

# Soft systems methodology for implementing clinical practice guidelines in a general hospital: a study protocol

**Ali Soltani**

Islamic Azad University Semnan Branch

**Ali Heyrani**

Hormozgan University of Medical Sciences

**Ali Fakh-Movahedi**

Semnan University of Medical Sciences and Health Services

**Abdoljavad Khajavi** (✉ [abjkhajavi@gmu.ac.ir](mailto:abjkhajavi@gmu.ac.ir))

Gonabad University of Medical Sciences <https://orcid.org/0000-0001-6625-6998>

---

## Study protocol

**Keywords:** Practice Guideline, Hospital, Implementation, Systems Thinking, Soft Systems Methodology

**Posted Date:** April 5th, 2021

**DOI:** <https://doi.org/10.21203/rs.3.rs-290681/v1>

**License:**  This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

---

# Abstract

**Background:** Adhering to Clinical Practice Guidelines (CPGs) serves as the driving force behind making decisions based on the best evidence and making efforts for improving the quality of patient care and outcomes. In 2010, promoting the quality of clinical care through implementing CPGs was turned into a priority health policy in Iran as in many other countries. Despite requiring Iranian hospitals to implement CPGs in January 2017, the concept and implementation method of CPGs remained to be clarified. This action research focuses on acquiring an in-depth understanding of how to define and implement CPGs in a selected general hospital in Iran.

**Methods:** This study employs Soft Systems Methodology (SSM) as a commonly-used approach for tackling complex problems with social, political and human dimensions. Given the inherent roles of technical processes, organizational culture, and personnel' perspectives in providing clinical care, implementing CPGs was considered a complex problem situation, and conceptualized by use of a purposeful activity model. We will conduct semi-structured in-depth interviews and hold group discussions with different stakeholders to enquire into the situation. Moreover, we will use SSM tools and techniques to identify the main areas of changes, and select necessary measures to facilitate the implementation of CPGs. Flexible qualitative methods of data collection and analysis are utilized throughout the study.

**Discussion:** Applying SSM in implementing CPGs can generate knowledge by recognizing hyper-complexity in healthcare setting, adopting an attitude of inquiry, and fostering dynamic changes in diverse and numerous worldviews of professionals in the accommodation process. This knowledge can provide a model for the successful implementation of CPGs at a macro-system level and facilitate the persuasion process at the hospital mesosystem level. More importantly, adopting SSM can create iterative learning loops over time and thus help the actors of clinical microsystems face future healthcare complexities.

## Contributions To The Literature

- This study describes complexities inherent in clinical practice guidelines' implementation.
- Applying soft systems methodology as a holistic approach to tackle complexities and find relevant proposals to implement clinical practice guidelines is well discussed in this action research study protocol.
- Reading this article can promote usage of the methodology in other complex issues in healthcare settings.

## Background

### Introduction to clinical practice guidelines and its implementation in Iran

Clinical practice guidelines (CPGs) can be used to improve the quality of healthcare, especially when designed to support appropriate or necessary behavioral changes [1]. The number of CPGs has dramatically increased in all fields of medicine since the late 1970s, when the first efforts were made to develop CPGs in several countries [2]. Despite the growing availability of CPGs since the early 1990s, evidence suggests little success in their clinical implementation [3].

The Institute of Medicine (IOM) defined CPGs as "the regularly-developed statements for assisting patients and physicians with their decision making for specific clinical circumstances" [4]. In 2011, the IOM emphasized the application of accurate methodologies in developing and implementing CPGs by updating this definition as "statements that propose approaches to optimize patient care by regularly investigating evidence and evaluating the advantages and disadvantages of alternative care options" and highlighting the need for a comprehensive approach beyond the development and publication of CPGs [1]. In an era of growing clinical information, which is available to healthcare professionals, effectively implementing CPGs requires adopting appropriate strategies [5].

The application history of CPGs in Iran suggests their lack of a special position at the heart of healthcare delivery in the country's hospitals by 2003 and their unsystematic development without a specific trustee in the following years. In 2010, after the segregation of the Health and Treatment Deputy of the Iranian Ministry of Health and Medical Education into the Health Deputy and Treatment Deputy, the legal and official structure of CPGs was established in the Department of Health Technology Assessment, Standard and Tariff Office, Treatment Deputy. The Office of Standardization and Development of CPGs has been, ever since, in charge of developing, finalizing and communicating health guidelines and standards and developing strategies for supporting the use of evidence in clinical decision-making and clinical knowledge management in the Iranian health system. The mission of this office is to lay plans for producing knowledge and achieving the desired outcomes based on national priorities and thus responding to the currently-confirmed needs of the target population in collaboration with healthcare policy makers and stakeholders [6].

### **Challenges of healthcare organizations in implementing CPGs**

Research on implementing CPGs suggests the treatment prescribed for patients might not comply with CPGs in about half of the cases [7]. Worst of all, some patients may receive unnecessary or even harmful treatments. Barriers to implementing CPGs can be generally categorized as (1) personal factors associated with the executing physician, i.e. knowledge and attitude, (2) factors associated with CPGs, i.e. development, publication and implementation, and (3) external factors, including lack of resources, organizational constraints, heavy workload and social norms [7]. These barriers globally constitute challenges for health care delivery systems in terms of applying and implementing CPGs for developing safe care and cost-effective interventions to deal with different clinical conditions and improve clinical outcomes [8, 9]. The evidence for supporting the different strategies that have been used to overcome these challenges is not adequately compelling [10], as these approaches have neither been successful nor received adequate support from different actors. Although CPGs are basically developed based on

accurate methods and principles to reach an accommodation among healthcare providers, they are mostly implemented incompletely owing to the complexities and role of technical and specialized processes and human perspectives in providing clinical care [11]. Approaches are therefore required to be proposed to effectively apply CPGs and monitor their implementation [12].

### **Challenges of implementing CPGs in Iran**

In Iran, providing high-quality healthcare in hospitals has been emphasized by the government as a fundamental target of the health system. Great efforts have been also made to apply quality improvement programs such as total quality management, clinical governance, internal audit, and CPGs implementation in Iranian hospitals [13]. In addition to incorporating CPGs implementation into the 4th, 5th and 6th national five-year development plans, efforts have been made in the Iranian Ministry of Health and Medical Education to employ these guidelines in hospitals; nevertheless, these efforts have yielded very limited practical success. According to the declaration of the first clinical guideline made in a one-day conference, which was held by the Ministry of Health in Iran in January 2017, *“Declaring these guidelines is a small part of the work and the main part is their implementation, which requires educational infrastructure and manpower training. Implementing CPGs requires considering the roles of incentives and deterrents, including insurance policies, and developing behaviors using financial incentives. To succeed in this path, one must have a holistic view, avoid partiality and know that changing behavior requires time. A requirement for properly implementing and managing CPGs is to pool all the health resources, including the credits of the Health Transformation Plan and insurance companies. Implementing CPGs will need to be further discussed in meetings in the upcoming years unless these resources are pooled now. The medical community should know that the country’s resources are limited, public expectations of the health system are high and these expectations being higher than the government’s revenue restricts public health expenditure, especially compared to in European countries where per capita income is significantly higher than that in Iran. CPGs can be implemented only in collaboration with the Medical Council, medical associations, the medical community, members of the Board of Medical Specialties and university teachers”* (Ministry of Health, Conference on declaring the first guideline to standardize health services, 2017). Although recent efforts in Iran have led to developing CPGs for physicians, nurses and other healthcare professionals, recommending the use of CPGs has not necessarily caused their practical application [14].

The initial interviews conducted in the present study with hospital managers and specialists showed their belief in the limited application of clinical guidelines developed and adapted in Iran. Moreover, barriers to implementing CPGs can be investigated at the levels of practice setting, evidence-based healthcare delivery system, individual skills and patient traits. Given the complexities of these levels and technical and specialized processes as well as their role and that of human worldviews in providing clinical care, using a system model to tackle the different problems of the health system and especially improve the quality of care is crucial. As an organized system model for involving in improving messy and complex situations, soft systems methodology (SSM) can be used to implement CPGs given its previous success in passing many tests.

## **Systems approaches and applied systems thinking**

“Systems approaches” are claimed to have emerged and evolved in response to uncertainty, diversity of problems, changes and increasing complexity in organizations [15, 16]. Despite the seemingly holistic nature of all systems approaches, they differ in their underlying assumptions, methodologies and practical methods [15].

Applied system thinking emerged in response to diverse problems, major changes in and increasing complexity of organizations. Perceived facts are compared with the system models introduced by system thinking. Lessons learnt from this comparison can be used to optimize the perceived reality and further clarify the status quo. Systems approaches are categorized as hard and soft groups. Goals and missions can be determined and methodologies be proposed to optimize the approaches in "hard" though simply-definable problems. On the other hand, "soft" problems are complicated, problematic, ambiguous, not simply definable and have numerous diverse sociopolitical and human components [15, 17].

According to SSM, making hasty efforts to frame a problem as a “system” and an early application of optimizing models can distort the actual situation [15]; rather, these approaches employ certain models to delve into and learn from a situation and reach an accommodation among different players to improve the situation [18].

### **Study objectives**

The present research is conducted mainly to propose system changes to facilitate the implementation of CPGs in a general hospital affiliated to a university of medical sciences in the east of Iran. Given that the implementation strategies should suit the existing structure and processes, the specific objectives of this study include: (1) determining the status of CPG-based clinical care delivery, (2) explaining purposeful activity systems associated with implementing CPGs, (3) identifying the main areas of changes required for implementing CPGs and (4) determining the necessary measures for facilitating the implementation of CPGs. Furthermore, the applied objective of this study is to promote the effectiveness and safety of clinical care through facilitating the implementation of CPGs in the hospital, thereby contributing to the quality improvement of clinical care in Iran.

## **Methods/design**

Given CPGs implementation as a complex problem, the present study applies SSM as a guiding methodology based on its power to address complex situations [19, 20]. SSM has been reported as the most theoretically-informed and widely used systems approach in practice [18, 21]. Moreover, it is known as the optimal methodology for developing and implementing interventions in different settings and levels of health systems [22, 23]. In addition, we followed the TIDieR-PHP checklist: a guideline for population health and policy interventions to set out the manuscript [24] (see Additional file 1).

SSM introduced by Peter Checkland at Lancaster University in 1972 is considered today a developed soft system approach to tackling complex problems with sociopolitical and human components. This methodology is used to examine a problem as a complex situation and part of a system rather than an individual problem [25]. Moreover, SSM is an organized way of facing situations that are perceived as socially-problematic and an action-oriented approach to organizing the way one perceives these situations in a way that actions can be taken to improve them. The complexity of real-world problems is rooted in the existence of numerous opposing perceptions of the “reality” of these non-static situations. In other words, different individuals may take it for granted that some untested assumptions are true based on their own worldviews. In addition to different worldviews involved in the problematic situations, there are always individuals who always seek to purposefully and intentionally act in these circumstances. As the foundations of SSM, “conflicting worldviews” and “purposeful actions” play key roles in finding a way to tackle problematic situations. SSM constitutes a process that acts through social learning on the way to “improvement” [26-28].

SSM comprises four basic activities, i.e., (1) understanding the problematic situation, including its cultural issues and power relationships, (2) developing certain “purposeful activity models” relevant to the perceived situation to delve more into the situation, (3) using a structured process of debate to compare the models with the perceived situation and thereby reach an accommodation among different stakeholders with different perspectives, and (4) finding ideas for improving the situation and defining “culturally-feasible and systemically desirable” changes to improve the situation [29].

## **Conceptual framework**

This study considers the CPGs implementation as a perceived very complex problematic situation encompassing conflicting perspectives. These viewpoints are assumed to constantly form and reform along with thoughts, dialogues and actions of individuals. It should be noted that the method of adapting to CPGs implementation and our research process to facilitate it can be organized in the form of a learning system derived from SSM, so the systemic concept of our research manifests in the process of reviewing CPGs implementation, not in the CPGs themselves. According to the present study protocol, implementing CPGs involves a set of purposeful actions that are performed in collaboration with experts and through interactions with different stakeholders in the selected hospital to reach an accommodation among the issue owners.

According to Figure 1, the present study began in April 2019 and will end as systematically-desirable solutions to implementing CPGs are achieved. These solutions should be feasible for individuals/ stakeholders with different backgrounds, culture and policies. In other words, the study process helps different individuals with different worldviews reach an accommodation and find changes which are acceptable to all sides with different attitudes.

The present study conceptualized the CPGs implementation as a SSM cycle using a purposeful activity model. Purposeful activity models are developed as system models to express a specific worldview and

can be used as a tool to discover the quality and characteristics of a problematic situation facing individuals. These models comprise nine steps as per Figure 1.

### **Study steps as a purposeful activity model related to the CPGs implementation**

#### **Step 1: Determining the status of clinical care delivery**

According to Checkland [26], after successfully passing many tests, four methods of identifying problematic situations have turned into conventional components of SSM. In the SSM language, these methods include creating and drawing a rich picture, self-intervention analysis, social analysis and political analysis [18, 30]. The complexity of human situations is always the result of multiple interactive relationships. The rich picture is drawn to describe the situation and effectively illustrate these relationships. In fact, this picture is significantly more effective than word processing in achieving the goal. According to SSM, the knowledge obtained from a situation by talking to people, conducting formal interviews, holding meetings, reading documents, etc. is conventionally used to draw simple pictures of the situation. Describing these pictures, a SSM user said, *"This is how we perceive your situation. Can we use this framework to encourage you to express your views on it and turn your attention to what you think is wrong or missed?"*. These pictures become richer as the research progresses, although they never reach their end of perfection. These pictures are very valuable for explaining vital relationships in the situation, especially for laying the groundwork for future discussions [26, 30].

SSM can be used to improve a problematic situation based on the self-intervention analysis by placing three elements of "methodology", "professional use of methodology" and "situation" side by side in a specific relationship, which always comprises three key roles: (1) a person or group as the client that forms the intervention, (2) a person or group as the practitioner who implements and most importantly, (3) issue owner(s) who are identified, by the practitioner, as individuals associated with or affected by the results of seeking to improve the situation [26, 27].

The social analysis requires a very clear idea of the human situation in which one is going to intervene and change. A perception of the so-called "social reality" should be acquired even though this potentially unclear and inaccurate reality is rooted in cultural norms and excitement. Social situations can be therefore modified by taking culture seriously and clarifying its concept, especially in case of employing action-oriented approaches such as SSM. The measures taken to improve a situation should yield desirable changes and be culturally feasible, especially for the target group with their special background and world-view. The local "culture" should be therefore interpreted beyond the worldview of an individual by paying a special attention to three elements, namely roles, norms and values. The roles represent social positions that show differences among the members of a group or organization. The norms are expected behaviors associated with the roles, and the values are standards or criteria that are based to judge the behaviors of the roles. These three elements should be perfectly elucidated and defined by the researcher during the research process [26, 30].

The political situation always plays a key role in implementing or not implementing a decision in the political analysis performed to understand a problematic situation. The political situation can be used as a highly-strong element in determining “cultural feasibility” to explain the power distribution of a situation and the processes that involve power. As part of culture, politics is directly involved and should be considered in investigating the roles, norms and values [26, 27].

As potentially-effective components in implementing CPGs, the self-intervention analysis, social analysis and political analysis are explained and rich pictures drawn in the present study. A harmony is achieved among the principles, techniques and methodology to help with taking measures to improve the situation while organizing the intervention.

## Step 2: Developing the purposeful activity model of the perceived situation

According to Chekland [26], SSM users create an organized process of research and learning by developing purposeful activity models and using them as the basis for asking questions about what exist in areal-world situation. These models are used given that every human situation involves people who act purposefully. Given that these models are individually developed based on a unique world-view, they cannot accurately describe the real world; rather, they are used as a view of a complex reality and a tool to ensure that the learning process is organized, retrievable and reliable rather than random. This step mainly involved developing a model of the purposeful activity system from the perspective of the world-view perceived in this study through presenting a “statement” to explain the activity system. This explanation is referred to as a “root definition” in SSM. The metaphor of “root” implies that this definition should be reinforced since it serves only as a core method of explaining the system. A root definition can be strengthened using different methods; for instance, this study explained and enriched root definitions as follows: “SSM is a system for the researcher to facilitate CPGs implementation through learning from its application as an action research by accommodating CPG stakeholders among proposed activity models”.

The formula for strengthening and enriching the root definition in SSM is referred to as PQR, in which P is implemented through Q to help achieve R. This formula is basically used to answer what, how and why questions. It responds to “what does the system?” as “accommodating CPG stakeholders among proposed activity models”, to “how” as “using the learning obtained from using SSM” and to “why” as “facilitating the implementation of the guidelines”. This definition being rooted in our perspective of the situation should be clarified in group discussions with stakeholders.

With the development of the idea of root definition as the source of our action research, a general model known as CATWOE<sup>a</sup> in SSM will be used as a reference for reinforcing thinking about purposeful activities, which is based on a worldview (W) that requires actors (A) for performing the activities that lead to a transformation process (T) that affects customers (C) while facing different constraints associated with the environment (E). Individuals representing as issue owners (O) can also change or stop activity. Moreover, CATWOE serves as an instruction for thinking about the model and specifying

operational measures for investigating and evaluating the system operation. There are also three criteria referred to as 3E that should be considered in all steps of the model: “efficacy” determines whether the transformation process (T) works properly and produces the desired results; “efficiency” determines whether the transformation (T) is performed using the minimum amounts of resources; and “effectiveness” determines whether (T) can help achieve higher-level goals [26-28].

### Step 3: Using the model to structure the discussion and identify the main axes of change

According to SSM, in the face of a problematic situation, its rich pictures should be drawn and the initial versions of self-intervention, social and political analyses should be implemented to obtain a clear understanding of the situation. A list of potential issue owners obtained from these analyses can help gain a deeper understanding of the situation and find measures to improve it. Developing one or two related models helps begin a structured discussion about the situation and how to change it and ultimately leads to performing the necessary actions. These models serve as tools that enable a structured rather than random discussion and as sources of questions about the situation that structure the discussions. This stage of SSM is commonly referred to as “comparison” between the situation and the model. The models cannot be regarded as a description of what one wants the real world to resemble, as this is impossible given that the models are developed as artificial tools based on a mere world-view, whereas human groups formed always include conflicting worldviews [26, 27].

According to the results of a study by the authors in 2012 on the use of SSM for conceptualizing and applying clinical governance in Iran [13], purposeful activity models cannot simply result in organized discussions. To help with structuring organized discussions, the model can be used to define a set of questions, including “Does the activity in the model exist in the real situation too?”, “Who does it, how and when?”, “Who else can do it?” and “How else can it be done?”. These questions can attract attention, excitement and emotions and help structure the discussions.

### Step 4: Identifying measures for improvement

“Discussion and debate” is explained in SSM in a way that an “accommodation” is reached in a group of people sharing the same concern. This “accommodation” should not be mistaken for “consensus” given that the ideas associated with accommodation and used in SSM to deal with the complexities of human affairs are subtler than those associated with consensus. In other words, the consensus achieved takes the more general form of accommodation. True consensus rarely occurs except for the case of trivial matters or those to which individuals do not have a strong attachment. From a general perspective, different hereditary traits individuals are born with and diverse experiences they gain in the world shape their different worldviews that are reflected in their different opinions. A group seeking to agree on a common decision in response to a problematic situation therefore requires an accommodation or a situation with which everyone gets along [26, 30].

### Step 5: Proposing solutions to facilitating the implementation

Taking action to improve a situation in the real world involves reaching an accommodation through discussion and negotiation (step 4) among different worldviews. Accommodation requires finding a form of the situation that is accepted by different individuals despite their different worldviews. This accommodation leads to creating solutions to improving the situation [26, 27].

#### Step 6: Learning about the implementation process

The inquiry performed in steps 1-5 is considered the principle of “never-ending learning process”. Taking action to improve a situation changes its characteristics in a never-ending manner. The study situation is therefore turned into a new less-problematic situation, and the process including steps 1-4 can be newly started given that learning is endless. According to the study purposeful activity model (Fig. 1), the operational judgment criteria (Step 7), monitoring of all the steps (Step 8) and control measures (Step 9) can be used in every new start.

#### **Data collection**

Given the application of SSM to solving complex problems with different stakeholders, behavioral patterns and cultural traits, the present research collects the data based on the study protocol by using written and electronic sources associated with the subject, observing current activities in the selected hospital, conducting semi-structured interviews with the participants and holding group discussion meetings. Furthermore, purposeful sampling is performed to select the subjects, the specialized texts related to the study and other documents relevant to clinical care delivery in the selected hospital, and continues with snowball sampling through authorities to provide maximum diversity until data saturation is reached. The inclusion criteria comprise awareness and mastery of the subject as well as willingness and possibility to participate in the study. The eligible candidates consist of the hospital managers, heads of clinical and educational departments, matrons, physicians, supervisors, nurses of different wards, para-clinical and information technology departments’ personnel. The researcher also decides on the composition of group discussion meetings based on the conditions of the participants to maximize their participation.

In step 1, the researcher presents to the hospital to observe its current activities, collect data on providing clinical care by the hospital staff and identify the status of clinical care delivery based on CPGs. The researcher in this field acts as a complete observer and each observation of the current activities of the selected hospital lasts about 2 hours. The researcher therefore observes how clinical care is provided and focuses on the status of delivering clinical care. Short field notes taken during the observation will be completed as soon as possible. After receiving informed consent from the participants, the researcher records the conversations and explanations during the observation and then labels and transcribes them immediately.

Semi-structured interviews are conducted with each of the “main stakeholders” in Step 2 to show the “problem conditions”, draw the “rich picture”, present the “root definition” and ultimately develop the “relevant purposeful activity models”. After providing informed consent and deciding on the time and

place of the interviews, the participants are interviewed based on the interview instructions and proper communication with the interviewer. The interviews are recorded and notes taken during and after the interviews to record and collect the data. Each interview lasts about one hour and begins by asking comprehensive and simple questions. The interviews are labeled and transcribed immediately. All the participants are briefed on the study objectives and data collection methods, including voice recording and note taking, assured of the confidentiality of their information and voluntary participation and then asked to complete informed consent forms before being interviewed.

The purposeful activity model is used in the third step to structure the discussion and identify the main axes of change. According to the type and process of the study, the current activities of the selected hospital and recommendations of the hospital authorities, matrons and ward heads, a different composition of participants is selected at this stage for group discussions compared to those already interviewed. After selecting the group members, meetings are held to identify the main axes of change, determine the angles through which the problem should be assessed, develop the purposeful activity system, label the existing problem-related subsystems and prepare for reaching an accommodation among the stakeholders.

Accurate plans are laid to hold group discussion sessions based on the study guideline and the participants are invited in advance. Conversations are recorded during these meetings and notes are taken during and after the meetings. Each meeting begins with comprehensive and simple topics and focuses on specific subjects of the study. Each group discussion session lasts 2-3 hours. The recorded conversations are labeled and the interviews transcribed immediately. The inclusion criteria for the group comprise awareness of the problematic situation and willingness to participate.

In step 4 of this study, group discussion sessions will be held using all the data collected in the previous step to specify feasible and desirable changes and help the individuals involved in the problem and analysts reach an accommodation about a conceptual model. This model will be then compared with the real world, and the analysts and individuals involved in the problem will exchange ideas to determine the changes required for improving the problematic situation.

## **Data analysis**

A qualitative content analysis is performed on all the data obtained in the first step. Their meanings and themes are also extracted after the initial descriptive synthesis. Prolonged engagement is used for repeatedly reading the notes and transcribing the texts to help the researcher establish an in-depth connection with the collected data, recorded conversations and interviews and collected documents. A qualitative content analysis is conducted on the data obtained from the semi-structured interviews transcribed in the second step and the themes are extracted and interpreted. The problem conditions are therefore shown and a rich picture is drawn. In the third stage of the research, a relational or semantic analysis conducted on the themes extracted from the previous steps and group discussions helps identify the main axes of change required for facilitating CPGs implementation. This analysis also helps

achieve the “purposeful activity system”, label the existing problem-related subsystems, create a “root definition” and ultimately propose a “conceptual model”.

In the fourth step, a qualitative content analysis is conducted on all the data collected in the previous steps to “identify feasible and desirable changes”. After performing a descriptive synthesis, the meanings and themes of the data are also extracted. After the individuals involved in the problem and the analysts agree on the conceptual model, these themes are used to compare this model with the real world. The analysts and the individuals involved in the problem exchange ideas at this stage, and its findings, the themes extracted from the previous steps and the findings obtained from a review of literature are descriptively synthesized to help the participants present propositions and agree on the changes required for improving the problematic situation and facilitating the implementation process of CPG. These changes are structural, procedural or behavioral in type. Efforts are made to take an integrated approach to controlling and guiding different study aspects, including (1) methods of data collection and stages of literature review, (2) the questions raised and the notes taken in the interviews and meetings, (3) methods of adjusting and using mental patterns, applying interventions and analyzing the collected data and (4) the findings obtained from each stage. The present study findings can be used to help develop knowledge.

### **Generalities of research in one comment**

This study is conducted mainly to propose solutions to implementing CPGs in a general hospital using SSM. Given the application of SSM to solving complex problems with different stakeholders, behavioral patterns and cultural traits, implementing CPGs is modeled as a perceived very complex problematic situation encompassing conflicting worldviews, which are assumed to constantly form and reform along with thoughts, dialogues and actions of individuals. Implementing CPGs is therefore conceptualized as a purposeful activity model derived from SSM (Figure 1) to achieve the practical goal of CPGs in the selected hospital, i.e. promoting the effectiveness and safety of clinical care and contributing to improvements in the quality of clinical care. The learning gained through repeatedly using SSM is broadened over time, which enables individuals to face future complexities. In other words, teaching the SSM learning cycle to the medical staff of the selected hospital can be considered a strength of the present research.

### **Ethical considerations**

The approval required for performing all the stages of the research and data collection was obtained from the Research Ethics Committee of Islamic Azad University (Code: IR.IAU.SMNAN.REC.1398.005). This code was also discussed and approved in the Research Ethics Committee of a university of medical sciences in the east of Iran (Gonabad University of Medical Sciences). In addition, the participants will be briefed on the study objectives and methods of data collection and recording to respect their voluntary participation and ensure their right to withdraw at their own discretion. They will then be asked to sign written informed consent forms. All the information of the participants will be kept completely confidential and the findings will be analyzed anonymously. The present findings will be open to the

participants upon their request. Efforts will be made to avoid prejudice and minimize the risk of bias by emphasizing the structured steps of the study based on a guideline designed for conducting different steps and interviews.

<sup>a</sup>CATWOE is a mnemonic for Customers, Actors, Transformation process, Worldview, Owner(s), and Environmental

## Discussion

Implementing CPGs in the selected hospital, as in other parts of the world, is affected by many factors. Knowing “what should be done, why and how” is challenging. The development process and methods of using CPGs have been evolved over time by their developers. To reap the benefits of CPGs, their developers and stakeholders are required to revise the publication, implementation and clinical application methods of these guidelines. Given that developing and publishing CPGs do not by themselves result in the application of these guidelines, certain methods appear necessary for their implementation. Despite employing different strategies to implement CPGs so far, no compelling evidence shows their in-field application; nevertheless, existing evidence suggests a systematic implementation can promote the application of CPGs [31].

Implementing evidence-based care and updating and improving healthcare practices are challenging issues given the complexity of healthcare delivery and the significant effect of context on the efforts for implementation and improvement. Flexible multi-dimensional methods of change such as SSM are therefore required for addressing these complexities [32].

Given the hyper-complexity of healthcare caused by the presence of professionals with a diverse range of dynamic interactive worldviews and purposeful individualistic roles, the authors believe that using SSM can be effective in implementing CPGs, elucidating these complexities and addressing the role of technical mechanisms and cultural and political issues in providing clinical care. This methodology is an evolved system approach to tackling complex problems [26, 27]. The present research will help gain an in-depth understanding of the definition and method of implementing CPGs in a general hospital based on system thinking and SSM and using action research. All the complex attitudes, structures, processes and relationships will be also addressed in the context of CPGs implementation in the selected hospital, the purposeful activity systems related to CPGs implementation will be explained and the main axes of change (intervention) identified to determine the measures required for implementing CPGs. The present findings will be published with a focus on “understanding the context and complexity of the effective factors in implementing CPGs”. The authors believe that adopting an attitude of inquiry and dynamically changing the diverse and numerous worldviews of professionals in the accommodation process, which is achieved using SSM, can help produce the knowledge that serves as a model for implementing CPGs for healthcare providers at the macro-system level [33]. In addition, the results of this study can be used at the hospital mesosystem level to facilitate the process of persuading to comply with CPGs and provide benefits for professional healthcare providers. They can therefore improve the quality of clinical decisions

and support quality improvement activities using the learning they gain from utilizing this methodology [34, 35]. More importantly, adopting SSM can enable clinical microsystem actors to face future healthcare complexities by creating repetitive learning loops over time.

The present study will pioneer the application of SSM to facilitate the implementation of CPGs in the health system of Iran. The limitations and challenges of this study are expected to include the issues associated with organizational culture, sources of power, certain backgrounds and attitudes, local facilities and patient preferences; nevertheless, the authors' experience in qualitative research coupled with their application of a flexible methodology will help overcome these berries.

## **Abbreviations**

CPGs: Clinical Practice Guidelines;

SSM: Soft Systems Methodology;

IOM: Institute of Medicine

## **Declarations**

### **Ethics approval and consent to participate**

The approval required for performing all the stages of the research and data collection was obtained from the Research Ethics Committee of Islamic Azad University (Code: IR.IAU.SMNAN.REC.1398.005). This code was also discussed and approved in the Research Ethics Committee of Gonabad University of Medical Sciences.

### **Consent for publication**

Not applicable

### **Availability of data and materials**

Not applicable

### **Competing interests**

The authors declare that they have no competing interests.

### **Funding**

This study protocol has been reviewed and supported by the Islamic Azad University of Semnan, Iran (Research Ethics Committee & Grant No.: IR, IAU.SEMNAN.REC.1398.005). The project is also supported by the Islamic Azad University of Gonabad.

## Authors' contributions

AS and AK conceived of the study. AS, AH, AFM and AK participated at various times in the study design and development, or were involved in selecting the field of study. AS drafted the manuscript. AH, AFM and AK provided feedback for revision of the draft manuscript. All authors read and approved the final manuscript.

## Acknowledgements

This is the study protocol of a PhD research submitted in the Islamic Azad University of Semnan. The authors gratefully acknowledge the Islamic Azad University of Gonabad and all managers and care providers in Allameh Bohlool hospital and Gonabad University of Medical Sciences for their sincere support.

## Authors' information

1. AS holds a Master of Nursing with more than 15 years of experience as a senior manager in the School of Nursing and Midwifery, Gonabad Islamic Azad University; and now is a PhD candidate in Health Services Management at Semnan Islamic Azad University.
2. AH is MD, PhD in Health Services Administration. He is an Assistant Professor in Department of Community Medicine, Hormozgan University of Medical Sciences; and chief of the Hormozgan Province Secretariat for Health Policy. AH is an expert in Clinical Governance, and also practiced SSM for more than 10 years.
3. AFM is an Associate Professor in Nursing and the head of Pediatric and Neonatal Nursing Department in Semnan University of Medical Sciences. AFM is also an expert researcher in both quantitative and qualitative approaches, and has studied on the topics of professional communication and clinical pathway development.
4. AK is MD, PhD in Health Services Administration. He is an Assistant Professor and the Director of Community Medicine Department, School of Medicine, Gonabad University of Medical Sciences. He has more than 7 years of experience as the Director of Teaching Hospitals. AK is also a National Assessor of the Institutional and Hospital Accreditation, granted by the Ministry of Health and Medical Education.

## References

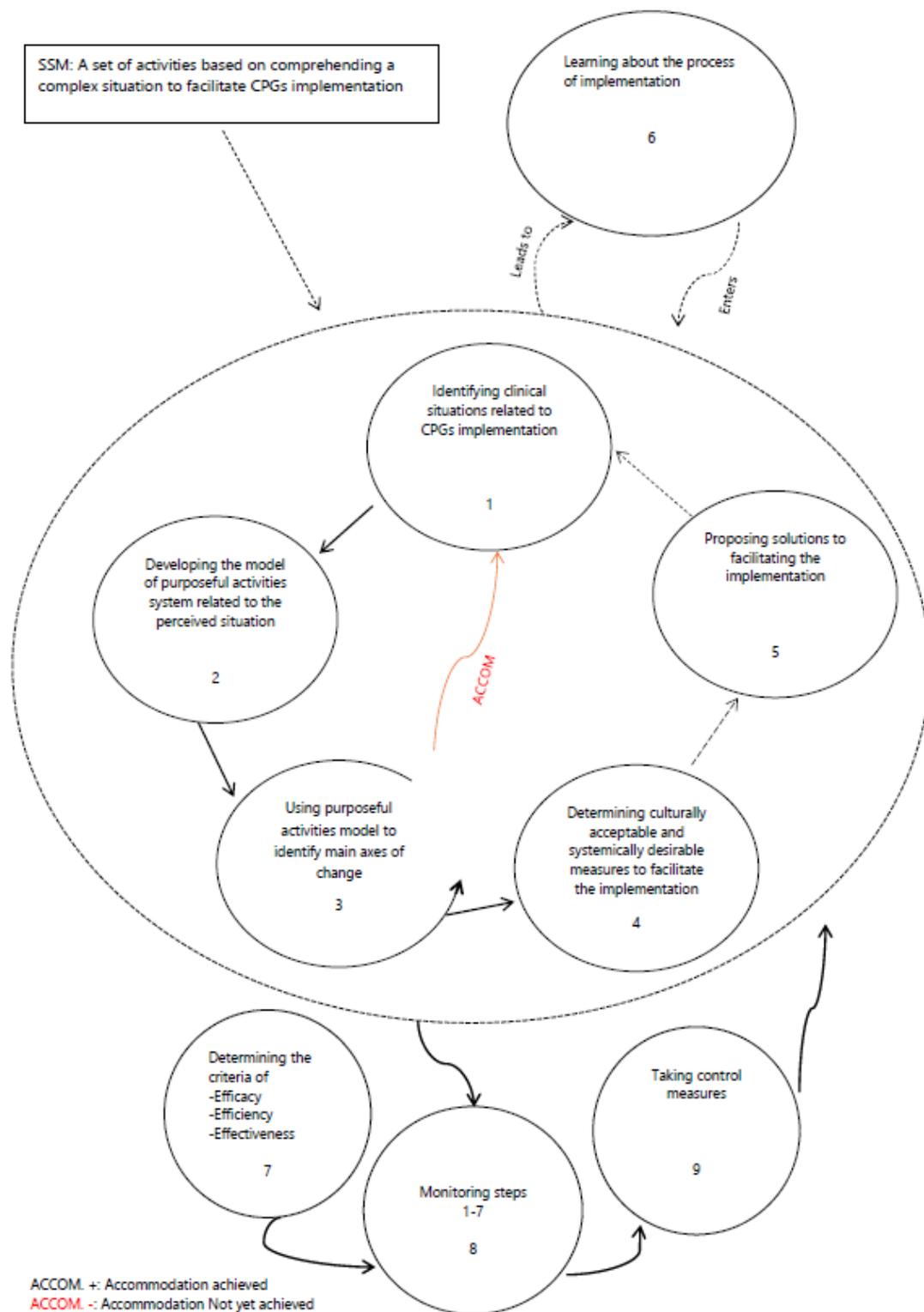
1. Fretheim A, Oxman AD, Havelrud K, Treweek S, Kristoffersen DT, Bjorndal A. Rational prescribing in primary care (RaPP): A cluster randomized trial of a tailored intervention. *PLoS Med.* 2006;3(6):e134; doi: 10.1371/journal.pmed.0030134.
2. Burgers JS, Grol R, Klazinga NS, Mäkelä M, Zaat J. Agree Collaboration. Towards evidence-based clinical practice: an international survey of 18 clinical guideline programs. *Int J Qual Health Care.* 2003;15:31-45; doi: 10.1093/intqhc/15.1.31.

3. Kryworuchko J, Stacey D, Bai N, Graham ID. Twelve years of clinical practice guideline development, dissemination and evaluation in Canada (1994 to 2005). *Implement Sci.* 2009;4:49; doi: 10.1186/1748-5908-4-49.
4. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E. *Clinical practice guidelines we can trust.* Washington DC: National Academies Press; 2011; doi:10.17226/13058.
5. Taba P, Rosenthal M, Habicht H, Tarien H, Mathiesen M, Hill S, et al. Barriers and facilitators to the implementation of clinical practice guidelines: A cross-sectional survey among physicians in Estonia. *BMC Health Serv Res.* 2012;12:455; doi: 10.1186/1472-6963-12-455.
6. Ministry of Health and Medical Education, The Office of Health Technology Assessment, Standard and Tariff, Treatment Deputy. 2021. <https://hetas.behdasht.gov.ir/> Accessed 15 Jan 2021.
7. Rauh S, Arnold D Braga S, Curca R, Eckert R, Fröbe A, et al. Challenge of implementing clinical practice guidelines. Getting ESMO's guidelines even closer to the bedside: introducing the ESMO Practising Oncologists' checklists and knowledge and practice questions. *ESMO Open.* 2018;3(5):e000385; doi: 10.1136/esmoopen-2018-000385.
8. Brozek J, Jankowski M, Placzkiewicz-Jankowska E, Jaeschke R. International Diabetes Federation document concerning postmeal glycemic control: assessment of quality of clinical practice guidelines using AGREE instrument. *Pol Arch Med Wewn.* 2009;119:18-24; doi: 10.20452/pamw.594.
9. Spuls PI, Nast A. Evaluation of and perspectives on guidelines: what is important? *J Invest Dermatol.* 2010;130:2348-9; doi: 10.1038/jid.2010.247.
10. Mathew P, Michelle G, Karen G. The effectiveness of clinical guideline implementation strategies – a synthesis of systematic review findings. *J Eval Clin Pract.* 2008;14(5):888-97; doi: 10.1111/j.1365-2753.2008.01014.x.
11. Bayer G. Clinical practice guidelines: what are they and how should they be disseminated? *Hand Clin.* 2014;30(3):361-5; doi: 10.1016/j.hcl.2014.04.007.
12. da Silva TM, Costa Lda C, Garcia AN, Costa LO. What do physical therapists think about evidencebased practice? A systematic review. *Manual Therapy.* 2015;20:388-401; doi: 10.1016/j.math.2014.10.009.
13. Heyrani A, Maleki M, Barati Marnani A, Ravaghi H, Sedaghat M, Jabbari M, et al. Clinical governance implementation in a selected teaching emergency department: A system approach. *Implement Sci.* 2012;7:84; doi: 10.1186/1748-5908-7-84.
14. Benevides TW, Vause-Earland T, Walsh R. Impact of a Curricular Change on Perceived Knowledge, Skills, and Use of Evidence in Occupational Therapy Practice: A Cohort Study. *Am J Occupational Therapy.* 2015;69:1-9; doi: 10.5014/ajot.2015.018416.
15. Jackson MC. *Systems thinking: Creative holism for managers.* Chichester: John Wiley & Sons, Ltd.; 2003.
16. Reynolds M, Holwell S. *Systems approaches to managing change: A practical guide.* Springer; 2010; doi.org/10.1007/978-1-84882-809-4.

17. Peters DH. The application of systems thinking in health: why use systems thinking?. *Health Res Policy Sys.* 2014 Dec;12(1):1-6; doi: 10.1186/1478-4505-12-51.
18. Checkland P. *Systems thinking, systems practice: A 30-year retrospective.* Chichester: John Wiley & Sons, Ltd., 1999.
19. Berwick DM. The science of improvement. *JAMA.* 2008;299:1182–4; doi: 10.1001/jama.299.10.1182.
20. Vretveit J. Producing useful research about quality improvement. *Int J Health Care Qual Assur.* 2002;15(7):294–302; doi: 10.1108/09526860210448465.
21. Minger J, White L. A review of the recent contribution of systems thinking to operational research and management science. *Eur J Oper Res.* 2010;207:1147–61; doi.org/10.1016/j.ejor.2009.12.019
22. Kalim K, Carson E, Cramp D. An illustration of whole systems thinking. *Health Serv Manage Res.* 2006;19:174–85; doi: 10.1258/095148406777888116.
23. Braithwaite J, Hindle D, Iedema R, Westbrook JI. Introducing soft systems methodology plus (SSM+): why we need it and what it can contribute. *Aust Health Rev.* 2002;25:191–8; doi: 10.1071/ah020191.
24. Campbell M, Katikireddi SV, Hoffmann T, Armstrong R, Waters E, Craig P. TIDieR-PHP: a reporting guideline for population health and policy interventions. *BMJ.* 2018;16:361; doi: 10.1136/bmj.k1079.
25. Sepehrirad R, Rajabzadeh, A. A soft systems methodology approach to occupational cancer control problem: a case study of the ministry of petroleum of Iran. *Syst Pract Action Res.* 2017;30(6):609-626; doi.org/10.1007/s11213-017-9409-8.
26. Checkland P, Poulter J. *Learning for action: a short definitive account of soft systems methodology and its use for practitioner, teachers and students.* United State: Wiley; 2006.
27. Checkland P. *Soft Systems Methodology: A Thirty Year Retrospective.* *Syst Res Behav Sci.* 2000; 17 Suppl 1:11-58.
28. Kotiadis k, Tako AA, Rouwette E, Vasilakis C, Brennan J, Gandhi P. Using a model of the performance measures in Soft Systems Methodology (SSM) to take action: a case study in health care. *Journal of the Operational Research Society.* 2013;64:125–37; doi:10.1057/jors.2012.21
29. Checkland P, Poulter J. *Soft systems methodology.* In: *Systems approaches to managing change: A practical guide.* Reynolds M, Holwell S. (Eds) London: Springer 2010; doi 10.1007/978-1-84882-809-4.
30. Bernardo H, Gaspar A, Antunes C. A combined value focused thinking-soft systems methodology approach to structure decision support for energy performance assessment of school buildings. *Sustainability.* 2018; 10: 2295; doi.org/10.3390/su10072295.
31. Florian F, Kerstin L, Kristina K, Wolfgang G, Alexander K. *Barriers and Strategies in Guideline Implementation—A Scoping Review.* *Healthcare.* 2016; 4(3):36; doi: 10.3390/healthcare4030036.
32. Hanna A, Kate Ch, Jeffrey B. Mapping the use of soft systems methodology for change management in healthcare: A scoping review protocol. *BMJ Open.* 2019;9(4): e026028; doi: 10.1136/bmjopen-2018-026028.

33. Bierbaum M, Rapport F, Arnold G, Easpaig BNG, Lamprell K, Hutchinson K, et al. Clinicians' attitudes and perceived barriers and facilitators to cancer treatment clinical practice guideline adherence: A systematic review of qualitative and quantitative literature, *Implement Sci.* 2020;15:39; doi: 10.1186/s13012-020-00991-3.
34. Amy RV, Della M, Lucie MR, Ravi S, Michelle C, Ajesh G. The effectiveness of guideline implementation strategies in the dental setting: a systematic review. *Implement Sci.* 2019(14):106; doi: 10.1186/s13012-019-0954-7.
35. Shekelle P, Woolf S, Grimshaw JM, Schünemann HJ, Eccles MP. Developing clinical practice guidelines: reviewing, reporting, and publishing guidelines; updating guidelines; and the emerging issues of enhancing guideline implementability and accounting for comorbid conditions in guideline development. *Implement Sci.* 2012;7:62; doi: 10.1186/1748-5908-7-62.

## Figures



**Figure 1**

CPGs implementation in the selected hospital conceptualized as a purposeful activity model

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Addionalfile1TIDieRPHPchecklist.pdf](#)