المجلس الصحي السعودي
Saudi Health Council

NATIONAL CENTER FOR EVIDENCE BASED MEDICINE

National Clinical Guidelines Basic Requirements

(V.1 – 2022)

shc.gov.sa

About This Document

This document describes the basic requirements of the National Center for Evidence Based Medicine (NCEBM) for the accreditation of clinical practice guidelines, it applies also to public health guidelines. The requirements along with the accreditation procedures, serve as the basis for evaluating the quality of the guideline.

These requirements are subject to periodic review and will be published in the SHC website.

National Clinical Guidelines Basic Requirements (V.1 - 2022)

The following sections must be included in the clinical guidelines and the requirements for each section are provided below.

- ☐ ESSENTIAL INFORMATION
- ☐ SCOPE
- ☐ GUIDELINE GROUP
- ☐ DECLARATION OF INTEREST
- ☐ METHODOLOGY
- ☐ RECOMMENDATIONS
- ☐ APPLICABILITY
- ☐ MONITORING
- ☐ EXTERNAL REVIEW
- ☐ UPDATE
- ☐ REFERENCES
- ☐ APPENDIX

ESSENTIAL INFORMATION

Fill in the **"Essential Information"** form. (***Appendix A***)

SCOPE

Purpose

State the overall purpose of the guideline using a structured format, preferably PICO (or PIPOH: Population, Intervention, Professionals, Outcomes, Health care Setting) format:

- Target Population (age, gender, inpatient or outpatient, stage and severity of disease… etc)
- Intervention (medication, test, program… etc)
- Comparator related to either no intervention or another intervention
- Outcome: specified health outcomes, preferably Patient-Oriented Evidence that Matters, like: improved morbidity, improved mortality, reduced cost, quality of life… etc.

Guideline Questions

List the guideline question/s that will be related to the recommendations. Details on the target population, intervention, and comparator should be part of the guideline question.

GUIDELINE GROUP

Panel

A team of experts in all relevant aspects of the topic. They are actively involved in formulating guideline questions, judging research evidence and finalizing and writing recommendations. The panel must have a chair and co-chair.

Stakeholders

Their role is to support the suitability of evidence and applicability of recommendations. They are not part of the voting process on recommendations with the panel members.

Patient representative is the most critical requirement, and target users as well. It is recommended where possible to involve any other representatives from either health or non-health sectors who are involved in the topic of the guideline.
Supportive Team It is the team that support the work of the panel during the guideline development stages to make a more informative decision. They are not part of the voting process on recommendations with the panel members. The members may include at least a medical writer; and a research methodologist and/or statistician. Preferably to have a basic knowledge of evidence-based medicine. Others are recommended to be included as well, like experts for example in a topic outside the scope of the panel members (e.g. economist).
Fill in the **"Guideline Group Information"** form. (***Appendix B***)

DECLARATION OF INTEREST

The declaration of interest information of all potential conflicts of interests is required by all members involved in the guideline, including the external reviewers, and how it was managed when present.
It should be conducted before starting the work.
Fill in the "**NCEBM Declaration of Interest"** form. (***Appendix C***)

METHODOLOGY

Provide details of the methodology used for evidence selection and the formulation of recommendations. This Involves the following:

1. Evidence Review Question/s

- Target Population details (age, gender, stage and severity of disease… etc)
- Intervention (medication, test, program… etc)
- Comparator related to either no intervention or another intervention
- Outcome: The "specified" health outcomes, preferably Patient-Oriented Evidence that Matters, like: improved morbidity, improved mortality, reduced cost, quality of life… etc.

- Setting: specify the targeted settings, like: health Care Settings (primary, secondary, tertiary), community…etc

2. **Methodology and Comprehensiveness of Literature Search, Appraisal and Selection of Evidence**
3. **Methodology for Reporting of Decisions and Recommendations**
4. **Risk of bias consideration**
5. **Benefits and harms of each intervention are quantitatively &/or qualitatively described.**

RECOMMENDATIONS

Recommendations should clearly provide an answer to the question/s provided in the scope section. Certainty of evidence and strength of recommendations should be considered as well. Indicate the type of each recommendation whether adopted, adapted or new.

APPLICABILITY

Make sure the recommendations are applicable within the local context, considering all types of facilitators and barriers, including:

1. Patient preferences
2. Social acceptability
3. Compatible with the health care system
4. Compatible with the Saudi FDA registration list of devices, medications, and other medical products. Unless, the evidence supports the efficacy of the unregistered intervention over the registered.
5. Compatible with CEBAHI standards
6. Cost effectiveness

MONITORING

Provide quality KPIs for assessing the impact of implementing the recommendations.

EXTERNAL REVIEW

A peer review by experts with scientific and clinical experience directly related to the guideline topic.
Additional review by other stakeholders including patients is preferred.
External review comments should be provided in the appendix and how it has been resolved.
Their consent to include their names in the guideline is required.
Fill in the **"Guideline Group Information"** form. (***Appendix B***)

UPDATE

Provide the suggested timeliness to update the guideline and process.

REFERENCES

Provide references for every information, evidence or methodological approach…etc included in the guideline. Its preferable to use APA or Vancouver style format.

APPENDIX

Any document that support the work made to develop the guideline should be included in this section, but the required documents are:

1. Search strategy (databases/registries, period, key words, inclusion/exclusion criteria)
2. Any methodology-related output
3. Declaration of interests forms

APPENDIX

Appendix A

Essential Information

Essential Information	
Title of CPG	*Specify in the title if the guideline is adapted.*
CPG Sources	*List the CPGs used to develop this CPG.*
Producing Body	
Contact Information	
Year of Publication	
Type of CPG	☐ New CPG (de Novo) ☐ Adapted ☐ Combination
Reason for Developing the CPG	☐ de Novo (No available trustworthy or valid guideline for the health issue) ☐ Guideline Update ☐ Current Guidelines are not adaptable or adoptable ☐ High Prevalence ☐ High Morbidity ☐ High Mortality ☐ Cost/Financial Implications ☐ Variation in clinical practice ☐ Emerging disease/health issue ☐ Rapidly changing or practice-changing evidence ☐ Others: (Please Specify) ……
Target Users	☐ Physicians (please specify)…… ☐ Nurses (please specify)…… ☐ other Healthcare providers (please specify)…… ☐ Patients ☐ Policy makers ☐ Public ☐ Others: (Please Specify)……

Appendix B

Guideline Group Information

GUIDELINE GROUP INFORMATION - PANEL			
MEMBER NAME	**SPECIALITY**	**AFFILIATION**	**ROLE**

GUIDELINE GROUP INFORMATION - STAKEHOLDERS			
MEMBER NAME	**SPECIALITY**	**AFFILIATION**	**ROLE**

GUIDELINE GROUP INFORMATION – SUPPORTIVE TEAM			
MEMBER NAME	**SPECIALITY**	**AFFILIATION**	**ROLE**

GUIDELINE GROUP INFORMATION – EXTERNAL REVIEWERS			
MEMBER NAME	**SPECIALITY**	**AFFILIATION**	**ROLE**

Appendix C

NCEBM DECLARATION OF INTERESTS 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_____

SAUDI HEALTH COUNCIL

NATIONAL CENTER FOR EVIDENCE BASED MEDICINE

NCEBM@SHC.GOV.SA