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How can healthcare providers involve with families in the care of patients with chronic mental illness? A mixed methods protocol study to adapt the clinical practice guideline

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Abstract:

BACKGROUND: Chronic mental illnesses have long periods, are recurring, and require continuous care as well as an integrated and collaborative approach to organize the care. The purpose of this article is to summarize the most important steps necessary for adapting a clinical practice guideline for family-centered collaborative care of patients with chronic mental illnesses referring to the medical centers.

MATERIALS AND METHODS: As the study will be an exploratory mixed methods study, the design will be carried out as a sequential qualitative-quantitative study (QUAL quan), consisting of 3 phases, 9 modules, and 24 sequential steps, which is based on the Guidelines International Network to adapt the guideline manual. In the first phase, the prerequisites for adaptation of the clinical guideline were established. In the second phase, to collect evidence, a qualitative study (semi-structured interview) will be conducted to explore the dimensions and components of the care needs of patients with chronic mental disorders and their families from the perspectives of patients, caregivers, and healthcare providers. Additionally, a literature review to extract relevant clinical guidelines and articles will be done. A panel of experts will screen and evaluate potential clinical guidelines, and a draft guideline will be developed.

DISCUSSION: It is expected that these findings will meet the needs of patients with mental illness and their caregivers by providing integrated care and improving collaborative care within the sociocultural context of Iran.

Keywords:

Care, family, guideline, mental disorders

Introduction

Chronic mental illnesses, including schizophrenia, bipolar disorder, and major depressive disorder, cause considerable disabilities for patients and impose a heavy burden on families and caregivers.^[1,2] These patients experience long and reversible periods of illness together with health and social consequences such

as functional loss and death. Cognitive and functional disabilities in a patient with mental illness cause a challenge for patients and their caregivers so the need for chronic care in these patients is significant psychiatric services.^[3,4] To prevent the complications of chronic mental illnesses, effective, and evidence-based interventions should be also performed at the societal

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level. However, despite all these serious problems, the heavy burden and the complications of the illnesses on patients, families, the economy, and society, and the recent global commitments to chronic mental illnesses, the performance of countries has been slow, inefficient, and fragmented.^[1,5] Moreover, global policymakers and investors have hitherto failed to prioritize the treatment of mental illnesses, and only a few countries have responded to the needs of these patients to enhance effective healthcare approaches.^[6-8]

Providing these holistic, collaborative, and flexible mental health services and treatments within the community is also one of the four main objectives of the Comprehensive Mental Health Action Plan 2020-2013, which was approved by the Sixty-sixth Assembly of the World Health Organization.^[9] Accordingly, family-centered care is one of the most integral pieces of the puzzle of caring for patients with special needs which can be useful for the patient, family, healthcare professionals, and service providers.^[10,11] Several studies have preferred the involvement of family and informal caregivers to mere patient-centered care provided for patients with Chronic Mental Illness (CMI) in all stages of treatment such as prevention, illness management and treatment, rehabilitation, and palliative care.^[12-14] We found no conclusive evidence that family collaboration is an effective method for caring for participants with chronic mental illness. The quality of life of supported individuals and medication compliance did not change between baseline and four months, according to Kidd. There was a significant reduction in caregiver burden scores with a large effect size, but the type of manual did not make a significant difference^[15] and stakeholder barriers prevented family intervention, according to Cohen.^[16]

In contrast, Tantirangsee and colleagues found that a brief intervention with family support improved family relationships,^[17] Research has shown that combining psychosocial treatment with family engagement promotes recovery from bipolar depression better than short-term treatment alone,^[18] other studies have shown that caregiver engagement promotes patient safety^[19] For the best care, caregivers should be recognized as partners in care planning. In a good quality mixed-methods study, a community-based rehabilitation intervention with family involvement may increase family support, access to healthcare services, income, and self-esteem.^[20,21]

Family-centered collaborative care emphasizes the significance of the individual's family, involving families as their experts and partners in all care systems. Using guidelines to improve the quality of care provides performance support, according to research, reduces unnecessary interventions, promotes the level of knowledge and skills, establishes leadership roles in

healthcare workers, and leads to competence in providing care.^[22] Because in Iran there is no guideline related to family participation in the care of patients suffering from chronic mental disorders this study aims to develop a guideline for family-centered collaborative care in patients with chronic mental illnesses. The development of such a guideline can take steps toward improving the health of patients with CMI and providing Iranian society with better care conditions. This guideline can be a roadmap to align health center cares based on a family-centered program to improve the health of the patients with CMI and their families.

Materials and Methods

Study design and setting

This is a mixed methods protocol study, the design will be carried out as an exploratory sequential study (QUAL-quant). At first, a qualitative study will be conducted, followed by quantitative steps. To develop this guideline, we will follow the steps of guideline adaptation provided by the Guidelines International Network in 3 main phases of planning, adaptation, and finalization of the guideline, which include 9 modules and 24 stages [Table 1].^[23]

Phase 1: Planning

Preparation module

This phase under the title of the preparation module will be conducted in six stages examining the feasibility of adaptation, formation of an executive committee, selecting a title for the guideline, checking sufficient resources and necessary skills, planning finalization, and writing the protocol of the guideline. For assessing the feasibility of adaptation, clinical guidelines about the selected topic on existing texts and websites will be reviewed and the related guidelines will be extracted. Necessary permits will also be obtained at this stage.

The Executive Committee includes the research team (a Ph.D. nursing student and three expert assistant professors for guideline adaptation and chronic mental illness) that will supervise the process of adapting the clinical guidelines and a member of the panel of experts that continues the adapting process.

In the present study, the required budget was determined by the research team and can be paid through the research credits of Isfahan, Iran. Key users will be the expert panels of the family-centered collaborative care clinical guideline for patients with CMI that will be experts in this area such as mental health nurses, psychiatrists, psychologists, and social workers.

In the planning finalization stage, the conditions are determined for performing the phases. Such conditions

Table 1: Guideline adaptation modules for the present research^[17]

Phases	Modules	Stages
Planning	Preparation module	<ol style="list-style-type: none"> 1. Examining the feasibility of adaptation 2. Formation of executive committee 3. Selecting a title for the guideline 4. Checking sufficient resources and necessary skills 5. Planning finalization 6. Writing the protocol of the guideline
Adaptation	<ol style="list-style-type: none"> 1. Scope & purpose module 2. Search module 3. Assessment module 4. Decision and selection module 5. Customization module 	<ol style="list-style-type: none"> 7. The process of determining research questions 8. Identifying and retrieving pertinent guidelines and other documents 9. Screening the obtained guidelines 10. Reducing the number of guidelines using the opinions of the panel of experts 11. Qualitative evaluation of guidelines 12. Assessing the value of the guideline 13. Content evaluation of guidelines 14. Consistency of the guidelines (Linking evidence with recommendations by searching and selecting studies) 15. Evaluating the recommendations' acceptability and applicability 16. To help with decision-making, the assessments will be reviewed 17. An adapted guideline is produced through selection of guidelines and recommendations 18. Developing a document that considers end users' needs, in addition to explaining the process clearly and accurately.
Finalization	<ol style="list-style-type: none"> 1. Acknowledgment and external review module 2. Aftercare planning module 3. Final production module 	<ol style="list-style-type: none"> 19. An external review by the target audience 20. Obtaining approval from the relevant institutions 21. Consultation with guideline developers 22. Document confirmation 23. An aftercare plan for the family-center collaborative care guideline for patients with CMI 24. Producing final high-quality guideline for the family-centered collaborative care of chronic mental illnesses

should be prepared by the executive committee and include the setting of general and specific objectives, the membership manner, the commitment of the required time, and the manner of holding the meetings. These conditions need to be shared with all members of the panel of experts for their consent, and a conflict of interest declaration must be completed and signed by all members of the executive committee.

Decisions need to be made on how to deal with potential problems. In the final stage of this phase, after completing the introductory phase, the executive committee and members of the panel of experts will agree on a plan for the adaptation process of the guideline. This formal program for guideline adaptation includes titles such as introduction, the research subject, panelists, statements of conflict of interest and credentials, condition of the panel, modules that will be implemented, the timeline for completion of the adaption process, the meetings schedule and, budget-related resources.

During this process, to increase reliability and citation, decisions made by the board of directors or executive committee will be documented for transparency in the adaptation process. At this stage, the chairperson of the executive committee will be also appointed, who are the supervisors in the present study.

Phase 2: Adaptation

This phase has 5 modules including:

The scope and purpose module

In which the research questions are determined based on the PIPOH model (Population: Iranian patients with CMI; Intervention: family-centered collaborative care of patients with CMI; Professionals: nurses, physicians, mental health nurses, psychiatrists, psychologists, social workers, families, or first-class caregivers; Outcome: improving the quality and coordination of family-centered collaborative care for patients with CMI, reducing the consequences of the illness, improving the quality of life and community-based care for these patients, empowering families; Health care setting: clinics and hospitals);

The search module

Consists of a 1) systematic search, 2) qualitative study, and 3) review of the country's upstream documents, and programs for the collaborative care of patients with CMI. Guidelines and other relevant documentation are searched for evidence retrieval. The obtained guidelines are screened, and the number of guidelines is reduced at the discretion of the panel of experts. To obtain high-quality guidelines and also to reach all the documents required in this stage, the guidelines-related

sites will be reviewed using a systematic search method. Moreover, to achieve the country's indigenous evidence for enriching the adaptation process, a qualitative research method will be used in this area.

Systematic search

Study design and setting

This review examines whether the collaboration of families with patients with chronic mental illness in care is acceptable, meaningful, and effective in the literature. Based on the guidelines in DSM-5 25, we will search for evidence using the term "family-centered care" by PRISMA's checklist^[24] and use the term "chronic mental illness" as an umbrella term for schizophrenia, major depressive disorder, and bipolar mood disorder.^[25]

Study participants and sampling

We will search 10 electronic databases for original articles published since 2000 (CINAHL, SID (Persian), Magiran (Persian), Embase, Cochrane, Proquest, Up to date, Science Direct, Scopus, Pubmed).

Data collection tool and technique

We will use the separate search terms according to each database's rules but in general, we will use "chronic mental disorder" AND "collaborative care*" OR "severe and persistent mental disorder" AND "family-center care*." RD will be screened all of these papers by title, abstract, and full text, while MF, MSH, and EM will analyze a sample of the papers to check for ineligibility. Articles published before the year 2000 will be excluded, without full text, not empirical articles, prerequisite or consequence of family intervention in treatment, not exploring adult chronic mental illness, family interventions were aimed at non-patient care, not exploring family center collaborative care (intervention on the family such as psycho-education, family therapy, coaching), Not exploring chronic mental illness, Not in English OR Persian.

2) Qualitative study

Study design and setting

A qualitative content analysis, with in-depth semi-structured interviews, will be conducted to explore the dimensions and components of the care needs of patients with chronic mental disorders and their families from the viewpoint of the patients, their families, and healthcare providers.

Study participants and sampling

The participants in this phase will include adult patients admitted to psychiatric wards or with experience of hospitalization in these wards and outpatients, families or first-class caregivers, and health service providers including mental health nurses, psychiatrists, psychologists, and social workers with at least three years of work experience in psychiatric wards. The

purposive sampling method will be used by maximum variation in age, sex, education level, and occupation.

Data collection and technique

The data collection method in this research is interviews, observations, and field notes, and it continues until rich, in-depth, and relevant data emerge. In addition, direct observations will be done, and field notes will be completed. The interviews will last for 30-70 minutes. Paying attention to the views and wishes of stakeholders, audiences, and the target community increases their acceptance of the guideline by them, thereby, increasing its practical application. For this reason and also given that the guideline obtained from this study is the first one providing family-centered collaborative care in patients with CMI, it identified the dimensions and components of the patient and family care needs by modifying the adaptation method and adding a phase to it as well as using the qualitative content analysis approach and conducting individual interviews with the main audience and the target community.

Ethical consideration

The study approval and permission to conduct the study by the Ethics Committee, School of Nursing and Midwifery, as well as from those of the health centers and unit charges were sought before the data collection. The participants with inclusion criteria and will willing to take part in the research will be provided with the details of the study including study objectives as part of the informed consent process before getting their written informed consent.

The review of the country's upstream programs and documents

This review concerning the collaborative care of patients with CMI will be performed simultaneously with the previous stage. At this stage of the research, the framework will be prepared based on the identification of indigenous documents related to the care of patients with CMI, developed by the Ministry of Health and Medical Education, medical universities, hospitals, and other health centers. The information gathered from this stage, especially about the existing gaps, will be considered by experts during the discussion for determining the recommendations, and actions in the guideline.

Assessment module

Guidelines are reviewed, analyzed, and synthesized by using GRADE (Grading of Recommendations, Assessment, Development, and Evaluation).^[26] The research executive committee will form the participation in the evaluation, which is the panel of experts, to analyze and synthesize the evidence. This stage will select guidelines for further review and assessment. The initial assessment will be performed with the help of PIPOH questions to exclude guidelines that are not explicitly

related to the key questions of the present study. In addition, the panel of experts should review other criteria, such as the date of publication of the guideline. To implement this method, a quality assessment is conducted for the evidence, and a summary of the conclusion can be made for each significant or specific outcome and key question.

Decision and selection module

The number of guidelines is reduced using the opinion of the panel of experts. During the search, if there are many relevant guidelines found, the panel of experts will evaluate them to reduce the number, and if they are removed, the exclusion criteria should be explicitly mentioned at this stage. The AGREE tool (Appraisal of Guidelines for Research and evaluation) is an effective strategy for reducing the number of guidelines and validating them.^[27] The 23 items of AGREE tool evaluate the methods used to prepare the guideline.

Customization module

An overall evaluation of the quality of guidelines, after using this tool, helps expert panels to make their judgments about the guideline: “strongly recommend,” “recommend with changes,” “do not recommend the guideline,” Or “not sure about the advice.” A guideline’s quality, value, copy, and consistency as well as its acceptability and applicability will be assessed in the assessment module. In the modules of decision and selection, assessments aid in decision-making, and guidelines and recommendations are chosen to make an adapted guideline. Finally, in the customization module, a guideline that supports the end user’s need provides a comprehensive and detailed explanation of the process is produced.

Phase 3: Finalization

Acknowledgment and external review module

The external review of the guidelines will be performed by the target users in the last phase and the external review and acknowledgment module. Then, the relevant institutions and the guideline producers will be consulted for approval and the documents are confirmed. In the aftercare planning module, counseling is performed to plan for the aftercare of the adapted family-centered collaborative care guideline for chronic mental illnesses. In the final production module, the high-quality guideline for the family-centered collaborative care of chronic mental illnesses will be produced.^[28]

After deciding on the guideline’s adaptation, the next step would be to send the adapted guideline of family-centered collaborative care for patients with CMI to the users of this guideline. For example, it includes policy-makers, decision-makers, representatives of the organization, and managers in this area. In the external

review, some questions should be asked about the users’ approval of the guideline draft and the identification of its strengths and weaknesses, and what needs to be corrected. Some questions may also be asked about whether or not they will use the guideline in practice or how it affects their current situation.

However, there may be questions regarding the acceptability of guidelines in the organization and the outcomes of the resources. Health systems must gradually reduce inadequate care and maintain adequate and essential care. Therefore, the “RAND/UCLA Appropriateness Method (RAM)” was created at RAND and the UCLA School of Medicine in the 1980s. This manual provides comprehensive guidelines for conceptualizing, designing, and conducting a RAM-based study that determines whether a medical procedure is appropriate. Therefore in this study, consensus based on RAM will be considered for the need for clinical recommendations. A structural questionnaire is useful for this stage. For the review and finalization of the guideline draft (consensus based on RAM), proof and finalization of the plan, online publication, and printing of the clinical guideline to complete and assess it, a group of experts and professionals can be used.^[27]

In this phase, the draft of the developed guideline will be validated by a group of experts. The RAM method will be used for the consensus of experts. The reason for using this method is that experimental studies, which are the original gold standard in evidence-based medicine, are often unavailable and do not provide sufficient support for clinical decisions. This method is a mixture of the best clinical evidence, together with expert judgments, for determining the appropriateness of a therapeutic care method.^[9]

The RAM method provides an opportunity for experts to discuss their judgments and receive group responses. Such an agreement method is an appropriate approach for measuring the quality of care in medical centers.

Aftercare planning module

In the guideline-related aftercare planning stage, plans will be designed to update the guideline of the present study in the future, and new evidence will be reviewed as well. An expert panel will decide on the initial evidence search at the scheduled planning date.

Final production module

According to the changes that have been made, a revised guideline will be sent to the experts, policymakers, and stakeholders for external review and their comments will be included in the final document, in the end, the document of the final guideline will be prepared. Execution programs and customization of the adapted

guidelines take place at the local level. The adapted guideline of this research will be on the clinical concepts as well as the organizational and cultural contexts of Iran, and the final product will be re-evaluated using AGREE instrument.^[28]

Discussion

Iranian society like the whole world is transitioning from experiencing various changes in social and health aspects, such as increasing chronic mental illnesses which affect the survival and health status of people. Mental illness accounts for 11.7% of the world's population living with a disability, making it one of the most common causes of disability in the world, based on the overall incidence of the illness burden.^[8] People with these illnesses experience long and recurrent periods of illness and health and social consequences, such as the loss of function and mortality. They, thus, are unable to perform their duties and responsibilities and need family care. Additionally, according to studies, cognitive and functional disabilities of patients with CMI may lead to behavioral problems for patients and create difficulties for their caregivers.^[4] In addition to the significance of family in caring for these patients, the evidence also suggests that integrated family-centered collaborative care of the healthcare system reduces the provision of fragmented care, prevents rework in infrastructure and services, and promotes the existing healthcare systems. It also meets the needs and expectations of people and, finally, strengthens healthcare systems and transforms them into centers for providing integrated and effective services.^[9] Several studies examined the effectiveness of family-centered collaborative care exploring family functioning as the primary outcome.^[17,29-33] Some analyses measured caregiver burden after family involvement, two of which have relieved family burden after that,^[31,34] and one study found caregivers' burden scores diminished significantly over a large effect size,^[15] also, family-center collaborative care program improves rates of engagement in family programs and retention.^[35] Family involvement in the care of patients facilitates treatment decision-making both within and outside of consultation, reduction in guilt induced by relatives, and increases empathy.^[33] In addition, in several studies, the patient's outcomes, such as re-hospitalizations, relapse rate, social cognition, quality of life, social functioning, a symptom of patients, general well-being, and positive, and negative symptoms were improved.^[12,14,17,31,36]

A systematic search of guidelines recommending the collaboration of family was conducted by the research team. The prevalence of guidelines is high quality, while some are medium quality. Family involvement in mental health care is only mentioned in rare guidelines. National Clinical Guidance (update: 2020) titled "Service

user experience in adult mental health, Improving the experience of care for people using adult NHS mental health service" emphasized the need for tailored, specific recommendations targeted to individuals with mental disorders.^[37] The NICE guideline titled "Supporting adult carers" likewise instantly addressed caregivers of patients with mental illnesses.^[38]

The guideline will be developed in this study can be given to members of the healthcare providers as a guide to improving the quality of life of patients with CMI and their families.

This guideline will be developed based on a holistic approach and will help the healthcare team to provide care in the form of an inter-professional team with the involvement of patients' caregivers that provide the patients with better services and satisfaction, reduce psychological distress, and improve the quality of life of CMI patients. Moreover, based on the developed guideline, recommendations for the involvement of informal caregivers of patients with CMI will be extracted by systematically reviewing the related literature and interviewing patients, their families, and healthcare providers. Using these recommendations by health team members will improve the quality of care and, consequently, the quality of life of these patients. Given the lack of a family-centered collaborative care guideline for CMI patients, this study is an attempt to find dimensions of involvement of families of patients with CMI and develop a clinical care guideline for them.

As such, this study will be a step toward the promotion of the involvement of family in the care of these patients in Iran. Accordingly, this guideline can be applied to cultural structures similar to Iran's. In other parts of the world, however, different socio-cultural contexts may restrict the use of this program. In using this approach, it is possible to reduce the separate care that people with CMI receive in the healthcare system as well as reduce financial and human resource waste.

Conclusion

Evidence-based guidelines are considered to be important tools for integrating care and improving patient outcomes. This protocol can guide healthcare professionals to use high-quality guidelines to increase the effective use of clinical services, reduce the diversity of optimal performance, increase the use of absentee services, promote health outcomes, and, finally, improve holistic care and, therefore, eliminate possible bias in the treatment of patients with CMI.

Implications for psychiatric nursing practice

In this protocol study, the role of the family is planned

in caring for participants with CMI. Families can play an important role in improving communication at home and patient rehabilitation, reducing rehospitalizations and relapse rates, increasing problem-solving ability in the family, and ultimately improving patient outcomes. Developing a family-center collaborative care guideline for patients with CMI, in addition to controlling physical symptoms, other aspects of quality of life such as social, and psychological dimensions will be considered and will improve the quality of life and health of patients and their informal caregivers.

Limitations, strong points, and recommendation

This research study is the first protocol study about guideline adaptation for family-center collaborative care of patients with CMI that will integrate the viewpoints of caregivers, patients, and healthcare providers and evidence so that the recommendations can be practical and acceptable. However, this study can have some limitations. It is anticipated that possible problems in this research, in the phase of qualitative data collection, changes in conversations and care measures due to being can be observed, the reluctance of some healthcare providers to participate in the interview, and membership in the panel due to busy work and the reluctance of the patient's families and there is not enough opportunity for them. Also, lack of access to the full text of some scientific articles and related guidelines may be one of the possible problems that the research team may face. In the present study, we will compile the guideline only for three chronic mental diseases so it is suggested to compile guidelines related to other chronic mental disorders in future studies.

Abbreviations

PIPOH: Population, Intervention, Professionals, Outcome, Health care setting

GRADE: Grading of Recommendations Assessment, Development and Evaluation

AGREE: Appraisal of guidelines for research and evaluation

RAM: RAND/UCLA Appropriateness Method

CMI: Chronic Mental Illness

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Ethics approval and consent to participate

Ethics approval from Isfahan University of Medical Sciences has been received (IR.MUI.RESEARCH.

REC.1399.502). Informed written consent will be obtained from participants in future stages and at the time of implementation of the protocol.

Authors' contributions

RD, MFM, MSH, and EMS were involved in the study conception, design, and drafting of the manuscript. RD wrote the first draft of the manuscript. MFM and MSH reviewed the first draft of the protocol and manuscript. MFM was responsible for coordinating the study. RD will be responsible for all guideline adaptation phases such as systematic review, interview with participants, description and data analysis, and other stages. MFM, EMS, and MSH will review and will involve in guideline adaptation phases. All authors read and approved the final manuscript.

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Conflicts of interest

There are no conflicts of interest.

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