The KAMS-KNCC CPG DEVELOPMENT PROTOCOL version 2.0

[Supp 1]

Title of the CPG

Protocol version	

Logo &
Name of
The Academic society

KNCC

Project Leader		Secretary	

Table of Contents

General Information

Intended Purpose of the Protocol

To support the clinical practice guideline (CPG) developers who want to develop good quality CPGs to establish plans in advance and proceed with transparent procedures according to the plan.

Who should participate in developing the Protocol

Clinical and methodological experts who participate in development of the clinical practice guideline

Proposal to utilize the Protocol

- Register the Protocol to the pertinent registry platform
- Provide the Protocol to the CPG readers as an annex information

Revision History for the CPG

Note: The CPG developers should prepare the CPG development protocol in the planning stage. Moreover, any changes made during the development process should be reflected in the protocol revision and recorded in the revision history of those changes.

Protocol version	Revision date	Major changes
Add the row, if necessary		

Part 1 Planning stage

1 Establishing the guideline development group (GDG)

1-1 Oversight committee

Note: Discuss and decide on major policies related to planning-related tasks and developing clinical practice guidelines.

	Name	Affiliation	Specialty	Role
1				
2				
3				
4				
5				
#				

1-2 Guideline panel

Note: It refers to members who review the scientific evidence and derive the draft recommendations for the key questions. The Practice Committee should include clinical experts relevant to the key questions and methodology expert(s) for CPG development.

	Name	Affiliation	Specialty	Role
1				
2				
3				
4				
5				
6				
7				
8				
9				
#				

1-3 Advisory committee (optional in planning stage)

Note: The CPG developer establishes the Advisory Committee to consult the appropriateness of conducting each step for the CPG development in the planning stage. Members of the Advisory Committee may change according to the development of guidelines if necessary. The Advisory Committee shall operate independently from the Oversight Committee and the Guideline Panel.
For methodology advice, it is recommended to include external methodology experts who are not included in the GDG.

	Name	Affiliation	Specialty	Role
1				
2				
3				
4				
5				
#				

1-4 Committee for the conflicts of interest (COI)

Note: The Oversight Committee may be in charge.

	Name	Affiliation	Specialty	Role
1				
2				
3				
4				
5				
#				

1-5 Secretariat

	Name	Affiliation	Role
1			
#			

2 Scope and purpose of the CPG

2-1 Intended purpose

Note: Describe the overall purpose of developing the CPG. In particular, the CPG developers should present the expected health benefits for the target population of the CPG and the impact of the healthcare practice in Korea.

2-2 Scope

Note: Before deciding the scope, the CPG developers should consider the budget, developing period, disease burden and clinical importance of the disease, and the quality and quantity of supporting evidence for CPG development.

PIPOH	Description
Population	
Intervention	
Professionals/patients	
Outcomes	
Healthcare setting	

2-3 Target population(s)

Detailed specification of the target population

Note: Please describe detailed characteristics of the target population according to the following features. If you omit any of the followings, you shall provide justifications you will not consider for each. Click "select" and choose yes or no.

		Description
disease/condition	select	
severity of the disease	select	
co-morbidity	select	
sex / age	select	
social characteristics	select	
	select	Add the row, if necessary

2-4 Intervention(s)

Intervention(s) / Exposure(s)

Add the row, if necessary.

2-5 Comparator(s)

Comparator(s)

Add the row, if necessary.

2-6 Health outcomes: Predefined rules to consider for concluding recommendation(s)

Note: Please specify GDG's rule regarding the following features related to the health outcomes that the GDG will consider to draw recommendations for each key question. The relative importance of health outcomes may vary according to the key clinical questions, and the variables considered through the CPG development process can change. If there are any changes from the protocol, the GDG should record those in the Revision History. Click "select" and choose the one.

Health outcome	Impact on decision making	List of health outcome variables
	Critical (be included in the SoF table)	
	Important (be included in the SoF table)	
Measure applied to set the priority of health outcomes	select	

Reference) GUYAT, G. H., et al. GRADE: what is 'quality of evidence' and why is it important to clinicians. Br. Med. J, 2008, 336: 924-926.

Hierarchy of outcomes according to importance to patients to assess effect of an intervention								
1	2	3	4	5	6	7	8	9
The least important								The most important
Not important for decision making (not be included in the SoF table)			Important for decision making (be included in the SoF table)			Critical for decision making (be included in the SoF table)		

3. Formulating the key questions

3-1 Methods to apply

Note: Please select the applied methods to determine 'Key Questions.' The GDG may utilize more than two methods at the same time presented below to decide on your key questions. Click "select" and choose yes or no.

select	Brainstorming within the GDG
select	Review of key questions of existing CPGs from overseas or the other groups
select	Review of the relevant systematic reviews of the target disease (or key question)
select	Suggested evidence gaps from existing CPGs
select	Information regarding the disease burden or variety of care, etc.
select	Issues raised from the pertinent academic societies or consumer organizations
select	Others those listed above

3-2 Listing of key questions and development methods for its recommendations

Note: Please consider the alignment with '4-1 target users of the CPG' and '4-2 target healthcare setting to apply the CPG's recommendations' in formulating the key questions.

Key questions (with PICO components)		Expert(s) in charge			Development method Click "select" and choose the one.
		main	sub	Supervisor, if necessary	
1					select
2					select
3					select
4					select
5					select
6					select
7					select
8					select
9					select
10					select
11					select
12					select
13					select
14					select
15					select
#					select

4. Target users and healthcare setting

4-1 Target users of the CPG

Target users

Note: It is desirable to check the applicability of the recommendations of CPG to the target users listed below. GDG may develop relevant tools to facilitate the implementation of recommendations to strengthen the applicability of recommendations.

Add the row, if necessary.

Self-assessment of alignment between target users and GDG	Is the guideline development group (GDG) composition sufficient to reflect the perspectives of the target users?	
	The GDG self-assess the score and chooses a score from 5 (very good) to 1 (very poor).	

4-2 Target healthcare setting to apply the CPG's recommendations

Target healthcare setting

Note: Expert(s) or personnel representing the target healthcare setting are encouraged to participate in the GDG.

Add the row, if necessary.

Self-assessment of alignment between target healthcare setting and GDG	Is the guideline development group (GDG) composition sufficient to reflect the perspectives of the target healthcare setting?	
	The GDG self-assess the score and chooses a score from 5 (very good) to 1 (very poor).	

5 Funding sources

Name of funder(s)	
Role of funder(s)	
The potential impact of funder(s) and ways to secure independence	

6 Terms of reference (optional)

Note: The Terms of Reference (TOR) contain the basic principles of developing CPG, the structure and operation of the oversight committee and guideline panel, and the management principles of conflicts of interest. The GDG should prepare the TOR at the planning stage of the development of CPG.

Person-in-charge	
TOR should attach as an Annex, and please specify the Annex number	

7 Conflicts of interest

Note: GDG may specify the time limit (e.g., two years) and threshold (e.g., 1 million KRW) of conflicts of interest in the TOR. Click 'select' and chooses the appropriate one if the TOR includes the relevant content. Please briefly summarize the relevant content from the TOR in the 'description' column.
The COI survey form should attach in an annex to the CPG protocol. Please specify the annex number in the table below.

Survey form for COI	Please specify the annex number below.

Conflicts of interest	Management criteria, specified in the TOR		
	Click "select" and choose yes or no.	Description	Management criteria
Employee of relevant enterprise (formal or informal positions)	select		select
Research grant, any rewards, consultancy fee, stocks, shares (regardless of having been listed on the stock market)	select		select
Relevant intellectual properties (Patent, Royalty, etc.)	select		select
Executive or director of relevant governmental body, academic society, organizations	select		select
Relevant research or publication related to the key questions	select		select
Add the row, if necessary.	select		select

8 Enterprises that can be influenced by the recommendations of CPG (optional)

Name of the enterprise (or group of enterprises)

Part 2 Development stage; from evidence to recommendation

9 Selection of relevant literatures

9-1 Literature searching

Literature searching

Person-in-charge		Expected completion date	

Any restrictions on literature searching
Note: Please specify if GDG considers any restriction in the literature search. GDG should differentiate the meaning from the exclusion criteria from the literature search result. Click “select” and choose yes or no.

Restriction factor	apply	Describe the reason why
language	select	
other	select	

9-2 Databases to use for search

Databases to include mandatorily	Medline
	EMbase
	Cochrane CENTRAL
	KoreaMed or KMbase
Please specify the database if you use those not listed above.	
	Add the row, if necessary

Selection (inclusion and exclusion) of literatures

Common criteria for selection if the GDG have any	
Expected completion date	

10 Evidence synthesis

10-1 Quality appraisal of selected literatures

Type of study	Appraisal tools to apply	
Randomized controlled trial	Cochrane ROB 2.0 (recommended)	
Non-randomized trial	select	
	Please describe if the GDG use other than specified above	
Diagnostic test accuracy study	QUADAS-2 (recommended)	
Systematic review	select	
Add the row, if necessary		

If any KQ applies adaptation methodology

CPGs	AGREE 2.0

10-2 Certainty of evidence

Measures to apply	GRADE level of evidence (recommended)	
	In case of updating the CPG	

Expression and its meaning of the levels of evidence
The CPG developer should fill in the below when using the self-developed evidence-level system and clearly describe the definition and meaning.
If the CPG developer utilizes the GRADE level of evidence system, you don't need to fill up the below.

Evidence level	Describe the meaning

11 From evidence to recommendation

11-1 Views and preferences of the target population

Purpose	Measures to apply	Select
Determine the scope (or key questions)	Will not be considered in determining the scope	☐
	Focus group interview	☐
	Literature review	☐
	Survey	☐
	Others not listed above please describe the method you will apply below 텍스트를 입력하려면 여기를 클릭하거나 탭하세요.	☐
Reflect on the patient's values and preferences to derive a recommendation	Will not be considered in reflecting on the patient's value and preference	☐
	Focus group interview	☐
	Literature review	☐
	Survey	☐
	Others not listed above please describe the method you will apply below 텍스트를 입력하려면 여기를 클릭하거나 탭하세요.	☐
Others (*add the condition here*)	No other circumstances to investigate the values and preferences of the target population	☐
	Focus group interview	☐
	Literature review	☐
	Survey	☐
	Others not listed above please describe the method you will apply below 텍스트를 입력하려면 여기를 클릭하거나 탭하세요.	☐

11-2 Equity

Note: Do one or more of the following three measures.

☐	Include 'equity' item in GRADE Evidence to Decision table
☐	Conduct a literature review of equity-related issues in the disease
☐	Describes whether there are any groups that will be disadvantaged in relation to the current disease or intervention

11-3 Implementability

Note: Do one or more of the following three measures.

☐	Develop a strategic plan to implement the recommendations and present the developed plan in the body content of the CPG
☐	Develop tools that will utilize in healthcare practices, such as algorithms and summary documents, and describe the barriers and facilitators for the implementation of the CPG
☐	Conduct the 'GuideLine Implementability Appraisal (GLIA)' tool

12 Making recommendations

12-1 Additional considerations to derive draft recommendations

Decision for consideration	Considering factors	Measures Click "select" and choose the appropriate one.	Remark
Mandatory	Benefits (favorable outcomes)	select	
	Harms (unfavorable outcomes)	select	
	Balancing benefits and harms	select	
	Certainty of effects (level of evidence)	select	
	Value	select	
The following items should be considered regarding facilitators and barriers, assuming the implementation of the recommendations to be presented. Click "select" and choose the appropriate one.			
Select yes/no	Required resources	select	
Select yes/no	Acceptability	select	
Select yes/no	Feasibility	select	
Select yes/no	Equity	select	

12-2 Strength of recommendation

Strength of recommendation	GRADE Evidence to Decision framework (recommended)	
	In case of updating the CPG	

Expression and its meaning of the strength of recommendation

The CPG developer should fill in the below when using the self-developed strength of recommendation system and clearly describe the definition and meaning.

If the CPG developer utilizes the GRADE EtD system, you don't need to fill up the below.

Recommendation strength	Describe the meaning

Part 3 Finalization

13 External review

Select	Type of external review	Timeline	Brief plan	Person-in-charge
☐	Consultation for methodology			
☐	Consultation for draft recommendations			
☐	Public hearing			
☐	Public notice			

14 Endorsement

	Name of organizations to request the endorsement
1	
2	
3	
4	
5	
6	

15 Reporting and authorship

Task	Person-in-charge / Rules to apply
Writing, draft version	
Writing, full version	
Authorship principles	

Part 4 Timetable of CPG development process

16 Timetable for De Novo development

Note: GDG can modify the timetable to your needs.

		Timeline													
Stages	Tasks	Year													
		Month	1	2	3	4	5	6	7	8	9	10	11	12	1	2
Planning	Establishing the GDGs														
	Defining the scope														
	Listing the clinical questions														
	Prioritize health outcomes														
	Final listing the key questions (PICO)														
Development	Request for literature search														
	Literature search														
	Selecting the evidence														
	Extracting the relevant data														
	Assessing the quality of evidence														
	Meta-analysis														
	Assessing the certainty of evidence														
	Developing the EtD framework														
	Making draft recommendations														
	Writing the initial draft														
	Internal review process														
Finalization	External review process														
	Consensus process to derive the final recommendations														
	Writing the clinical practice guideline (full version, etc.)														

17 Timetable for adaptation

Note: GDG can modify the timetable to your needs.

		Timeline														
Stages	Tasks	Year														
		Month	1	2	3	4	5	6	7	8	9	10	11	12	1	2
Planning	Establishing the GDGs															
	Defining the scope															
	Listing the clinical questions															
	Prioritize health outcomes															
	Final listing the key questions (PICO)															
Development	Searching and selecting the existing CPGs															
	Assessing the quality of the existing CPGs															
	Summarizing the characteristics and contents for existing CPGs															
	Planning to ensure the currency of evidence															
	Literature search to ensure the currency of evidence															
	Selecting the evidence															
	Extracting the relevant data															
	Assessing the quality of evidence															
	Meta-analysis															
	Assessing the certainty of evidence															
	Developing the EtD framework															
	Making draft recommendations															
	Writing the initial draft															
	Internal review process															
Finalization	External review process															
	Consensus process to derive the final recommendations															
	Writing the clinical practice guideline (full version, etc.)															

Part 5 Annexes

- The CPG developer should attach relevant annexes if you specify in the CPG protocol (e.g., TOR, COI survey form)

18 Annex 1 *add the title here*

19 Annex 2 *add the title here*