المجلس الصحي السعودي
Saudi Health Council

# SAUDI HEALTH COUNCIL
# NATIONAL CENTER FOR EVIDENCE BASED HEALTH PRACTICE
## CLINICAL PRACTICE GUIDELINES BOOKLET

# Table of Contents

# Introduction:

**This booklet contains tools and template for adaptation/adoption of Clinical Practice Guidelines (CPGs). These forms have been collected after careful consideration of the best available evidence from several international sources in order to facilitate the production of clinical practice guidelines for all healthcare practitioners in Saudi Arabia.**

The National Centre for Evidence-based Healthcare,
Saudi Health Council

## The following sections includes step by step process of CPG adaptation:

The method was prepared and summarized by the National Center for Evidence Based Health Practice (NCEBHP) at the Saudi Health Council (SHC). This standardized process methodology is based on The ADAPTE Collaboration (2009): The ADAPTE Process: Resource Toolkit for Guideline Adaptation. Version 2.0
(https://www.g-i-n.net/document-store/working-groups-documents/adaptation/adapte-resource-toolkit-guideline-adaptation-2-0.pdf/view)

## 1. CPG Adaptation/adoption process

This process is divided into three phases (Set Up, Adaptation and Finalization); each phase with several modules, steps and tools. The whole process includes 23 steps including the followings:

### 1.Phase One - Set Up (1 Module, 7 Steps): Preparation module:

**Step1: Approach from a national (scientific society/ organizations/university or research center).**

After approval of accepting the CPG adaptation, a memorandum of understanding will be prepared, completed and signed between the local national body and the National Center of Evidence Based Health Practice at the Saudi Health Council.

**Step2: Establish national multidiscipline expert group (Task Force):**

a. A representor from the national body and the director of the NCEBHP will officially nominate the members of the multidiscipline experts group (Task Force).
Members of the task force should have Clinical knowledge in the topic area.

b. Members of the task force will be recruited as per regulations of The Saudi Health Council. Therefore, they will send their CV, National ID and IBAN to the NCEBHP center.

c. The first meeting, the task force will sign their contract and conflict of interest form (Form8, page 24)

d. The NCEBHP will deliver a training on the method of CPG adaptation.

**Step 3: Check whether adaptation is feasible:**
**Search for any published CPGs for the selected topic using the following basic list of online CPGs databases that have been made possible through:**

a. Guidelines International Network (G-I-N) http://www.g-i-n.net

b. EBSCO – DynaMed, https://dynamed.ebscohost.com/

c. US National Library of Medicine, National Institutes of Health (PubMed)
http://www.ncbi.nlm.nih.gov/pubmed

d. Trip database https://www.tripdatabase.com/

e. Agency for Healthcare Research and Quality https://www.ahrq.gov/gam/index.html

f. Emergency Care Research Institute https://www.ecri.org/

g. Google Scholar (free) http://scholar.google.com/
In addition, CPGs that are published by national and international specialized scientific societies/ associations relevant to the topic of the CPG.

### Step 4. Identify necessary resources and skills

**In addition to ensuring that there are existing guidelines to support adaptation, there need to be sufficient resources to complete the process, resources that include the following:**
**a. Commitment by the panel members to at least one face-to-face meeting and to conference calls**
**b. Commitment by the panel members, outside of meetings, to review all documents**
**c. Coverage of meeting costs**
**d. Possible honorariums for panel members to cover the time spent appraising guidelines**
**e. Availability of project management personnel and administrative support for guideline collection, storage documentation; and meeting coordination**
**f. Coverage of the costs of implementing the guideline (if relevant).**

### Step 5: Select included CPGs:

**Examples of inclusion criteria for selection of high priority health topics for CPGs:**
**a. Existence of relevant good quality Evidence-based (EB) CPGs.**
**b. Prevalence of the condition (common conditions/ diseases/ diagnoses presented by patients)**
**c. Existence of underuse, overuse or misuse of intervention.**
**d. Existence of practice variation (according to baseline data on the current practice)**
**e. Costs associated with different practice options (if available).**
**f. The likelihood that the CPG will be effective in influencing practice.**
**g. The potential for improving quality of care and/or patient outcomes.**
**h. CPGs also could be recommended by different taskforce members, National Scientific Societies organizations and other regulatory bodies based on their needs of having an evidence-based CPG.**

### Step 6: Complete tasks for Set-Up Phase:

**a. Terms of reference (TOR): scope of work, registration in the AGREE website, time commitment required and meeting schedule.**
**b. Consensus process: how the panel will manage decisions (e.g. through either a formal or informal consensus process).**
**c. Guideline authorship: for each specific CPG topic, the draft and the final adapted CPG will be written by the task force member and reviewed by the center with regards of methodological content and the process to insure high quality of the production and the drafting of the CPG.**
**d. The principles and order of authorship will be agreed upon.**
**e. Dissemination and implementation Strategies will be discussed.**

### Step 7: Write Adaptation Work Plan.

**At the completion of the preliminary phase, the taskforce should agree about a plan that outlines the adaptation process to be followed. The formalized plan might include the following headings:**

- **Introduction**
- **Taskforce members, roles, credentials, and declarations of conflicts of interest**
- **Modules to be followed**
- **Timeline for completion of the adaptation process and committed target date for completion including meeting schedule**
- **Funding source(s) if available.**

**Throughout the process, each decision taken by the taskforce should be well documented to make the process transparent. A person- taskforce coordinator- needs to be identified to manage and communicate this plan to all panel members.**

## ii. Phase Two - Adaptation (5 Modules, 11 Steps):

### 1. Scope and Purpose Module

### Step 8: Determine the Health Questions (PIPOH Model page 11):

**The following five PIPOH items will be used for identifying the needed health question(s) and its relevant aspects:**

**Patient population (P): the characteristics of disease/ condition.**
**Intervention (I): e.g. screening, diagnosis, treatment, or management.**
**Professionals (P): target users of the CPG (clinical specialty, table4, page 13)**
**Outcomes (O): patient outcomes, system outcomes, and/or public health outcomes**
**Healthcare setting (H): the setting/ context in which the CPG will be implemented.**

### 2. Search and Screen Module

### Step 9: Screen retrieved CPGs

**Inclusion/ Exclusion CPGs Selection Criteria checklist including methodology of development authorship, country, date of publication, language, and CPG status**

### Step 10: Reduce a large number of retrieved CPGs.

**Whenever the CPG taskforce decides to reduce the number of retrieved source CPGs, the PIPOH inclusion/exclusion criteria, and AGREE II instrument will be used for final approval.**

### 3. Assessment Module (5 assessments)

### Step 11: Assess guideline quality: By utilizing the AGREE II instrument page16:

**https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf**

**At least two to four assessors/ appraisers will be assigned for each included CPG. The AGREE II instrument includes 23 questions organized in 6 domains. The AGREE criteria include all the standards for high quality CPGs.**

**Step 12: Assess guideline currency:**

**By checking the publication date or the period covered by the evidence, to ensure that the most current CPG documents have been included.**

**Step 13: Assess guideline content:**

**If the selected CPGs are more than one their assessment can be done by creating 'Recommendation matrices' from the CPGs under review. These matrices can be used by the taskforce for decision making by comparing, identifying, and discussing recommendations. The taskforce can decide not to utilize it if only one CPG is selected (optional step).**

**Step 14: Assess guideline consistency:**

**This include evaluation of search strategy and selection of evidence supporting the recommendations and evaluation of the consistency between selected evidence its interpretation and resulting recommendations. The taskforce can decide not to utilize it if it relies on AGREE II scores of Domain 3 (optional step).**

**Step 15: Assess acceptability and applicability of recommendations:**

**(The taskforce can decide not to utilize it if it relies on AGREE II scores of Domains 2 and 5).**

**4. Decision and Selection Module**

**Step 16: Review assessments:**

**The results of the assessment module provide an explicit basis for informed and transparent decision making around the selection and modifications of source guidelines.**

**Step 17: Select between CPGs and recommendations to create an adapted/ adopted CPG:**

**If the CPGs taskforce lacks the skills for proper handling of evidence and systematically formulating the recommendations, then the method should be direct adoption of the selected CPG and therefore the process of decision making and selection should be then around only two options either reject the whole CPG or Accept the whole CPG and all of its recommendations. And in case of any needed recommendations or practice parameters that are essential for completeness of the CPG, continuity of care and positive patient outcomes are not presented in the body of recommendations of the selected source CPG; the taskforce team could decide to include them as a Good Practice Point (GPP) that is consensus/expert-based or in a separate paragraph section from the adopted recommendations.**

**5. Customization Module**

**Step 18: Prepare draft adapted/ adopted CPG document: The Adapted CPG template.**

**Once the taskforce has reached a decision on the content of the adapted guideline, a draft document will be produced that should include details on the process followed.**

**iii. Phase Three – Finalization (3 Modules, 6 steps)**

**1. External Review and Acknowledgment Module:**

**Step 19: External review by target users of the CPGs:**

**The reviewer(s) will use the External review panel form below (section 1.4 & 1.5).**

**Step 20: Consult with endorsement bodies:**

**All relevant Clinical Departments and if possible relevant Specialized Saudi Society (Association) and the Guidelines International Network.**

**Step 21: Consult with source CPG developers:**

**The CPG adaptation group will communicate with the developers of the source CPG to seek their permission with a deadline to respond within 2-3 weeks otherwise the group will consider that they approved in order not to significantly delay the process. These communications should be clearly documented in the acknowledgment section with the date of the sent email and the response (if applicable).**

**Step 22: Acknowledge source documents:**

**All documents used should be referenced in the final document.**

**2. Aftercare planning Module:**

**Step 23: Plan for aftercare of the adapted CPG:**

**A process for update/ review is included in each CPG document which is average after 3-5 years of the issue date except if any new evidence-based recommendations or update of the source CPG is accessible before that designated date.**

**3. Final production Module:**

**Step 24: Produce high quality final adapted CPG full document:**

**since a high quality CPG is one that leads to improved outcomes for patients, it is recommended to design an action plan for future dissemination, implementation and evaluation of the CPG and include it in the adapted CPG.**

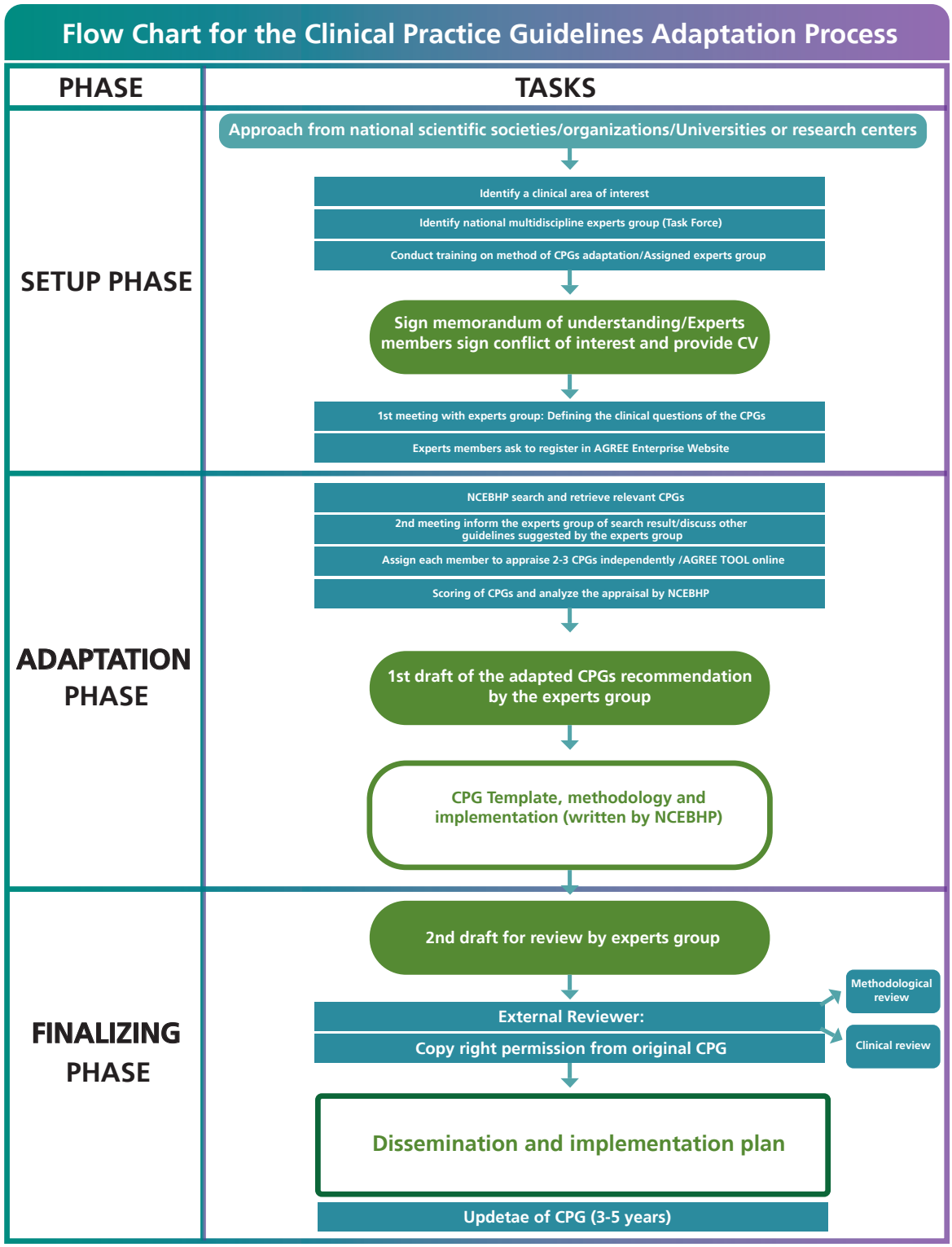
**a. Inclusion of the 'Implementation considerations and tools' section:**

**The selection of the type of CPG Implementation tool is based on the department's setting and needs, context and decision according to which will have the most positive impact on patient care and outcomes. The 'implementation tools and considerations' section should be prepared in collaboration with the Department's Quality Team. These clinical decision support tools are either adapted/ adopted from the original source CPGs or designed de novo. Any designed implementation tool included should be based on and consistent with the recommendations of the adapted CPG.**

**Examples of CPG implementation tools (list is not exclusive):**

**1- Protocols;**
**2- Policies and Procedures;**
**3- Clinical Algorithms;**
**4- Clinical/ Integrated Care pathways;**
**5- Integration in the health information system as Computerized Physician Order Entry (CPOE) with Order Sets or CDS**
**6- Quick Reference Guides (key recommendations);**
**7- Performance measures/ Key performance indicators (KPIs)**
**8- Slide presentation;**
**9- Patient Educational Guides in patients' native language(s)(e.g. Arabic);**
**10- Mobile App.**

## 2- Flow Chart for CPGs Adaptation Process



## 3. Protocol for a new CPG adaptation project

### Potential Clinical Practice Guideline (CPG) Health Topic Protocol

**Application for inclusion in the CPG Program**

| Table 1. Basic information on the Proposed CPG Project |
|---|
| 1. Contact person(s) and his/her department and unit proposing health topic for CPG adaptation and implementation |
| |
| 2. Proposed title of the CPG |
| |
| 3. Define the health question(s) of the proposed CPG using the PIPOH Model (Attached Table 2) |
| Please use the [Health/ Clinical Questions Checklist |
| 4. Give a brief justification for selection of the proposed health topic supported by data that indicates any existing variation in clinical practice or clinical outcomes in the management of this condition |
| |
| 5. Give any evidence of existing variation in practice in the management of this condition across Saudi Arabia (if available) |
| |
| 6. Is there any, in your knowledge, existing CPG adaptation project currently in progress in similar CPG programs/initiatives in Saudi Arabia(e.g. in Ministry of Health Saudi EBHC Center, National Guard NGEBHC Center..etc.)YES☐NO☐UNKNOWN☐ |
| If YES, please specify: |
| 7. Identify inclusion/exclusion selection criteria of source CPGs (Attached Table 3) |
| Please use the [Inclusion/ exclusion CPGs Selection Criteria Checklist |
| 8. Please indicate which specialty/ subspecialty should assist in the preparation and finalization of this proposed CPG |
| |
| 9. Please provide us with a written adaptation work plan, timeline and meeting schedule (ADAPTE Tool 5) |
| |

Signature _____ Date: _____

**Thank you for completing this form**

## 4. Modified ADAPTE Tool 6 health questions (PIPOH) checklist

**PIPOH Model (modified tool)**

**Table 2. Modified ADAPTE Tool 6 health questions (PIPOH) checklist**

### Patient population (P)

Gender: Male☐ Female☐ both genders☐
Age group: Child☐ Adult☐ Elderly☐ Specific age: _____ (years)
Disease/conditions: _____
Co-morbidity: No☐ Yes☐
If yes, Specify: _____

### Intervention (I)

Diagnosis☐ Specify: _____ (e.g. clinical, laboratory, radiological/ imaging,…etc. or all)
Treatment☐ Specify: _____ (e.g. medical, surgical, pharmacological, non-pharmacological, Physiotherapeutic,…etc. or all)
Prevention☐ Screening☐ Management (all)☐
Professionals (P)

### Professionals (P)

Physicians☐ Clinical Specialty: _____
Nurses ☐ Specify: _____
Pharmacist☐ Specify: _____
Allied Health Professionals☐ Specify: _____ (e.g. technician, therapists…etc.)

### Outcome (S) (O)

Primary (specific) outcomes: _____
Secondary (general) outcomes: (e.g. improve patient outcomes, patient safety, and decrease variation of practice…etc.)
Others: Specify: _____

### Health care settings/content (H)

Type: Primary☐ Secondary☐ Tertiary☐
Health care sector:
Government: University☐ Ministry of Health☐ Military☐ National Guard☐
Others: Specify: _____
Non-government: Private☐ NGO☐
Others: Specify: _____
Hospital☐ Specify: _____ Specify department: _____
Outpatient clinic☐ Specify: _____ Other:☐ Specify: _____

## Table 5. Adaptation Working Plan Template

| | CPG Phase | Tasks | Corresponding Modules | Timeline |
|---|---|---|---|---|
| Preliminary Phase (Set Up ) | Initial Meeting with National Scientific body | Approach from a national (scientific society/ organizations/university or research center). | Preparation Module | (WEEK) MONTH, YEAR |
| | | Establish national multidiscipline expert group (Task Force) | | |
| | | Identify necessary resources and skills | | |
| | 1st meeting with experts group | Decide on terms of reference/consensus process | | |
| | | Check whether adaptation is feasible | | |
| | | Establish CPG inclusion/exclusion criteria | | |
| | | Identify key search terms | | |
| | | Identify key documents/ sources | | |
| | | Experts members ask to register in AGREE Enterprise Website | | |
| Adaptation Phase | NCEBHP task | NCEBHP search and retrieve relevant CPGs | Scope and Purpose Module | (WEEK) MONTH, YEAR |
| | | Refine topic area | | |
| | 2nd meeting with experts group | Narrow list of CPGs (if needed) by inclusion/ exclusion criteria | Search and Screen Module | (WEEK) MONTH, YEAR |
| | | Assess CPGs<br>Complete AGREE appraisal<br>Assess CPG Currency | | |
| | | Complete evaluations(literature search and evidence consistency of evidence and conclusions, conclusions and recommendations) for all recommendations(optional) | Assessment Module | (WEEK) MONTH, YEAR |
| | | Prepare recommendations matrix | | |
| | Taskforce | Decide and Select<br>Review all data<br>Decide on recommendations for adapted CPG | Decision and Selection Module<br>Customization Module | (WEEK) MONTH, YEAR |
| Finalization Phase | | Draft CPG Report<br>Write first draft of CPG and/or report on process | | |
| | 3rd meeting with experts group | Review and approve first draft<br>(Clinical content and Methodology) | | (WEEK) MONTH, YEAR |
| | NCEBHP task to contract | External Review<br>Send for external review and consultation<br>(Clinical content and Methodology) | External Review Module | MONTH, YEAR (WEEK) |
| | 4th meeting (Optional) | Discuss feedback from review and consultation | | |
| | | Plan for Future review and update<br>Decide on update process | Aftercare planning Module | |
| | | Produce Final CPG<br>Create final adapted CPG<br>Including Implementation tool(s) and Performance Measures | Final Production Module | |
| Implementation Phase | | Consider implementation issues and strategies based on the Implementation tools and performance measures (KPIs)<br>Planning is a collaborative effort between CGC-d and DQT. | | MONTH, YEAR (WEEK) |

## Table 6. Inclusion/exclusion selection criteria for retrieved source CPGs checklist (new tool)

### Inclusion/ exclusion selection criteria

**Table 3. Inclusion/exclusion selection criteria for retrieved source CPGs checklist (new tool)**

| | Include | Exclude | |
|---|---|---|---|
| 1. Methods of development | ◯ | ◯ | Evidence-based CPGs (detailed methodology of development documented; link recommendations with evidence; link to systemic reviews) |
| 2. Author (s) | ◯ | ◯ | Consensus-based CPGs (expert opinion) |
| | ◯ | ◯ | Organization (CPG development group) |
| | | | ◯ CPGs database (producer or finder) |
| | ◯ | ◯ | ◯ Specialized society (clinical specialty) |
| | | | Single author |
| 3. Country | ◯ | ◯ | |
| | ◯ | ◯ | National |
| | | | International |
| 4. Date of publication | ◯ | ◯ | Range of years (preferably not older than 5 years) |
| | ◯ | ◯ | One year (current year) |
| 5. Language (s) | ◯ | ◯ | English |
| | ◯ | ◯ | Arabic |
| | ◯ | ◯ | Other |
| 6. Status | ◯ | ◯ | Original source CPG (de novo developed) |
| | ◯ | ◯ | Adapted (provided fulfillment of all criteria of a high quality adapted CPG; e.g. ADAPTE process, AGREE criteria |

Comments: _____
_____

## 7. Checklist for identification of relevant departments/ specialties for stakeholder involvement

| Department | Check all applicable |
|---|---|
| ▪ Anesthesiology Department | ☐ |
| ▪ Cardiac Sciences Department | ☐ |
| ▪ Critical Care Department | ☐ |
| ▪ Dermatology Department | ☐ |
| ▪ Emergency Medicine Department | ☐ |
| ▪ Medicine Department | ☐ |
| ▪ Nursing Department | ☐ |
| ▪ Oncology/Hematology Center | ☐ |
| ▪ Obstetrics and Gynecology Department | ☐ |
| ▪ Ophthalmology Department | ☐ |
| ▪ Otorhinolaryngology Department | ☐ |
| ▪ Orthopedic Surgery Department: | ☐ |
| ▪ Laboratory Medicine and Pathology Department | ☐ |
| ▪ Pediatrics Department | ☐ |
| ▪ Pharmacy Department | ☐ |
| ▪ Psychiatry Department | ☐ |
| ▪ Primary Care Clinics (Family Medicine Center) | ☐ |
| ▪ Radiology Department | ☐ |
| ▪ Rehabilitation Medicine Department | ☐ |
| ▪ Occupational Health and Safety Department | ☐ |
| ▪ Health Education Center | ☐ |
| ▪ Clinical Nutrition Department | ☐ |
| ▪ Infection Control Department | ☐ |
| ▪ *Other, Please Specify* _____ | |
| _____ | ☐ |
| | |
| ▪ Patients Relations Department | ☐ |

## 8. AGREE II instrument

**How to assess the Quality (Methodological rigor and confidence in resulting Recommendations) of any Clinical Practice Guideline ?**

AGREE

### APPRAISAL OF GUIDELINES FOR RESEARCH & EVALUATION II (AGREE II) Instrument

**DOMAIN 1. SCOPE AND PURPOSE**

1. The overall objective(s) of the guideline is (are) specifically described.
2. The health question(s) covered by the guideline is (are) specifically described.
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

**DOMAIN 2. STAKEHOLDER INVOLVEMENT**

4. The guideline development group includes individuals from all relevant professional groups.
5. The views and preferences of the target population (patients, public, etc.) have been sought.
6. The target users of the guideline are clearly defined.

**DOMAIN 3. RIGOUR OF DEVELOPMENT**

7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strengths and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.

**DOMAIN 4. CLARITY OF PRESENTATION**

15. The recommendations are specific and unambiguous.
16. The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.

**DOMAIN 5. APPLICABILITY**

18. The guideline describes facilitators and barriers to its application.
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.
20. The potential resource implications of applying the recommendations have been considered.
21. The guideline presents monitoring and/or auditing criteria.

**DOMAIN 6. EDITORIAL INDEPENDENCE**

22. The views of the funding body have not influenced the content of the guideline.
23. Competing interests of guideline development group members have been recorded and addressed.

**OVERALL GUIDELINE ASSESSMENT**

1- Rate the overall quality of this guideline.
2- I would recommend this guideline for use (Yes/ Yes, with modifications/ No)

**NOTES**

## 9. External review panel survey form

### Table 1.4.1. External Review/ Consensus Panel Form
### External Review Survey (Clinical Content Review)

***Note: Please complete this survey after reading the full adapted CPG document for "_____"***

*score each question with the provided Likert scale (1: strongly agree, 2: agree, 3: neutral/ neither agree nor disagree, 4: disagree, and 5: strongly disagree)*

| *Are you responsible for the care of patients for whom this draft CPG report is relevant? This may include the referral, diagnosis, treatment, or follow up of patients.* | ***Yes*** ☐ | ***No*** ☐ | ***Unsure*** ☐ |
|---|---|---|---|

*If you answered "No" or "Unsure", please return this questionnaire to the National Center for Evidence Based Health Practice, if you answered "Yes", please answer the questions below and then return.*

**Department: _____, Unit: _____**

**Years of clinical experience as a ….**

☐ Physician ☐ Clinical Pharmacist ☐ Nurse ☐ Technologist ☐ Clinical Nutritionist

☐ Other (specify: _____): ___Years

**Gender:** Female ☐ Male ☐

**Practice setting**: University ☐ Ministry of Health ☐ National Guard ☐ Military ☐ Security Forces ☐ Private sector ☐

***Which CPGs for _____ do you currently follow:*** *(add from retrieved source CPGs)*

☐ _____

☐ _____

☐ Other international CPG: please specify which: ……

☐ Other national CPG: please specify which: ……

☐ Not sure

| For each item, please check off the box that most adequately reflects your opinion | **Strongly Agree** | **Agree** | **Neutral** | **Disagree** | **Strongly Disagree** |
|---|---|---|---|---|---|
| Current use of clinical practice guidelines (CPGs) | **1** | | | | **5** |
| I receive CPGs on _____ from a variety of sources | ☐ | ☐ | ☐ | ☐ | ☐ |
| I receive CPGs on _____ that contradict one another | ☐ | ☐ | ☐ | ☐ | ☐ |
| Contradictory CPGs make it difficult to decide which to use | ☐ | ☐ | ☐ | ☐ | ☐ |
| The CPG Consensus Statement/ Consensus statement/recommendations | | | | | |
| There is a need for a CPG in this topic | ☐ | ☐ | ☐ | ☐ | ☐ |
| The CPGs panel is credible | ☐ | ☐ | ☐ | ☐ | ☐ |
| The consensus statement/ recommendations made by the panel is reasonable | ☐ | ☐ | ☐ | ☐ | ☐ |
| The consensus statement/ recommendations may have been influenced by vested interests | ☐ | ☐ | ☐ | ☐ | ☐ |
| The process used by the panel to come to consensus is credible | ☐ | ☐ | ☐ | ☐ | ☐ |
| The literature search is relevant and complete (e.g. no key CPGs were missed nor any included that should not have been) in the full CPG document. | ☐ | ☐ | ☐ | ☐ | ☐ |
| I would find it useful to have access the AGREE II appraisals of the source CPGs that were potentially considered for adaptation | ☐ | ☐ | ☐ | ☐ | ☐ |

| | | | | | |
|---|---|---|---|---|---|
| If I agree with the consensus statement/recommendations, I would use a CPG that was developed outside of Saudi Arabia | ☐ | ☐ | ☐ | ☐ | ☐ |
| The draft consensus statement/recommendations are suitable for the patients whom they are intended. | ☐ | ☐ | ☐ | ☐ | ☐ |
| The consensus statement/ recommendations in this CPG is (are) applicable to the majority of patients in my practice | ☐ | ☐ | ☐ | ☐ | ☐ |
| Following this consensus statement/ recommendations would not require major changes to my practice | ☐ | ☐ | ☐ | ☐ | ☐ |
| To apply the consensus statement/recommendations will require reorganization of services/care in my practice setting. | ☐ | ☐ | ☐ | ☐ | ☐ |
| When applied, the consensus statement/recommendations will result in better use of resources than current usual *practice (If they are the same as current practice, please tick NA)* ***NA ☐*** | ☐ | ☐ | ☐ | ☐ | ☐ |
| The consensus statement/recommendations in this CPG are too expensive to apply. | ☐ | ☐ | ☐ | ☐ | ☐ |
| To apply the draft consensus statement/recommendations will be technically challenging. | ☐ | ☐ | ☐ | ☐ | ☐ |
| The consensus statement/recommendations is (are) likely to be supported and used by a majority of my colleagues | ☐ | ☐ | ☐ | ☐ | ☐ |
| If I follow the draft consensus statement/recommendations in this CPG, the expected effects on patient outcomes will be obvious. | ☐ | ☐ | ☐ | ☐ | ☐ |
| The draft consensus statement/recommendations in this CPG reflect a more effective approach for improving patients' outcomes than is current practice. *(If they are the same as current practice, please tick NA).* ***NA ☐*** | ☐ | ☐ | ☐ | ☐ | ☐ |
| The consensus statement (recommendations) is (are) flexible enough to allow for clinical judgment and/ Neither agree or clinical autonomy | ☐ | ☐ | ☐ | ☐ | ☐ |
| The consensus statement (recommendations) in this CPG presents options that will be acceptable to patients. | ☐ | ☐ | ☐ | ☐ | ☐ |
| The consensus statement/recommendations are too rigid to apply to individual patients. | ☐ | ☐ | ☐ | ☐ | ☐ |
| When applied, the consensus statement/recommendations will produce more benefits for patients than harms. | ☐ | ☐ | ☐ | ☐ | ☐ |
| If the National Center for Evidence Based Health Practice endorsed this consensus statement (recommendations) of this CPG, I would be more likely to follow it | ☐ | ☐ | ☐ | ☐ | ☐ |
| If the concerned Saudi Scientific Societies endorsed this consensus statement, I would be more likely to follow it | ☐ | ☐ | ☐ | ☐ | ☐ |
| I would ACCEPT the consensus statement/ recommendations made by the expert panel of this CPG | ☐ | ☐ | ☐ | ☐ | ☐ |
| I would FOLLOW the consensus statement /recommendations made by the expert panel of this CPG | ☐ | ☐ | ☐ | ☐ | ☐ |

***Total number of external review members who participated in this survey was (____)***

**COMMENTS ABOUT THE FINALIZED DRAFT CPG**

**All the comments discussed and written by the External Review panel members will be compiled and used to create the final adapted CPG document**

……

…

……

……

**Thank you for taking time to respond.**

## 10. CPG Methodology Review and approval form (for CPG steering committee)

### Part 1. Checklist for compliance with CPG Standards of the Guidelines International Network

### GUIDELINES INTERNATIONAL NETWORK (G-I-N) STANDARDS FOR CLINICAL PRACTICE GUIDELINES

| | |
|---|---|
| **Title of the Guideline** | |
| | |
| **Name of the Developing Organization** | |
| ***Name of the Adapting Organization*** | |
| | |
| **Publication Date of the Source CPG** | |
| ***Publication Date of the Adapted CPG*** | |

**Effective August 2013, GIN is requesting voluntary reporting on the G-I-N Guideline Standards when a guideline is submitted for inclusion in the G-I-N Library.**

**Is your organization willing to complete the form to provide information to a reader about your guideline?**

**YES** ☐

**NO** ☐

**If yes, please complete the checklist on the next page.**

**Reference**

Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P. Guidelines International Network: toward international standards for clinical practice guidelines. Annals of Internal Medicine. 2012; 156(7):525-31. https://annals.org/article.aspx?articleid=1103747

| GIN Standards and Description | Standard Achieved? | If Yes, Page number (s)/ document where the information is available |
|---|---|---|
| Composition of Guideline Development/ Adaptation Group<br>**Guideline development panel includes diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for adapted CPGs* |
| Decision-making Process<br>**Guideline describes the process used to reach consensus among the panel members and, if applicable, approval by the sponsoring organization. This process was established before the start of guideline development/ adaptation.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for adapted CPGs* |
| Conflicts of Interest (disclosure)<br>**Guideline includes disclosure of the financial and nonfinancial conflicts of interest for members of the guideline development/ adaptation group.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for adapted CPGs* |
| Conflicts of Interest (resolution)<br>**Guideline describes how any identified conflicts were recorded and resolved.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for adapted CPGs* |
| Scope of a Guideline<br>**Guideline specifies its objective (s) and scope** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for adapted CPGs* |
| Methods<br>**Guideline clearly describes the methods used for the guideline development/ adaptation in detail.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for adapted CPGs* |
| GIN Standards and Description | **Standard Achieved?** | **If Yes, Page number (s)/ document where the information is available** |
| Evidence Reviews<br>**Guideline uses systematic evidence review methods to identify and evaluate evidence related to the guideline topic.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for adapted CPGs*<br>**Note:** In cases of adapted CPGs, Evidence Reviews will refer to ***"Source CPGs" Reviews*** |
| Guideline Recommendations<br>**Guideline recommendation clearly stated and based on scientific evidence of benefits; harms; and, if possible, costs.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for the Source (de novo developed) CPG(s).* |
| Rating of Evidence<br>**Guideline uses a rating system to communicate the quality and reliability of the evidence.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for the Source (de novo developed) CPG(s).* |
| Rating of Recommendations | | *This standard is applicable for the Source (de novo developed) CPG(s).* |

| | | |
|---|---|---|
| **Guideline uses a rating system to communicate the quality and reliability of the strength of its recommendations.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | |
| Peer Review and Stakeholder Consultations<br><br>**Review by external stakeholders conducted before guideline publication.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for adapted CPGs* |
| Guideline Expiration and Updating<br><br>**Guideline includes an expiry date and/or describes the process that the guideline groups will use to update recommendations.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for adapted CPGs* |
| Financial Support and Sponsoring Organization<br><br>**Guideline discloses financial support for the development of both the evidence review as well as the guideline recommendations.** | ☐ **YES**<br>☐ **NO**<br>☐ **Somewhat** | *This standard is applicable for adapted CPGs.*<br>***Note:** In case of adapted CPGs, the support will be for the whole adaptation process and production of the final adapted CPG document* |

## Additional Comments

## Part 2. CPG review and approval form

| Wide Clinical Practice Guidelines (CPGs) Steering Committee<br>Methodologists Form For Final Review And Approval Of Adapted CPGs | |
|---|---|
| CPG Title, Edition and Date of Issue | _____ |
| CPG Code/ Reference No. | _____ |
| Hospitals' Departments involved | _____ |
| Final Decision:- | |
| ☐ Approved<br>☐ Conditional Approval (Accepted with Modifications) | |
| Specific notes:<br>.....<br>.....<br>..... | |
| CPG Methodologists who reviewed the document(s) | |
| Name, Affiliation | **Signature** |
| ☐ _____ | |
| ☐ _____ | |
| ☐ _____ | |
| Date: - - / - - / - - - - | |

## 10. Declaration of conflicts of interest form

**CONFLICT OF INTEREST**
**DISCLOSURE DECLARATION**

**NAME** _____

**NAME OF PANEL** _____

**DATE** _____

The following questions are designed to allow participants in the guideline appraisal group to disclosure any real or apparent conflict (s) of interest with respect to their activities in guideline development. Conflicts of interest include appraisers' participation in the development or endorsement of any of the guidelines that are being reviewed for the purpose of this project. They may also involve relationships with pharmaceutical companies or other corporations whose products or services are related to the guideline topics. Financial interests or relationships requiring disclosure include but are not limited to honoraria, consultancies, employment, or stock ownership.

The intent of the disclosure declaration is to have the participants in the guideline appraisal identify any potential conflict (s) in relation to any of the guidelines that are under consideration in order that appraisal group members can form their own judgements, while taking conflict (s) of interest of other group members into consideration.

**Please answer each of the following questions by circling either "NO" or "YES". If your answer "YES" to any question, please describe the nature of the interest and/or relationship, and identify the relevant commercial entity.**

1. **PARTICIPATION IN GUIDELINE DEVELOPMENT**

Have you been involved in the development on any of the guidelines under review (e.g., a member of the guideline development committee)?

**YES** **NO**

If YES, please identify the guideline and describe your involvement:
Title of the guideline:

_____
_____
_____

**2. GUIDELINE ENDORSEMENT**

Have you directly participated in any processes to formally endorse any of the guidelines under review?

**SET UP PHASE**
**Preparation Module**

**YES** **NO**

If YES, please identify the guideline and describe your involvement:
Title of the guideline:

_____
_____
_____
_____
_____
_____

**3. EMPLOYMENT**

Are you or have you been employed by a guideline developer or an entity having a commercial interest in any of the guidelines under consideration?

**YES** **NO**

If YES, please describe:

_____
_____
_____
_____
_____
_____

**4. CONSULTANCY**

Have you served as a consultant for any guideline developer or an entity having commercial interest in any of the guidelines under consideration?

**YES** **NO**

If YES, please describe:

_____
_____
_____

**5. OWNERSHIP INTERESTS – PART A**

Do you have any ownership interests (including stock options) in any entity, the stock of which is not publicly traded, which has a commercial interest in any of the guidelines under consideration?

**YES NO**

If YES, please describe:

_____
_____
_____
_____
_____
_____

6. **OWNERSHIP INTEREST – PART B**

Do you have any ownership interests (including stock options but excluding indirect investments through mutual funds and the like) valued at $1500 or more in any entity that has a commercial interest in any of the guidelines under consideration?

**YES NO**

If YES, please describe:

_____
_____
_____
_____
_____
_____

**7. RESEARCHING FUNDING**

Are you currently receiving or have you received research funding from any entity that has a commercial interest in any of the guidelines under consideration?

**YES NO**

_____
_____
_____
_____

**SET UP PHASE**
**Preparation Module**

_____

**8. HONORARIA**

Have you been paid honoraria or received gifts of value equal to or greater than $3500 per year or $7500 over a three-year period from guideline developer or an entity having a commercial interest in any of the guidelines under construction or from the developers of any of the guidelines under consideration?

**YES** **NO**

If YES, please describe:

_____
_____
_____
_____
_____
_____

**9. OTHER POTENTIAL CONFLICT (S) OF INTEREST**

_____
_____
_____
_____
_____
_____
_____
_____
_____

**SIGNATURE** _____

**DATE:** **(Please print)** _____