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MAJOR REVIEW (ORIG)

From Idealist to Realist—Designing and Implementing Shared Decision-Making Interventions in the Choice of Antipsychotic Prescription in People Living with Psychosis (SHAPE): A Realist Review
Part 1—Implementing Shared Decision-Making: Policy, Governance and System Factors.

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Abstract

***Background*: Shared decision-making (SDM) implementation remains limited in psychosis management, particularly within antipsychotic prescribing. When and why prescribers engage in SDM within these contexts is largely unknown. Part 1 of this two-part realist review aimed to understand the impact of structural and contextual factors on prescriber engagement in SDM within antipsychotic prescribing.**

***Study design*: CINAHL Plus, Cochrane Library, Embase, PsycINFO, PubMed, Scopus, Sociological Abstracts, Web of Science, and Google Scholar were searched for evidence to develop realist program theories outlining the relationship between macro-level contexts and their impact on prescriber behaviors.**

***Study results*: From 106 included documents, five program theories explaining relationships between (i) leadership and governance, (ii) workforce development, and (iii) service delivery contexts and their impact on reducing prescriber engagement with behaviors required of SDM application were developed. No facilitative macro-level contexts were identified. Key mechanisms reducing prescriber engagement in desired behaviors include fear of individual blame for adverse outcomes and exposure to liability, pressure from service environments to prioritize decreasing risk of harm, devaluing of experiential knowledge, and beliefs that SDM conflicts with duties of beneficence and non-maleficence.**

***Conclusion*: Even empirically efficacious interventions will be difficult to implement at scale within real-world settings due to misalignment with complex cultural, legal, and professional realities prominent therein. Mechanisms responsible for reducing prescriber engagement in SDM should be the target of structural interventions necessary to support contextual integration into psychosis management. Part 2 outlines features of service delivery contexts, workforce development, and technology that can increase prescriber engagement in SDM.**

Introduction

Shared decision-making (SDM) is a process whereby clinicians and patients collaborate to make treatment decisions

based on clinical evidence and patients' informed preferences.[1] SDM is considered a key component of person-centered care and is advocated for as an exemplary model of decision-making within mental health policy internationally.[2–4] Despite SDM being increasingly featured in the rhetoric of government policy and best practice guidance, a disconnect exists between policy ideals and much of standard clinical practice.[5–7] This is particularly so among individuals experiencing psychosis and within antipsychotic treatment decisions, where evidence suggests even beyond acute treatment, clinician-led decision-making prevails.[8–10] Antipsychotics are essential treatments within psychosis management.[11,12] Differences in average efficacy estimates between antipsychotics are small and, in most cases, lack clinical significance. In comparison, the risk of many side effects between individual antipsychotics does differ to a clinically significant extent.[12] Thus, in non-treatment-resistant cases, most major guidelines within psychosis management advocate for the choice of antipsychotic to be primarily informed by an individual's preferences for side effects, rather than by the superiority of certain antipsychotics based on available efficacy estimates.[11,13] Despite such recommendations, diversity within antipsychotic prescribing patterns, aligned to the natural variation in side effect preferences across the diverse range of individuals presenting with psychosis, is not seen.

International trends of antipsychotic prescribing patterns within psychosis management consistently demonstrate high prescribing rates of a small number of antipsychotics, namely olanzapine, risperidone, and quetiapine.[14–17] Thus, despite the increased application of collaborative models of decision-making being advocated for within mental health policy, clinical practice guidelines, and supported by individuals with severe mental illnesses (SMI) and various mental health professionals,[8–10] implementation remains limited. In comparison to continued research focussing on identifying trends of antipsychotic prescribing, the development of knowledge addressing how to influence antipsychotic prescribing behaviors among clinicians receives comparatively much less attention within international research.

While many interventions have been assessed for their efficacy in increasing SDM application within antipsychotic prescribing, results have proven variable and inconsistent.[18] Little consideration has been given to understanding causative processes responsible for effective interventions.[19] Despite prior evidence syntheses, questions of why some interventions work, and others do not remain.[18,20] Even in the case of empirically efficacious interventions,[21,22] their widespread implementation in practice is limited—mirroring the "know-do gap" prevalent within mental health research.[23] Thus, within SDM research in psychosis management, a need exists for evidence outlining how successful interventions work, for whom, and under what circumstances. Evidence syntheses attempting to address these questions require a methodology that can provide answers about "how" and "why" interventions work and account for contextual factors within implementation settings.[19]

Realist reviews are a theory-building, interpretative approach to evidence synthesis aiming to identify how contexts and mechanisms combine to produce outcomes. Unlike systematic reviews, realist reviews aim to generate explanations as to how and why interventions work (or not) within settings where they are implemented. Within this methodological orientation, interventions generate outcomes through individuals' responses to resources, ideas, and practices that interventions introduce, which are shaped by wider contexts. Realist reviews aim to move from empirical observation to developing causal explanations to understand what interventions generate change (ie, mechanisms) and under what circumstances these mechanisms are triggered (ie, contexts), subsequently generating outcomes of interest. These 3 elements, that is context, mechanism, and outcome, are linked together as a context-mechanism-outcome configuration (CMOC) and are presented collectively within a program theory.[24–26]

Realist methodology attends to the ways complex interventions—implemented within typically complex settings—may have different effects among different people, depending on the contexts in which they are introduced.[27] Realist program theory produces explanations of how outcomes of interest are generated. Thus, they also provide a methodology to "diagnose" problems. Within interventions aimed at generating behavior change, realist reviews can be used to explain how and why both desirable and undesirable outcomes occur. Recommendations for policy, practice, and intervention design are informed by the understanding captured within program theories (PTs).[24,26]

This realist review aimed to address two research questions:

1. Within antipsychotic treatment decisions during psychosis management, what are the impacts of structural and contextual factors on prescriber engagement with SDM processes? Here, structural and contextual factors refer to factors that exist at an institutional or societal level and are beyond the influence of individual organizations or practitioners but can influence individual prescriber behaviors within practice settings. Such factors may include broader political, cultural, economic, social, and environmental conditions at local, national, or international levels.[23]
2. How do interventions designed to improve SDM application within antipsychotic treatment decisions work; what intervention strategies are likely responsible for effective interventions?

Outline of Review Results

Due to volume, review results have been divided into two parts. This paper (part 1) addresses the first research question; part 2 addresses the second and is available

Table 1. Division of Realist Review Results Across Paper 1 (Part 1) and Paper 2 (Part 2). Definitions of Macro-, Meso-, and Micro-Level Factors Can Be Found Elsewhere.[29,30]

Part 1—Macro-level factors: structural or contextual factors that exist at an institutional* or societal level and are beyond the influence of individual organizations or practitioners
- PT 1—Biomedical model informing clinician training and professional socialization
- PT 2—Legislative and regulatory frameworks prioritizing harm reduction
- PT 3—Absence of committed leadership
- PT 4—Cultural and social norms within psychosis management
- PT 5—Insufficient resourcing of mental health services

Part 2—Meso-level factors: Local organizational* influences that typically characterize or define parameters of service delivery.
- PT 6—Established trust in prescriber-patient relationships
- PT 7—Multidisciplinary responsibility for facilitating SDM

* Institution here refers to a broader concept that encompasses established systems, norms, and practices that govern and influence the wider practice of mental health. Organization refers to a structured entity formed by individuals with a common purpose or goal.

Part 2—Micro-level factors: Attributes or characteristics of individual practitioners and their practice environments that shape prescribing behaviors.
- PT 8—Workforce training in SDM skillsets
- PT 9—Patient training in SDM skillsets
- PT 10—Antipsychotic treatment decision aids

elsewhere.[28] To direct readers, an overview of PTs addressing both research questions, and divided according to whether they address macro-, meso-, and micro-level influences, are outlined in **Table 1**.

Methods

Work conducted within this review was informed by continuous engagement with clinicians and lived experience stakeholder groups.[19] The clinician stakeholder group represented consultant psychiatrists, non-consultant psychiatric doctors, psychiatric nurses, and psychiatric pharmacists. Clinicians also represented those working in practice and within policy development. Peer support worker representation was also included within the clinician stakeholder group. Members of this group were identified through places of work, partnership organizations, and through contacts of the research team. Stakeholder groups met online via virtual meetings five times over the course of the project and had further discussions via email correspondence. The role of stakeholder groups included (i) deciding on the initial focus of the review and advising on content within initial program theories (ii) providing feedback on the credibility or completeness of emerging program theories, and (iii) identification of additional data sources not previously identified.

An assumption underpinning this review is that SDM implementation is clinically appropriate and ethically justifiable. A collaborative decision was made to focus on developing an in-depth understanding of when and why prescribers engage with SDM processes within psychosis management. Thus, this review does not focus directly on patient needs. This decision was agreed upon on the basis that a significant contributor to the SDM implementation gap is a lack of understanding regarding prescriber needs for engaging in behaviors required of effective SDM application. This was supported by scoping searches prior to review commencement.[18,20] However, data sources considering patient perspectives on when and why prescribers engaged them in SDM within psychosis management remained eligible for inclusion. Here, prescriber refers to medical prescribers and non-medical prescribers i.e., nurses and pharmacists.[31] Where a specific prescriber group is being referred to, this is highlighted within program theories.

Review methods were published a priori (PROSPERO CRD42023443783).[19] A brief overview is outlined here. **Table 2** contains a review of inclusion and exclusion criteria. This review included five iterative stages adhering to the methodology outlined by Pawson et al and followed RAMESES publication standards for reporting realist review findings.[26,32,33] A completed checklist is contained within the Supplementary Appendix, alongside any protocol deviations.

Initial Program Theories

Initial program theories (IPT) containing explanatory statements to be subsequently tested and refined were constructed via scoping searches to identify (i) common SDM intervention strategies (ii) existing theoretical perspectives underpinning the inclusion of selected intervention strategies and (iii) impact of contextual factors on prescriber engagement with SDM interventions. IPTs were further developed by consulting research team member's experience within current psychiatric practice and two 1.5-hour online workshops with clinician and lived experience stakeholder groups. Within workshops, facilitators and barriers to prescriber engagement with SDM practices and principles within psychosis management were discussed. IPTs were then subject to formal testing via literature searching.

Table 2. —Review Inclusion and Exclusion Criteria.

Population	Include: • Adult participants (aged 18-65 years) experiencing an episode of psychosis in the context of a psychotic illness where extended antipsychotic treatment is indicated. Exclude: • Participants with treatment-resistant schizophrenia (due to clozapine being the preferred treatment choice among this cohort). • Participants experiencing substance/medication-induced psychosis or psychosis in the context of an underlying medical condition where continued antipsychotic treatment is unlikely.
Intervention	Any intervention designed to increase application of SDM between prescribers and patients within decisions impacting antipsychotic treatment. Whilst within implementation research "interventions" can broadly encompass individual-level, system-level and organizational-level programs, government systems, or organizational policies,[34] the majority of SDM research within psychosis management has focussed on developing individual-level strategies, and more recently, optimizing local service delivery contexts.[18] Hence, the term "intervention" here refers to its use within these contexts.
Comparator	Not applicable.
Outcome	In the case of studies assessing the efficacy of SDM interventions, eligible studies included those where outcomes related to evidence of SDM application. Assessing effective SDM application has been assessed using a variety of different outcome measures, typically measured via assessments of patient-perceived involvement in decision-making.[18] For example, use of the Shared-Decision Making Questionnaire (SDM-Q-9), the CollaboRATE scale, or the Perceived Involvement in Care Scale (PICS).[35] We also included studies where prescriber-perceived involvement in SDM was the primary outcome measure.
Timing	Use of interventions to inform choice of antipsychotic treatment (including initial treatment, change of treatment or continuation of treatment) as part of acute psychosis management i.e., when an individual is experiencing an episode of psychosis or in the initial recovery period.
Setting	Include •Inpatient and outpatient settings, including community mental health teams and primary care settings, to account for differing models of care within mental health service delivery Exclude: •Forensic settings.

Formal Literature Searching

Literature searches combined terms in various combinations across four categories: shared decision-making, intervention design/implementation, antipsychotic treatment, and psychosis or psychotic illnesses. CINAHL Plus, Cochrane Library, Embase, PsycINFO, PubMed, Scopus, Sociological abstracts, and Web of Science were searched from 1990 to December 13, 2023. A grey literature search was undertaken via Google Scholar on June 24, 2024 following guidance by Haddaway et al.[36] Alerts were established across databases to identify data sources published until October 2024. Only English language data sources were included. Screening of all articles was undertaken using Covidence (http://www.covidence.org).[19] To adequately address research questions of how and why interventions work, the range of data sources eligible for inclusion in a realist review must diverge from agreed practice within traditional systematic reviews. Within realist reviews, data sources are selected based on their ability to provide relevant explanatory information for identifying contexts, mechanisms and outcomes and building associated configurations. Consequently, rich data sources can include grey literature. Thus, data sources that were considered eligible for inclusion included quantitative (eg, randomized controlled trials, survey research) and qualitative research studies, but also grey literature, for example, policy and government documents, book chapters, and editorials.[18–20]

An illustrative example of the integration of these methodologically diverse data sources is provided by the following: results of randomized controlled trials are eligible for inclusion based on providing detailed information about an intervention strategy, which is seen as modifying the context within a context-mechanism-outcome configuration. Results of intervention studies also provide useful information regarding the average efficacy of an intervention, that is, an outcome. However, to identify the mechanism(s) responsible for the success of a specific intervention strategy, results of semi-structured qualitative interviews, or focus group research, would likely be required. Furthermore, when attempting to explain the results of a successful implementation attempt of the intervention strategy in one clinical practice setting, but not in another, grey literature documents detailing the comparative design and delivery of mental health services in the respective settings, would also be required.

Further Literature Searches Informed by Stakeholder Engagement

Following IPT development, subsequent engagement with stakeholder groups identified formalized risk management practices as a prominent barrier to prescriber engagement with SDM processes, particularly positive risk-taking. Positive risk-taking is defined as risk management which

improves a patient's quality of life and plans for recovery while remaining aware of the person's safety needs, their care, and the public.[37] Positive risk-taking conceptually overlaps with much of the theory informing SDM models and a willingness to engage in positive risk-taking is a prerequisite for prescriber engagement in SDM.[38] Adhering to movement through Pawson's methodology in a non-linear fashion,[32] it was agreed that additional IPTs were required outlining the relationship between risk management practices and their impact on individual prescriber behaviors. Additional searches within PubMed, Embase, PsycINFO, CINAHL, and Google Scholar were undertaken from 1990 to June 24th, 2024 to identify data sources discussing factors influencing prescriber adoption of risk-averse prescribing behaviors or positive risk-taking within psychosis management. Results were used to test, refine, or refute these IPTs. All search methods are contained within the Supplementary Appendix.

Selection Criteria

Data sources selected for inclusion focused on relevance (whether data could contribute to testing, advancement, or development of IPTs) and rigor (whether methods used to generate data were credible and trustworthy). The richness of each individual data source was also considered, according to criteria originally outlined by Booth et al and expanded upon by others,[39,40] whereby data sources could have "conceptual richness" or "contextual thickness." Conceptual richness describes the degree of theoretical and conceptual development that explains how an intervention is expected to work. Contextual thickness entails sufficient detail that enables the reader to establish (i) what is occurring in the intervention and in the wider context, and (ii) to infer whether findings can be transferred to other people, places, situations, and environments.[39,40] Quality assurance checks were completed as outlined in the study protocol,[19] with a quality measurement assigned to each individual data source based on a global assessment of the relevance, rigor, and richness using a 1-5 star rating system as outlined by Howe et al.[41] Only four- and five-star documents contributed to program theory development.[19] Five-star documents were deemed the most conceptually rich, or contextually thick, and so, most relevant to program theory development.

Data Extraction and Analysis

Relevant excerpts from data sources were extracted and mapped onto IPTs using a standardized data extra form. All data were coded using NVivo (Release 1.7.1 for Mac). Sections of text were initially coded into broad conceptual categories. Subsequently, a realist logic of analysis was applied, whereby data excerpts were coded as a CMOC, where applicable, and in other cases, as dyads (C-M, M-O, C-O).[27] Tentative CMOCs and PTs were reviewed independently by research team members and refined iteratively before being finalized. The wording of final PTs was also by stakeholder group members to support the assessment of the simplicity and coherence of the argument. Assessment of quality was also made at the level of arguments made by assessing coherence and of the final PTs by assessing plausibility, based on available data and arguments made.[42]

Substantive (Formal) Theory

To support the development of coherent arguments, the project team's theoretical knowledge base was consulted to identify relevant substantive theory within other domains or disciplines to further refine PTs.[42,43] Potentially suitable substantive theories were assessed using criteria outlined by Shearn et al.[44] Given the focus on understanding prescriber behaviors, the COM-B Model for Behaviour Change was used as a framework to further strengthen the plausibility of CMOCs and resultant PTs.[45] The COM-B model proposes that to engage in a behavior (B), a person must feel they are both physically and psychologically capable of doing so (C), and have the social and physical opportunity (O) to exhibit the behavior, and the want or the need to demonstrate the behavior more than competing behaviors at that moment—motivation (M). Capability and opportunity are seen as influencing the relationship between motivation and behavior, rather than motivation itself.[45,46]

Results

Through initial and targeted searches, 3,927 data sources were identified for initial screening. A further 1221 were identified through supplementary searching methods. Following title and abstract screening of 3540 data sources, 295 full texts were assessed for eligibility. A total of 106 data sources were subsequently included for screening against IPTs and the development of new program theories. Searching and screening results are summarised in **Figure 1**.

Quality assessment of individual data sources assigned 21 data sources a 5-star rating and 52 a 4-star rating. Details of study characteristics and quality assessments can be found in the Supplementary Appendix. While final PTs are presented in **Table 3**, the Supplementary Appendix contains:

1. Individual CMOCs that contributed to each program theory
2. List of data sources that contributed to PTs 1-5
3. Excerpts from data sources used to build CMOCs
4. Theory from COM-B model used to inform data interpretation and CMOC development

Macro-Level Factors Influencing Prescriber Engagement with SDM Processes

Five PTs outlining the impact of structural factors on reducing prescriber engagement with behaviors necessary

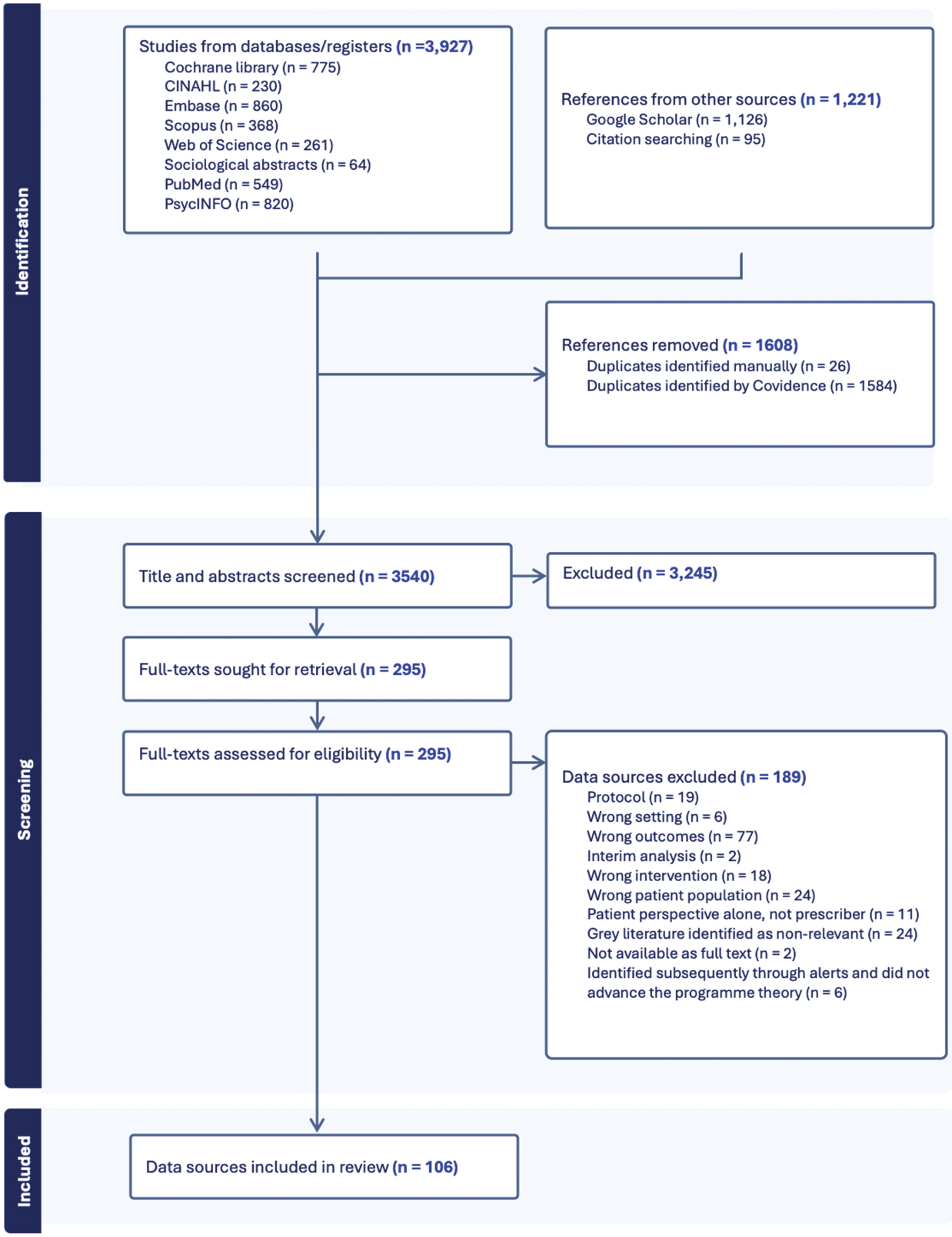

Figure 1. —PRISMA flow diagram of review searching and screening.

Table 3. Wording of Final Program Theories 1–5.

PT1—Biomedical model informing clinician training and professional socialisation
The biomedical model dominates the training and subsequent practices of psychiatric clinicians within many countries. Within the biomedical model, a state of wellness is defined by the absence of illness. Associated goals of treatment are to alleviate psychotic symptoms as much as possible and restore health. Among clinicians where the biomedical model dominates their practice, including their prescribing behaviors (context), prescribers are less likely to engage with shared decision-making practices, where equal value is assigned to clinician and experiential knowledge in informing antipsychotic treatment decisions (outcome), as they question the validity of experiential knowledge compared to that of scientific knowledge and their own medical expertise (mechanism).

PT2—Legislative and regulatory frameworks prioritizing harm reduction
Where legislative and regulatory frameworks governing practice within acute mental health services are perceived to prioritize prescriber responsibility for reducing risk of harm to patients or others (context), prescribers are more likely to adopt risk-averse prescribing practices (outcome) as they perceive this meets the legislative requirements governing their practice (mechanism). Even among prescribers who otherwise support SDM practices (context), they are also more likely to adopt risk-averse prescribing practices (outcome) as they feel legislative pressure to weigh decisions towards maximizing patient safety, even at the cost of patient autonomy (mechanism). In both cases, prescribers fear, that should they not adopt risk-averse prescribing practices, they are exposing themselves to legal and professional repercussions (mechanism). This fear among prescribers (context) increases the likelihood of them engaging in behaviors and practices to promote patient agreement with risk-averse treatment decisions (outcome), resulting in reduced prescriber anxiety about exposure to liability (mechanism) in the event of patient harm. For example, incomplete information sharing regarding the range of antipsychotic treatments and their side effects. In the presence of this fear, implementation of initiatives promoting shared responsibility for treatment decisions and positive risk-taking (context), are unlikely to be successfully adopted by prescribers (outcome) as they do not feel confident legislation would protect them (mechanism) in the event of adverse outcomes.

PT3—Absence of committed leadership
Where responsibility for implementing SDM practices is placed with individual prescribers within organizations where local governance structures (policies, guidelines) are developed with the implicit goal of maximising reduction in risk to patient harm (context), prescribers are less likely to engage with SDM processes (outcome) as they perceive there is a lack of organizational support for positive risk-taking practices (mechanism) inherent in SDM models. Where prescribers perceive there is a lack of organizational tolerance for positive risk-taking, or where there is an absence of explicit organizational guidance to support prescribers in balancing their duty to both reduce risk of patient harm, whilst promoting positive risk-taking (context), prescribers are less likely to implement initiatives that rely on their engagement in positive risk-taking (outcome), as they fear their professional judgment about the appropriateness of engaging in such practices would not be trusted (mechanism) and they would be individually blamed by management (mechanism) in the event of an adverse outcome. This fear of individual blame and associated consequences (context) increases the likelihood of prescribers adopting decision-making styles that reflect a defensive position (outcome) as they perceive such actions reduce their exposure to professional risk (mechanism). Approaches to increase prescriber engagement with SDM processes within these organization cultures, or offerings from management of training without enacted organizational support (including in policy, guidance, and action taken following any adverse outcomes) (context) are likely to be met by low rates of prescriber uptake (outcome) as the fear of individual responsibility for adverse outcomes has not been addressed (mechanism).

PT4 - Cultural and social norms within psychosis management
The appropriateness of clinician-led prescribing can be reinforced by prescriber assumptions about and assessments of capacity. Where prescribers assume capacity is absent or consider capacity as a binary concept (context), these prescribers do not believe SDM within psychosis management is applicable (mechanism), and so do not attempt to share decisions impacting any aspect of antipsychotic treatment with these patients (outcome). Viewing insight into illness as a pre-requisite to SDM (context) is another reason some prescribers do not consider SDM applicable among those with psychosis (mechanism) and again, do not attempt SDM in these circumstances (outcome). Attempts to initiate collaborative discussions about antipsychotic treatment, where patient preferences for treatment would be sought among those where illness reduces insight, is viewed as unproductive and a source of avoidable interpersonal patient-prescriber conflict (mechanism).
Clinicians can also lack confidence in the ability of patients with a serious mental illness to cope with the responsibilities inherently involved in SDM. Where these beliefs exist among prescribers (context), prescribers are more likely to promote clinician-led decision-making (outcome), as this is viewed by them as a way of protecting patients from the responsibility of decision-making (mechanism) and the consequences of making an "unwise" decision (mechanism). Societal perceptions of those with psychosis also influence the actions of prescribers. A perception exists among prescribers in some countries that the general public expects them to be risk-averse within treatment decisions among those with psychosis, due to public fear of the perceived risk those with a psychotic illness pose. This perception, coupled with their duty to protect the welfare of people other than their immediate patients (context), leads prescribers to be less willing to engage in SDM with this patient cohort (outcome) as they fear they will be publicly shamed (mechanism) should an adverse event occur following the non-adoption of the most risk-aversive approach to treatment.

PT5—Insufficient resourcing of mental health services
Where insufficient resourcing within acute care services results in focus on crisis management, prescribers face competing priorities for their time (context). Prescribers are less willing to attempt engagement in SDM during initial antipsychotic treatment decisions (outcome) as they perceive the use of their limited time to negotiate treatment options to be inefficient (mechanism) and conflicting with a service priority to start medication quickly (mechanism). Where resourcing is perceived as insufficient (context), prescribers are more likely to engage in strategies to encourage patient compliance with prescriber-led decision-making (outcome), for example, incomplete information sharing, as this is perceived as the quickest way of prescribing antipsychotics in a resource-efficient manner (mechanism). Similarly, service prioritization on reducing the length of inpatient stay (context) can lead prescribers to feel pressure from the service environment to prioritize reducing the risk of relapse of psychosis at the cost of increasing patient autonomy within antipsychotic treatment decisions (mechanism). As such, prescribers within these settings are less likely to initiate discussions with patients about collaboratively reviewing initial treatment regimens (outcome).

for SDM application were identified. No facilitative influences at macro-level on systematically promoting prescriber engagement with SDM were identified. Structural factors reducing the likelihood of prescriber engagement with desired behaviors related to clinician training and socialization (PT1), leadership and governance structures common within mental health settings (PT2 + 3), cultural and social norms among clinicians within psychosis management (PT4) and insufficient resourcing of mental health services (PT5). The relationship between these contexts, their impact on prescriber behaviors, and explanations of why (mechanisms) are contained within **Figure 2**. The term clinician is used here where supporting evidence relates to mental health professionals involved in psychosis management within acute care settings.

PT1—Biomedical Model Informing Clinician Training and Socialization

The biomedical model of health is a medical model informing the training and socialization of clinicians within many countries internationally.[4,5,47] This model is based on the theory that a state of health is understood purely by the absence of illness and is defined by a focus on diagnosis, symptom management, and alleviation of illness.[48] Goals of pharmacological treatment reflected within the biomedical model can conflict with those of recovery-orientated practices, including SDM. SDM is predicated on the assumption that each partner has unique knowledge to contribute to treatment decisions; neither clinical nor experiential knowledge is assigned greater value within decision-making.[49] Within the biomedical model, scientific knowledge and medical expertise primarily inform clinicians' prescribing behaviors; significant value is not assigned to a person's preferences or their experiential knowledge in informing treatment decisions.[5,50] Prescribers whose education and professional experience have been largely informed by the biomedical model are less likely to engage with patient preferences for treatment due to an inadvertent devaluing of experiential knowledge reflected in their training.[5,51,52] This is particularly the case where patient preferences contrast with the prescriber's goal of minimizing symptoms or preventing their return.[53–55] For example, changing antipsychotic to align with patient's side effect preferences, where an inherent risk is potential worsening or return of psychotic symptoms.

PT2—Legislative and Regulatory Frameworks Prioritizing Harm Reduction

The dominant emphasis within current approaches to risk management in psychiatry is concerned with reducing the risk of harm.[56] This includes harm to individuals with mental illness and those around them. In many countries, the formalization of risk management is well-developed within mental health legislation.[56,57] A common risk management strategy is to assign the management of certain risks to a limited number of people, typically psychiatrists.[57,58] The perceived prioritization on harm reduction or "risk" within mental health legislative and regulatory frameworks has contributed to increasing pressure among clinicians to control negative outcomes from occurring.[59] Among prescribers in many countries, the perception that legislative frameworks prioritize prescriber responsibility for harm reduction increases the likelihood of them adopting risk-averse prescribing behaviors and engaging in methods to promote patient agreement. For example, incomplete information sharing regarding the range of antipsychotic treatments or their side effects.[57–63]

Some prescribers believe that these behaviors are encouraged within mental health legislation and as such, their adoption of risk-averse prescribing practices is adhering to legislative requirements.[4,57,62] For prescribers who individually support positive risk-taking practices, they often feel personally unsafe when managing risk. They fear, should they not be risk-averse in their prescribing behaviors, they are exposing themselves to liability and associated repercussions in the event of subsequent adverse outcomes.[37,57,59–61,64] These prescribers feel legislative pressure to weight decisions towards maximizing harm reduction, at the cost of increasing patient autonomy, and to intervene if an individual is making a decision that could be viewed as "unwise."[57,59,60] Engagement in risk aversion decreases prescriber anxiety about exposure to liability. Initiatives promoting sharing of decision-making responsibility and positive risk-taking practices within settings where prescribers perceive mental health legislation prioritizes prescriber responsibility for reducing harm are unlikely to achieve widespread uptake. In the absence of targeted intervention to reduce fear of exposure to liability, prescribers do not feel confident that they would be legally protected in the event of harm following SDM application.[38,61,63,65]

PT3—Absence of Committed Leadership

Common to the operation of mental health services is a top-down, protocol-driven approach to organizational performance.[62,66–69] Disciplinary forms of power are also prevalent within mental health systems.[70] Staff behavior within hierarchical models of service delivery is strongly influenced by the attitudes and actions of those in management and leadership positions.[38] Formalisation of risk management and perceived prioritization of harm reduction within mental health legislation has contributed to organizational cultures of risk-aversion common within psychiatry.[56,58–60,71] Subsequent prioritization of harm reduction within organizational policy, or reflected within actions of those in managerial and leadership positions, can create a perception among clinicians of a

lack of organizational tolerance for positive risk-taking. This subsequently impacts their tolerance for risk.[37,57,59,72] Prescribers tasked individually with implementing positive risk-taking practices within perceived risk-averse organizational cultures fear their professional judgment will not be trusted by those to whom they are answerable. In the event of subsequent adverse outcomes following positive risk-taking, these prescribers fear singular blame, with associated professional and personal consequences.[37,38,56,57,61,63,73]

Fear of sole responsibility for adverse outcomes increases prescriber adoption of defensive prescribing practices and clinician-led decision-making in an attempt to reduce their perceived exposure to professional risk.[57,63] Attempts to increase prescriber engagement with SDM processes where there is a perceived lack of organizational tolerance for positive risk-taking are likely to be met by low rates of implementation as the fear of a punitive response in the event of harm remains unaddressed.[38,57,63] Even in cases of apparent organizational support for increased application of SDM by individual prescribers, the absence of tangible workforce support, particularly practical supports addressing the apparent tension between positive risk-taking and protecting patient safety, increases the likelihood that staff perceive such calls as spurious.[57,74,75]

PT4—Cultural and Social Norms Within Psychosis Management

Cultural and social norms are unspoken rules or expectations of behavior based on shared beliefs within specific groups. Such norms offer social standards for behavior, governing what is (and is not) acceptable in interactions among people and are known to have a high degree of influence on individual behaviors.[76] The appropriateness of paternalism within healthcare decisions impacting individuals with psychosis remains dominant among clinicians and wider society.[6,38,77,78] Three norms among clinicians were identified as increasing the likelihood of their adoption of clinician-led decision-making and reducing their engagement with SDM behaviors within psychosis management. These norms reflect: (i) assumptions about decisional capacity (ii) assumptions about insight and (iii) the need to protect people with psychotic illnesses from responsibilities involved in SDM.

The appropriateness of clinician-led prescribing can be reinforced by prescriber assumptions about, and assessments of, decisional capacity.[10] Where prescribers assume capacity is absent, or consider capacity a binary concept, a decision-specific consideration of the appropriateness of SDM is not undertaken.[77,79,80] Instead, the SDM application is rejected based on a belief of inappropriateness among individuals experiencing psychosis.[10,70,81,82] Many prescribers also believe insight into psychotic symptoms is a prerequisite for SDM.[9,53,62–64,79,83–85] The presence of such insight is necessary for these prescribers to view patients as capable of sharing decision-making responsibility, and for their treatment preferences to be considered valuable within decision-making.[5,9,62,63] In its absence, attempts to initiate collaborative discussions about antipsychotic treatment are viewed as unproductive and a source of avoidable patient-prescriber conflict.[64,79,84,86] In either case, the adoption of clinician-led decision-making is justified by prescribers as being appropriate to discharge their duty of care and ensure timely access to treatment.[9,61,78,79,87]

Even where decisional capacity is acknowledged, clinicians often lack confidence in the ability of people with SMI to cope with the responsibilities involved in SDM.[4,9,38,63,66,70,78] Adoption of clinician-led decision-making, and use of methods to promote patient agreement, is viewed by these prescribers as a means of protecting patients from decision-making responsibility and the consequences of "unwise" decisions.[61,66,78,88,89] Perceptions among wider society can also impact prescriber engagement in SDM. Societal beliefs about dangers posed by those with mental illness and the expectation of risk aversion can decrease prescriber's perceived ability to increase patient autonomy within decision-making.[54–56,63] Where prescribers perceive society expects them to be risk-averse in their care of people with SMI, particularly within countries where investigations following serious incidents are publicized within mainstream media, fear of public shaming reduces the likelihood of prescribers engaging in SDM within psychosis management.[60,61,75,90]

PT5—Insufficient Resourcing of Mental Health Services

Insufficient resourcing of mental health services necessitates the focus of staff on crisis management and contributes to common short-term, risk-averse service delivery cultures.[62,89,91] A resultant pressure is exerted on clinicians to treat symptoms quickly and discharge patients following sufficient symptom reduction, such that the person is deemed no longer in crisis.[62,66,70,89,91–93] Attempting to address the pressure to prescribe antipsychotics in a resource-efficient manner, prescriber adoption of methods to encourage patient concordance with clinician-led decision-making is increased.[61,62,90,94,95] Similarly, service prioritization of reducing admission length also increases the likelihood of clinician-led decision-making within continued antipsychotic treatment decisions.[10,79] Where reduced decisional capacity initially precluded SDM, service prioritization of reducing the length of stay exerts pressure on prescribers to prioritize reducing the risk of relapse over increasing patient autonomy within decision-making.[52,64,85] Thus, prescribers are less likely to initiate discussions about collaboratively reviewing initial treatment decisions.[10,79] Attempts to increase SDM application by prescribers within settings where workforce

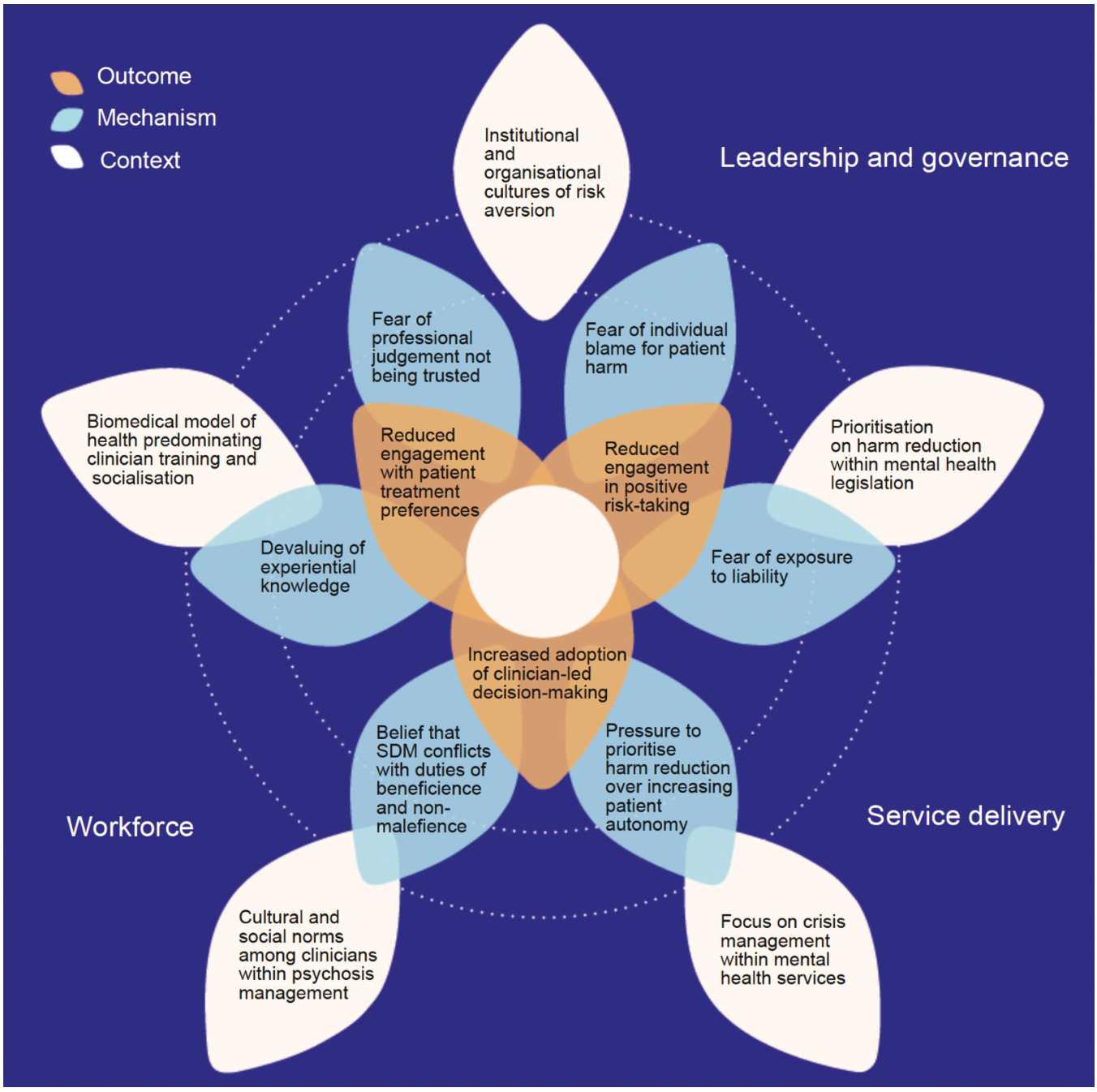

Figure 2. —Programme theories 1-5 outlining structural and contextual factors identified as reducing prescriber engagement with behaviors required of effective application of SDM and those that increase the likelihood of prescriber engagement with clinician-led decision-making. In the case of institutional and organizational cultures of risk aversion, two mechanisms and related outcomes are linked to this one context.

behaviors are targeted towards crisis management are unlikely to achieve widespread uptake. Clinicians perceive the application of SDM to be time-consuming and antipsychotic prescribing complex.[66,79,90] SDM engagement by individual prescribers within services focussed on crisis management is viewed as onerous, inefficient use of limited consultation time, and conflicting with a priority to treat symptoms quickly to meet service demands.[62,64,66,85,90]

Discussion

In part 1 of this two-part realist review, we sought to understand structural and contextual influences on prescriber adoption of behaviors required of their engagement with SDM within psychosis management. Whilst interventions designed to increase SDM application within antipsychotic prescribing have largely focussed on optimizing patient-prescriber interactions,[5] this review

identified most barriers to prescriber engagement existing in realms beyond the influence of these intervention strategies.[10] Five PTs were developed outlining the relationship between contexts within leadership and governance structures, workforce development, and service delivery that can systematically reduce prescriber adoption of behaviors required of SDM within initial and continued antipsychotic treatment decisions. Features of these contexts that, where present, function to reduce contextual integration of SDM into psychosis management have been made explicit to facilitate the development of targeted solutions.

The prevalence of the biomedical model of health within clinician education and professional socialization was identified as a significant structural challenge within workforce development to achieving the ideals of SDM in practice.[5] Although this review identified why, "disease-focused" and "overly medicalized" models of care have previously been identified as barriers to SDM implementation.[54,64] Value placed on different types of knowledge contributes to the perceived legitimization of involvement by people with SMI in decision-making.[62,64] An unintended consequence of the predominance of the biomedical model in influencing clinician behavior is the inadvertent devaluing of patient preferences and experiential knowledge within decision-making.[51,53] Within settings studied here, integration of patient preferences into prescribing decisions was increased where clinicians explicitly valued lived experience.[84,89] Whilst some interventions provide prescriber training,[21,22] it is likely that preparation for implementing recovery-orientated practices needs to be considered much earlier in clinical training, including within undergraduate curricula and continuing professional development. Whether the systematic incorporation of lived experience into early education and training is effective in addressing the so-called epistemic injustice precluding widespread SDM implementation within antipsychotic prescribing is worthy of future research.[96,97]

Several conceptual barriers contributing to a belief that SDM conflicts with the ethical principles of beneficence and non-maleficence within psychosis management were identified. Most amenable to intervention are assumptions about the universal absence of decisional capacity and lack of insight into psychotic symptoms precluding decision-specific SDM application. Differences were identified in clinicians' attitudes to capacity impairment associated with psychosis and its impact on SDM application.[6,62,77] Whilst some clinicians view reduced capacity as a restriction on SDM and attempt to maximize patient involvement despite capacity impairments (eg, ascertaining prior treatment preferences), others regard reduced capacity as a contraindication to SDM.[10,70,79,85] Research has identified a spectrum of decision-making capacity for treatment decisions among individuals with psychosis.[98] One review identified around 50% of inpatients as demonstrating decision-making capacity, consistent with heterogeneity associated with psychotic illnesses.[99] Decisional capacity impairments are also temporal and identifiable, with some being responsive to intervention.[98] Such features, and the decision-specific nature of capacity impairment, are often not referred to by those who view "lack of capacity" as a major barrier to SDM.[79]

Insight is relevant but not determinative of capacity.[100] A specific lack of insight into psychosis is not always relevant for an individual's ability to partake in treatment decisions, as treatment options can often be discussed in terms of symptoms of which the individual is aware.[82] Prior research has recognized the multidimensionality of insight and suggested the conceptualization of insight is best considered as a continuous distribution across several domains.[3,79] Thus, whilst agreement exists that reduced decision-making capacity and insight into psychosis impairs consistent SDM application, precisely where that threshold lies appears to be influenced by clinicians' individual attitudes.[10] Even where decisional capacity is acknowledged, clinicians' beliefs about the inability of people with a psychotic illness to cope with decision-making responsibility represent another cognitive obstacle reducing their engagement in SDM.[4,66,77,78] Efforts to address subjectivity within capacity assessments and reduce stigmatizing attitudes present among some clinicians will likely be required to support individualized, decision-specific implementation of SDM.

Mental health legislative and regulatory frameworks—far from their intended purposes of increasing accountability and transparency—were identified as decreasing prescriber engagement in positive risk-taking and increasing clinician-led decision-making.[59,60,63] Among clinicians in the UK,[56,60,77,101] Germany,[86] Sweden,[58] the USA,[4,72] and Australia,[59] a perception was identified that government policy and mental health legislation encourages their engagement in risk-aversion and paternalism to reduce risk of harm to patients or to others. This perception was generated through (i) a perceived dominant emphasis within legislation on prescriber responsibility for managing "risk" without adequate or explicit consideration of patient autonomy and the changeable nature of capacity,[51,58–60,101] (ii) harmful events being responded to by increasing regulation,[56,102] (iii) experiences of harm reduction being prioritized during inspection processes,[75] and (iv) media representation of high profile judgments following harm to, or caused by, people with SMI.[60,61] The perception of harm reduction being prioritized within mental health legislation has contributed to decreased psychological safety among prescribers when attempting to increase patient autonomy within decision-making and reported difficulties distinguishing between defensible positive risk-taking practices and actions that could be viewed as negligent.[38,57,59]

Even in the case of supplementary legislation supporting clinician engagement in positive risk-taking, for

example, the UK's Mental Capacity Act 2005,[103] clinicians are often unaware of these frameworks or do not feel confident that they would protect them from exposure to professional risk in the event of harm.[57,77] This suggests primary mental health legislation and associated regulatory practices are a more important influence on clinician behaviors. Although risk management in psychiatry centers around harm reduction, the preoccupation with reducing risk to safety and increasing patient harm by restricting their autonomy within decision-making has previously been raised.[57] An established perception among clinicians that many jurisdictions do not permit acceptance of positive risk-taking within psychiatry and a belief their implementation of recovery-orientated practices conflicts with prescriber legal obligations serve as major barriers to SDM implementation.[38,101]

Contradictory frameworks of practice also contribute to the tension prescribers feel when managing risk, reducing harm, and implementing SDM. This includes organizational policy and guidance emphasizing protection, harm minimization, and duty of care, while also recommending the delivery of recovery-orientated care.[57,63,101] To address the apparent tension between promoting patient autonomy and their primary duty of treating individuals, prescribers require tangible organizational support.[57,66,74] In the context of harm reduction being prioritized within current practice,[60] simple organizational policy promoting individual prescriber engagement in SDM is likely insufficient in promoting widespread engagement.[37] Effective prescriber support should include sufficient resourcing of services to create a perception of capacity among staff such that they can safely increase patient autonomy within decision-making.[70] The requirement for specific prescriber training and supervision will be discussed in Part 2.[28]

Processes inherent in SDM, including providing patients time to consider treatments, are also frequently deemed at odds with service delivery priorities within mental health.[64] Adequate staffing and reduced pressure to discharge patients are required to challenge informal norms among staff—contributed to by macro-level resource constraints—that core roles of acute care services are crisis management and reducing proximal risk of harm.[62,75,89,91] However, within cultures where fear of individual blame for adverse outcomes is prominent among clinicians, adequate resourcing alone is unlikely to sufficiently counter the perceived lack of organizational tolerance for positive risk-taking.[38,57,63] Effective leadership needs to model and actively support positive risk-taking.[34] Rather than fearing a punitive response, leadership committed to implementing SDM should invest in efforts to provide staff with reassurance that they have the professional autonomy and flexibility required to be constructive in responding to risk and providing individualized care.[38,57,59] Top-down, protocol-driven practices and disciplinary forms of power are direct barriers to achieving this.[70,104]

This review is not without limitations. SDM as a concept stems from a Western, liberal, and individualistic view of human relations.[95] Most evidence assessing SDM within SMI also originates from high-income countries with structured mental health systems.[20] Within low- or middle-income countries, structural and contextual impacts on prescriber behaviors identified here may differ. This review does not directly address patient needs for SDM engagement, including the role of caregivers in patient advocacy. This is an obvious area for complementary realist research. An epistemological assumption with a realist methodological orientation is that knowledge is always partial and accruing.[26] Thus, despite its comprehensiveness, this review does not claim to represent a definitive picture of structural and contextual factors decreasing prescriber engagement with SDM practices, nor a definitive statement of the universal practices of all clinicians. Rather, it explains factors that influence prescriber behaviors supported by currently available empirical and grey literature, with the intention of highlighting factors beyond the influence of individual clinicians and services requiring purposeful intervention for SDM implementation.

Conclusion

Five program theories explaining relationships between specific leadership and governance (mental health legislation and regulatory frameworks prioritizing harm reduction), service delivery (absence of committed leadership, insufficient resourcing of mental health services), and workforce development (the biomedical model informing clinician training and professional socialization, cultural and social norms among clinicians) factors and their impact on reducing prescriber engagement with behaviors required of SDM application were outlined. Key mechanisms responsible for reduced prescriber engagement in desired behaviors included fear of individual blame and exposure to liability in the event of patient harm, pressure from service environments to prioritize decreasing risk of harm, devaluing of lived experience, and beliefs that SDM conflicts with duties of beneficence and nonmaleficence within psychosis management.

Even empirically supported SDM interventions will be difficult to implement at scale within real-world settings studied here due to misalignment with the complex cultural, legal, political, and professional realities prominent within these settings. For widespread prescriber uptake of behaviors required of SDM structural interventions, focussing on altering contexts in which health services operate is essential. Although the target of SDM interventions is typically individual prescribers, much greater responsibility for implementing SDM within psychosis management is required at the organisational-, institutional- and policy level. These five program theories should be used as a guide for policymakers, researchers,

and funders as to the requirement for creative, scalable solutions addressing identified contextual factors decreasing prescriber adoption of desired behaviors.

Supplementary Material

Supplementary material is available at https://academic.oup.com/schizophreniabulletin.

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Author Contributors

IF conceptualized the initial idea with the final concept for the study informed by all authors. J.H. and I.M. provided realist methodological support. L.S. and E.C. provided supervision to I.F. I.F., L.S., and E.C. coordinated project administration, including providing access to resources and software. I.F. conducted the literature searches. I.F., L.S., and E.C. conducted the screening and selection of final data sources. Data extraction was conducted by I.F. with methodological support from JH. Rigour, richness, and relevance assessments were conducted by I.F., E.C., and L.S. All authors were involved in data analysis, including the interpretation and finalizing wording of CMOCs and PTs. I.F. drafted the initial paper and prepared the figures. All authors reviewed, contributed, and edited the final manuscript.

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Conflict of Interest

MH has received honoraria for consultancy/speaking from H. Lundbeck and Otsuka. YZI has received honoraria for consultancy/speaking from SMI Adviser and is a member of PCORI's Advisory Panel on Clinical Effectiveness and Decision Science (CEDS).

Data Sharing

All data analysis documents are included in the Supplementary Appendix included with this study.

Ethics Committee Approval

Primary data was not collected and therefore, ethical approval was required for this review.

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