# INPLASY PROTOCOL

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## Government Policies, Hospital-Community Management and Pharmacological Treatment of Schizophrenia in China: Protocol for A Scoping Review

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Review question / Objective: In the planned scoping review, the study objective will be to answer, "What are the national and regional government policies relating to the care and treatment of patients with schizophrenia that have been reported or taken place in China? What are the current evidence and possible knowledge gap regarding the community-based approaches for patients with schizophrenia in China? And what is the treatment status, clinical effectiveness/efficacy/safety and treatment retention of LAI antipsychotics among Chinese patients with schizophrenia?" Condition being studied: The scoping review will focus on all outcomes related in patients diagnosed with schizophrenia.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 May 2022 and was last updated on 10 May 2022 (registration number INPLASY202250056).

#### INTRODUCTION

Review question / Objective: In the planned scoping review, the study objective will be to answer, "What are the national and regional government policies relating to the care and treatment of patients with schizophrenia that have been reported or taken place in China? What are the current evidence and possible knowledge gap regarding the community-based

approaches for patients with schizophrenia in China? And what is the treatment status, clinical effectiveness/efficacy/safety and treatment retention of LAI antipsychotics a mong Chinese patients with schizophrenia?"

Condition being studied: The scoping review will focus on all outcomes related in patients diagnosed with schizophrenia.

#### **METHODS**

Participant or population: Patients diagnosed with schizophrenia according to any of the standardized diagnostic criteria will be included. No restrictions on patient characteristics such as sex, ethnicity, age, or regions will be applied. Review authors will exclude studies which involve mixed population and cannot extract results for Chinese population separately.

Intervention: Not applicable.

Comparator: Not applicable.

Study designs to be included: This scoping review will consider all evidence-based published studies related to the government policy of hospital-community management or the implementation of the policies, the effectiveness of community management, and the clinical evidence of LAI antipsychotics. Relevant secondary sources (i.e., reviews, editorials, commentaries, news report, personal opinions, reply and letter) and case-report will be excluded. Master/doctoral theses, and non-journal articles like posters and conference abstracts will be excluded.

Eligibility criteria: The eligibility criteria for identified studies will be based on the Population, Concept, Context (PCC) strategy. Population: Patients diagnosed with schizophrenia according to any of the standardized diagnostic criteria will be included. No restrictions on patient characteristics such as sex, ethnicity, age, or regions will be applied. Concept: Concepts of this scoping review are community management and clinical evidence. Due to differences in the community management patterns and methods among different regions, community management in this study is defined as broad management in the community including medication, psychosocial interventions, family-based interventions, social skills training, cognitive-behavioural therapy, casemanagement, assertive community treatment, etc. Clinical evidence will be defined as the effectiveness and safety of interested interventions including the community management and LAI in patients with schizophrenia assessed by a series of clinical endpoints and outcomes. Context: The context of this review is Chinese patients with schizophrenia. No restrictions are being applied in terms of management pattern or geographic location.

Information sources: Seven electronic databases will be included: China national knowledge infrastructure (CNKI), Wanfang, Pubmed, Embase, Medline, the Cumulative Index to Nursing & Allied Health Literature (CINAHL), and PsycArticles.

Main outcome(s): The main outcomes will include but not limited to the following: Study characteristics (e.g., author, year, title, journal, region, study design, study duration, study population, sample size, study site including hospital-grade, department, inpatient/outpatient) Patient characteristics (e.g., demographic characteristic including age and sex, clinical characteristic including disease. comorbidity, and course of the disease) Summary of policy and experience of policy implementation (e.g., policy documents, policymakers, release date, implementation region, implementation date, main content of policy, implementation effect) Disease treatment or management (e.g., type of management like case management, assertive community treatment or psychological intervention, disease treatment including oral antipsychotics and LAI) and corresponding clinical endpoints (e.g., Positive and Negative Syndrome Scale, the Brief Psychiatric Rating Scale, Clinical Global Impressions scale, emergency department visit rate, all-cause hospitalization rate, recurrence rate, medication compliance and persistence, health-related quality of life, caregiver burden, adverse effect).

Quality assessment / Risk of bias analysis: Study screening will be conducted by two independent reviewers through two phases: title and abstract screening and full-text review. Any disagreement will be resolved by discussion between reviewers. If consensus cannot be reached, a third reviewer will be involved in the final decision. Title and abstract screening: After the removal of duplicates, titles and abstracts will be screened before a full-text review by two independent reviewers. Each study will be classified as: 'included' or 'excluded'. All studies marked as 'included' will be passed to full-text review. For excluded studies, the reason for exclusion will be documented. Full-text review: All available full-text will be screened for final inclusion by two independent reviewers. Reasons for excluding studies that do not meet the inclusion criteria will be recorded. The search results and the screening process will be described in the final report and presented with a flow diagram. For data extraction, two reviewers will independently collect data from all eligible articles. Subsequently, the retrieved information will be cross-checked in a consensus meeting. Any disagreement will be discussed and a third reviewer will be involved if necessary. Attempts to contact the authors of the included studies will be made if there are any missing or additional data needed. Since the scoping review aims to identify and describe the currently existing evidence, the quality of individual studies will not be assessed specifically.

Strategy of data synthesis: The extracted data will be presented in tables or charts in accordance with the objectives of this scoping review. A narrative summary of the findings will be presented regarding current policies and experience of national and representative provinces/regionals in China, the clinical evidence of community management, and LAI antipsychotics on schizophrenia patients in China. The extracted results will be further organized to better reflect the questions of the study, such as the distributions of policies and implementations (including nationwide, Shanghai, Beijing, Guangdong, Fujian, and other provinces), and management patterns (such as case management, medication, LAI, etc.) depending on the variety and sufficiency of extracted data. A flow diagram will be created to illustrate the progress of studies through the selection process and screening. A

summary of the main characteristics of each included study will be presented, including author, year, study design, sample size, methodology, and main findings. Descriptive statistics including the mean, the median, and the standard deviation (SD) will be extracted for outcomes described as continuous variables, while counts and proportions will be extracted for categorical outcomes as categorical variables. Charting results will be summarized and/or presented in detail. The facts and gaps in knowledge identified from the results of this review will be identified to provide clear and specific suggestions for future research. Descriptive statistics will be used to summarize data extracted from included studies as following: Study characteristics including the year of publication, published journal, region, study sites, study design, study population will be described, charted, and summarized by counts and proportion. The mean (SD), median, inter-quartile range (IQR) of sample size data extracted from included studies will be presented. Patient characteristics including but not limited to age, gender, treatment history and comorbidities will be described and charted. The range of mean (SD) / median (IQR) of age reported by included studies, the range and median of frequency/ proportion of gender, treatment history and comorbidities will be calculated. Policy documents related to community management will be systematically sorted. The analysis dimensions include but are not limited to policymakers, policy release year, policy release region, policy content, to identify the priorities and trends in the schizophrenia area from the perspective of government. Besides, the implementation experience will be summarized by regions (e.g., Shanghai, Guangdong, Beijing) to identify regions with successful management experience. The frequency and proportion of treatment reported will be calculated, including but not limited to oral antipsychotic medications (e.g., paliperidone palmitate, aripiprazole, risperidone) and LAI (e.g., paliperidone palmitate monthly, paliperidone palmitate every three months, risperidone biweekly). The approaches of community management being studied will be classified and the frequency and proportion of the approaches mentioned in included studies will be calculated. Results regarding the corresponding effectiveness for those treatment/management will be charted and narratively reported if available. For continuous variables, such as scales and quality of life, mean, median and SD will be extracted and presented in tables. For categorical variables, such as relapse rate and adverse effect, counts and proportion will be extracted.

Subgroup analysis: Not applicable.

Sensitivity analysis: Not applicable.

Country(ies) involved: China.

Keywords: Schizophrenia, hospitalcommunity management, government policy, clinical outcomes, scoping review.

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Conflicts of interest: Chong Ye, Xin Li, Han Wen and Bin Wang are employees of Xian Janssen Pharmaceutical, China. Other author declared no conflicts of interest to this work.