Guideline-based clinical decision support framework for multimorbidity: a protocol for formulation and testing

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Abstract

Introduction: The burden of multimorbidity is increasing globally, which complicates the use of guidelines in clinical practice and healthcare: practitioners may need to increasingly refer to multiple guidelines with potentially conflicting recommendations. We aim to develop a guideline-based decision support framework for the management of multimorbid patients to help clinicians efficiently evaluate, select and adapt recommendations focusing on the different comorbidities and aspects of multimorbidity.
Methods and analysis: We will conduct the project in the following steps: 1) Confirming the need for the framework; 2) Establishing international working groups (coordination team, evidence support group, consensus group); 3) Conducting literature reviews and original research to formulate an initial draft framework; 4) Consensus process including expert survey and consensus meeting; 5) Formulating and releasing the final framework; and 6) Testing the framework. We plan to complete the project within three years.
Strengths and limitations of this study: This framework will help clinicians from all levels of health care institutions to make decisions in the management of multimorbid patients based on the latest available evidence and reduce potential health risks to their patients. The limitation of this framework is that such a broad framework may not fit all disease combinations or realistic situations so well. To reduce the degree of inapplicability, after completion of the framework, we will continue to monitor its use with regular updates as needed.

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Original Manuscript

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Keywords: Multimorbidity; Comorbidity; Guidelines; Decision Support

Introduction

An increasing number of people, especially the elderly, are suffering from multimorbidity, a situation where the patient has multiple (chronic) conditions at the same time [1]. As a result, multimorbidity is becoming a defining challenge for health systems [2]. Interactions between drugs, interventions and diseases can impair the patients' quality of life and physical functioning [3,4], while healthcare providers also face challenges in managing the increasingly complex health situations of multimorbid patients [5].

Healthcare providers should generally refer to clinical practice guidelines (CPGs) or guideline like documents such as expert consensus statements to ensure that their decisions are based on the latest evidence [6]. In multimorbidity practice, the choice of recommendations becomes, however,

challenging. Due to the complex health situation of the patients, health providers may need to consult a large number of guidelines, including traditional CPGs focusing on the target condition(s) and guidelines related to multimorbidity in a broader sense. Multimorbidity guidelines can further be divided into health-centered guidelines that address the condition and management of multimorbid patients in general, and disease-centered guidelines that address specific diseases and their combinations. Only few health-centered multimorbidity guidelines have so far been published: a systematic search conducted in 2018 identified only eight [7]. Although the use of multiple single-disease guidelines may seem a feasible approach, this approach does not consider the interactions or special conditions related to the co-existence of multiple diseases, and may further lead to potentially hazardous side effects, overtreatment, and high costs [8]. Therefore, in the care of multimorbid patients it is crucial to consider carefully which guideline recommendations are chosen and how they are applied to support clinical decision-making.

Our project aims to develop a guideline-based decision support framework for clinical practice and management of multimorbid patients. The framework will help clinicians evaluate, choose and adapt recommendations from guidelines focusing on the different comorbidities and aspects of multimorbidity efficiently.

Methods and analysis

The framework we plan to develop in this project will be formed as a decision tree. The user will first answer questions related to the setting, patient, target condition/problem(s), and other details, which will lead to various steps to detailed instructions on how to select the recommendations from different guidelines considering also the potential interactions. We plan to conduct the project in the following steps: 1) Confirming the need for the framework; 2) Establishing working groups; 3) Formulating an initial draft framework; 4) Consensus process including expert survey and consensus meeting; 5) Formulating and releasing the final framework; and 6) Testing the framework. The steps of the development process are illustrated in Figure 1, and the proposed schedule is shown in Figure 2.

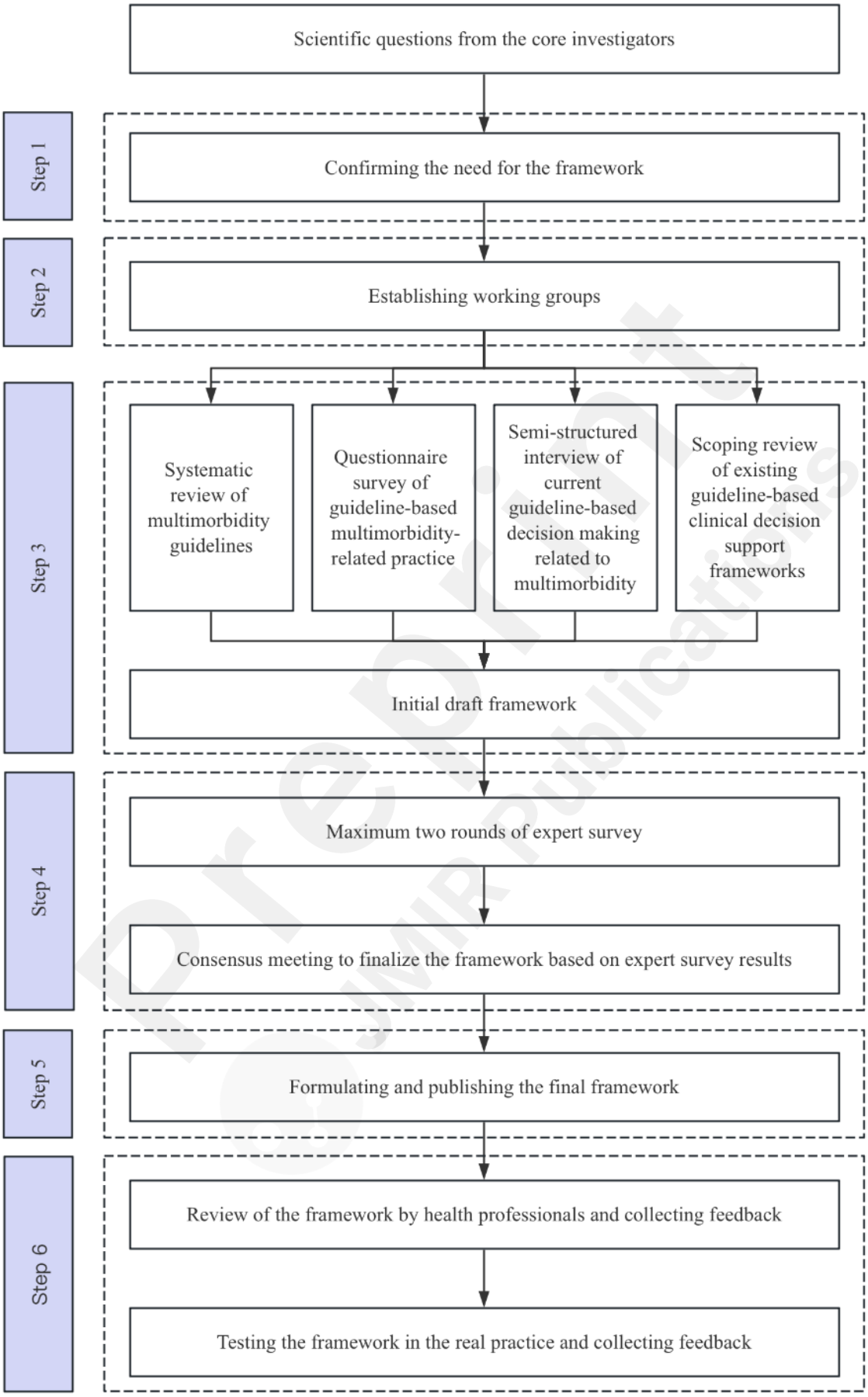

Figure 1 The development process of the framework

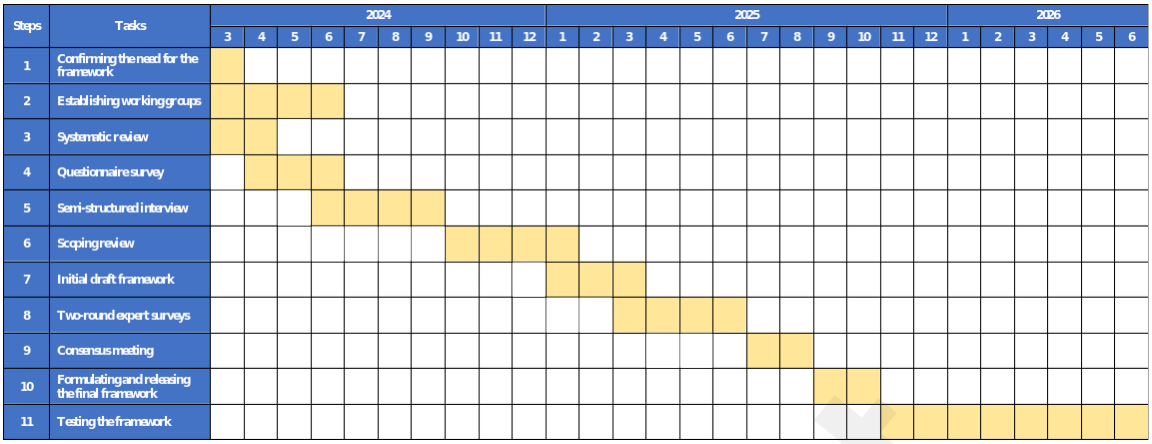

Figure 2 Timeline for the development of framework

Confirming the need for the framework

To identify the need for this new framework, we searched the published literature and documents on improving the use of guidelines in multimorbid practice. We found a limited number of decision-making frameworks for multimorbidity [8-13], but we have various reasons to believe they are not sufficient to comprehensively guide the care of multimorbid patients. First, the aim of all frameworks we identified was to solve problems arising from the use of multiple single-disease guidelines, while multimorbidity guidelines (both disease- and health-centered) were usually ignored. Second, most frameworks were published at least five years ago without being updated thereafter. Third, many of the frameworks focused on the management of comorbidities rather than multimorbidity in general. Although these concepts are closely related, their perspectives are different. The concept of comorbidity includes the idea of focusing on a primary target disease and its interactions with other conditions, whereas multimorbidity refers to the patient's health condition as a whole[14]. Finally, many frameworks were restricted to specific diseases or their combinations, such as type 2 diabetes and hypertension, and their scope of application is thus very narrow. Therefore, in our opinion there is a clear need for a comprehensive decision-making framework that focuses on multimorbidity in the broad sense.

Establishing working groups

Three working groups will be established for this project: the coordination team, the evidence support group and the consensus group.

The coordination team will consist of the three members who initiated the study (ZW, YC, JE). They will lead and coordinate all steps of the project and ensure its timely completion. The coordination team is responsible for forming the initial draft framework with the help of the evidence support group, responding to the suggestions and opinions of experts during the consensus process, revising the framework, and collecting the feedback through testing process of the framework. In addition, they will support the consensus group, and seek advice from external parties when necessary throughout the whole process.

The evidence support group will be composed of five to six members with experience in evidence-based medicine and guideline methodology. This group will support the coordination team in forming the initial draft framework by: 1) systematically gathering, summarizing and/or evaluating the relevant literature and guidelines; and 2) collecting the results of the questionnaire survey and interviews and performing preliminary analyses of the results.

The consensus group will be composed of 20 to 30 experts with experience in multimorbidity research or practice and/or guideline development or methodology. Members of the consensus group

will be recruited worldwide in two ways: 1) through contact networks of the coordination team; and 2) by contacting authors of key articles relevant to the topic. The consensus group will participate in an online survey and consensus meetings, provide their views during the formulation process, and approve the final version of the framework.

Formulate the initial draft framework
The coordination team will formulate the initial draft framework in two steps.

First, the evidence support group will collect data and ideas through a series of studies under the supervision of the coordination team (Table 1): systematic reviews of guidelines, a questionnaire survey, interviews, and a scoping review of existing decision-making frameworks, to set up a pool of key information.

In the second step, the coordination team will discuss the findings based on their own experience to reach consensus on the format of the framework. A draft version of the framework will be built after the discussion.

Table 1 Summary of the studies conducted to collect the pool of key information

Research questions	Study type	Source of information (data or participants)	Methods
What are the characteristics of current multimorbidity guidelines?	Systematic review	1) Health centered multimorbidity guidelines (e.g. guidelines for the care of multimorbid patients regardless of the diseases) 2) Disease centered multimorbidity guidelines (e.g., guidelines for the management of hypertension in combination with other diseases)	Qualitative content analysis
How are guidelines used in multimorbidity-related practice at present?	Questionnaire survey	Individuals with experience in multimorbidity management (particularly frontline workers)	Descriptive analysis, qualitative analysis
What should we pay attention to when making multimorbidity decisions?	Semi-structured interview	Individuals with experience in multimorbidity research (experts, especially guideline developers and methodologists)	Thematic analysis
How do existing guideline-based clinical decision support framework work?	Scoping review	Guideline-based clinical decision support frameworks	Qualitative content analysis

Consensus process and formulation of final checklist

We will first conduct online expert surveys among the consensus team, following a procedure similar to the Delphi process. During the first round of the survey, all members of the consensus group will receive a draft version of the framework. In this draft version, the framework will be shown in two ways: as a decision tree, and as a list of all items from the framework. The participants will anonymously rate each item on a 7-point Likert scale to indicate their level of agreement with the importance of the item to be included in the framework [15]. Free text boxes will be included in the survey to collect comments (both on the overall structure and on each item of the framework) or propose additional items. The scale and definitions of different conclusions are shown in Table 2. Items that achieve agreement are included in the final version and removed from subsequent rounds; items with disagreement are removed from the framework; and items rated as ambivalent will be revised to reflect points raised by the consensus group and included in the next round of survey. In addition, the coordination team may propose some new items based on the free-text comments. All members who participated in the first round are asked to rate the new items and items on which no consensus was reached. Free text boxes will again be available for comments. If there are only few items that need discussion, we may consider to skip the second round and proceed directly to the consensus meeting. After a maximum of two rounds of survey, we will formulate a revised version of the framework which will be discussed in the next step (consensus meeting).

Table 2. The 7-point Likert scale and definitions of consensus

Score	Meaning	Definitions of conclusions regarding consensus
1	Strongly disagree	"Disagreement": More than 80% of the participants choose score 1 to 3
2	Disagree	
3	Somewhat disagree	
4	Neither agree nor disagree (neutral)	"Ambivalent": the conditions for neither "agreement" nor "disagreement" are fulfilled
5	Somewhat agree	
6	Agree	"Agreement": More than 80% of the participants choose score 6 or 7, and there are no major comments suggesting a revision
7	Strongly agree	

We will organize a consensus meeting either online, in person, or in a hybrid format. All members of the coordination team and consensus group will be invited to attend and discuss the revised version of the framework. If online format is chosen, multiple meetings can be arranged to keep the number of attendees on a manageable level to and accommodate participants from different time zones. The meeting(s) will be recorded and transcribed. The coordination team will review all feedback and suggestions given during the meeting(s) and send the final version of the framework together with responses to the main suggestions to the consensus group.

Testing

We will evaluate the practical usability of the framework through two steps of testing. Health professionals from different types of facilities (e.g., hospitals, community health centers, or nursing homes) who commonly manage multimorbid patients and who were not involved in any step of the development (including the surveys and interviews) will be invited to take part. In the first step, we will give an introduction of the framework to the participants, and educate them how to use it. The participants will be asked to comment on the usability and integrity of the framework based on their experience. In the second step, the participants will be asked to use this framework in their daily practice related to multimorbidity management and provide feedback on the applicability and

feasibility of the framework, barriers and facilitators to this process, as well as opportunities that should be explored further to refine the framework. We will collect and compare the feedback from both steps, and form suggestions and directions for future improvements to the framework. The coordination team will continue to meet twice a year to discuss any feedback from users, recent developments in multimorbidity research and policies, and the need of updating the framework.

Discussion

This framework will help clinicians make well-informed decisions in the management of multimorbid patients and thus reduce potential health risks to their patients. The framework is not limited to the selection of recommendations from disease-specific guidelines, but also considers the use of general multimorbidity guidelines. The framework will cover all levels of health care from community facilities and residential homes to referral hospitals. There may be some risk that such a broad framework may not fit all disease combinations or realistic situations so well. To reduce the degree of inapplicability, we will continuously revise the framework based on feedback from users. With the help of different partner institutions across the world we will adapt the framework to the local contexts of different settings, and consider developing extension versions for specific situations where the core framework alone is not sufficient. Ultimately, we hope this framework will lead to a more standardized approach in the care of multimorbid patients in different situations, guiding the way towards a more personalized and patient-centered health care.

Patient and public involvement:

Patients and/or the public were involved in

Ethics and dissemination

The project is approved by the Institute of Health Data Science, Lanzhou University (reference no. HDS-202404-01). The framework will be disseminated through scientific articles and international conferences.

Authors' contributions

Authors ZW, YC and JE advanced the initial idea for the protocol. LW, BW, HH, ZL, DZ, JZ and HZ evaluated the research value of the project with major contribution from LW. ZW and JE drafted the manuscript. All authors have commented on the draft, read and approved the final version.

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Competing interests statement

None declared.

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