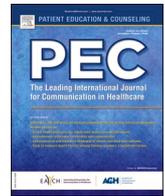




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It is time to recognise shared decision-making as a complex intervention

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ABSTRACT

Objective: Shared decision-making (SDM) is a core component of personalised health care. Populations continue to diversify in their health and social care needs. We argue that established SDM models (focusing on the interaction between patient and practitioner) do not reflect the complexity of patient presentations nor the wider influences on patients' health and health care encounters. The route from SDM to positive health and health service outcomes are currently obscured. For SDM to be utilised without limit, and for SDM to impact health care policy, it is best understood as a complex intervention.

Discussion: SDM as a complex intervention is characterised by multiple interacting components, influenced by agents acting at several levels of a socioecological model (personal-, interpersonal-, organisational-, societal-, policy- level). The components have non-linear pathways (from cause to effect) existing within and interacting with the context in which SDM is implemented. SDM components are tailorable: Tailoring can enable personalised care for individuals and effect changes in desired outcomes for specific populations and settings. The development of programme theory, for example utilising logic modelling, will be essential for articulating and planning the evaluation of these complex pathways. A standardised framework of SDM outcomes, spanning the socioecological model, would guide the assessment of SDM process and effect. Programme theory, logic modelling, and consistent assessment will together reveal the route to positive outcomes for patients, carers, practitioners and health services and, in turn, will impact policy.

Conclusion: It is time to recognise SDM as a complex intervention. Simplistic definitions should no longer be attempted. SDM should be conceptualised as being wider than the consultation itself with components that are defined by and tailored to the context of its adoption, implementation and sustainability, considering influences that span the socioecological model of the health care system.

1. Shared decision-making for unmet need

Shared decision-making (SDM) is a core component of personalised health care and an ethical approach to patient-centred consultations. Meeting the personalised needs of real-world patients, within the organisational constraints of the health care system, is challenging. There have been decades of research in the field of SDM [1,2]. We argue that the established SDM models do not reflect the day-to-day complexity of individual patient presentations nor the context and wider influences on patients' health problems and health care encounters. This limits the visibility of SDM as a health care intervention, hinders its implementation, measurement and evaluation, and therefore obscures the route to positive health outcomes and impact on policy.

Interventions such as personalised care, when delivered within health care systems, are designed and developed to meet a health or

social care need. The World Health Organization recognises the need for patients to be involved in decision-making about their care and to be enabled to participate in this involvement [3]. A recent independent investigation into the National Health Service (NHS) in England [4] called for a health service in which patients are empowered to make choices and to take 'as much control of their care as possible' and where practitioners, 'widely admired for their skill and strength of their clinical reasoning', can be re-enthused in clinical practice that 'treats people with dignity, compassion and respect'.

The proportion of people's lives spent in ill-health is increasing and the population continues to diversify in its complexity of health and social care needs [5]. The prevalence of people living with multiple long-term conditions (MLTC), including mental health conditions, is greater among ethnic minority groups and in areas of socioeconomic deprivation [6]. This is a global priority for research [7] and yet there

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are real risks of worsening health inequality and strain on health care systems if the needs of these people are not met holistically [8]. As MLTCs and their treatments often interact, quality-indicated care for single conditions cannot meet the needs of people living with MLTCs. People with MLTC may present with problems that do not fit neatly into specialist categories of care. There is a subsequent risk to patients from polypharmacy, and inefficiency in health care resource, from the provision of multiple appointments for separate conditions, for example. Access to high-quality, appropriate care for people with MLTC is not met. Commonly cited attributes of models of care for people with complex needs include person-centred approaches [9–11] because personalised care can enable identification of unmet need and allow early intervention [12,13].

2. Re-framing shared decision-making as a complex intervention

Despite inconsistency around a definition [14,15], highly-cited models of SDM [16,17] share common features. These include understanding patient priorities, providing information about management options and agreeing collaboratively on a plan of action.

Existing models of SDM are arguably too simplistic and have limits [18]. For SDM to be utilised without limit, it is best understood as a complex intervention. A complex intervention is characterised by multiple interacting components that may have non-linear causal pathways [19]. Importantly, complex interventions delivered in a health care system exist within, and interact with, the contexts and settings in which they are implemented and may require adaption and/or tailoring to effect changes in desired outcomes [20]. Historically, developers of SDM models have focused on the decision-making process between the patient and the practitioner and have failed to fully consider contextual or

socioecological factors [21] influencing delivery and implementation. This may explain why reasons provided for a lack of uptake of SDM in the UK include a lack of cultural and organisational changes to support SDM [22].

Patient decision aids (PDAs) [23] can reflect the simplicity of existing models of SDM. PDAs are frequently used to aid discussion around condition-specific treatment options between patient and practitioner. There is limited certainty of evidence for effects on health outcomes, quality or costs of care, or whether they ‘foster’ SDM [24]. It is unclear whether PDAs contribute to treatment burden for people living with MLTC, by encouraging a condition-specific approach, or whether they might drive inequality of care by failing to consider the patient’s preferences for their use or a holistic view of patient priorities. However, if PDAs are utilised as one tailorable component of SDM when viewed as a complex intervention (as has been demonstrated in the context of shared decision-making for people with kidney failure [25], these concerns might be addressed.

Within the socioecological model of a health care system [21], individual ‘agents’ can implement change over aspects of the environment in which SDM is delivered (Fig. 1). The patient can implement change at a *personal level* by expressing their preferences for involvement and communicating their personal priorities. Multidisciplinary practitioners can be trained [26,27] to implement change at an *interpersonal level* by facilitating SDM, tailored to their individual patients, through altering their attitudes and behaviours, utilising decision aids or risk-benefit tools, as well as through skilful communication. At an *organisational level*, practitioner roles and skillsets can be redefined, along with the reorganisation of the workforce (e.g., to improve access to a multidisciplinary team, and facilitate continuity of care [28] and appropriate duration of appointment), to influence interpersonal relationships between patients and practitioners. At the *societal level*, people’s diverse

AN EXAMPLE OF A SOCIOECOLOGICAL MODEL OF SHARED DECISION-MAKING (SDM)

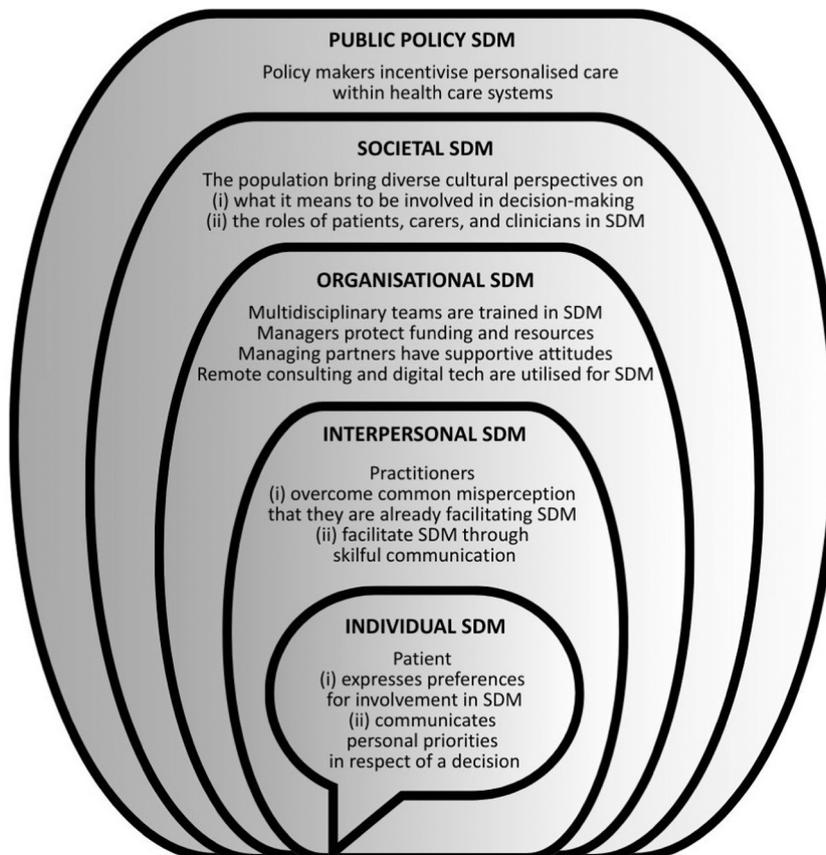


Fig. 1. An example of a socioecological model [21] of shared decision-making (SDM).

cultural backgrounds can influence how empowered they feel when seeking or expecting involvement through health care organisations and with individual practitioners [21]. At a national *policy level*, the incentivisation of enhanced personalised care services (as opposed to pay-for-performance criteria) can filter through to societal and organisational levels, to influence interpersonal- and individual-level factors.

When conceptualised as a complex intervention, viewed through the socioecological model, SDM can be effectively adopted, implemented and maintained through behaviour change (e.g., utilising techniques such as training, modelling and enablement [29]) targeting individuals acting at the various levels, as well as through structural changes aligned to these behaviours.

A key feature of a complex intervention is that it allows for tailoring of the intervention and adaptation to different contexts [19]. Therefore, SDM as a complex intervention can go beyond the limits of existing models. For example, NICE recommends that research explores what influences the acceptability of SDM for patients who believe in deferring to the decisional authority of the practitioner [15], “you tell me what to do doctor”. SDM as a complex intervention can meet a spectrum of patient preferences for involvement. At the interpersonal level, this can be facilitated by enabling patients to communicate their day-to-day values and priorities in respect of a decision. Looking at the other layers of the socioecological model, patient preferences for involvement can be met by considering a patient’s beliefs about the role of the practitioner, providing continuity of care to develop trusting relationships, facilitating an appropriate mode of consultation, enabling digital access to health information, or by addressing health literacy within the consultation, for example.

SDM may also feel limited from a practitioner’s perspective. Clinical decision-making is fraught with ambiguity, particularly for patients with MLTCs. Practitioners find it easier to involve patients in situations with clear options when evidence is readily available [30]. However, SDM provides the best value in situations of clinical uncertainty [31]. Here, patient priorities can be considered, in context, alongside the medical perspective of the practitioner, as has been previously advocated [32]. By training health care practitioners to work with complexity and uncertainty within a socioecological model of SDM, those practitioners may experience greater job satisfaction and wellbeing [33].

3. Assessing the effectiveness of shared decision-making

Measuring the process of SDM remains a challenge. There are a plethora of measures seeking to evaluate the constructs of SDM [34] but few have been developed or tested in the context of complex patient presentations e.g., for people living with MLTC [35]. Existing measures reflect the limitations of existing models of SDM; they do not capture the broader health care context in which SDM is being delivered or the influences of relevant agents operating throughout the socioecological model. Therefore, the processes relevant to SDM as a complex intervention are not currently assessed in a way that can prove consistent, equitable delivery of SDM within metric-driven health care systems. **Measuring SDM processes across the socioecological model** could address this. For example, at a *personal level*, assessments of whether the patient’s preferences for involvement were met, and whether the patient was enabled to communicate their wider life priorities in the context of the decision, would be appropriate. At the *interpersonal level*, assessments might include whether the practitioner had the knowledge, skills and confidence to implement a SDM intervention (particularly relevant where a PDA or clinical guideline was not applicable e.g., in the context of MLTC). Assessments of whether the practitioner experienced, or communicated, clinical uncertainty would also be relevant. At the *organisational level*, assessments of whether training in SDM is being delivered to allied health practitioners, whether there was continuity of care, whether consultation duration or frequency is optimal for the context of the decision-making, and whether SDM is the cultural norm amongst multidisciplinary teams, could be considered. Assessments of

the cost of delivery of SDM processes, vs. ‘usual care’, would be important. The tailoring of SDM processes, to reflect cultural diversity or to avoid condition-specific decision-making for MLTC, for example, could be assessed at *societal level*, along with a review of whether these processes are supported by *policy level* initiatives.

Similar challenges occur with evidencing the effects and outcomes of SDM interventions. Personalised care is posited to reduce harm from inappropriate intervention or prescribing (whilst improving adherence to appropriate treatment), to improve patient satisfaction with care and trust in the practitioner, reduce the burden on formal or informal carers and family members, and bring job-satisfaction and associated improvements in staff wellbeing [26,36–41]. Most of these reported benefits centre on short-term outcomes, often evidenced by patient experience measures, and may not be sufficient to influence organisational changes or meaningfully inform policy, training and practice. The pathways from SDM through to expected longer-term benefits (such as reduced health care costs and improvements to patients’ quality of life), have been challenging to model or evidence. This was demonstrated by the 3D study (one of the few studies that have attempted the evaluation of complex interventions in this field) [11]. There is a need for a standardised framework of SDM outcomes that could usefully span the socioecological model [42,43].

Consistent assessment of SDM outcomes across the socioecological model would support evaluation of the impact of SDM. Outcomes of SDM at the *personal level* might include the patient’s knowledge of the options that were available (including risks and benefits) and their certainty in the chosen option, as well as their confidence in the management of their own health and care as a result of SDM. Assessments relating to patient health status (e.g., risk of having a stroke after a shared decision to deprescribe cholesterol-lowering medication) could be selected depending on context. Assessments at the *interpersonal level* and *organisational level* might include a practitioner’s satisfaction with the care that they provided, rates of complaints or litigation against individual practitioners or organisations, and practitioner attendance at the workplace. Capturing the economic impact of SDM e.g., by reducing rates of patient reattendance (through patient enablement and self-care, or by reducing the need for a second opinion on a decision), or through a reduction in workforce absenteeism, would be important. At *societal level*, effects on equity in health care delivery and health outcomes, as a result of an emerging culture of SDM within organisations, could be assessed in the longer term. Assessments of *policy level* changes could be designed to evaluate whether emerging effects of SDM on patient outcomes, and organisational culture, are reflected in policy targets.

4. Discussion and conclusion

4.1. Discussion

To model SDM, it is important to recognise that as a complex intervention, SDM is characterised by multiple interacting components acting at multiple levels of the socioecological model and that these components have non-linear pathways from cause through to effect [19]. The development of programme theory for SDM is therefore an essential step when articulating and evaluating these pathways. Programme theory is often expressed diagrammatically through a logic model [44], allowing transparent description of the theoretical underpinnings of a complex intervention and the context in which it has been developed and evaluated [19,45,46]. Logic models can provide guidance when testing the theories and mechanisms underlying both core and tailorable components of SDM and enable the mapping of SDM processes through to outcomes. The methods typically used in other fields [19], to evaluate both processes and outcomes of complex interventions (e.g., considering the interaction of intervention and context, capturing assessments from the perspectives of diverse stakeholders, comparing resource use to implement SDM with the consequences of its outcomes), could then be applied to SDM, aided by

programme theory and logic modelling.

4.2. Conclusion

It is time to recognise SDM as a complex intervention. Simplistic definitions should no longer be attempted. SDM should be conceptualised as being wider than the consultation itself with components that are defined by and tailored to the context of its adoption, implementation and sustainability, considering influences that span the socioecological model of the health care system.

4.3. Practice implications

Patient need will continue to diversify. These complex needs can be met with SDM as a complex intervention. Patients and the public, the evolving clinical workforce, managers and policy makers can be empowered and enthused to expect, and facilitate, the incorporation of both patient and practitioner perspectives into a consultation that centres around SDM. An organisational and system-wide culture of SDM will be important [22]. The reinvigoration of a health care system [4] that can adapt and flex to provide a personalised, patient-centred model of SDM, reflecting the complexity of individual patients and the way that they interact with the system, will benefit patients, practitioners and organisations.

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Suzanne H Richards: Writing – review & editing, Conceptualization. **Karen Mattick:** Writing – review & editing. **Joanne E Butterworth:** Writing – review & editing, Writing – original draft, Conceptualization.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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