives

Our overall review question is: What are, from the perspective of stakeholders, the key decisional needs of patients with complex care needs (PCCNs)? In line with the Knowledge Translation (KT) cycle [39], the purpose of our systematic review is to provide the needed groundwork to assess

decisional needs of PCCNs. With a task force and a multidisciplinary team including researchers and knowledge users in community-based primary health care (see table 1), this review aims to:
(1) Assess decisional needs of PCCNs from the perspective of stakeholders;
(2) Build a taxonomy of these decisional needs;
(3) Prioritize decisional needs with knowledges users (clinicians, patients, managers).

## Methods

This review will use a multipronged approach. First, we will conduct a systematic mixed studies review (including qualitative, quantitative and mixed methods studies) [40]. Mixed studies reviews provide a rich and highly practical understanding of complex health issues [41-46]. Second, we will use an organizational participatory research approach, involving researchers and knowledge users (clinicians, patients, managers), to determine key decisional needs.

We will, thus, blend research with action using a number of iterative cycles, thereby producing knowledge that can inform healthcare practices [47-50]. Organizational participatory research consists of doing research with patients and practitioners, rather than on them; it is a strategy for organizational change and practice improvement [50-54]. It also supports the idea of producing knowledge that respond to the needs and perspectives of the knowledge users rather than producing knowledge to which they need to adapt. This approach is suitable for this review as the pilot project emerged from practice. A multidisciplinary team blending scientific and practical knowledge is necessary to achieve our objectives (table 1). Team members are researchers with various expertise, and knowledge users (directors and clinicians, patients and managers of the four Quebec network of Practice Based Research Networks (PBRN)[55] and the Quebec SPOR SUPPORT Unit (SPOR standing for Strategy for Patient Oriented Research). In partnership with knowledge users, we will systematically search, identify, select, appraise, and synthesize qualitative and quantitative evidence. An executive task force will lead the review and mobilize the participatory review team (knowledge users, co-researchers, patient experts, and international experts).

## Information sources and search strategy

Building on our previous work [9 10], the concept map and the search strategy was written and tested in collaboration with specialized librarians. Based on the scoping review [9], we anticipate retrieving about 4500 potentially relevant database records (authors, title, source, abstract) in MEDLINE (Ovid), Embase (Ovid), PsycINFO (Ovid), CINAHL (EBSCOhost) and Social Sciences Citation Index (SSCI). In addition, our librarians will provide guidance in searching the grey literature using Google Scholar, Conference Proceedings Citation Index-Science (CPCI-S) and specialized websites. After the selection stage, other potentially relevant records will be sought by tracking citations of included studies using Scopus, up to saturation (no additional studies found). Our team members, including knowledge users, will be emailed to request additional records or bibliographies.

## Eligibility criteria and identification of potentially relevant studies

Eligibility criteria will be based upon the previous scoping reviews on PCCNs [10] with a focus on interactional and decisional issues. A study will be included if it is a French, English, or Spanish language empirical study about:

(1) Patients with complex care needs (any study dealing directly or indirectly with PCCNs or a population with at least one of the following characteristics: multiple chronic conditions; mental health issues; drug interactions; social vulnerability; or health care services overuse, underuse and misuse);

(2) Primary health care setting (any study dealing directly with primary health care setting or indirectly, e.g., links between primary care and secondary or tertiary care setting)

(3) Interpersonal relationships (reciprocal interaction of two or more persons, e.g., interprofessional, or professional-patient, patient-family or professional-family);

(4) Decisional needs (frequent or difficult decisions regarding situations where multiple options are possible, factors affecting the decision making process, decisional conflict, support and resources used or needed to improve decision quality, barriers and facilitators to using decision supports).

We expect to identify about 300 potentially relevant studies. We will use EndNote (reference management software) to remove duplicates and store records with indexing terms. For each record, two reviewers will independently assign codes according to our eligibility criteria using specialized software (DistillerSR). For each code, we will measure the agreement between reviewers (kappa) [56 57]. When reviewers disagree, the record will be included in the following selection process.

## Selection of relevant studies (coding full-text documents)

We anticipate including 150 relevant studies as follows. The two reviewers will independently code each full text paper identified in the previous step. As with identification, inter-reviewer agreement will be measured. Disagreements that are not resolved easily will be referred to a third party [58].

## Critical appraisal of included studies

Critical appraisal is a core component of systematic reviews [39 58]. It provides a rationale to break down the synthesis of included studies by level of quality. We will use the Mixed Methods Appraisal Tool (MMAT) [42 59 60], a unique validated tool for critically appraising the quality of qualitative, quantitative and mixed methods studies in systematic mixed studies reviews [61]. Using the 2011 version of the MMAT [62] appraisal form and user-manual, two reviewers will independently appraise included studies. As with selection, inter-reviewer agreement will be measured, and disagreements resolved.

## Synthesis design

Included studies will be described in a summary table [58 61 63]. Then, guided by a sequential mixed methods design [40 46 64], we will conduct a 3-step synthesis.

Step 1: Objective 1 -Assess decisional needs of PCCNs from the perspective of stakeholders

For each included study, two reviewers will independently list decisional needs using a deductive/inductive qualitative thematic analysis with specialized software (NVivo 11) [65-68]. For each decisional need (e.g., goal setting), type of stakeholder (e.g. patient), the facilitators (e.g., interpreter) and barriers (e.g., language) influencing the decision will be listed, including stakeholders' information needs (e.g., list of option with their, respective, potential benefits and harms), values, preferences and sources of support.

Data extraction: A hybrid thematic analysis (deductive/inductive) will be used. All articles will be coded using predefined themes (codebook) derived from the IP-SDM model and the ODSF (framework for decisional needs assessment)[38], as well as themes suggested by the data; thus, creating an inventory of decisional needs and their facilitators and barriers. All team members, including knowledge users, will have the opportunity to discuss and refine the code book during online workshops with the executive task force. Consistency and rigor will be ensured via a process of combining interpretations and dialogues [67 69]. Executive task force team members will examine the inventory and written interpretations, and ask the reviewers to explain strengths and limitations of their interpretations (trustworthiness) and to suggest alternative interpretations.

A comparative analysis will be conducted to explore similarities/differences among stakeholders' perspectives. Using NVivo 11, the qualitative data (excerpt of the selected studies) will be assigned to the following 'type of stakeholder' attribute value: patients, family, caregivers, practitioners, others. This will allow us, for example, to compare the perceptions that patients have of their decisional needs with those of practitioners. We will also assign other categories of attributes (e.g., types of practitioners) to the data.

Data synthesis: A summary table of the analysis will be made by systematically noting the following for all decisional needs: label, definition, type of stakeholder, facilitators that simplify patients' decisions, barriers that make decisions difficult with patients, key excerpts of articles broken down by decisional need (illustrative examples). The summary table will be posted on our review blog, and the team members (researchers and knowledge users) will provide feedback. Given the feedback, some of the decisional needs will be revised, and modifications will be discussed. Then, a harmonization of themes will be conducted [70]. For each term, the usage will be confirmed in reference to documents on decision making (distinguishing accurate from improper usage), and accurate usages will be adopted to avoid ambiguity.

Step 2: Objective 2 – Build a taxonomy of decisional needs

The Configurational Comparative Method (CCM) is a case-based analysis useful for building taxonomies [71 72]. For this review, each included study will be a case. Using CCM, we will determine commonalities in the relationships between decisional needs, their facilitators and barriers. We will use CCM to test relationships between decision-related variables using Boolean algebra. The main steps of a CCM analysis are: defining conditions and outcomes, extracting data, preparing a truth table (cases in row, and conditions and outcome in columns), performing data minimization with specialized software (QCA-GUI), and interpreting results. CCM is appropriate for two reasons: the theory-driven approach (IP-SDM) and the heterogeneity of study designs. The conditions and outcomes will be determined following the qualitative synthesis of the included studies.

Data extraction: We will use a data extraction form to ensure a systematic process [73]. Then, we will conduct a quantitative content analysis [74]. The codebook will contain categories listed in step-one (deductive coding), and will be tested by two coders using a random sample of 10% of our cases (studies). For each case, the two coders will independently assign text excerpts to codes (variables and values). This will produce a table of raw data. Inter-coder agreement will be measured (kappa). Disagreements that are not resolved easily will be referred to a third party. For each code with less than substantial agreement (kappa<0.61) [57], the codebook will be revised (label, definition and key extracts) and an additional random sample of cases (10%) will be coded.

Data synthesis: Data will be discussed by executive task force members, to produce a table of binary variables with cases in rows and variables in columns. Then, we will conduct the CCM [71] [72], group similar cases in sets, and produce a table of configurations of decisional needs (sets in rows, variables in columns). Results will be interpreted by going back and forth between configurations and cases. The configurations will allow us to 'pose more focused questions' on the cases [72]. Configurations of decisional needs and interpretations will be reviewed. The configurations of decisional needs will be posted on the blog, and feedback provided by the team members. Discrepancies that are not resolved easily will be referred to a third party. The synthesis will produce a comprehensive taxonomy of decisional needs for PCCNs.

Step 3: Objective 3 - Determine key decisional needs

The taxonomy will be discussed in half-day workshops with team members, and a penultimate taxonomy will be posted on the blog. Then, the importance of decisional needs (taxonomy elements) will be rated by the team members with a blog-embedded web-questionnaire and a 5-item Likert scale (from 'not important at all' to 'extremely important'). Discrepancies (e.g., a need with a variety of ratings from low to high importance) that are not resolved easily will be referred to a third party. This will produce a taxonomy of key decisional needs, facilitators and barriers.

The taxonomy will be compared and integrated with the results of a parallel qualitative decisional need assessment of PCCNs that is part of the provincial "Demonstration project" of the Quebec SPOR SUPPORT Unit funded by CIHR (Canadian Institutes of Health Research), Quebec Ministry of Health and FRQS (Quebec Research Fund). In this parallel qualitative study, conducted by co-authors of this review, semi-structured interviews and focus group will be done with patients/relatives, health and social primary care practitioners and decision makers to empirically assess decisional needs of PCCNs. This qualitative study will involve four expert patients, including one who is participating in all stages of the systematic review. The qualitative decisional need assessment and this systematic review will be done concurrently to validate emerging decisional needs. This will give a deeper and broader understanding to better inform the subsequent user-centered design of an IP-SDM support tool.

## Discussion and dissemination

Patients with complex care needs (PCCNs) are associated with unmet health care needs, overuse, underuse or misuse of health care services, low quality of care, and increased costs of health systems [75-77]. Given the aging population and rising rates of chronic disease, the number of PCCNs is growing [2 5 78]. This systematic review, together with the parallel qualitative study, will contribute to the assessment of decisional needs of PCCNs from the perspective of stakeholders (substantive contribution). The ultimate result of this work will be a working taxonomy of key decisional needs of PCCNs (ontological contribution). We will adapt the IP-SDM model, normally dealing with a single decision, for PCCNs who experience a cascade of complex interrelated decisions involving different stakeholders with various opinions (theoretical contribution). The taxonomy of key decisional needs will inform the subsequent user-centered design an IP-SDM support tool (practical contribution). This tool will frame PCCNs' decisional needs, help stakeholders prioritize decisions and understand options and PCCNs' goals, and facilitate finding a common ground crucial for improving patient-practitioner and interprofessional interactions, quality of decisions and care [79].

This systematic review will help bridge two knowledge gaps: on the one hand, the majority of intervention studies address simple care needs rather than complex ones; on the other hand, current systematic reviews typically focus on one condition and one homogeneous population [80-84]. The studies' heterogeneity challenge will be addressed by using an innovative mixed methods design 3-step synthesis to build a taxonomy presenting various key decisional needs' configurations.

Previous studies showed that PCCNs are typically facing interactional issues, which justifies framing this proposal within the IP-SDM model. Evidence shows that SDM support tools improve patient-practitioner interactions and decision quality, and reduce ineffective care [3 85-87]. However, we know of no decision support tool that could facilitate shared decision making between PCCNs and multiple professionals. One contribution of this review will be to enhance decision support for these patients.

As with all systematic reviews, due to publication bias, this work will be biased toward positive results and runs a risk of conflating pre-determined outcomes that were identified by authors of the studies with the decisional needs of PCCNs. This limitation will be reduced by validating the results with the knowledge users (clinicians, patients and managers) and the qualitative results of the Demonstration project of the Quebec SPOR SUPPORT Unit).

This review emerged from two Quebec PBRN pilot work, addresses an important issue for knowledges users and is a priority of the Quebec Ministry of Health [88]. In line with Canadian Institutes for Health Research (CIHR) priorities[1], patients' perspectives will be included in this review given our organizational participatory research approach and our user-centered design. Diffusion will involve raising general awareness about our results through conference presentations and publications. Dissemination, a more active and targeted strategy, will consist of

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[1] http://www.cihr-irsc.gc.ca/e/193.html

reaching other knowledge users through websites, listservs, and peer networks through Quebec PBRNs and the Canadian SPOR networks.

## SYSTEMATIC REVIEW STATUS

The review is currently in the protocol and search strategy updating phase. We are testing the search strategy in Ovid MEDLINE (2017/02/06). We expect to complete the selection of relevant studies in 2017 and design the first version of the IP-SDM support tool in 2018.

## ABBREVIATIONS

- CIHR : Canadian Institutes of Health Research
- FRQS: Fond de recherche du Québec – Santé
- IP-SDM: Interprofessional Shared Decision Making
- KT: Knowledge Translation
- ODSF: Ottawa Decision Support Framework
- PCCNs : Patients with complex care needs
- PBRN: Practice Based Research Network
- SPOR: CIHR Strategy for Patient Oriented Research

## KEY TERMS

- KNOWLEDGE USERS: The directors and the members (clinicians, patients, managers) of the four Quebec PBRNs and the Quebec SPOR SUPPORT Unit.
- TEAM MEMBERS: all co-authors (knowledge users and researchers) and collaborators (see acknowledgements).
- PRIMARY CARE: Community based primary health care.
- STAKEHOLDERS: Patients with complex care needs, their families, their caregivers, their health care practitioners or any other people involved in decisions-making related to their complex care needs (e.g. surrogate, significant others, case manager, decision coach, navigator, mediator, interpreter).

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## AUTHOR CONTRIBUTIONS

PP, FL and MB conceived and designed the review with input from all team members. MB drafted the manuscript. All authors (MB, PP, FL, JH, GG, RES, MEP, MCB, MDB, PLB, YC, BD, JG, AG, RG, VG, SG, CH, BK, EK, IK, BL, CL, MTL, CM, QN, RP, BR, ER, IS, NS, DT, MT, IV, BV, MW) read, critically revised, and approved the final manuscript and will participate to workshops. Executive task force are (MB, PP, RES). Team members are (i) knowledge users (JH, MCB, MDB, BD, BK, IK, MTL, CM, ER, IS, NS, RG, SG); (ii) co-researchers (FL, GG, MEP, PLB, YC, JG, AG, VG, CH, EK, BL, CL, QN, RP, BR, DT, MT, IV, BV, MW, BPL, CY, GA); (iii) international experts (RB, RP, NS, MT, BV, MW). The executive team is doing the bulk of the work. GG participated intensively in the systematic search strategy planning and operationalisation. The authors of this systematic review who are also involved in the qualitative decisional need assessment study are MEP, FL (co-leaders), MB, CH, PP (co-researchers) and BD, MDB (knowledge users).

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## COMPETING INTERESTS

The authors declare no competing interests.

**Table 1 The multidisciplinary expertise of the research team and collaborators**

| **EXPERTISE** | **NAMES*** | **N** |
|---|---|---|
| Home health care | Beaulieu, M-C.; Duong, S.; Kremer, B.; Poitras, M-E. | **4** |
| Interprofessional / Integrated care | Beaulieu, M-C.; Bujold, M.; Couturier, Y.; Haggerty, J.; Légaré, F.; Poitras, M-E.; Vedel, I. | **7** |
| Knowledge transfer and participatory research | Bigras, M.; Boulet, A.; Bujold, M.; Bush, P.L.; Duong, S.; Giguere, A.; Grad, R.; Goulet, S.; Granikov, V.; Haggerty, J.; Kremer, B.; Kroger, E.; Légaré, F.; Lussier, M-T.; Martello, C.; Pluye, P.; Pratt, R.; McLauchlin, L.R.; Samson, I.; Senn, N.; Tsujimoto, M.; Ventelou, B.; Vedel, I.; Wensing, M. | **24** |
| Patients with complex care needs | Bigras, M.; Boulet, A.; Bujold, M.; Couturier, Y.; Débarges, B.; Duong, S.; Goulet, S.; Grad, R.; Granikov, V.; Hudon, C.; Kremer, B.; Kroger, E.; Lebouché, B.; Loignon, C.; Lussier, M-T.; McLauchlin, L.R.; Martello, C.; Poitras, M-E.; Pluye, P.; Pratt, R.; Rosenberg, E.; Samson, I.; Senn, N.; Ventelou, B.; Tsujimoto, M.; Vedel, I.; Wensing, M. | **26** |
| Patient and partner engagement | Bujold, M.; Bush, P.L.; Débarges, B.; Granikov, V.; Loignon, C.; Pluye, P.; Poitras, M-E.; Samson, I. | **8** |
| Populations in situations of vulnerability | Couturier, Y.; Giguere, A.; Hudon, C.; Loignon, C.; Lebouché, B.; Kroger, E.; Rosenberg, E.; Tsujimoto, M.; Samson, I.; Ventelou, B. | **10** |
| Shared Decision Making | Bujold, M.; Légaré, F.; Haggerty, J.; Hudon, C.; Giguere, A.; Lussier, M-T.; Pluye, P.; Poitras, M-E.; Rosenberg, E.; Senn, N.; Wensing, M. | **11** |
| Systematic mixed studies reviews | Bujold, M.; Bush, P.L.; El Sherif, R.; Gore, G.; Kroger, E.; Lebouché, B.; Légaré, F.; Pluye, P.; Rihoux, B.; Rosenberg, E.; Tang, D.; Vedel, I.; Wensing, M. | **13** |
| Tool development and validation | Bujold, M.; El Sherif, R.; Grad, R.; Giguere, A.; Lussier, M-T.; Légaré, F.;, Li Tang, D.; Pluye, P.; Pratt, R.; Senn, N.; Wensing, M. | **11** |
| **PROFESSION** | **NAMES*** | **N** |
| Biology | Bujold, M.; Débarges, B.; Giguere, A. | **3** |
| Computer science | Tang, D., | **1** |
| Epidemiology | Haggerty, J.; El Sherif, R.; , Kröger, E. | 3 |
| Librarianship | Gore, G.; Granikov, V. | 2 |
| Medicine | Bigras, M.; Beaulieu, M-C.; Beaulieu, M.D.; Goulet, S.; Grad, R.; Hersson, F.; Hudon, C.; Lebouché, B.; Légaré, F.; Lussier, M-T.; Martello, C.; McLauchlin, L.R.; Pluye, P.; Pratt, R.; Rosenberg, E.; Samson, I.; Senn, N.; Ventelou, B.; Wensing, M. | **19** |
| Nursing | Boulet, A.; Poitras, M-E.; | **2** |
| Occupational/physical therapy | Bush, P.L. | **1** |
| Pharmacy | Duong, S.; Kroger, E. | **2** |
| Public health | Légaré, F.; Loignon, C.; Pluye, P.; Vedel, I.; Wensing, M. | **5** |
| Social work and social sciences | Bujold, M.; Couturier, Y.; Gagnon, J.; Hudon, C.; Loignon, C.; Rihoux, B. | **6** |

*Alphabetical order

**Figure 1 legend.** The Interprofessional Shared Decision Making (IP-SDM) model was designed to broaden the perspective of shared decision making (SDM) beyond the patient-practitioner dyad and include interprofessional (IP) teams. For more details on the IP-SDM model, please consult the following website: http://www.decision.chaire.fmed.ulaval.ca/en/research/projects/interprofessional-approaches/

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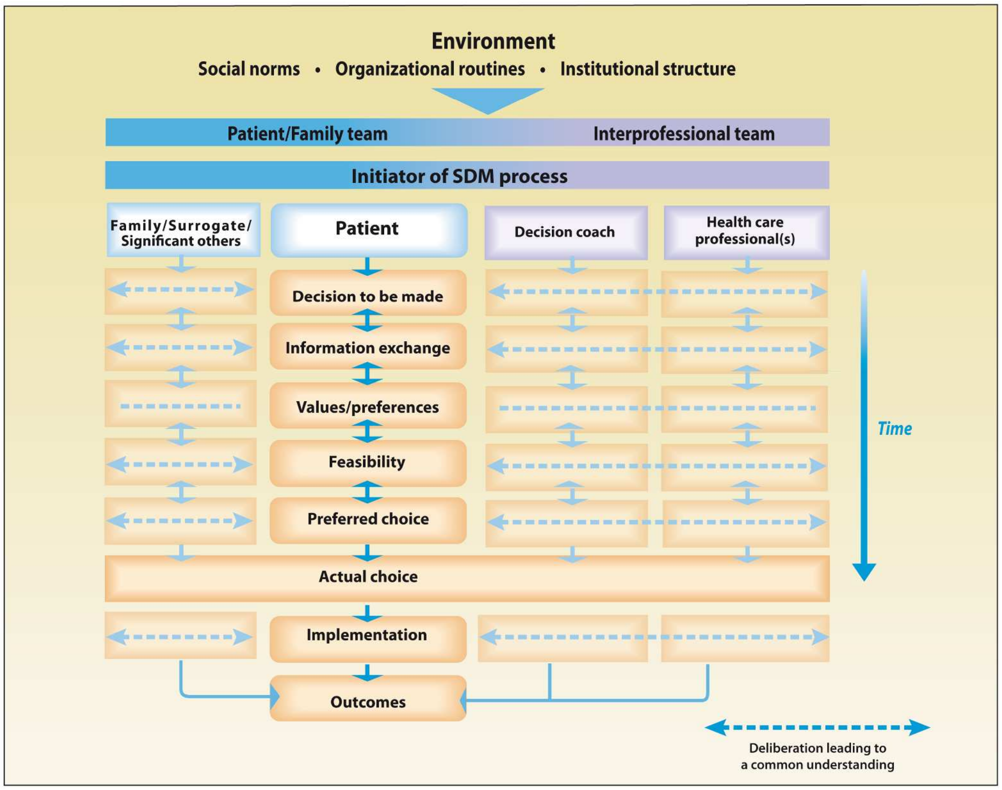

The Interprofessional Shared Decision Making (IP-SDM) model was designed to broaden the perspective of shared decision making (SDM) beyond the patient-practitioner dyad and include interprofessional (IP) teams. For more details on the IP-SDM model, please consult the following website: http://www.decision.chaire.fmed.ulaval.ca/en/research/projects/interprofessional-approaches/

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| **Checklist** | **Page / Line**<br>(Main document) | **Section and topic** | **Item No** | **Checklist item (http://www.bmj.com/content/349/bmj.g7647)** |
|---|---|---|---|---|
| | | **Administrative information** | | |
| | | Title: | | |
| ✓ | Page 1 - Line 2 | Identification | 1a | Identify the report as a protocol of a systematic review |
| n/a | | Update | 1b | If the protocol is for an update of a previous systematic review, identify as such |
| ✓ | Page 3 - Lines 10-11 | Registration | 2 | If registered, provide the name of the registry (such as PROSPERO) and registration number |
| | | Authors: | | |
| ✓ | Page 1 - Lines 4-30<br>Page 2 - Lines 1-8 | Contact | 3a | Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author |
| ✓ | Page 15 - Lines 9-22 | Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review |
| n/a | | Amendments | 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 protocol amendments |
| | | Support: | | |
| ✓ | Page 15, lines 2-3 and 25-27 | Sources | 5a | Indicate sources of financial or other support for the review |
| ✓ | Page 15, lines 2-3 | Sponsor | 5b | Provide name for the review funder and/or sponsor |
| ✓ | Page 15, lines 25-27 | Role of sponsor or funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol |
| | | **Introduction** | | |
| ✓ | Page 4, lines 3-31 to page 5, lines 1-2 | Rationale | 6 | Describe the rationale for the review in the context of what is already known |
| ✓ | Page 6, lines 29-32<br>Page 7, lines 1-5 | Objectives | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) |
| | | **Methods** | | |
| ✓ | Page 8, lines 13-28 | 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 |
| ✓ | Page 8, lines 1-11 | 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 |

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| ✓ | Page 8, lines 1-31 and page 9, lines 1-10 | 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 |
| | | Study records: | | |
| ✓ | Page 8, lines 30-31 and page 9, lines 1-4 | Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review |
| ✓ | Page 9, lines 1-19 | 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) |
| ✓ | page 10, lines 1-9 | 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 |
| ✓ | Page 10, lines 27-31 | 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 |
| ✓ | Page 11, lines 2-7<br>Page 11, lines 29-31<br>Page 12, lines 1-5 | Outcomes and prioritization | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale. |
| ✓ | Page 9, 12-19 | 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 |
| ✓ | Page 9, lines 21-23<br>Page 11, lines 19-27<br>Page 11, lines 29-31<br>Page 12, lines 1-5 | 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 $I^2$, Kendall's $\tau$) |
| n/a | | | 15c | Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) |
| ✓ | Page 10, line 18-26 | | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned |
| n/a | | Meta-bias(es) | 16 | Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) |
| ✓ | Page 9, lines 12-19 | Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (such as GRADE) |

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# Decisional needs assessment of patients with complex care needs in primary care: a participatory systematic mixed studies review protocol

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# Decisional needs assessment of patients with complex care needs in primary care: a participatory systematic mixed studies review protocol

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## Abstract

INTRODUCTION

Patients with complex care needs (PCCNs) often suffer from combinations of multiple chronic conditions, mental health problems, drug interactions and social vulnerability, which can lead to health care services overuse, underuse or misuse. Typically, PCCNs face interactional issues and unmet decisional needs regarding possible options in a cascade of interrelated decisions involving different stakeholders (themselves, their families, their caregivers, their health care practitioners). Gaps in knowledge, values clarification and social support in situations where options need to be deliberated hamper effective decision support interventions. This review aims to: (1) assess decisional needs of PCCNs from the perspective of stakeholders; (2) build a taxonomy of these decisional needs; and (3) prioritize decisional needs with knowledges users (clinicians, patients and managers).

METHODS AND ANALYSIS

This review will be based on the Interprofessional Shared Decision Making (IP-SDM) model and the Ottawa Decision Support Framework. Applying a participatory research approach, we will identify potentially relevant studies through a comprehensive literature search; select relevant ones using eligibility criteria inspired from our previous scoping review on PCCNs; appraise quality using the Mixed Methods Appraisal Tool; conduct a 3-step synthesis (sequential exploratory mixed methods design) to build taxonomy of key decisional needs; and integrate these results with those of a parallel PCCNs' qualitative decisional need assessment (semi-structured interviews and focus group with stakeholders).

ETHICS AND DISSEMINATION

This systematic review, together with the qualitative study (approved by the CIUSSS-SLSJ ethical committee), will produce a working taxonomy of key decisional needs (ontological contribution), to inform the subsequent user-centered design of a support tool for addressing PCCNs' decisional needs (practical contribution). We will adapt the IP-SDM model, normally dealing with a single decision, for PCCNs who experience cascade of decisions involving different stakeholders (theoretical contribution). Knowledge users will facilitate dissemination of the results in the Canadian primary care network.

**Trial registration number:** Our protocol is registered with PROSPERO (registration number CRD42015020558).

**Strengths and limitations of this study**

- This work will be conducted with a participatory research approach involving multiple knowledge users', including patients' perspectives.
- Large team governance can be an issue; thus, an executive task force will carry out the review.
- The studies heterogeneity challenge will be raised by using an innovative mixed methods design 3-step synthesis to build a taxonomy presenting various key decisional needs configuration.

## Introduction

### Rationale for the review

Community-based primary health care (hereafter, primary care) plays a key role regarding situations of complex care needs [1-3]. Patients with complex care needs (PCCNs) often suffer from combinations of multiple chronic conditions, mental health problems, drug interactions and social vulnerability, which can lead to health care services overuse, underuse or misuse [1 4 5]. However, this does not fully capture the complex care needs experience that encompasses individual (patient and practitioner), interpersonal (patient-practitioner or interprofessional), organizational (e.g., resources), and socio-cultural characteristics (e.g., values) [4 6-8]. Typically, PCCNs face interactional issues related to personal uncertainty or disagreements regarding possible options (decisional conflict) and unmet decisional needs (e.g., knowledge acquisition, clarification of values and preferences, support, and resources). The complexity of decision-making could be exacerbated by a cascade of interrelated decisions involving different stakeholders (PCCNs, their families, their caregivers, their health care practitioners, etc.). Gaps in knowledge, values clarification and social support in these situations where multiple options need to be deliberated (decisional needs) hamper decision support interventions.

In a quality improvement process, a group of health and social primary care practitioners, patients and researchers from Practice Based Research Networks (PBRNs) identified the necessity to better understand PCCNs' decisional needs. Team members contributed to a pilot project that sought to identify characteristics of PCCNs and possible support interventions [9 10]. A case series[9] and a scoping review[10] revealed that interprofessional coordination of care and lack of stakeholders' agreement are two major issues affecting this population. It is necessary to better understand the decisional needs of PCCNs associated with mismatched knowledge, expectations, personal values, as well as social support related to a variety of personal, socio-cultural and clinical characteristics. Three individual evaluation tools of complex care needs [11-13] and one study about patient preference in the context of multi-morbidity were identified [14 15]. In the literature, we found no tool to facilitate shared decision making between PCCNs, their families and caregivers, and health care providers. Thus, our target population, PCCNs, may benefit from a decisional needs assessment to inform the design of an interprofessional shared decision making tool that accounts for their knowledge, values and preferences[16].

## Interprofessional Shared Decision Making (IP-SDM) model

Shared Decision Making (SDM) is a process where one patient and one health professional work together to make a healthcare choice; it is essential for informed consent and patient centred care [17-22]. Industrialised countries such as Australia[23], UK[24] and USA[25] are currently implementing large SDM initiatives. SDM is an effective decision making process when careful deliberation is needed to address uncertainties inherent to evidence-based medicine, and to weigh the risks and benefits of patients' healthcare choices (based on their values and preferences). Many factors may influence the choices individuals make and the roles they attribute to others and to themselves in the context of interprofessional care [26-29], which justifies framing this review with the Interprofessional Shared Decision Making (IP-SDM) model [30].

The IP-SDM model extends the SDM beyond the patient-health professional dyad to interprofessional (IP) teams [30-32]. In addition to its interprofessional component, this model proposes to include family members and potential caregivers in a patient-centered process (Figure 1). This model aims to stimulate deliberation and reach a common understanding among patients, family/surrogate/significant others, decision coaches, and health care professionals. The IP-SDM model follows a patient-centered step by step process: (1) choose a decision to make and explore related options; (2) exchange information; (3) clarify values and preferences; (4) assess the feasibility of the decision; (5) choose the preferred decision option; (6) implement the decision; (7) assess the outcome. Based on the IP-SDM model interventions have been developed for specific decision-making situations. For example, a study is currently under way to scale up and evaluate the implementation of IP-SDM intervention for frails elderly clients or their caregivers facing a decision about staying at home or moving elsewhere [33 34]. The IP-SDM also takes into account the environmental complexity in which the SDM takes place (socio-cultural norm, organizational routines, and institutional structure). This model is particularly relevant to help IP teams respond to decisional needs of PCCNs as it helps the stakeholders reach informed value-based decisions [30 31 35]. Typically, the IPSDM is used for one decision. We will be the first team to adapt this model for PCCNs who experience complex interrelated decisions involving different stakeholders with various opinions.

## Decisional needs assessment

A decisional need is usually derived from a needs assessment that addresses or focuses on a situation where multiple options need to be deliberated. Assessing decisional needs is needed in order to elaborate effective decision support, even more so when an interprofessional team is required to provide decision support to a patient. A decisional needs assessment is particularly relevant for PCCNs, such as prioritizing a cascade of complex decisions that involve multiple stakeholders. Decision support interventions address stakeholders' decisional needs (decisional conflict, lack of knowledge and information exchange, values, expectation and preferences clarification, support and resource). Indeed, unmet decisional needs affects the decision quality (e.g., uninformed, incongruent with values and unsupported socially). This in turn may affect behaviour (e.g., uptake and maintenance of the chosen option), lead to negative emotions (e.g., decision regret) and impact health care use (e.g., overuse, underuse and misuse). The Ottawa Decision Support Framework (ODSF) informs the conduct of the decisional needs assessment [36 37].

The decisional needs assessment for PCCNs will answers the following questions: What are the types of decisions have to make complex care needs situations? Which decisions are most frequent? Which decisions are the most difficult to make and why? How these decisions are interrelated? Who are the stakeholders involved in the decision? What is needed to better support regarding the interprofessional shared decision making process (e.g., information, values clarification, social support or else)? What is currently being done? What are the barriers and facilitators for applying this decision support? Several strategies could be mobilized to assess decisional needs of a population[16 38]. One of them consists to review the existing information (i.e. previous studies)[16].

## Review question and objectives

Our overall review question is: What are, from the perspective of stakeholders, the key decisional needs of patients with complex care needs (PCCNs)? In line with the Knowledge Translation (KT) cycle [39], the purpose of our systematic review is to provide the needed groundwork to assess decisional needs of PCCNs. With a task force and a multidisciplinary team including researchers and knowledge users in community-based primary health care (see table 1), this review aims to:

(1) Assess decisional needs of PCCNs from the perspective of stakeholders;

(2) Build a taxonomy of these decisional needs;

(3) Prioritize decisional needs with knowledges users (clinicians, patients, managers).

## Methods

This review will use a multipronged approach. First, we will conduct a systematic mixed studies review (including qualitative, quantitative and mixed methods studies) [40]. Mixed studies reviews provide a rich and highly practical understanding of complex health issues [41-46]. Second, we will use an organizational participatory research approach, involving researchers and knowledge users (clinicians, patients, managers), to determine key decisional needs.

We will, thus, blend research with action using a number of iterative cycles, thereby producing knowledge that can inform healthcare practices [47-50]. Organizational participatory research consists of doing research with patients and practitioners, rather than on them; it is a strategy for organizational change and practice improvement [50-54]. It also supports the idea of producing knowledge that respond to the needs and perspectives of the knowledge users rather than producing knowledge to which they need to adapt. This approach is suitable for this review as the pilot project emerged from practice. A multidisciplinary team blending scientific and practical knowledge is necessary to achieve our objectives (table 1). Team members are researchers with various expertise, and  knowledge users (directors and clinicians, patients and managers of the four Quebec network of Practice Based Research Networks (PBRN)[55] and the Quebec SPOR SUPPORT Unit (SPOR standing for Strategy for Patient Oriented Research). In partnership with knowledge users, we will systematically search, identify, select, appraise, and synthesize qualitative and quantitative evidence. An executive task force will lead the review and mobilize the participatory review team (knowledge users, co-researchers, patient experts, and international experts).

## Information sources and search strategy

Building on our previous work [9, 10], the concept map and the search strategy (see table 2) was written and tested in collaboration with specialized librarians. Based on the scoping review [9], we anticipate retrieving about 4500 potentially relevant database records (authors, title, source, abstract) in MEDLINE (Ovid), Embase (Ovid), PsycINFO (Ovid), CINAHL (EBSCOhost) and Social Sciences Citation Index (SSCI). No search date limit will be used. In addition, our librarians will provide guidance in searching the grey literature using Google Scholar, Conference Proceedings Citation Index-Science (CPCI-S) and specialized websites. After the selection stage, other potentially relevant records will be sought by tracking citations of included studies using Scopus, up to saturation (no additional studies found). Our team members, including knowledge users, will be emailed to request additional records or bibliographies.

## Eligibility criteria and identification of potentially relevant studies

Eligibility criteria will be based upon the previous scoping reviews on PCCNs [10] with a focus on interactional and decisional issues. A study will be included if it is a French, English, or Spanish language empirical study about:

(1) Patients with complex care needs (any study dealing directly or indirectly with PCCNs or a population with at least one of the following characteristics: multiple chronic conditions; mental health issues; drug interactions; social vulnerability; or health care services overuse, underuse and misuse);

(2) Primary health care setting (any study dealing directly with primary health care setting or indirectly, e.g., links between primary care and secondary or tertiary care setting)

(3) Interpersonal relationships (reciprocal interaction of two or more persons, e.g., interprofessional, or professional-patient, patient-family or professional-family);

(4) Decisional needs (frequent or difficult decisions regarding situations where multiple options are possible, factors affecting the decision making process, decisional conflict, support and resources used or needed to improve decision quality, barriers and facilitators to using decision supports).

We expect to identify about 300 potentially relevant studies. We will use EndNote (reference management software) to remove duplicates and store records with indexing terms. For each record, two reviewers will independently assign codes according to our eligibility criteria using specialized software (DistillerSR). For each code, we will measure the agreement between reviewers (kappa) [56 57]. When reviewers disagree, the record will be included in the following selection process.

### Selection of relevant studies (coding full-text documents)

We anticipate including 150 relevant studies as follows. The two reviewers will independently code each full text paper identified in the previous step. As with identification, inter-reviewer agreement will be measured. Disagreements that are not resolved easily will be referred to a third party [58].

### Critical appraisal of included studies

Critical appraisal is a core component of systematic reviews [39 58]. It provides a rationale to break down the synthesis of included studies by level of quality. We will use the Mixed Methods Appraisal Tool (MMAT) [42 59 60], a unique validated tool for critically appraising the quality of qualitative, quantitative and mixed methods studies in systematic mixed studies reviews [61]. Using the 2011 version of the MMAT [62] appraisal form and user-manual, two reviewers will independently appraise included studies. As with selection, inter-reviewer agreement will be measured, and disagreements resolved.

### Synthesis design

Included studies will be described in a summary table [58 61 63]. Then, guided by a sequential mixed methods design [40 46 64], we will conduct a 3-step synthesis.

Step 1: Objective 1 -Assess decisional needs of PCCNs from the perspective of stakeholders

For each included study, two reviewers will independently list decisional needs using a deductive/inductive qualitative thematic analysis with specialized software (NVivo 11) [65-68]. For each decisional need (e.g., goal setting), type of stakeholder (e.g. patient), the facilitators (e.g., interpreter) and barriers (e.g., language) influencing the decision will be listed, including stakeholders' information needs (e.g., list of option with their, respective, potential benefits and harms), values, preferences and sources of support.

Data extraction: A hybrid thematic analysis (deductive/inductive) will be used. All articles will be coded using predefined themes (codebook) derived from the IP-SDM model and the ODSF (framework for decisional needs assessment)[38], as well as themes suggested by the data; thus, creating an inventory of decisional needs and their facilitators and barriers. All team members, including knowledge users, will have the opportunity to discuss and refine the code book during online workshops with the executive task force. Consistency and rigor will be ensured via a process of combining interpretations and dialogues [67 69]. Executive task force team members will examine the inventory and written interpretations, and ask the reviewers to explain strengths and limitations of their interpretations (trustworthiness) and to suggest alternative interpretations.

A comparative analysis will be conducted to explore similarities/differences among stakeholders' perspectives. Using NVivo 11, the qualitative data (excerpt of the selected studies) will be assigned to the following 'type of stakeholder' attribute value: patients, family, caregivers, practitioners, others. This will allow us, for example, to compare the perceptions that patients have of their decisional needs with those of practitioners. We will also assign other categories of attributes (e.g., types of practitioners) to the data.

Data synthesis: A summary table of the analysis will be made by systematically noting the following for all decisional needs: label, definition, type of stakeholder, facilitators that simplify patients' decisions, barriers that make decisions difficult with patients, key excerpts of articles broken down by decisional need (illustrative examples). The summary table will be posted on our review blog, and the team members (researchers and knowledge users) will provide feedback. Given the feedback, some of the decisional needs will be revised, and modifications will be discussed. Then, a harmonization of themes will be conducted [70]. For each term, the usage will be confirmed in reference to documents on decision making (distinguishing accurate from improper usage), and accurate usages will be adopted to avoid ambiguity.

Step 2: Objective 2 – Build a taxonomy of decisional needs

The Configurational Comparative Method (CCM) is a case-based analysis useful for building taxonomies [71 72]. For this review, each included study will be a case. Using CCM, we will determine commonalities in the relationships between decisional needs, their facilitators and barriers. We will use CCM to test relationships between decision-related variables using Boolean algebra. The main steps of a CCM analysis are: defining conditions and outcomes, extracting data, preparing a truth table (cases in row, and conditions and outcome in columns), performing data minimization with specialized software (QCA-GUI), and interpreting results. CCM is appropriate for two reasons: the theory-driven approach (IP-SDM) and the heterogeneity of study designs. The conditions and outcomes will be determined following the qualitative synthesis of the included studies.

Data extraction: We will use a data extraction form to ensure a systematic process [73]. Then, we will conduct a quantitative content analysis [74]. The codebook will contain categories listed in step-one (deductive coding), and will be tested by two coders using a random sample of 10% of our cases (studies). For each case, the two coders will independently assign text excerpts to codes (variables and values). This will produce a table of raw data. Inter-coder agreement will be measured (kappa). Disagreements that are not resolved easily will be referred to a third party. For each code with less than substantial agreement (kappa<0.61) [57], the codebook will be revised (label, definition and key extracts) and an additional random sample of cases (10%) will be coded.

Data synthesis: Data will be discussed by executive task force members, to produce a table of binary variables with cases in rows and variables in columns. Then, we will conduct the CCM [71] [72], group similar cases in sets, and produce a table of configurations of decisional needs (sets in rows, variables in columns). Results will be interpreted by going back and forth between configurations and cases. The configurations will allow us to 'pose more focused questions' on the cases [72]. Configurations of decisional needs and interpretations will be reviewed. The configurations of decisional needs will be posted on the blog, and feedback provided by the team members. Discrepancies that are not resolved easily will be referred to a third party. The synthesis will produce a comprehensive taxonomy of decisional needs for PCCNs.

Step 3: Objective 3 - Determine key decisional needs

The taxonomy will be discussed in half-day workshops with team members, and a penultimate taxonomy will be posted on the blog. Then, the importance of decisional needs (taxonomy elements) will be rated by the team members with a blog-embedded web-questionnaire and a 5-item Likert scale (from ‘not important at all’ to ‘extremely important’). Discrepancies (e.g., a need with a variety of ratings from low to high importance) that are not resolved easily will be referred to a third party. This will produce a taxonomy of key decisional needs, facilitators and barriers.

The taxonomy will be compared and integrated with the results of a parallel qualitative decisional need assessment of PCCNs that is part of the provincial “Demonstration project” of the Quebec SPOR SUPPORT Unit funded by CIHR (Canadian Institutes of Health Research), Quebec Ministry of Health and FRQS (Quebec Research Fund). In this parallel qualitative study, conducted by co-authors of this review, semi-structured interviews and focus group will be done with patients/relatives, health and social primary care practitioners and decision makers to empirically assess decisional needs of PCCNs. This qualitative study will involve four expert patients, including one who is participating in all stages of the systematic review. The qualitative decisional need assessment and this systematic review will be done concurrently to validate emerging decisional needs. This will give a deeper and broader understanding to better inform the subsequent user-centered design of an IP-SDM support tool.

## Ethics and dissemination

Patients with complex care needs (PCCNs) are associated with unmet health care needs, overuse, underuse or misuse of health care services, low quality of care, and increased costs of health systems [75-77]. Given the aging population and rising rates of chronic disease, the number of PCCNs is growing [2 5 78]. This systematic review, together with the parallel qualitative study, will contribute to the assessment of decisional needs of PCCNs from the perspective of stakeholders (substantive contribution). The qualitative study was approved by the scientific and ethical committee of the “*Centre Intégré Universitaire de Santé et Service Sociaux du Saguenay-Lac-Saint-Jean*” (Integrated University Centre of Health and Social Services). The ultimate result of this work will be a working taxonomy of key decisional needs of PCCNs (ontological contribution). We will adapt the IP-SDM model, normally dealing with a single decision, for PCCNs who experience a cascade of complex interrelated decisions involving different stakeholders with various opinions (theoretical contribution). The taxonomy of key decisional needs will inform the subsequent user-centered design an IP-SDM support tool (practical contribution). This tool will frame PCCNs' decisional needs, help stakeholders prioritize decisions and understand options and PCCNs' goals, and facilitate finding a common ground crucial for improving patient-practitioner and interprofessional interactions, quality of decisions and care [79].

This systematic review will help bridge two knowledge gaps: on the one hand, the majority of intervention studies address simple care needs rather than complex ones; on the other hand, current systematic reviews typically focus on one condition and one homogeneous population [80-84]. The studies' heterogeneity challenge will be addressed by using an innovative mixed methods design 3-step synthesis to build a taxonomy presenting various key decisional needs' configurations.

Previous studies showed that PCCNs are typically facing interactional issues, which justifies framing this proposal within the IP-SDM model. Evidence shows that SDM support tools improve patient-practitioner interactions and decision quality, and reduce ineffective care [3 85-87]. However, we know of no decision support tool that could facilitate shared decision making between PCCNs and multiple professionals. One contribution of this review will be to enhance decision support for these patients.

As with all systematic reviews, due to publication bias, this work will be biased toward positive results and runs a risk of conflating pre-determined outcomes that were identified by authors of the studies with the decisional needs of PCCNs. This limitation will be reduced by validating the results with the knowledge users (clinicians, patients and managers) and the qualitative results of the Demonstration project of the Quebec SPOR SUPPORT Unit).

This review emerged from two Quebec PBRN pilot work, addresses an important issue for knowledges users and is a priority of the Quebec Ministry of Health [88]. In line with Canadian Institutes for Health Research (CIHR) priorities[1], patients' perspectives will be included in this

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[1] http://www.cihr-irsc.gc.ca/e/193.html

review given our organizational participatory research approach and our user-centered design. Diffusion will involve raising general awareness about our results through conference presentations and publications. Dissemination, a more active and targeted strategy, will consist of reaching other knowledge users through websites, listservs, and peer networks through Quebec PBRNs and the Canadian SPOR networks.

## SYSTEMATIC REVIEW STATUS

The review is currently in the protocol and search strategy updating phase. We are testing the search strategy in Ovid MEDLINE (2017/02/06). We expect to complete the selection of relevant studies in 2017 and design the first version of the IP-SDM support tool in 2018.

## ABBREVIATIONS

- CIHR : Canadian Institutes of Health Research
- CIUSSS-SLST : *Centre Intégré Universitaire de Santé et Service Sociaux du Saguenay-Lac-Saint-Jean* (Integrated University Centre of Health and Social Services).
- FRQS: Fond de recherche du Québec – Santé
- IP-SDM: Interprofessional Shared Decision Making
- KT: Knowledge Translation
- ODSF: Ottawa Decision Support Framework
- PCCNs : Patients with complex care needs
- PBRN: Practice Based Research Network
- SPOR: CIHR Strategy for Patient Oriented Research

## KEY TERMS

• KNOWLEDGE USERS: The directors and the members (clinicians, patients, managers) of the four Quebec PBRNs and the Quebec SPOR SUPPORT Unit.

• TEAM MEMBERS: all co-authors (knowledge users and researchers) and collaborators (see acknowledgements).

• PRIMARY CARE: Community based primary health care.

• STAKEHOLDERS: Patients with complex care needs, their families, their caregivers, their health care practitioners or any other people involved in decisions-making related to their complex care needs (e.g. surrogate, significant others, case manager, decision coach, navigator, mediator, interpreter).

## ACKNOWLEDGEMENTS

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## AUTHOR CONTRIBUTIONS

PP, FL and MB conceived and designed the review with input from all team members. MB drafted the manuscript. All authors (MB, PP, FL, JH, GG, RES, MEP, MCB, MDB, PLB, YC, BD, JG, AG, RG, VG, SG, CH, BK, EK, IK, BL, CL, MTL, CM, QN, RP, BR, ER, IS, NS, DT, MT, IV, BV, MW) read, critically revised, and approved the final manuscript and will participate to workshops. Executive task force are (MB, PP, RES). Team members are (i) knowledge users (JH, MCB, MDB, BD, BK, IK, MTL, CM, ER, IS, NS, RG, SG); (ii) co-researchers (FL, GG, MEP, PLB, YC, JG, AG, VG, CH, EK, BL, CL, QN, RP, BR, DT, MT, IV, BV, MW, BPL, CY, GA); (iii) international experts (RB, RP, NS, MT, BV, MW). The executive team is doing the bulk of the work. GG participated intensively in the systematic search strategy planning and operationalisation. The authors of this systematic review who are also involved in the qualitative decisional need assessment study are MEP, FL (co-leaders), MB, CH, PP (co-researchers) and BD, MDB (knowledge users).

## FUNDING STATEMENT

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## COMPETING INTERESTS

The authors declare no competing interests.

**Table 1 The multidisciplinary expertise of the research team and collaborators**

| **EXPERTISE** | **NAMES*** | **N** |
|---|---|---|
| Home health care | Beaulieu, M-C.; Duong, S.; Kremer, B.; Poitras, M-E. | **4** |
| Interprofessional / Integrated care | Beaulieu, M-C.; Bujold, M.; Couturier, Y.; Haggerty, J.; Légaré, F.; Poitras, M-E.; Vedel, I. | **7** |
| Knowledge transfer and participatory research | Bigras, M.; Boulet, A.; Bujold, M.; Bush, P.L.; Duong, S.; Giguere, A.; Grad, R.; Goulet, S.; Granikov, V.; Haggerty, J.; Kremer, B.; Kroger, E.; Légaré, F.; Lussier, M-T.; Martello, C.; Pluye, P.; Pratt, R.; McLauchlin, L.R.; Samson, I.; Senn, N.; Tsujimoto, M.; Ventelou, B.; Vedel, I.; Wensing, M. | **24** |
| Patients with complex care needs | Bigras, M.; Boulet, A.; Bujold, M.; Couturier, Y.; Débarges, B.; Duong, S.; Goulet, S.; Grad, R.; Granikov, V.; Hudon, C.; Kremer, B.; Kroger, E.; Lebouché, B.; Loignon, C.; Lussier, M-T.; McLauchlin, L.R.; Martello, C.; Poitras, M-E.; Pluye, P.; Pratt, R.; Rosenberg, E.; Samson, I.; Senn, N.; Ventelou, B.; Tsujimoto, M.; Vedel, I.; Wensing, M. | **26** |
| Patient and partner engagement | Bujold, M.; Bush, P.L.; Débarges, B.; Granikov, V.; Loignon, C.; Pluye, P.; Poitras, M-E.; Samson, I. | **8** |
| Populations in situations of vulnerability | Couturier, Y.; Giguere, A.; Hudon, C.; Loignon, C.; Lebouché, B.; Kroger, E.; Rosenberg, E.; Tsujimoto, M.; Samson, I.; Ventelou, B. | **10** |
| Shared Decision Making | Bujold, M.; Légaré, F.; Haggerty, J.; Hudon, C.; Giguere, A.; Lussier, M-T.; Pluye, P.; Poitras, M-E.; Rosenberg, E.; Senn, N.; Wensing, M. | **11** |
| Systematic mixed studies reviews | Bujold, M.; Bush, P.L.; El Sherif, R.; Gore, G.; Kroger, E.; Lebouché, B.; Légaré, F.; Pluye, P.; Rihoux, B.; Rosenberg, E.; Tang, D.; Vedel, I.; Wensing, M. | **13** |
| Tool development and validation | Bujold, M.; El Sherif, R.; Grad, R.; Giguere, A.; Lussier, M-T.; Légaré, F.;, Li Tang, D.; Pluye, P.; Pratt, R.; Senn, N.; Wensing, M. | **11** |
| **PROFESSION** | **NAMES*** | **N** |
| Biology | Bujold, M.; Débarges, B.; Giguere, A. | **3** |
| Computer science | Tang, D., | **1** |
| Epidemiology | Haggerty, J.; El Sherif, R.; , Kröger, E. | 3 |
| Librarianship | Gore, G.; Granikov, V. | 2 |
| Medicine | Bigras, M.; Beaulieu, M-C.; Beaulieu, M.D.; Goulet, S.; Grad, R.; Hersson, F.; Hudon, C.; Lebouché, B.; Légaré, F.; Lussier, M-T.; Martello, C.; McLauchlin, L.R.; Pluye, P.; Pratt, R.; Rosenberg, E.; Samson, I.; Senn, N.; Ventelou, B.; Wensing, M. | **19** |
| Nursing | Boulet, A.; Poitras, M-E.; | **2** |
| Occupational/physical therapy | Bush, P.L. | **1** |
| Pharmacy | Duong, S.; Kroger, E. | **2** |
| Public health | Légaré, F.; Loignon, C.; Pluye, P.; Vedel, I.; Wensing, M. | **5** |
| Social work and social sciences | Bujold, M.; Couturier, Y.; Gagnon, J.; Hudon, C.; Loignon, C.; Rihoux, B. | **6** |

*Alphabetical order

## Table 2 – Search Strategy in Medline - Concept map (Concepts #1 and #2 and #3 and #4)

| **CONCEPT #1 - PATIENTS WITH COMPLEX CARE NEEDS** |
|---|
| 1 (complex adj4 (problem* or issue* or patient? or need? or care or existence? or experience? or live? or realit* or journey? or situation?)).ti,ab,kf. |
| 2 complex case?.mp. |
| 3 (complexity adj4 (clinical or patient? or science or theory)).mp. |
| 4 ((high-effort or burden or complicated or demanding) adj patient?).mp. |
| 5 exp Vulnerable Populations/ |
| 6 poverty/ or poverty areas/ or unemployment/ or homeless persons/ or homeless youth/ or exp *aged/ or frail elderly/ or exp "Emigrants and Immigrants"/ or minority groups/ or exp disabled persons/ or drug users/ or medically uninsured/ or refugees/ or exp culture/ |
| 7 (poverty or disadvantaged or underserved or under served or indigen* or tribe? or tribal or native? or aboriginal* or low income* or unemploy* or underemploy* or under employ* or homeless* or street people or street person? or (social* adj (isolat* or stigma*)) or inequalit* or uninsured or underinsured or unader insured or uneducated or low* educat* or poor* educat* or illitera* or (low adj2 litera*) or functional* impair* or disabled or disabilit* or handicap* or physical* challenge* or mental* challenge* or ((drug or substance) adj (abuse* or addict* or dependen* or habit? or "use*")) or minorit* or emigra* or immigra* or migra* or foreigner* or refugee*).ti,ab,kf. |
| 8 (vulnerab* or aged or elderly or frail* or senior?).ti. |
| 9 ((frail* or vulnerab* or at risk or high risk or low function or dependent) adj2 (older or elder* or senior* or patient*)).ti,ab,kf. |
| 10 (cald or (cultural* adj3 divers*) or multicultur* or intercultur* or (patient* adj cultur*) or (cultural* adj3 (background* or differen*)) or ethnocultural* or (cultural* adj (aware* or competen* or appropriate* or relevan* or safe* or train*))).ti,ab,kf. |
| 11 (vulnerab* adj (patient? or population? or social*)).ti,ab,kf. |
| 12 sensitive population?.ti,ab,kf. |
| 13 ((Frequen* or high) adj2 (attend* or consult*)).ti,ab,kf. |
| 14 ("frequent visit*" or "frequent flyer*" or "heavy user*" or "repeat use").ti,ab,kf. |
| 15 ((((frequen* or high) adj2 (user* or utili*)) or "high use" or "frequent use") adj3 (patient* or hospital* or emergency or ED or services)).ti,ab,kf. |
| 16 "revolving door".ti,ab,kf. |
| 17 "frequent hospitali#ation*".ti,ab,kf. |
| 18 ((preventable or avoidable) adj2 (utili* or visit* or hospitali* or consultation*)).ti,ab,kf. |
| 19 (high adj2 risk adj3 hospitali#ation*).ti,ab,kf. |
| 20 ("frequent use*" or "frequent utilis*" or "high use*" or "high utili*").kf. |
| 21 mental disorders/ or mental health/ |
| 22 ((mental* or psychiatric) adj (health* or disorder* or disease* or ill*)).ti. |
| 23 comorbidity/ |
| 24 (comorbidit* or multi* morbidit* or multimorbidit*).ti,ab,kf. |
| 25 exp polypharmacy/ |
| 26 exp drug interactions/ |
| 27 exp "Drug-Related Side Effects and Adverse Reactions"/ |
| 28 (adverse adj (effect? or event? or reaction?)).ti. |
| 29 ((multi* adj (therap* or treatment* or drug? or medication?)) or polypharmac*).ti,ab,kf. |
| 30 drug* interact*.ti,ab,kf. |
| 31 exp complementary therapies/ |

| |
|---|
| 32 exp herbal medicine/ |
| 33 ((alternative* or complementar* or folk* or herbal or integrat* or natural or non-prescription or over the counter or traditional) adj2 (health* or medication* or medicine* or product* or remedy or remedies or therap* or treatment*)).ti,ab,kf. |
| 34 or/1-33 |

| **CONCEPT #2 - PRIMARY HEALTH CARE** |
|---|
| 35 exp Primary Health Care/ |
| 36 exp Primary Care Nursing/ |
| 37 exp General Practice/ |
| 38 Community Health Services/ |
| 39 exp Community Pharmacy Services/ |
| 40 Community Mental Health Services/ |
| 41 Community Health Nursing/ |
| 42 Social Work/ |
| 43 General Practitioners/ |
| 44 Physicians, Family/ |
| 45 Physicians, Primary Care/ |
| 46 Social Workers/ |
| 47 (primary care or primary health care or primary healthcare or community nursing or family practice or general practice or family medicine or family physician* or family practitioner* or family doctor* or general physician* or general practitioner* or community based medicine or community mental health service* or community mental health nursing or community health nursing or community health service* or community pharmac* or primary practice or primary practitioner* or psychologist* or social service* or social work* or (communit$3 adj5 nurse?)).ti,ab,kf. |
| 48 or/35-47 |

| **CONCEPT #3 - INTERPERSONAL RELATIONS** |
|---|
| 49 exp Interpersonal Relations/ |
| 50 exp patient care team/ |
| 51 (exp nurses/ or exp physicians/ or pharmacists/ or social workers/ or (nurse* or pharmacist* or physician* or psychologist* or social worker* or clinician* or doctor* or practitioner* or gps or health care professional* or healthcare professional* or health care provider* or healthcare provider* or ((primary care or primary healthcare or primary health care) adj provider*) or resident*).ti.) and (exp patients/ or caregivers/ or exp Family/ or (patient* or consumer* or people* or carer? or caregiver? or family or families).ti.) |
| 52 exp consumer participation/ or ((patient* or consumer*) adj6 (interaction* or empower* or engagement* or involvement* or involving* or participation* or participating*)).ti,ab,kf. |
| 53 (exp patients/ or (patient* or inpatient* or outpatient* or hospitali#ed or institutionali#ed or consumer* or people*).ti.) and (caregivers/ or exp Family/ or (carer* or caregiver* or family or families).ti.) |
| 54 (collaborat* or team*).ti,ab,kf. |
| 55 (interprofessional* or inter professional* or interdisciplinar* or inter disciplin* or interoccupation* or inter occupation* or multiprofessional* or multi professional* or multidisciplin* or multi disciplin* or multioccupation* or multi occupation*).ti,ab,kf. |
| 56 (interpersonal* or shared care).ti,ab,kf. |
| 57 or/49-56 |

| **CONCEPT #4 - DECISIONAL NEEDS** |
|---|
| 58 (decision* or decided or decides or deciding or choice*).ti,ab,kf. |

| | |
|---|---|
| 59 | exp decision making/ or informed consent/ or exp problem solving/ or (exp patient preference/ and patient education as topic/) |
| 60 | ((patient* adj3 (voice* or perspective*)) or preference* or deliberation* or navigat* or accommodation* or accord? or agree* or arrangement or compromise or conciliation or counterbalance or counterpoise or equipoise or mediation or negotia* or poise or prioriti?ation or prioriti?e* or prioriti?ing or reconciliation).ti,ab,kf. |
| 61 | (regret* or blame* or uncertaint* or disagreement or disconcerted or faithless or dissension or dissent* or distrust* or indecision or indecisive or refusal or trustless or undecided or untrustworthy or untrusting or mistrust*).ti,ab,kf. |
| 62 | or/58-61 |
| | |
| 63 | 34 and 48 and 57 and 62 |
| 64 | Limit 63 to (English or French or Spanish) |

**Figure 1 legend.** The Interprofessional Shared Decision Making (IP-SDM) model was designed to broaden the perspective of shared decision making (SDM) beyond the patient-practitioner dyad and include interprofessional (IP) teams. For more details on the IP-SDM model, please consult the following website: http://www.decision.chaire.fmed.ulaval.ca/en/research/projects/interprofessional-approaches/

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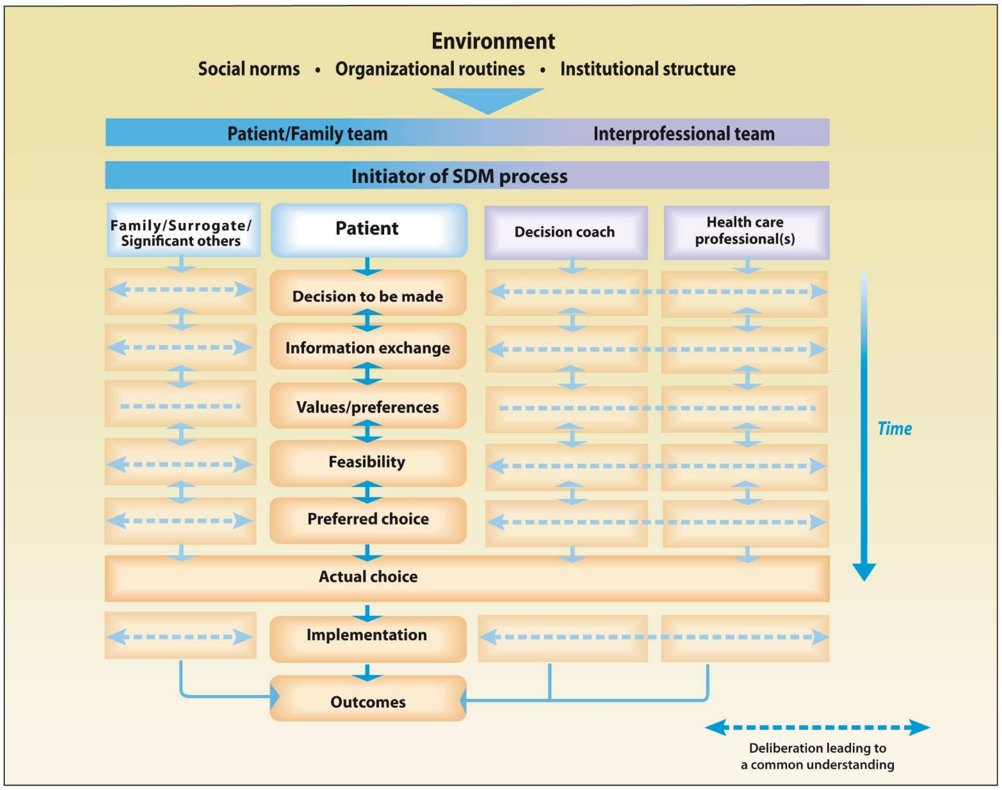

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| **Checklist** | **Page / Line**<br>(Main document) | **Section and topic** | **Item No** | **Checklist item ([http://www.bmj.com/content/349/bmj.g7647](http://www.bmj.com/content/349/bmj.g7647))** |
|---|---|---|---|---|
| | | **Administrative information** | | |
| | | Title: | | |
| ✓ | Page 1 - Line 2 | Identification | 1a | Identify the report as a protocol of a systematic review |
| n/a | | Update | 1b | If the protocol is for an update of a previous systematic review, identify as such |
| ✓ | Page 3 - Lines 10-11 | Registration | 2 | If registered, provide the name of the registry (such as PROSPERO) and registration number |
| | | Authors: | | |
| ✓ | Page 1 - Lines 4-30<br>Page 2 - Lines 1-8 | Contact | 3a | Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author |
| ✓ | Page 15 - Lines 9-22 | Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review |
| n/a | | Amendments | 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 protocol amendments |
| | | Support: | | |
| ✓ | Page 15, lines 2-3 and 25-27 | Sources | 5a | Indicate sources of financial or other support for the review |
| ✓ | Page 15, lines 2-3 | Sponsor | 5b | Provide name for the review funder and/or sponsor |
| ✓ | Page 15, lines 25-27 | Role of sponsor or funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol |
| | | **Introduction** | | |
| ✓ | Page 4, lines 3-31 to page 5, lines 1-2 | Rationale | 6 | Describe the rationale for the review in the context of what is already known |
| ✓ | Page 6, lines 29-32<br>Page 7, lines 1-5 | Objectives | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) |
| | | **Methods** | | |
| ✓ | Page 8, lines 13-28 | 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 |
| ✓ | Page 8, lines 1-11 | 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 |

| | | | | |
|---|---|---|---|---|
| ✓ | Page 8, lines 1-31 and page 9, lines 1-10<br>page 17, Table 2 | 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 |
| | | Study records: | | |
| ✓ | Page 8, lines 30-31 and page 9, lines 1-4 | Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review |
| ✓ | Page 9, lines 1-19 | 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) |
| ✓ | page 10, lines 1-9 | 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 |
| ✓ | Page 10, lines 27-31 | 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 |
| ✓ | Page 11, lines 2-7<br>Page 11, lines 29-31<br>Page 12, lines 1-5 | Outcomes and prioritization | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale. |
| ✓ | Page 9, 12-19 | 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 |
| ✓ | Page 9, lines 21-23<br>Page 11, lines 19-27<br>Page 11, lines 29-31<br>Page 12, lines 1-5 | 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 $I^2$, Kendall's $\tau$) |
| n/a | | | 15c | Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) |
| ✓ | Page 10, line 18-26 | | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned |
| n/a | | Meta-bias(es) | 16 | Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) |
| ✓ | Page 9, lines 12-19 | Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (such as GRADE) |