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What Influences the Implementation of Shared Decision Making: An Umbrella Review

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Abstract

Objective: To provide a cogent summation of the evidence base of the key barriers and facilitators to implementing shared decision making (SDM). **Methods:** An umbrella review of existing reviews on SDM was adopted. Databases were searched from 1997 to December 2018. Studies were included if they performed a review of barriers and facilitators to SDM.

Results: 7 eligible reviews were identified. The five themes identified were: patient factors, professional factors, environmental factors, relationship factors, and factors related to information provision. Lack of time was the main factor hindering the implementation of SDM. Encouragement and motivation of providers to use SDM was a significant enabler of SDM implementation. **Conclusions:** The provision of time and resources are insufficient if not accompanied by efforts to support and motivate providers to use SDM. **Practice**

implications: Healthcare providers need to be educated on the importance of building a relationship with their patients. To enhance this relationship, physicians may need to improve their interaction skills. They need to be curious and explore their patients' preferences, listen to them and respect their opinions, explain options and outcomes, and encourage them to participate in the decision making.

Keywords: Shared decision making, umbrella review, patient-centred care, barriers/facilitators, implementation.

1. Introduction

In recent decades, Shared Decision Making (SDM) in healthcare has been increasingly advocated as an idealized form of clinical practice (1). Involving patients in the process of decision making has a positive impact including decreased decisional conflict, increased patient knowledge, and improved health outcomes such as improved patient satisfaction and quality of life (1,2). SDM is defined as a collaborative process between patients and their physicians where they clarify treatment or self-management support, and share information about options and preferred outcomes, to form an agreed clinical decision on the best course of action (3). The need for SDM arises in situations where there is more than one medically acceptable option and where no specific option is clearly best (4). Consideration of patients' preferences of the risks and benefits are important in such decisions (3), and SDM helps patients to choose the most appropriate treatment that suits their preferences.

Patients and clinicians in both Western and non-Western countries have expressed positive attitudes and preferences toward SDM (5–7). However, despite the apparent benefits of SDM and the policies that support its implementation, SDM is not embedded in routine clinical practice. There are many barriers that hinder its implementation such as overworked physicians, poor patient-physician communication, and the lack of tools and resources. A number of factors have been identified which may facilitate SDM such as the provision of allocated time for SDM and encouragement of physicians to conduct SDM. A fuller understanding of these barriers and facilitators could help enable and optimise the implementation of SDM.

Research in this topic has grown over the years, and there are a number of systematic reviews published on SDM. There is a wide range of studies from around the world on this topic, spanning a myriad of different clinical settings, and a multitude of different facilitators and barriers have been reported. This diversity makes it difficult to characterise and make sense of the literature. Consequently, there is a need for a cogent summation of the evidence base that identifies and articulates the key barriers and facilitators to implementing SDM.

One possible solution is the adoption of the umbrella review approach. This involves synthesis of existing reviews that enables researchers to collect evidence from multiple healthcare settings without the need to conduct a systematic review in each setting. In essence, it is a review of existing reviews to provide an overview of the available evidence

for a particular topic and allows for comparisons between the published reviews (8). Moreover, it enables compilation of the evidence-base related to a specific question in a shorter timeframe (9). We have adopted this umbrella review approach to provide an overview of factors that may either facilitate or inhibit the implementation of SDM.

2. Methods:

2.1 Search Strategy

MEDLINE via Ovid, PsycINFO via Ovid, CINAHL, Scopus, and Cochrane Library databases were searched for relevant articles published between 1997 to December 2018. The search also included other sources such as reference lists of included reviews, articles citing the included reviews, as well as a Google Scholar websearch. The search strategy was based on the search strategy used by Legare and colleagues' for their systematic review (10) of the barriers and facilitators to implementing SDM. The searches were restricted to articles in English and by publication type (i.e. meta-analyses and systematic reviews). The search terms used were "decision aids", "decision making", "patient involvement", "patient participation", "shared decision", and "informed decision". Other search terms included "MEDLINE.tw.", "systematic review.tw.", and "meta-analysis.pt." that were added in order to identify reviews in MEDLINE. See Appendix A for more details of the search strategy.

2.2 Inclusion Criteria

Articles were included if they were published in English, reported barriers/facilitators to implement SDM as primary or secondary objectives, and were a systematic review, scoping review, literature review, or meta-analysis. All patient population groups, health conditions, and healthcare settings were included.

2.3 Study Selection

Electronic search results were exported to a reference management software (Mendeley) and duplicated records were identified and excluded. Two reviewers (NA and TA) independently screened titles and abstracts, and then full-text articles, for inclusion or exclusion. Where there were any uncertainties about the relevance of an article, the decision to include was discussed with researchers (PT) and (AL) and agreed by consensus. The study selection process is summarised in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Figure 1).

2.4 Data Extraction and quality assessment

One reviewer (NA) extracted data and assessed the quality of the included reviews. The other reviewer (TA) verified the accuracy of data extraction and quality assessment of all the included reviews. Any discrepancies were discussed until consensus was reached.

A data extraction sheet was developed for this study by the reviewers (NA, AL, PT) and used to extract variables that were relevant to the scope of the current review. Extracted variables included the type of review, range of years reviewed, the total number of studies included in the review, country of origin, aims or objectives of the review, participants, settings, as well as barriers and facilitators identified. As the aim was to provide a broad overview, all barriers and facilitators in each review were extracted except for those that were infrequently reported (i.e. those reported by only a few studies).

The quality of the included reviews was assessed using the Critical Appraisal Skills Programme (CASP) (11) quality assessment tool for appraising systematic reviews, which uses 10 criteria across three broad domains: validity, reliability, and applicability of the review.

2.5 Data Synthesis

The characteristics of the included reviews were tabulated to describe the main features of each review (see Table 1). Barriers and facilitators were thematically analysed. Each review article was read carefully to identify and extract the reported barriers and facilitators. The extracted barriers and facilitators were then compiled, and common themes were identified and reviewed. An initial classification of themes was performed after reading all the included reviews. The barriers and facilitators were then grouped into broad themes and then categorised into minor and major themes (see Table 2 and Appendix Table A.3). Any uncertainties regarding the thematic categorisations were resolved through discussion and consensus by the reviewers. From the descriptive summary of the reviews tabulated, the number of studies mentioning each barrier/facilitator was determined to identify commonly recurring barriers/facilitators (see Appendix Table A.1).

3. Results:

3.1 Study selection

The literature search initially yielded 505 articles. The total number of articles after removing duplicates was 414. Of these, 388 were excluded after screening by title and abstract. Of the remaining 26 full text articles retrieved, seven eligible reviews (five systematic reviews and two scoping reviews) were identified. The main reasons for exclusion were: barriers were limited to a specific treatment or decision (such as cardiopulmonary resuscitation decision), or were not about the shared approach, or were focused on the effectiveness of specific interventions used to facilitate SDM.

| Review | Type of Review | Years covered | Number of studies in the review | Country | Setting | Aim/ Objective | Participants |
|-----------------------------|-----------------------|------------------------|--|--|-------------------------------------|---|---|
| Legare et al. (10) | Systematic review | 1990 to December 2006 | 38 | UK, USA, Canada, Netherlands, France, Mexico, Australia, Norway, Germany, China. | General | Review of factors perceived by health professionals as barriers and facilitators to implementing SDM in clinical practice. | Health professional |
| Daly et al. (12) | Systematic review | 1996 to October 2016 | 19 | UK, USA, France, Australia, Norway, Holland, Sweden | Extended care setting or home | Objective to understand the factors that hinder and promote the effectiveness of SDM for people with dementia and their relatives. | People with dementia or cognitive disorder |
| Robertson et al. (13) | Systematic review | 1990–2017 | 17 | US, Netherlands, Denmark, Canada | Paediatric oncology clinical trials | Highlight recommended strategies to facilitate SDM in paediatric oncology clinical trials. | Parents, young people, healthcare professionals |
| Gondek et al. (14) | Systematic review | Until 6 November 2015 | 23 | UK, USA, Canada, Hong Kong, Australia, Sweden, Belgium | Mental health services | Review the influencing factors for patient centred care reported by providers, service users/carers in mental health services for children or young people. | Professionals, service users and carers in mental health services |
| Joseph-Williams et al. (15) | Systematic review | Until 15 August 2012 | 45 | UK, USA, Canada, Netherlands, Australia, Norway, Germany, and China, Sweden, Iran, Belgium, Indonesia, Japan, South Korea, Finland | General | Review of barriers and facilitators to SDM reported by patients. | Patients |
| Cheng et al. (16) | Scoping review | 1806 to September 2016 | 22 | UK, USA, Canada, Netherlands, Australia | Mental health | Scoping review of approaches used to promote SDM in child and youth mental health. | Child, adolescent, or their carers |

| | | | | | | | |
|-----------------------|-------------------|-------------------------|----|--|---------|--|----------------------------|
| Scholl et al. (17) | Scoping review | 1997 to October 2016 | 48 | USA, UK, Australia, Finland, Canada | General | Scoping review of organizational and system-level characteristics which influence the implementation of SDM, as well as strategies to overcome barriers. | Implementation projects |
|-----------------------|-------------------|-------------------------|----|--|---------|--|----------------------------|

Table 1 Characteristic of included reviews

3.2 Quality assessment

Six of the included reviews did not search grey literature and restricted their search strategies to the English language (11-16), so there is a possibility that some relevant studies may not have been included in these reviews. All of the reviews assessed the quality of studies included within each review with the exception of one scoping review (17). A quality appraisal of all the included reviews in our review was carried out and is detailed in Appendix A Table A.2.

3.3 Overview of the Included Reviews

Table 1 presents a general overview of five systematic reviews and two scoping reviews that identified SDM studies published up to 2017. More than half of the reviews were published in the last five years, indicating that the level of awareness and interest in SDM is increasing. Three of the reviews described facilitators and four examined both barriers and facilitators.

There was significant variation in the number of studies included in each review. This tended to depend on the scope of the review. For instance, the three reviews that were broad (i.e. not limited to a specific healthcare setting or condition) (10,15,17) included a greater number of studies than reviews that were limited to specific health settings or conditions. Likewise, the reviews that were conducted recently included more studies than the older reviews, reflecting the increasing amount of relevant literature over time. The studies included in the reviews were carried out in 19 countries, most of which were high-income countries in North America and Europe. Very few studies were from low- and middle-income country settings.

There was considerable diversity in terms of study settings as well as intended objectives of the included reviews. This ranged from one review focused on identifying strategies to encourage SDM within paediatric oncology (13), to another focused on understanding factors that hindered or promoted effective SDM for people with dementia and other types of cognitive impairment within extended care settings or their own home (12). Two reviews concentrated on SDM within a mental health setting (14,16). Three reviews were general and did not comprise of any specific healthcare settings. Of these, two of them primarily focused on exploring barriers and facilitators to implementing SDM as perceived by patients (15) and health professionals (10), whilst the other focused on understanding the organizational and

system-level characteristics that affected the implementation of SDM (17). Most of the target study participants in the reviews were healthcare practitioners and service users. Three reviews considered parents and carers of patients.

3.4 Barriers and facilitators to SDM

The five themes identified were: patient factors, professional factors, environmental factors, relationship factors, and factors related to information provision. The factors under each theme were classed as barriers or facilitators based on the description provided in the included reviews. Table 2 presents a summary of barriers and facilitators identified under each theme; these are described in more detail below.

3.4.1 Patient Factors

This theme comprised of patient perceptions, preferences and fears, and patient capacity (i.e. patient related factors that can be barriers or facilitators to SDM). The most common barrier was the patient's belief that the "doctor knows best" and that the patient lacked knowledge, as was reported in 29 studies in one review (15). Other common barriers were the nature of the health condition (e.g. infectious disease, severity of symptoms, drug addiction) as reported in 28 studies in two reviews (10,15), the patient's belief that only the clinician could make decisions (15), individual characteristics of the patient (10), and the patient's fear of the consequences of being described as difficult or troublesome that may result in poorer quality care or less attention (15). The most frequently identified facilitators were related to the patient's perception of the acceptability of asking questions (10), their acknowledgement that the medical encounter involves two experts (doctor and patient) (10), and their acceptance of responsibility for participating in decision making (10).

3.4.2 Professional Factors

This theme encompassed professionals' perceptions, characteristics, and behaviours. The key barriers included: clinicians not adequately listening to or respecting the patients' concerns or opinions (as reported in 24 studies in two reviews) (14,15), clinicians not asking the patient about their preferred role in decision-making (reported in 19 studies in two reviews) (10,15), clinicians with poor interpersonal skills (15), and clinicians believing that patients prefer not to be involved in decision making and did not need it. (15). The main facilitators identified in three separate reviews included: clinicians who listened to service users/carers and respected

their opinions (13–15), clinicians who discussed the preferences of patients/families with regards to their involvement in decision making (10,13,15), and clinicians who used simple terminology (13,15).

3.4.3 Environmental Factors

Organizational characteristics and characteristics of the healthcare system were two other common themes that emerged from the analysis. The most common barriers were time constraints (as stated in 34 studies in two different reviews) (10,15), the lack of resources (10,12,14), and clinicians being too busy to involve patients in the SDM process (10). Efforts to encourage and motivate providers to use SDM (as reported in 31 studies in two different reviews) (10,17) and provide adequate time for SDM were important facilitators for the implementation of SDM (10,13,17).

3.4.4 Relationship Factors

Many factors related to the clinician-patient relationship were identified under this theme. They included poor clinician-patient relationships (12,14), or patients who are not known by the clinician (15). Of these, the most common factor was the patients' trust in their clinicians which reflects the quality of the relationship between the clinicians and patients (10). The quality of this relationship was clearly identified as a key enabler in four other reviews (12–15).

3.4.5 Factors related to information provision

The lack of information sharing, particularly with regards to the patients' condition, treatment options and outcomes, was the most frequently identified barrier to SDM (14,15). Conversely, the provision of sufficient information about the patients' condition, options and outcomes (13–15) was a key facilitator

Table 2 Barriers and facilitators to SDM (10,12–17)

| | | |
|-------------------------------------|--|--|
| <p>Environmental Factors</p> | <p>Organizational factors</p> <ul style="list-style-type: none"> • Time (bar and fac) • Too many clinicians involved in care (bar) • Inadequate environmental conditions (bar) • Lack of resources (bar) • Support for the use of decision aids (bar and fac) • Motivation of healthcare professionals to implement SDM (bar and fac) • Multiple consultations for SDM (bar and fac) • Electronic health record prompt for SDM (fac) • Performance measurement and feedback on SDM (fac) • Engagement of non-physician personnel(e.g. nurse, social workers) (bar and fac) | <p>Healthcare system factors</p> <ul style="list-style-type: none"> • Policies and regulations (bar and fac) • Embedded SDM communication skills into medical education (fac) • Using a payment model to incentivize providers to involve patients in SDM (fac) |
| <p>Professional Factors</p> | <p>Professional behaviour</p> <ul style="list-style-type: none"> • Discussing patients’ preferences (bar and fac) • Listening and respecting patients’ concerns or opinions (bar and fac) • Checking information comprehension regularly (fac) • Giving explicit permission to participate in SDM (bar and fac) • Not giving explicit choices to patients (bar) • Explaining treatment options and outcomes (bar and fac) • Using simple terminology (bar and fac) • Using decision support tools (fac) • Sharing responsibility with Patient (fac) | <p>Professional characteristics</p> <ul style="list-style-type: none"> • Interpersonal skills (bar and fac) • Lack of familiarity with SDM (bar) • Authoritarian style in decision making (bar) • Shared style in decision making (fac) • Social attitudes (bar) <p>Professional perception</p> <ul style="list-style-type: none"> • View that patients prefer not to be involved and do not need it (bar) • Recognising abilities and rights of patients to be involved in a decision making (bar and fac) |

| | | |
|---|---|--|
| | | <ul style="list-style-type: none"> • Expectations about SDM on patient outcomes and healthcare process (fac) • Agreement of aspect of SDM (bar and fac) |
| Patient/Family Factors | <p>Patients' perceptions</p> <ul style="list-style-type: none"> • Belief that “doctor knows best” (bar) • Not capable of understanding medical information (bar) • Acceptability of asking questions (bar and fac) • Clinicians are against the involvement of patients (bar) • Acknowledgement that the medical encounter involves two experts (fac) • Recognizing equipoise and uncertainty (fac) • Accepting the responsibility to participate (bar and fac) • Lack of expectation for SDM in consultations (bar) | <p>Patient capacity</p> <ul style="list-style-type: none"> • Health condition (bar and fac) • Patient characteristics (bar and fac) • Lack of self-efficacy (bar) • Parental involvement (fac) <p>Preferences and fears</p> <ul style="list-style-type: none"> • Preferences to be involved (bar and fac) • Fear the consequences of being described as difficult (bar) • Fear of knowing and accepting a diagnosis (bar) |
| Relationship Factors | <ul style="list-style-type: none"> • Quality of the relationship (bar and fac) • Trust in clinician (bar and fac) • Patient is known/not known by the clinician (fac and bar) • Difference in personal characteristics of the patients and clinicians (e.g. sex, language) (bar) | |
| Factors related to information provision | <ul style="list-style-type: none"> • Provision of sufficient information on options and outcomes (bar and fac) • Provision of information in multiple modalities (fac) • Repetition of information at multiple time-points (fac) • Provision of translated materials or interpreters (fac) • Provision of psychoeducational information (fac) | |

When a factor was reported as a facilitator or barrier to SDM, this is indicated: Fac = Facilitator; Bar = Barrier

4. Discussion and Conclusion

4.1 Discussion

Our umbrella review highlighted different factors that influence the implementation of SDM, provide decision-makers in healthcare with an overview of the field, and provides information for the implementation of SDM. The majority of included reviews were published in the last five years which confirms the growth and interest in the field of SDM. However, there is considerable heterogeneity of the evidence base on SDM that makes translation into practice challenging.

It is apparent from the reviews that time constraints was the main factor hindering the implementation of SDM. Physicians are often under considerable time pressure during the consultation as they have to complete recommended tasks and clinical documentation, which reduces the time for conversation with their patients (18). The lack of time may also result in the lack of listening to patients and lack of sharing of sufficient information between physicians and patients. The provision of ample time in consultations could make a significant difference as longer consultations are more likely to involve elements of SDM (19,20).

However, there is a debate about the additional time required to engage in SDM with some studies suggesting that SDM could be carried out within the usual time allocated for a consultation (21), and other studies reporting that not all applications of SDM increase the time requirements for the consultation (22,23). In this review, it was found that encouragement and motivation of providers to use SDM was also a significant enabler of SDM implementation. It should be noted that the provision of resources, such as time, information, or SDM tools alone, is insufficient if not accompanied by efforts to support and motivate providers to use SDM (24,25).

Another key barrier was the patient's belief that the "doctor knows best". This perception is reinforced through the lack of information sharing by the clinician involved. Consequently, the patients feel that they lack knowledge and confidence which disempowers them from participating. Unsurprisingly, they are more likely to leave the decision to their clinicians. This finding mirrors an Italian study that found that most people wanted to be involved in decision making, but their lack of knowledge was a barrier to their participation (26).

The process of SDM starts with the interaction between physicians and patients. Good communication enhances the experience of collaboration and should lead to the engagement of physicians in behaviours that are specifically oriented to SDM (27). However, we also identified factors that influence the quality of communication between physicians and patients, such as a lack of listening and respect for the patient's concerns or opinions, and the lack of sufficient information provision. Patients who experienced these behaviours might be less inclined to engage in the decision-making process.

Patients value building a respectful and trustful relationship with their clinicians, and the open exchange of information (28,29). It requires clinicians to listen to their patients and to elicit their preferences and fears. It enables patients to ask their clinicians for information they need without hesitation. In addition, such a relationship enables clinicians to encourage their patients to participate in the decision making. Consequently, patients may feel better supported by their clinicians and permitted to take an active role in the decision making.

Decision aids also facilitate the implementation of SDM. They reduce decisional conflict, and improve patient knowledge and patient-clinician communication (30–32). The measures that facilitate the use of decision aids include allowing flexibility on the use of decision aids, having decision aids/tools available in workspaces and exam rooms, using electronic health records (EHRs) to identify eligible patient for decision aids, and providing decision aids on EHRs and patient portals. In addition, our review found that some professional and practitioner behaviours, such as the use of decision supportive tools with patients (e.g., for action planning or goal setting, as discussion prompts, and written decisions) also promote and support SDM.

SDM might not be appropriate in all circumstances. The clinical situation or health condition of the patient may affect their capacity and willingness to be involved in the decision making. Patients with more acute, severe or life-threatening conditions may be less inclined to participate in SDM. In these instances, SDM may be less appropriate or desired. However, it should be noted that even in these situations, some patients may want to be involved in decisions despite their health conditions, but their clinicians may not be aware or supportive of their desire for SDM. Indeed, some studies have found that patients value SDM even in the case of severe illness (33,34), which raises the question as to whether the acuity and severity of the health condition is a genuine patient barrier or a clinician-perceived phenomenon.

Similarly, the patients' capacity to be involved may be assumed by clinicians, particularly for those with mental disorders. Yet our review found studies where people with mental disorders did desire and could be engaged in SDM in this setting. The professional biases of clinicians may need to be tempered and their assumptions challenged regarding patient capacity (and readiness) to participate as they may be incorrect. More recent evidence shows that physician perceptions change based on a recognized learning curve to SDM implementation(35). In addition, Hargraves and colleagues highlight a model of SDM that directly refutes the notion that SDM is only applicable to highly specific clinical scenarios(36).

Most of the studies included in the reviews were conducted in Western countries which reflect the trends in those healthcare systems that is increasingly driven by the patient-centred care approach. But this is not yet the case in non-Western countries. Consequently, the findings may not be transferable to non-Western cultures, and especially in developing countries where values, social contexts, and healthcare systems are different. The SDM concept has propagated internationally as globalization brings Western views and ideas about choice, disclosure, and autonomy to patients in non-Western countries. However, SDM may not be fully available in many of those settings (37,38). Further research is needed to understand differences in the extent to which SDM can be applied in these countries, as well as the barriers, and the strategies needed to address them. In particular, health communication behaviours associated with health delivery have been widely reported to be a barrier or enabler to the implementation of SDM. These interpersonal communication challenges seem important both across health systems and within systems.

Limitations

The findings in this manuscript are subject to some limitations. First of all, some of the included reviews have some limitation in their search strategies (e.g., no search for grey literature or they did not include non-English publications) and there is a possibility of missing some of the relevant studies. A potential limitation to the umbrella review approach could be overlapping studies that appear in more than one review (39). However, when the studies included in each review were reviewed, there was only one instance where one study appeared in two reviews (15,17). Another limitation to the umbrella review approach is that it can only report what researchers have investigated and published. For example, some factors

may have a strong influence, but if they were not adequately investigated in the included studies they may be reported as less important factors, or they may not even be included in the review (40). We acknowledge that the identification of barriers and facilitators based solely from the synthesis of reviews found in our umbrella review might lead to bias (e.g. some of the findings may seem out of place when uninformed by other non-reviews in the field). In order to mitigate this issue, other key literature not identified in this umbrella review were actively referenced. Lastly, the inclusion criteria were restricted to reviews that reported barriers/facilitators to implementing SDM as the primary or secondary objectives of the reviews. Thus, there is a possibility that some of the excluded reviews may have useful information relevant for the implementation of SDM (41–43). Finally, whilst our review focussed on barriers and facilitators to implementation, we acknowledge that there are many other considerations such as. incentive structures and poor protocol fidelity.

4.2 Conclusions

The lack of time is perceived as the main factor that hinders the implementation of SDM. Strategies such as the engagement of non-physician personnel (e.g. nurse, social workers) throughout the process of decision making, and provision of multiple consultations for SDM, may overcome this barrier. However, the provision of time and resources is insufficient if not accompanied by efforts to support and motivate providers to use SDM. Healthcare providers need to be motivated, provided with regular training to use SDM and educated on the importance of building a trusting relationship with their patients.

The quality of the clinician-patient relationship is crucial, and the willingness to share information is a key part of this. To enhance this relationship and obtain the most out of the consultation, physicians need good interaction skills. They need to be curious and explore their patients' preferences, listen to their patients and respect their opinions, explain treatment options and outcomes, and encourage their patients to ask and participate in the decision making process. Patients have to acknowledge they have role as well and need to engage with their physicians in information sharing.

4.3 Implications for future research

Implementation issues are likely to be dissimilar between Western and non-Western countries, so there remains a need for further research on SDM to be conducted in non-

Western settings. The generalisability of findings worldwide as well as its translation into practice is uncertain. Most of the studies focused at the clinician-service user/carer level which highlights a paucity of research at the systems-level. Consequently, further research is also needed to understand factors that influence organizational managers and policymakers that may facilitate the implementation of SDM.

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Conflict of interest

The authors have no conflicts of interest.

Ethical approval

Ethical approval was not required

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