Shared Decision-making in Healthcare in Mainland China: A Scoping Review Protocol

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Protocol

Abstract

Background: Shared decision-making (SDM) has been increasingly studied and applied to improve patients' decision qualities and health outcomes. Little is known about its development status in mainland China. The Ottawa Decision Support Framework (ODSF) has been extensively used to guide clinicians and patients facing difficult healthcare decisions. It claims that decision quality can be improved though the implementation of decision support interventions that address patients' decisional needs.

Objective: Based on ODSF, the objective of the scoping review is to systematically map the existing research literature to answer the following three questions: 1) What healthcare decisional needs were examined within Chinese population? 2) What decision support interventions (SDM theories, tools, processes, implementation determinants) were used to address the healthcare decisional needs? and 3) What SDM outcomes were reported?

Methods and analysis: We will conduct the scoping review following Arksey and O'Malley' six-stage methodological framework. Seven databases: Ovid MEDLINE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), EMBASE, China National Knowledge Infrastructure, Wan Fang Database, The VIP Database, and China Biology Medicine will be searched to identify relevant studies. Four reviewers will independently screen studies based on the eligibility criteria. The ODSF, as a guiding framework, will be used to develop the data extraction form and guide data analysis. All the retrieved information will be coded and mapped into the three key components of ODSF, namely decisional needs, decision support interventions, and decision outcomes. We will report our review findings following the Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR) reporting guidelines.

Discussion: This study will be the first comprehensive and systematic review to understand the SDM research status in mainland China. The results of this review will help us to identify the gaps in current SDM research and inform future theoretical and empirical studies.

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Strengths And Limitations Of This Study

► This will be the first scoping review to examine the SDM development status in healthcare in mainland China.

►It is also because this is the first review on this topic, so we did not find any reference materials to help us formulate the Chinese search strategy. To make up for this defect, we will invite professional library experts to help. And we will also carry out pre search and adjust the search strategy.

► The scoping review will be conducted based on ODSF, which is a globally recognized framework in SDM and can facilitate our systematic and comprehensive understanding of SDM in healthcare in mainland China.

► Policymakers are very key stakeholders in SDM. Due to the resource constraints, we will not include policymakers in the consultation part of this study, which may limit our understanding of the barriers and likelihood of implementing SDM from a policy-making perspective.

Introduction

Since the founding of the people's Republic of China in 1949, the clinical decision-making in China has been seriously influenced by the healthcare policies and culture [1]. For 60 years in a row, doctors have dominated the clinical decision-making (paternalistic decision-making) and have been making decisions for patients [2]. Chinese scholars named this time the "doctor monopoly" stage in healthcare decision-making history, during which time doctors were considered the only subject of healthcare knowledge with absolute authorities in making decisions [3]. Patients often felt powerless with limited channels to express their personal values or concerns, even when they were unsatisfied with the treatment plan [4]. With the prevalence of Internet and social media, patients and lay people gradually have access to various medical information, evidence-based or non-evidence-based. They come to question treatment plans with the knowledge obtained and eager to have more voice in making healthcare decisions [5]. This trend challenges the long-hold authorities of doctors and the dominate unilateral doctor-patient communication model. It pushes doctors to delve into patients' personal values and decisional needs, and explains to patients different decision options. A new healthcare decision model is urgently needed to guide clinicians to make healthcare decisions together with patients.

There is increasing recognition of the ethical imperative to make important healthcare decisions together with patients [6]. Western countries widely advocate consumer engagement in decision make, namely shared decision-making (SDM), to achieve person-centred care [7]. SDM is an iterative process wherein consumers, their families and health professionals exchange information, discuss options, and reach an agreement [8, 9]. SDM highlights a shift away from illness-oriented unilateral care model towards person-centred interaction [10]. Consumers and health professionals have interactive communication to establish a trusting relationship, and discuss the benefits and harms of different opinions towards one specific decisional needs [11]. This process involves patients and clinicians working together to determine an optimal treatment plan through collaborative deliberation and use of research evidence [12]. SDM interventions targeting patients can reduce patients' decision regret, decision conflict, as well as reduce doctor-patient conflict [13]. SDM is also an essential process in implementing evidence-based practice and is considered as the pinnacle of patient-centered care [14].

However, most current SDM studies have been conducted outside the Chinese context [15, 16]. In the seminal Cochrane systematic review conducted by Stacey and colleagues in 2018, they only found one

randomized controlled trail conducted in Hongkong China investigating the effectiveness of a patient decision aid on breast cancer surgery [17, 18]. In Légaré and colleagues' Cochrane systematic review of interventions for improving SDM adoption by healthcare professionals in 2014, none of the 39 included studies came from China [19]. Again, in Légaré and colleagues' systematic review of the barriers and facilitators to implementing SDM, only one study conducted by Zhang in 2006 was included [20]. It was about the difficulties and attitudes of Chinese doctors towards patients' participation in treatment decision-making [21]. Overall, very little is known by global audience on the patient decision aid effectiveness, SDM interventions, and barriers and facilitators of implementing SDM in Chinese context. And even with the global advancement in SDM, it is still unknown whether the western evidence is appliable in Chinese context, which has an utterly different healthcare system and tradition [22].

In China, Professor Zhao Mingjie, a medical ethics expert at Dalian Medical University, first introduced the concept of SDM to mainland China in 1998 [23]. While, through our preliminary searches, we surprisingly found that there had not been any systematically and rigorously conducted SDM reviews in mainland China within those 20 years. Nevertheless, we've found some original studies of SDM, most of them are predominately cross-sectional studies investigating patients' and clinicians' beliefs and attitudes towards the engagement in healthcare decision-making and confirmed the desirability and feasibility of implementing SDM in clinic [24]. In 2014, a survey of 40 public hospitals in Shanghai reported that patients highly valued their own experience during consultation with doctors. SDM increased patients' sense of ownership of their nursing care, and was very likely to improve treatment compliance and self-management [25]. In 2019, another outpatient experience survey covering 136 tertiary hospitals in 31 provinces in mainland China also obtained consistent results [26]. We also see some intervention studies. Many Chinese clinical disciplines, including mental health, cardiovascular, Ophthalmology have begun to implement SDM [27–29]. Their preliminary results showed that SDM can help doctors and patients communicate better, increase the mutual trust between doctors and patients, and improve patients' satisfaction and treatment compliance [30]. To sum up, researchers have conducted preliminary explorations on the development and implementation of SDM in mainland China. However, there is no published review in this field yet.

Admittedly, the SDM studies in western countries have offered a large amount of valuable resources (eg: SDM models and tools) for China. Nevertheless, the stark differences on the healthcare system and traditions trigger us to question the feasibility of simply transferring western SDM products into China. At present, patients healthcare expectations are often inconsistent with the actual situation in mainland China [31]. Many hospitals in Chinese are named "Super Hospitals", which means they have better medical resources than other hospitals [32]. Therefore, patients from all over the country gather in these hospitals, requiring the most advanced treatment, which results in the extreme imbalance of doctors to patients and nurses to patients ratios among hospitals [33]. Therefore, patients may get more professional medical treatment in these super hospitals, but they have little opportunity to engage with healthcare professional to discuss important decisions [34]. In remote areas or low-level hospitals, medical resources

are relatively scarce, and some patients may feel distrustful and dissatisfied with diagnosis and treatment [35]. In addition, the lack of understanding of medical care, the inconsistent educational level of patients, and the difference of regional economic level have brought practical problems to the implementation of SDM [36]. Therefore, while learning from foreign experience is essential, we should also fully understand the current situation of SDM in mainland China to identify the gaps in current studies and inform future theoretical and empirical studies on SDM in China context [37].

The Ottawa Decision Support Framework (ODSF) [38, 39] conceptualizes the support needed by patients, families, and their practitioners when deliberating about options. It has guided practitioners and patients facing difficult decisions for 20 years. And it was devised to guide development of interventions aimed at preparing patients and providers for SDM [39]. The ODSF helps patients and providers make their way through a structured process of SDM. It guides practitioners and researchers in assessing participants' decisional needs, providing decision support interventions, and evaluating the effects of decision support on decisional outcomes throughout the whole SDM process. The latest version of 2020 ODSF [40] assets that decision process includes three core elements of "decisional needs", "decision support" and "decision outcomes". Among them, "decisional needs" means the factors that may affect the quality of decision-making. In other words, they are also factors that need to be focused on and improved in the decision-making process, including difficult decision type / decision timing / unreceptive decision stage / decision conflict (uncertainty) / adequate knowledge / unrealistic expectations / unclear values / adequate support & resources / personal & clinical needs. These factors are usually closely related to the situation of patients themselves, and often need to be focused in the study of shared decision-making [41]. "Decision support" usually refers to the SDM theories, process, tools and implementation determinants [42]. "Decision outcomes" refers to the indicators to evaluate the effectiveness of decision-making, including quality of the decision / quality of the decision process / impact [43]. As we know, theoretical framework can guide the direction of the whole research, and also help us make reasonable assumptions and expectations before the start of the research [44]. The theoretical framework is closely related to the determination of research problems. An appropriate theoretical framework can help us to summarize the important concepts related to research problems and the relationship between them, and help to clarify the scope, content dimension and level of research problems. It can make some hypotheses hidden in researchers' mind clear [45, 46]. Therefore, ODSF will be selected as the theoretical framework of this study in this scoping review. And the core conceptual elements of ODSF will be referred to in clarifying research questions, guiding data extraction and data analysis of this study.

Review Objective

The purpose of this study is to describe the current research on the SDM in mainland China. Based on the ODSF, the objective of this scoping review is to systematically map accessible research literature to answer the research questions: 1) For the decisional needs in Chinese context, we will examine the decision-making situation of patients, including their decision type / decision timing / decision stage / needs' manifestation and how decisional needs were identified. 2) What SDM decision support

interventions (SDM theories, process, tools, implementation determinants) were described to address the healthcare decisional needs? and 3) What SDM outcomes (quality of the decision, quality of the decision-making process, impact) were reported?

Methods

Scoping studies are an increasingly popular approach to reviewing health research evidence. In an effort to provide guidance to authors undertaking scoping studies, Arksey and O'Malley [47] developed a six-stage methodological framework: 1) identifying the research question, 2) searching for relevant studies, 3) selecting studies, 4) charting the data, 5) collating, summarizing, and reporting the results, and 6) consulting with stakeholders to inform or validate study findings (optional). Although Arksey and O'Malley think that consulting with stakeholders is optional, Levac' D [48] recommends consulting with stakeholders in scoping review. As far as our research is concerned, because the development of SDM in China is not mature enough, and we are also in the trial stage of SDM research, so it is particularly important for this study to consult with stakeholders. This framework provided an excellent methodological foundation. The study findings will be reported following the Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR) reporting guidelines [49].

Stage 1: identifying the research question

We are interested in the origin and development history of SDM in mainland China. So we want to trace back the starting time, research methods, fund types and the publication status of SDM research in mainland China. Whereas, our primary focus are three research questions. Theories and frameworks are means for identifying and defining research questions [50]. Therefore, the following questions are determined based on the three core elements of ODSF. First of all, we want to examine the healthcare decision needs of Chinese population. In this part, we want to answer current Chinese decision type/timing, decison stage, decisional needs and their most frequent manifestations in the areas of inadequate knowledge/information, unclear values, decisional conflict/uncertainty, and inadequate support. Secondly, to understand the decision support interventions of SDM in mainland China, we should learn the SDM theories, process, tools, imlpementation determinants in the SDM from previous studies. Finally, in order to clarify the effect of the SDM in mainland China , we should describe the outcomes of the shared decision-making in mainland China.

By answering these questions, we can gain a comprehensive understanding of the development process of SDM in mainland China and the gaps between China and western studies. Moreover, the results may inform future theoretical and empirical studies.

Stage 2: identifying relevant studies

With the assistance of an experienced research librarian, we will search three English databases: Ovid MEDLINE English electronic database: the Cumulative Index to Nursing and Allied Health Literature (CINAHL), EMBASE. We will also search four Chinese databases: China National Knowledge Infrastructure, Wan Fang Database, The VIP Database, and China Biology Medicine. These four Chinese databases are the largest and most commonly used databases, which can basically cover all the literature published in Chinese journals [51]. All databases will be searched from 1968 (this year was chosen as the starting year due to the prevalence of SDM publications since that time [52]) to present. The retrieval will not be limited to published peer-reviewed literature but also include unpublished grey literature. Grey literature will be searched using Baidu scholar search tools (https://xueshu.baidu.com/). These strategies will ensure that documents on SDM in mainland China are identified in the search of literature.

The search is limited to the study of SDM in mainland China. The definition of SDM in this study includes researches on demands and experience of both healthcare provider and patients for SDM, researches on the SDM participation process of patients and their families when facing difficult medical decision-making, researches on the development and application of patient' decision aids. We will conduct a preliminary search in one English and one Chinese database to check whether the search strategies are appropriate. If required, the search strategy will be modified to improve the quantity and relevance of the findings. A preliminary search strategy has been developed for MEDLINE and is shown in online supplementary Appendix A. This search strategy will be modified as required so that it can be used with other electronic databases. There will be no limitations to the date or language of the published articles, nor will there be limitations pertaining to the geographic location of the publication. This step will be completed by April 2021.

Stage 3: study selection

This study will integrate all the studies on SDM in mainland China as thoroughly as possible, so we developed a relatively broad initial eligibility criteria. Inclusion criteria are 1) The research setting is located in the mainland China. 2) Study design: no restrictions on the study design. 3) Research topics: healthcare provider and patients make medical decisions together, the development and use of patient decision-making aids, SDM related demands and experience of healthcare provider and patients. 4) Context: any place providing medical services. 5) There is no limitation to the research object and disease type. Exclusion criteria are 1) Non-empirical research; 2) Conference proceedings, book chapters.

Following execution of the search strategy, the first stage of the selection process will take place. Titles and abstracts of publications will be read independently by two members (LH and XL) of the research team and deemed eligible if inclusion and exclusion criteria are met. Covidence (Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia) will be used to facilitate the screening and data extraction. This software supports research teams in tracking the number of duplicate articles, facilitating the independent screening of the articles by two team members (LH and XL) and tracking the

eligibility process. Studies that are duplicates, irrelevant or unrelated will be removed from the study at this time. If the relevancy of the publication is unclear from the title or abstract, we will temporarily include this kind of literature and conduct a second screening in the next step of full-text screening. This process will be completed on the first 20 citations and Cohen's kappa will be calculated. A minimum kappa of 0.80 will be set as a threshold to achieve before continuing with the study selection process. In this stage, team members will discuss the inclusion and exclusion criteria regularly, and modify the initial inclusion and exclusion criteria as necessary.

Once completed, the second stage of the selection process will commence. The eligible publications screened in the first stage will be independently read in full by two investigators (MM and LH) to further establish whether the publication contains data/research relevant to informatics SDM in mainland China. When agreement cannot be reached, another two investigators (JZ, XL) will be consulted. Finally, the PRISMA flow diagram will be populated with the search and eligibility screening findings, and used to provide a visual of the data selection process.

Stage 4: data collection

The identified articles and documents that meet all of the eligibility criteria will be thoroughly read, and relevant data will be extracted by the investigators (XL, JZ, LH, MM). We will design a content extraction chart. The chart will be divided into two sections. The first section is "basic characteristics", in this section, we will extract the basic information of the publication, including title, journal, authors' names, country, language, year of publication, fund type, study design and setting. The second section is "ODSF research questions". It includes three main questions that reflect the objectives of this review. we focused on the decisional needs in the study on SDM in mainland China in the first part. In this part, we want to extract the basic information of patients who participate in the shared decision-making, their decisional needs, methods used to identify the decisional needs, and the manifestations of decision needs. The second part is concerned with the decision support intervention of SDM in mainland China. we will extract the relevant theories used to inform the SDM study, processes, tools, promoting factors and barriers related to implementing SDM. The third part is the outcomes of the shared decision-making. The outcomes reported in the SDM studies will be extracted. We are also open to other key information that we consider important, but cannot be collated to ODSF. So, in the process of literature extraction, if other contents related to the research objective are found (which cannot be placed in the chart), researchers will adjust the chart.

The final included literatures will be divided into four parts, and the content will be extracted independently by four researchers (XL, JZ, LH, MM). In the process of extraction, any researcher can initiate a discussion on the extraction content at any time. If consensus cannot be achieved, YH will adjudicate. Online supplementary Appendix B shows the proposed data extraction table.

Stage 5: data summary and synthesis of results

The charted data from published articles and grey literature will be analysed using two main strategies. 1) A descriptive numerical summary. We will describe the basic characteristics and other numerical data by calculating their number and proportion. 2) A qualitative framework analysis approach will be used to synthesize the qualitative data[53]. The framework method sits within a broad family of analysis methods often termed thematic analysis or qualitative content analysis [52]. By applying approach, we can identify commonalities and differences in qualitative data, before focusing on relationships between different parts of the data, thereby seeking to draw descriptive and/or explanatory conclusions clustered around categories. Generally, our strategy is to conduct coding on those qualitative data and map them into ODSF. There is no specific classification of implementation determinants of SDM in ODSF. We will choose the Consolidated Framework for Implementation Research (CFIR) framework [54] to guide the coding and classification of the implementation determinants of SDM. CFIR was developed by unifying key implementation constructs across 19 theories to build a comprehensive, "meta-framework" that examines various aspects of implementation, including technology features, characteristics of individuals, and features of the implementation settings [55]. The CFIR was chosen to guide the coding of determinants because of its comprehensiveness, allowing for the categorization of diverse implementation factors across a variety of studies and healthcare settings [55,56]. Specifically, two researchers (XI, LH) will do open coding of the chart data independently, i.e. coding anything that might be relevant from as many different perspectives as possible [53]. After coding the chart data, all researchers involved would meet to compare the codes they have applied to reach an agreement. Codes are then be grouped together into categories, which are then mapped in ODSF and CFIR. In addition, if some codes may not be classified into any ODSF categories, we will report the new findings beyond ODSF. Therefore, some new SDM related concepts and specific connotations that ODSF does not mention may appear in our final analysis results. After the previous process is completed, we will conceptualize a preliminary framework on SDM based on ODSF from a China context perspective.

Stage 6: consultation

As Levac' suggested [56], involving SDM participations in the research process can also make researchers distinguish the research results that need to be focused on more clearly. We will invite SDM research stakeholders to participate in this meeting including healthcare professionals (SDM researchers, clinical nurses, physicians, and nurse managers) and patients who have conducted or are going to take part in SDM process in their healthcare settings. To facilitate a meaningful and effective discussion among panel members, we will only invite six healthcare professionals and two patients. We will share our preliminary research findings with the panel in advance and hold a one-hour meeting with them. The aim of this meeting will be to (1) make sure that our findings are clear, understandable, and meaningful to them; (2) confirm that the results of the study are consistent with their experience; and (3) make a list of recommendations on how to implement SDM in Chinese Context (if possible).

Ethics and dissemination:

Since the scoping review methodology consists of reviewing and synthesizing published data, this part of the study is not subject to ethical approval. Ethical approval and informed consent will be obtained prior to the consultation stage.

Discussion And Dissemination

This scoping review is the first comprehensive review for SDM research in mainland China. With its results, we can understand the gap and differences between China's SDM development and Western countries clearly. It is also because this is the first review on this topic, so we did not find any reference materials to help us formulate the Chinese search strategy. To make up for this defect, we will invite professional library experts to help. And we will also carry out pre search and adjust the search strategy. It should be noted that the whole research process of this study relies heavily on ODSF. So there may be some valuable information omitted. Fortunately, ODSF is the most widely used and the longest used SDM framework in the world [40], and we still think it is very worthy of adoption. It's a pity that we have not been able to include policy makers in the consultation. Scoping the existing literature will provide a foundation for further development of related patient decision aiding tools and path for SDM. When we have completed the scoping review, we will consider a subsequent systematic review as preparation for a possible evaluation of implementing SDM in mainland China. We intend to publish the results and summary of the review in a relevant international journal as well as presenting the results in national and international networks on SDM and at conferences, following publication.

Abbreviations

SDM: Shared decision-making; ODSF: The Ottawa Decision Support Framework; QOL: Quality of life; PRISMA-ScR: Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Reviews; CINAHL: Cumulative Index to Nursing and Allied Health Literature

Declarations

Ethics approval and consent to participate

Since the scoping review methodology consists of reviewing and synthesizing already published data, this part of the study is not subject to ethical approval. Ethical approval and informed consent will be obtained prior to the consultation stage.

Consent for publication

All the authors agree that this article can be published.

Availability of data and material

Not applicable

Competing interests

There are no any conflicts of interest.

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Authors' contributions

XL and JZ contributed in designing the protocol and drafting the manuscript, YH and LH participated in study design and manuscript revision and refinement, XZ and MM conceived, funded and facilitated the whole study. All authors have read and approved the manuscript.

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