المجلس الصحي السعودي
Saudi Health Council

National Center for Evidence Based Medicine

GUIDELINES PRINCIPLES

2022

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National Center for Evidence-Based Medicine Guidelines principles

Background

The Institute of Medicine (IOM) defines clinical practice guidelines as "statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."

Clinical guidelines support complex medical decisions to optimize patient care. When rigorously developed using a transparent, systematic, and unbiased process, and effectively disseminated and implemented for clinical adoption, they have been shown to improve healthcare decisions, and enhance healthcare quality and clinical outcomes.

In Saudi Arabia, over the last few decades, numerous organizations and societies have independently undertaken the task to create clinical guidelines for use by Saudi clinicians. Despite the dedication and hard work of the involved experts, these largely disjointed efforts have been hampered by several factors such as

- Undeclared conflicts of interest within expert panels;
- Lack of involvement of key stakeholder groups such as patients, nurses or allied health professionals;
- Lack of methodological rigor when identifying, assessing, synthesizing, and documenting the underlying evidence base, and for reaching and formulating recommendations;
- Underuse of increasingly sophisticated digital tools for the development of systematic reviews and clinical guidelines;
- Absence of a timely dissemination and implementation strategy;
- Insufficient monitoring of and feedback loop about clinical adoption;
- Lack of appropriate updating of available recommendations driven by new evidence or novel diagnostic or therapeutic interventions.

These issues have resulted in a lack of reliable, clinically credible, accessible, locally applicable, and nationally adopted guidelines, ultimately impacting on the overall healthcare objectives of the Kingdom’s Vision 2030.

National Center for Evidence-Based Medicine

The National Center for Evidence-Based Medicine (NCEBM) was established in 2019 following the Council of Ministers approval No. (14227) in 03/12/1440 H, on the Saudi Health Council Resolution No. (4/79) in 01/07/1439 H. The main objective of the center is to ensure that clinical care is evidence-based and disseminated to all levels of care.

NCEBM aims to guide and promote evidence-based medicine in a scalable, consistent, and responsible manner. NCEBM also intends to reduce care variance and promote accountable care by regularly adapting, creating, aligning, educating, and disseminating clinical practice recommendations. To that end, the center, upon the recommendation of its scientific committee, has launched a program accreditation process to assess whether the guideline is rigorously developed and to help organizations ensure that recommendations are evidence-based and identify truly high-quality guidelines for users.

About this document

This document describes the standards and procedures used by NCEBM in the accreditation of clinical practice guidelines. The standards along with the accreditation procedures, serve as the basis for evaluating the quality of the guideline. Supporting documentations such as the guideline template and conflict of interest policy will be provided separately.

The standards are subject to periodic review and revision and will be published in the NCEBM website.

Accreditation program

A guideline accreditation program aims to ensure that by evaluating the processes used in the development of guidelines through other organizations, the center can ensure consistency in quality and enable easier updating and dissemination. For guideline producers, it provides an opportunity to have a positive impact on the health of the population, and for clinicians the confidence that they will have access to the best available recommendations regardless of their source to help them deliver excellent patient care.

This accreditation process consists of a review and assessment of the guideline using appropriate standards of minimum requirements to which an accredited guideline is held accountable. Guidelines that successfully complete the accreditation program are subsequently eligible for recognition at the center and for dissemination across all levels of care.

Benefits of accreditation

- Accountable and recognized guidelines.
- Use of NCEBM logo in the guideline
- The guideline will be published in the official site of NCEBM and promoted by the saudi health council and the national center of EBM
- Dissemination and implementation of the guideline to all levels of care..
- Third party publication of the guideline in a well-known guideline databases (e.g. G-I-N or NICE databases).

Procedures and process for seeking NCEBM accreditation

1. Registration

Author submit the complete Clinical Practice Guideline (CPG) as MS Word file along with his basic personal information (F1 form) and CPG basic information (F2 form)

2. Guideline review for adherence to principles

National EBM Center reviews the submission to ensure complete adherence to the center principles of the CPG submitted using the Review Form (F3).

If the guideline was not approved, the submission will be returned to the author for revision and resubmission based on the comments.

3. Critical Appraiser review

If the National EBM Center approved the submission, the guideline will move forward to Critical Appraisers (CA) for reviews according to Critical Appraiser Evaluation Form (F4)

National EBM Center aggregate the CAs appraisals and reflect the results

If CA results do not reach the desired score, National EBM Center to review CA comments to be sent to the author for revision and resubmission.

4. Public consultation

If CA results reach the desired score, or the resubmission addressed all CA comments paper will be accepted and move forward to be published for Public Review

Public members complete the public evaluation form (F5) aggregated by the National EBM Center and forward them to the Author for action. Comments to be provided in an action file with sections for author's reply and resubmission.

5. Scientific Committee Review

If Author revisions are deemed adequate by the National EBM Center, the submission moves to the Scientific Committee for their final review and feedback.

If the Scientific Committee does not accept the CPG, the submission is to be rejected.

If the Scientific Committee accepts the CPG with modification, revision comments are sent to the Author for action and resubmission.

6. Approval and Publication

If Scientific Committee accepts the CPG, it will be sent for publication within the NCEBM guideline portal

Guidelines prerequisites

Guidelines should:

1. include a dissemination and implementation plans and tools that make recommendations actionable, decidable, and executable.
2. be developed for national use within Saudi Arabia (not for a specific local context or health service).
3. be presented in a standardized format (refer to **NCEBM guideline template document**) that
    - makes the task of guideline authors more efficient.
    - ensures high-quality standardized guideline reports.
    - optimizes transparency and understanding by end users.

- eases and reinforce the process of review, evaluation and accreditation.
- standardizes web publishing, dissemination.
- enables automated data flow between systems and easy translation into several outputs; such as decision aids, clinical decision support systems, order sets within the electronic medical record, tablets, mobiles, online and as PDFs.
- facilitates continuous updating and adaptation to local settings, thereby minimizing the workload for guideline developers and policymakers.

Guidelines should **NOT** be:

4. developed and issued by individuals who are not officially sponsored or supported by one of the expert organizations (including medical colleges, peak bodies representing medical specialists, medical special interest associations, professional societies, public or private health organizations, non-government agencies).
5. developed, published or funded by industry groups (or organizations whose main source of funding is derived from industry groups) with a financial interest in the guideline clinical area.

National Center for Evidence-Based Medicine Standards

National Center for Evidence-Based Medicine (NCEBM) adheres to the established development standards from the Guidelines International Network (G-I-N) for the development of high-quality and trustworthy guidelines and those guidelines that fulfill these requirements are eligible for NCEBM accreditation. These include:

1. Composition of Guideline Development Group

A guideline development panel should include diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients or other health care consumers.

2. Decision-Making Process

A guideline should describe the process used to reach consensus among the panel members and, if applicable, approval by the sponsoring organization. This process should be established before the start of guideline development.

➔ *The use of formal consensus development methods, such as the Nominal Group Technique or the Delphi method should be applied.*

➔ *Consensus-based recommendations are acceptable only when evidence is weak or lacking.*

3. Conflicts of Interest

A guideline should include disclosure of the financial and nonfinancial conflicts of interest for members of the guideline development group. The guideline should also describe how any identified conflicts were recorded and resolved.

Conflict of Interest Declaration, Assessment, and Publication:

NCEBM has adopted the 9 Guidelines International Network (G-I-N) Principles (**where No. 6 has been modified to our needs and standards)**, and the declaration of interest (DOI) form developed by WHO.

➔ *For full guidance on COI declaration and management, and associated forms, please see **NCEBM COI policy document**.*

G-I-N principles

1. Guideline developers should make all possible efforts to not include members with direct financial or relevant indirect COIs
2. The definition of COI and its management applies to all members of a guideline development group, regardless of the discipline or stakeholders they represent, and this should be determined before a panel is constituted
3. A guideline development group should use standardized forms for disclosure of interests
4. A guideline development group should disclose interests publicly, including all direct financial and indirect COIs, and these should be easily accessible for users of the guideline
5. All members of a guideline development group should declare and update any changes in interests at each meeting of the group and at regular intervals (for example, annually for standing guideline development groups)
6. Chairs of guideline development groups should have no direct financial or relevant indirect COIs **with no exceptions**.
7. Experts with relevant COIs and specific knowledge or expertise may be permitted to participate in discussion of individual topics, but there should be an appropriate balance of opinion among those sought to provide input.
8. No member of the guideline development group deciding about the direction or strength of a recommendation should have a direct financial COI
9. An oversight committee should be responsible for developing and implementing rules related to COIs.

At least two weeks before the project kicks off, all members of the Task Force and Guideline Support team declare any relevant Conflicts of Interest (COIs) from the previous 4 years using a Declaration of Interest (DOI) form customized from the form used by the WHO (appendix 1).

Declarations cover direct (financial) and indirect (non-financial) conflicts relevant to the guideline topic up to agreed thresholds. Signed and dated declarations are collected in electronic or paper format and stored securely in line with international best practice and local data retention, confidentiality and security guidance for a defined period after the end of the guideline development process.

Declared conflicts of interest are assessed by a Responsible Officer according to the WHO assessment steps to ensure that only participants without conflicts vote on related recommendations.

Conflicts of interest are read out at the beginning of each task force meeting and checked for updates. A summary of all declarations and actions taken to manage any declared interests are published in resulting reports and work products.

Summary assessment of conflicts of interest completed by each member of the development group, as well as the decision reached by leaders should be presented in the guideline document according to the following table

Name	Role in the guideline	A. Specific and/ or nonspecific personal financial interest	B. Specific and/ or nonspecific non-personal financial interest	C. Personal non-financial interest	D. Specific and/ or nonspecific personal financial interest of a family member	Any other circumstances that could affect your objectivity or independence in the process?

- **Specific interest** relates to an item under consideration. This will be clearly defined and communicated in advance e.g. an item on the meeting's agenda.
- **Non-specific interest** relates to an interest that is not under discussion.
- **Personal financial interest** is when there is or may be opportunity for personal financial gain or financial gain to an immediate family member. Examples include: being a recipient of payment, fees or shareholdings.
- **Personal non-financial interest** is when a person has published an opinion or an academic paper on matters under consideration by the sponsoring body.
- **Non-personal financial interest** relates to the organization in which the person is employed being in receipt of payment or benefit including commissioned research contracts.

4. Scope of a Guideline

A guideline should specify its objective(s) and scope.

5. Methods

A guideline should clearly describe the methods used for the guideline development in detail.

6. Evidence Reviews

Guideline developers should use systematic evidence review methods to identify and evaluate evidence related to the guideline topic.

7. Guideline Recommendations

A guideline recommendation should be clearly stated and based on scientific evidence of benefits; harms; and, if possible, costs.

8. Rating of Evidence and Recommendations

A guideline should use a rating system to communicate the quality and reliability of both the evidence and the strength of its recommendations.

9. Peer Review and Stakeholder Consultations

Review by external stakeholders should be conducted before guideline publication.

Public consultation will be conducted during the accreditation process by the center.

The comments and suggestions of the review group should be applied, either by modifying the guideline or by giving reasons why they were discarded.

Authors name, affiliation, comments and the response of the development group should be included in the report according to the following table

Expert name	Expert affiliation	Expert Comments	Response of the development group

10. Guideline Expiration and Updating

A guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.

11. Financial Support and Sponsoring Organization

A guideline should disclose financial support for the development of both the evidence review as well as the guideline recommendations.

Methodology approaches accepted by the center

The first obstacle to creating the center is the lack of trust in guidelines. Therefore, the center highly recommends the adaptation and development of guidelines on rigorous, unbiased methods using the GRADE system, with a mechanism to ensure the participation of system stakeholders.

The center will accept the following methodology approaches for developing clinical practice guidelines:

- De novo development of new clinical guidelines using GRADE methodology.
- GRADE-ADOLOPMENT approach .
- The ADAPTE framework.
- KSU-modified-ADAPTE.
- Other methodeologies that adhere to the G-I-N principles.

Guideline adaptation

Regardless of the process, a high-quality adapted guideline should adhere to the evidence of the original guideline while at the same time reflect the modifications required for the adapting country.

Evidence quality is reported, preferably using a standard quality-appraisal methodology (eg, GRADE, Cochrane Risk of Bias, Effective Public Health Practice Project Quality Assessment Tool).

Source guidelines must provide the necessary details about the judgments that a guideline panel makes when formulating recommendations. Thus, proper adoption or adaptation of recommendations requires a transparent description of the processes used by the original guidelines, including the methodology used and how conflicts of interest were managed.

Handling expert input: expert opinion is not evidence per se and should not be used as evidence; rather, experience or observations that support expert opinions should be described, identified and, if possible, appraised in a systematic and transparent way, e.g. in the conceptual framework.

Selection criteria

To identify guidelines that may be suitable for adaptation, the following inclusion and exclusion criteria must be added

- Guidelines that use the GRADE methodology
- Guidelines published or updated in the last 3 years

Guidelines quality evaluation

The guideline should be independently evaluated according to the AGREE tool by at least two members of the development group (preferably four), who should have received prior training on the use of this instrument. Once the evaluation of the retrieved guidelines is complete, any existing discrepancies must be recognized and sources evaluated. Any disagreements must be resolved so that the guideline can be generally appraised as recommended or not recommended.

If a retrieved guideline is intended to be used as a source of evidence, its standardized score should exceed 60% in ≥ 4 AGREE-II domains while the scores of the remaining domains must be ≥ 30% and >60% for the domain rigor of development with an overall appraisal of “recommended”.

Deciding which guideline can be adapted

The guideline to be adapted will be selected by informal consensus with the full participation of the development group. To reach this consensus, it is desirable to use a decision matrix that will serve as a basis and help guide and focus the discussion.

The most relevant aspects for each guideline evaluated should be included in this matrix, and the group should identify and define the most appropriate guideline, based on local needs and context.

It must be determined whether or not each selected guideline meets the following criteria:

- Consistency with the proposed guideline’s scope and objectives;
- The degree to which it answers the guideline’s questions,
- Recommendation based on the AGREE II quality rating;
- Availability of search strategies;
- Language; and
- availability of GRADE evidence profiles.

Using this information, the GDG members will reach an agreement on which guideline or guidelines could be adapted. It is recommended that a maximum of two complementary guidelines be used.

Example of decision matrix:

Preselected guideline	Consistent with scope and objectives of the proposed CPG?	Answers questions of the proposed guideline	AGREE II rating	Availability of search strategy	Language	Availability of GRADE evidence tables	Final GDG Decision
CPG 1	No	Partially	Recommended	Yes	English	No	No
CPG 2	Yes	Yes	Recommended	Yes	Spanish	Yes	Yes

The guideline to be developed should contain a summary of the process that led to selection of the guideline to be adapted.

Authorization of the adapted guidelines

The institution that developed the guideline authorizes its adaptation. The development group should contact the institution that developed the original guideline to be adapted or the entity that owns the copyright (for example, publishers or development groups) to request authorization to begin the adaptation process. Partial or full permission may be requested.

Guidelines should pass AGREE II tool assessment

The guideline will undergo critical appraisal with AGREE II and should pass the following criteria:

- standardized score should exceed 60% in ≥ 4 AGREE-II domains while the scores of the remaining domains must be ≥ 30% and >60% for the domain rigor of development with an overall appraisal of “recommended”.

Appendix 1. NCEBM Declaration of Interest Form

Adapted from WHO DOI Form - https://www.who.int/about/ethics/doi-form-EN.pdf?ua=1

DECLARATION OF INTERESTS

The work of NCEBM requires the assistance of experts who may have interests related to their expertise. To ensure the highest integrity and public confidence in its activities, NCEBM requires that experts disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved.

All experts must disclose any circumstances that could represent a potential conflict of interest (i.e., any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). You must disclose on this Declaration of Interest (DOI) form any financial, professional or other interest relevant to the subject of the work or meeting in which you have been asked to participate in or contribute towards and any interest that could be affected by the outcome of the meeting or work. You must also declare relevant interests of your immediate family members (see definition below) and, if you are aware of it, relevant interests of other parties with whom you have substantial common interests and which may be perceived as unduly influencing your judgment (e.g., employer, close professional associates, administrative unit or department). Please note that not fully completing and disclosing all relevant information on this form may, depending on the circumstances, lead NCEBM to decide not to appoint you to NCEBM functions in the future.

Please complete this form and submit it to the GAB if possible, at least 4 weeks but no later than 2 weeks before the first guideline meeting. All experts must complete this form before participation in meetings or work can be confirmed. You must also promptly inform the GAB if there is any change in this information prior to, or during the meeting or work. Please note that depending on the circumstances, not fully completing and disclosing all relevant information on this form may lead the NCEBM to decide not to appoint you to NCEBM functions in the future.

Answering "Yes" to a question on this form does not automatically disqualify you or limit your participation in meetings or work. Your answers will be reviewed by the GAB to determine whether you have a conflict of interest relevant to the subject at hand. One of the outcomes listed in the next paragraph can occur depending on the circumstances (e.g., nature and magnitude of the interest, timeframe, and duration of the interest).

The GAB may conclude that no potential conflict exists or that the interest is irrelevant or insignificant. If, however, a declared interest is determined to be potentially or clearly significant, one or more of the following three measures for managing the conflict of interest may be applied. The GAB (i) allows full participation, with public disclosure of your interest; (ii) mandates partial exclusion (i.e., you will be excluded from that portion of the meeting or work related to the declared interest and from the corresponding decision making process); or (iii) mandates total exclusion (i.e., you will not be able to participate in any part of the meeting or work).

All potentially significant interests will be disclosed to the other participants at the start of the activity and you will be asked if there have been any changes. A summary of all declarations and actions

taken to manage any declared interests will be published in resulting reports and work products. Furthermore, if the objectivity of the work or meeting in which you are involved is subsequently questioned, the contents of your Declaration of Interest form may be made available by the GAB to persons outside NCEBM if the NCEBM Lead considers such disclosure to be in the best interest of the NCEBM, after consulting with you. Completing this Declaration of Interest form means that you agree to these conditions.

If you are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, you must disclose that a conflict of interest may exist and the GAB may decide that you be totally recused from the meeting or work concerned, after consulting with you.

Name: Institution: Email:

Date and title of meeting or work, including description of subject matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached by the organizer of the activity):

Please answer each of the questions below. If the answer to any of the questions is "yes", briefly describe the circumstances on the last page of the form.

The term "you" refers to yourself and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your children). "Commercial entity" includes any commercial business, an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related to the subject of the meeting or work. "Organization" includes a governmental, international or non-profit organization. "Meeting" includes a series or cycle of meetings.

NCEBM DECLARATION OF INTERESTS FORM		Yes	No
EMPLOYMENT AND CONSULTING Within the past 4 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work?			
1a	Employment	•	•
1b	Consulting, including service as a technical or other advisor	•	•
RESEARCH SUPPORT *Within the past 4 years, have you or has your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work?*			
2a	Research support, including grants, collaborations, sponsorships, and other funding	•	•
2b	Non-monetary support valued at more than US $1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.) Support (including honoraria) for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with an interest related to the subject of the meeting or work?	•	•
INVESTMENT INTERESTS *Do you have current investments (valued at more than US $5 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified and on which you exercise no control.*			
3a	Stocks, bonds, stock options, other securities (e.g., short sales)	•	•
3b	Commercial business interests (e.g., proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company)	•	•
INTELLECTUAL PROPERTY *Do you have any intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?*			
4a	Patents, trademarks, or copyrights (including pending applications)	•	•
4b	Proprietary know-how in a substance, technology or process	•	•

PUBLIC STATEMENTS AND POSITIONS (during the past 3 years)			
5a	As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization?	•	•
5b	Have you held an office or other position, paid or unpaid, where you represented interests or defended a position related to the subject of the meeting or work?	•	•
ADDITIONAL INFORMATION			
6a	If not already disclosed above, have you worked for the competitor of a product that is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a personal, professional, financial or business competitive advantage?	•	•
6b	To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)?	•	•
6c	Excluding NCEBM, has any person or entity paid or contributed towards your travel costs in connection with this meeting or work?	•	•
6d	Have you received any payments (other than for travel costs) or honoraria for speaking publicly on the subject of this meeting or work?	•	•
6e	Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence?	•	•

EXPLANATION OF "YES" RESPONSES: If the answer to any of the above questions is **"yes", check above and briefly describe the circumstances on this page. If you do not describe the nature of an interest or if you do not provide the amount or value involved where relevant, the conflict will be assumed to be significant.**

Nos. 1 - 4: Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) and basic descriptive details.	Name of company, organization, or institution	Belongs to you, a family member, employer, research unit or other?	Amount of income or value of interest (if not disclosed, is assumed to be significant)	Current interest (or year ceased)
Nos. 5-6: Describe the subject, specific circumstances, parties involved, time frame and other relevant details				

CONSENT TO DISCLOSURE. By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product.

DECLARATION. I hereby declare on my honor that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the responsible staff of NCEBM and complete a new declaration of interests form that describes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

Date: _____ Signature_____