Organizational- and system-level factors that influence the implementation of SDM – a scoping review protocol

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Note: This protocol adheres to the PRISMA-P checklist for the development of review protocols (Moher et al., 2015), as far as applicable to the scoping review methodology. Currently, there is no reporting guidance for scoping reviews, however this seems to be forthcoming (PRISMA-ScR) (Colquhoun et al., 2014). Upon completion of the scoping review, the website of the Equator Network will be checked again to determine the availability of this guidance document.

Introduction

In the last years, there has been growing interest in advancing shared decision-making (SDM) in routine healthcare. In many countries, health policy demands the implementation of SDM. However, despite this legal commitment towards SDM and its inclusion in a range of clinical practice guidelines, it seems poorly implemented in routine care (Charles, Gafni, & Whelan, 2004; Coulter, 2009; Foundation for Informed Medical Decision Making, 2009; Stiggelbout et al., 2012; Vogel, Helmes, & Hasenburg, 2008).

A lot of work on barriers and facilitators of SDM identified mostly contributors at the individual level of care (Légaré, Ratté, Gravel, & Graham, 2008; Shepherd, Tattersall, & Butow, 2007, 2008). More recent work, has acknowledged the importance to take the organizational level (e.g. organizational culture, innovation climate, leadership effectiveness, inter-professional collaboration, clinical information systems, quality management documents) into account (Müller, Hahlweg, & Scholl, 2016). This is in line with research on the implementation of health innovations, which has shown that it is crucial to take into account variables at the level of health institutions in order to change practice (Chaudoir, Dugan, & Barr, 2013; Damschroder et al., 2009). These institutional characteristics will otherwise function as powerful barriers towards implementing SDM at the individual encounter level.

To date, no studies have synthesized the literature around organizational- and system-level factors that influence the implementation of SDM in routine care. However, this would be an important step in order to be able to explore solutions that address these factors. Thus, the aim of this scoping review is to compile a comprehensive overview on organizational- and system-level factors that influence the implementation of SDM in routine care.

Methods

We use the definition of scoping review given by Colquhoun and colleagues, describing it as "a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined area or field by systematically searching, selecting, and synthesizing existing knowledge" (Colquhoun et al., 2014).

We base our methodology on the Arksey and O'Malley framework (Arksey & O`Malley, 2005), as well as on subsequently published guidance on how to conduct scoping reviews (Daudt, van Mossel, & Scott, 2013; Khalil et al., 2016; Levac, Colquhoun, & O'Brien, 2010). The following six steps will be conducted and are described below: 1) identifying the research question, 2) identifying relevant studies, 3) study selection, 4) charting the data, 5) collating, summarizing and reporting the results. We will not appraise the methodological quality or risk of bias of the included studies, which is consistent with guidance on the conduct of scoping reviews (Arksey & O`Malley, 2005).

1) Identifying the research question

In this first step of the scoping review, its objective, purpose, envisioned outcome, and review questions are specified and the concepts in the review questions are defined.

This step has already been conducted, leading to the following specifications.

Objective: to compile a comprehensive overview on organizational- and system-level factors that have shown to influence the implementation of SDM in routine care.

Purpose: A greater understanding of the organizational- and system-level factors that influence implementation of SDM in routine care, may be helpful to find ways to acknowledge these factors in implementation strategies in order to foster the implementation of SDM in routine care.

Envisioned outcome: <u>a list</u> of main organizational- and system-level characteristics and proposed solutions to address these characteristics towards the implementation of SDM in routine care.

Review questions (RQ)

RQ 1: What is known from the existing literature about organizational- and system-level barriers and facilitators towards the implementation of SDM in routine care? RQ 2: What solutions that address these characteristics are discussed in the literature? **Definition of the concepts in the RQs:**

organizational-level factors: characteristics of a healthcare organization or institution (e.g. a hospital, a practice); also described as institutional level or meso level of care
system-level factors: characteristics of the health care system, i.e. factors that influence more different organizations

- SDM: 'an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences' (Elwyn et al., 2010). While SDM is a communicative process that can be achieved through the use of decision aids, decision aids are not necessary nor sufficient for SDM (Elwyn et al., 2016).

- Implementation: putting something (e.g. an intervention, in this case SDM) into action in routine health care

2) Identifying relevant studies

The following electronic databases will be searched: Medline, CINAHL, and Web of Science Core Collection. We will limit the search to articles published after 1997, the year in which Charles and colleagues described the concept of SDM in their seminal article (Charles, Gafni, & Whelan, 1997). The search will also be limited to articles published in English or German. The secondary search strategy will consist of reference tracking of included articles and contacting of experts. Grey literature will be included by searches on a range of websites (see separate document).

3) Study selection

This scoping review includes primary and secondary studies that report on empirical data regarding organizational- and system-level factors that influenced the implementation of SDM in routine care. Final eligibility (inclusion and exclusion) criteria will be developed post hoc, based on increased familiarity with the literature.

This stage will be considered an iterative process involving searching the literature, refining the search strategy, and reviewing articles for study inclusion.

Two researchers will then use those criteria to independently screen the titles and abstracts of the retrieved records and assess eligibility of full-texts. Disagreements about study inclusion will be resolved by discussion. If necessary, a third reviewer will be consulted. The study selection process will be supported by importing all identified records to a reference management software and by assigning them individual ID numbers.

4) Charting the data

The data charting form will be developed by one team member, then pilot tested by two team members using two included studies, and subsequently revised to reach consensus on the data collection process and to add additional categories. As this step is considered an iterative process, the charting form will be continually updated if necessary. We will both extract general information on each study and specific information related to RQs.

The search decision process will be described narratively as well as using the PRISMA flowchart.

5) Collating, summarizing and reporting the results

We will conduct a descriptive numerical analysis of characteristics of the included studies (e.g. types of study design, years of publication), as well as a qualitative thematic analysis of the organizational- and system-level factors identified in the studies. The results of this thematic analysis will be reported in a tabular form (i.e. a list of factors). Furthermore, the meaning of the results will be discussed in relation to the overall study purpose.

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