

BMJ Open Pharmacists' roles in supporting people living with severe and persistent mental illness: a systematic review protocol

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ABSTRACT

Introduction Severe and persistent mental illness (SPMI) can significantly impact a person's social, personal and professional life. Previous studies have demonstrated pharmacists' roles in mental healthcare; however, limited studies to date have focused on pharmacists' roles in providing healthcare services, specifically, to people living with SPMI. The aim of this systematic review is to explore the pharmacists' roles in providing support to people living with SPMI.

Methods and analysis A systematic search will be conducted in Medline, Embase (Ovid), PsycINFO, CINAHL, Web of Science, Scopus, Cochrane Library, International Pharmaceutical Abstracts and ProQuest Dissertations and Theses to identify potentially relevant primary research for inclusion. This will be guided by the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols checklist for systematic reviews. All primary research publications regardless of study design exploring or reporting on pharmacists' involvement in supporting people living with SPMI will be considered for inclusion. A tabular summary will be completed using data extracted from each included publication. Data synthesis and quality assessment methods will be chosen based on included study designs.

Ethics and dissemination The results will be published in a peer-reviewed journal and used to inform the development of a pharmacist-specific training package to support people living with SPMI.

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INTRODUCTION

Severe and persistent mental illness (SPMI), including (but not limited to) schizophrenia and other psychotic disorders, bipolar disorder and severe and recurrent major depression, refers to any mental illness that has a continuous and significant lifelong impact on a person's relationships, social functioning, education and livelihood.¹ People living with SPMI are at a considerable higher risk of premature death, in that they die 10–20 years earlier than the general population.^{2–3} For people living with schizophrenia, this gap in mortality has increased over time, mainly due to preventable physical

Strengths and limitations of this study

- To our knowledge, this is the first systematic review investigating the roles of pharmacists in any health-care setting, supporting people living with severe and persistent mental illness (SPMI).
- Inclusion of all study types will allow for a comprehensive overview of the literature relating to pharmacists' roles in supporting people living with SPMI.
- Broad inclusion criteria may present challenges for synthesising the evidence, but will allow for the identification of gaps in the existing literature.
- A limitation of this review is the potential to exclude relevant studies published in other languages, as this review will be restricted to articles published in English.
- Data extraction and quality assessment of included studies will be conducted by one member of the research team.

illnesses such as cardiovascular and metabolic disease, the side effects of second generation antipsychotic medicines used for treatment.^{2–4} Furthermore, people living with SPMI, such as schizophrenia, are also more likely to die by suicide.⁴ Moreover, smoking is up to three times more prevalent among people living with a mental illness, and up to five times more prevalent among people living with SPMI.⁵ Despite these known preventable risk factors, people living with SPMI receive poorer physical healthcare, compared with the general population.² The WHO recognises that people living with SPMI require improved access to healthcare services to facilitate the recognition, diagnosis, treatment and monitoring of comorbid physical health problems.² Consequently, WHO guidelines highlight key priority areas for improvement including weight management, substance use disorders, cardiovascular disease and risk, diabetes, HIV/AIDS, infections and tobacco cessation.² Hence, people living with SPMI require access to a range of healthcare professionals in order to manage

their illness(es) and treatment(s), including primary healthcare professionals.²

Pharmacists are increasingly being recognised for their current and emerging roles in mental healthcare, as evidenced by guidelines, reports and frameworks which highlight their integral contribution to screening, initiating and maintaining treatment, improving medicine adherence and providing medicines information, in both primary and secondary care settings.^{6–8} This is reflected in the literature, whereby recent research has demonstrated that pharmacists are capable of screening to identify people at risk of depression and referring appropriately for diagnosis and therapy,^{9–11} managing psychotropic medication-related problems,^{12–15} providing antidepressant adherence support and working within multidisciplinary mental healthcare teams.^{16–18} However, research supporting pharmacists' roles in caring for people living with SPMI is lacking. Preliminary evidence indicates that pharmacists hold generally positive attitudes towards people living with SPMI; however, lack of time and confidence have been identified as barriers to their involvement in supporting this consumer population.¹⁹ Lack of confidence among healthcare professionals in supporting people experiencing mental illnesses and crises is not uncommon. For example, a recent systematic review exploring healthcare professionals' confidence in caring for people at risk of suicide identified that lack of confidence in this area was attributable to inadequate suicide education and training in healthcare curricula.²⁰ Consequently, healthcare professionals often rely on upskilling through education and training programmes post-registration (eg, continuing professional development) to improve their knowledge of and confidence in supporting people experiencing mental health crises, such as, suicide.²⁰

Given the accessibility of community pharmacies, pharmacists are in an ideal position to provide a triage-style role and refer/signpost consumers to relevant healthcare professionals and local services. Furthermore, given the physical illnesses that may arise as a result of the side effects of psychotropic medicines and symptoms of SPMI, pharmacists' roles as medicines experts enables them to support the physical healthcare of people living with SPMI. There is evidence to support the acceptability, feasibility and effectiveness of pharmacist-led interventions for a range of physical health conditions, including but not limited to tobacco cessation,^{21–23} alcohol use,²⁴ cardiovascular risk,^{25–26} diabetes^{27–28} and infectious illnesses,²⁹ among diverse populations. However, research exploring pharmacist-led risk assessment and service provision for people living with SPMI is lacking.

A 2018 Cochrane intervention review identified that non-dispensing pharmacist services can have a positive impact on consumers' health, with comparable outcomes to services delivered by other healthcare professionals.³⁰ However, this Cochrane review did not solely focus on people living with SPMI.³⁰ Other reviews have explored the literature pertaining to pharmacist-delivered

interventions, for mental illnesses, generally,^{31–32} and specifically for depression.^{33–34} There have also been literature reviews pertaining to pharmacists' roles in improving adherence to antidepressant medicines.^{35–37} However, there is no comprehensive literature review specifically exploring pharmacists' roles in providing services or care for people living with SPMI. Hence, the aim of this systematic review is to explore the literature surrounding the role of pharmacists in supporting people living with SPMI. Specifically, this systematic review will identify the types of services and interventions delivered by pharmacists for consumers living with SPMI and their impact on consumer outcomes.

Research questions

1. Have pharmacists been involved in providing support for people living with SPMI?
2. What is pharmacists' level of involvement; and nature, extent and outcomes of their support for people living with SPMI?
3. What type of education and training do pharmacists undertake prior to providing support for people living with SPMI?
4. What are the barriers to and facilitators of pharmacists' involvement in supporting people living with SPMI?

METHODS AND ANALYSIS

This systematic review will be guided by the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) checklist.³⁸ The PRISMA-P checklist was completed and can be seen in online supplementary appendix 1.

Database search

Medline, Embase (Ovid), PsycINFO, CINAHL, Web of Science, Scopus, Cochrane Library, International Pharmaceutical Abstracts and ProQuest Dissertations and Theses will be searched systematically to identify publications for inclusion. The search will be based on two concepts relating to (1) pharmacy and (2) SPMI, using keywords and Medical Subject Headings (MeSH terms), where relevant, depending on the database.

The search strategy was developed by four members of the research team, in consultation with an academic librarian. The search strategy was informed by the aim of the systematic review, as well as, the WHO definition of severe mental disorders:

... a group of conditions that include moderate to severe depression, bipolar disorder, and schizophrenia and other psychotic disorders²

The search strategy was then discussed with other members of the research team, and pilot tested with another academic librarian prior to conducting the main searches. The final search was peer-reviewed by an academic librarian. A sample search strategy can be seen in online supplementary appendix 2. The final search will

be conducted by one research team member with experience in database searching.

Screening

Electronic search results will be downloaded into Endnote, duplicates will be removed automatically and manually, followed by screening of titles, abstracts and full-texts of potentially relevant citations. The first stage of screening involving duplicate removal and title screening will be conducted by one member of the research team. At the abstract stage, citations will be imported into the Covidence software.³⁹ Two members of the research team will conduct the abstract and full-text screening process, within the Covidence systematic review software program. The results will be recorded in the program and disagreement at any stage of the screening process will be reconciled with a third member of the research team through discussion. The reference lists of included full-text citations will also be screened by these two members of the research team to identify any potentially relevant publications for inclusion. Any disagreements will be discussed and resolved through consultations with a third member of the research team.

Eligibility criteria

The title and abstract (or summary) of each exported citation will be included in the next stage of full-text screening if it meets the following criteria:

1. Published after 1990 (until 1 April 2020).
 - a. This date was chosen as it closely corresponds to the time when second generation antipsychotics were introduced⁴⁰ and there was a global shift towards community-based mental health care.^{41–43}
2. Specifically refers to people living with SPMI, or mentions any of the following mental illnesses:
 - a. Schizophrenia.
 - b. Bipolar disorder.
 - c. Any psychotic illness (eg, schizoaffective disorder, psychotic depression).
 - d. Moderate-to-severe depression.
 - e. Moderate-to-severe anxiety.
 - f. Substance use disorders.

If a study reports on a mixed population of consumers which includes people living with SPMI, it will be considered for inclusion if the outcomes pertaining to pharmacist-led support for people living with SPMI, specifically, can be extracted.
3. Involves pharmacists or pharmacy staff or a multidisciplinary healthcare team which may involve pharmacists.
4. Refers to any setting where pharmacists may have a role in providing healthcare/services for consumers, such as:
 - a. Hospitals.
 - b. Community pharmacies.
 - c. Outpatient/community settings.
 - d. Aged care/residential facilities.

Citations will be included at this stage if they meet the above criteria, regardless of study design. All study designs will be considered for inclusion in this systematic review. Citations will be excluded at this stage if they describe any non-primary research, such as, letters, editorials, commentaries and protocols. Reviews of the literature will be excluded but first assessed for any potentially relevant individual studies that they have included.

Based on the above criteria, articles will be identified for full-text screening. This systematic review will include studies with any design and will not limit study inclusion to specific outcomes (ie, inclusion will not be limited to studies reporting on specific consumer-reported or pharmacist-reported outcomes, only). Hence, non-randomised controlled trial study designs, including but not limited to implementation, observational and qualitative studies may be included. In addition to the criteria for title and abstract screening, articles will be considered for inclusion at the full-text screening stage if they meet the following criteria:

1. The study involves the delivery of a service by a pharmacist, pharmacy support staff member or pharmacy student, individually or as members of a broader healthcare team.
 - a. If a study reports on a mixed population of healthcare professionals, including pharmacists, pharmacy staff or pharmacy students, supporting people living with SPMI, the study will be included if the outcomes specifically pertaining to pharmacist-led support for people living with SPMI can be extracted.
2. The service is provided to consumers living with SPMI.
 - a. The study specifically states that the consumers were living with SPMI and/or
 - b. the consumer population is living with a psychotic illness (eg, psychotic depression, schizophrenia, schizoaffective disorder, bipolar disorder) and/or
 - c. the consumer population is living with moderate-to-severe depression, anxiety or any other mental illness (with the exception of substance-use disorders, only) that is described as severe or persistent, in the manuscript. If those exact terms were not used, but the study provided a detailed description regarding the significant impact the mental illness caused to the person's life whereby it could be deduced that the illness would be categorised as an SPMI (ie, not mild depression that is chronic), then the study would be eligible for inclusion, provided that it met other inclusion criteria. Particular attention will be paid to studies that use the terms 'chronic', 'recurrent' and/or 'treatment-resistant' to describe the mental illness experienced by the study population.
3. The study occurs in any setting that involves providing healthcare/services for consumers living with SPMI.
 - a. For example, a study conducted in a university classroom setting would not be eligible for inclusion, but a study conducted in a teaching hospital would be

eligible for inclusion.

4. The full-text of a peer-reviewed publication is available, regardless of study design type.

The following exclusion criteria will also be applied:

1. Publications reporting on non-primary research, such as editorials, letters, book chapters, case reports, protocols and commentaries.
2. Studies focusing solely on pharmacist services for people living with substance use disorders (eg, opioid, tobacco, alcohol) will be excluded. Pharmacists' roles in the provision of services (eg, naloxone dispensing, smoking cessation therapy, alcohol misuse screening) for people living with substance-use disorders have been established and explored previously through published reviews of the literature.^{23 44–49}
 - a. If study participants are living with an SPMI, as defined in our inclusion criteria (above) and are also experiencing a comorbid substance-use disorder, then outcomes pertaining to both the SPMI and the substance-use disorder will be reported.
3. Studies published in languages other than English.

Data extraction

A comprehensive overview of included studies will be presented, with detailed information provided about each included study relating to the SPMI, extent of pharmacist involvement, study setting and service/intervention provided. Data from each study will be reported in a tabular format including, but not limited to, information about the country where the study was undertaken, study aim, definition of SPMI used in the study, study design, study consumer and healthcare professional population(s), description of the intervention, nature and extent of pharmacist involvement in relation to the intervention and training received by pharmacists to deliver the intervention (if any). Furthermore, the following outcomes will be presented, when reported in included studies:

1. Consumer-reported outcomes.
2. Pharmacist-reported outcomes.
3. Outcomes attributable to pharmacist involvement.
 - a. For example: cost-effectiveness, qualitative evaluations and impact on other healthcare professionals.

Data extraction for reporting will be conducted by one member of the research team. Ambiguities relating to data extraction will be discussed with other members of the research team. Depending on the included study types, appropriate cross-checks will be conducted to ensure the accuracy of the extracted data.

Data synthesis

This systematic review aims to include all studies that meet the inclusion criteria. Hence, it is anticipated that publications employing a broad range of study designs will be included and it is not possible to determine which data synthesis method will be most appropriate, a priori. Therefore, the included studies will inform the selection of appropriate data synthesis methods. For example, if a significant proportion of studies are

quantitative evaluations of interventions reporting on a specific outcome, a meta-analysis may be appropriate. However, if the majority of included studies identified are qualitative, a meta-synthesis may be deemed more appropriate. On the other hand, if included studies employ a variety of heterogeneous study designs, it may be more appropriate to employ a narrative synthesis. The Guidance on the Conduct of Narrative Synthesis in Systematic Reviews, developed by Popay *et al*⁶⁰ provides guidance for the conduct of narrative reviews and may be used for data synthesis. A combination of different tools and techniques may be used to synthesise the data (where appropriate), including textual descriptions, tabulation, grouping and thematic/content analysis. The data synthesis approach will be discussed in consultation with the research team using an iterative and inductive approach. Furthermore, since a mixture of study types is expected a combination of data synthesis methods may be required.

Consumer and public involvement

This systematic review protocol was developed and coauthored by a team of health services researchers including pharmacists, individuals with lived experience of mental illness, as well as, individuals with experiences of caring for someone living with mental illness, thereby engaging the expertise of practitioners, consumers and carers. The definitions and terminology used in this manuscript have been reviewed by mental health consumers and modified according to their suggestions and preferences. People with lived experience and their carers will continue to be involved in future stages of this research, including the systematic review, and the development (eg, content development, resource identification) and delivery (eg, workshop material delivery) of training and education for community pharmacists, informed by the results of this systematic review. For example, they will be involved in the development, piloting and delivery of some components of the training package. Furthermore, they will be recruited as members of any committees or governance structures overseeing the broader research.

Quality assessment

This systematic review aims to provide a comprehensive overview of the literature pertaining to the nature and extent of pharmacists' involvement in providing health-care/services for people living with SPMI. To meet this aim, we anticipate the inclusion of a broad range of study designs. Hence, it is not possible to determine which quality assessment tool is most appropriate until data extraction is complete. Quality assessment will be conducted using appropriate tools depending on study type. For example, the ROBINS-I⁵¹ and RoB 2⁵² tools may be used for included studies assessing the impact of an intervention, as appropriate for non-randomised and randomised studies of interventions, respectively. The Mixed Method Appraisal Tool⁵³ may be used if included studies employ mixed methods.

Patient and public involvement

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

ETHICS AND DISSEMINATION

The findings of this systematic review will be disseminated through scholarly conference presentations and peer-reviewed publication(s). Furthermore, the findings of this systematic review will be used to inform the development of a pharmacist-specific education and training package to support people living with SPMI. This training and education package will be developed in consultation with people with a lived experience of mental illness, carers, multidisciplinary experts and representatives from professional pharmacy, medical and mental health organisations. Hence, the results of this systematic review, as well as, the input of clinical experts and consumers with lived experience will facilitate the development of the education and training package.

CONCLUSION

There is a need for a comprehensive review of pharmacists' roles in supporting people living with SPMI, to explore pharmacists' current roles in this area and the outcomes related to their involvement in service provision for people living with SPMI. This systematic review protocol describes the process that will be used to conduct the search for, as well as, screening, data extraction, data synthesis and quality assessment of studies exploring pharmacists' roles in supporting people living with SPMI. By including all studies that explore pharmacists' roles in SPMI, the resulting systematic review will provide a comprehensive overview of all the primary research conducted in this area, highlighting gaps in the current literature and building a solid foundation for training development and the establishment of pharmacist-led services and interventions for people living with SPMI.

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