Roadmap for the

National Program for Guideline Adaptation in Egypt

Developed by:

Division of Science, Information and Dissemination
WHO Regional Office for the Eastern Mediterranean
In collaboration with
WHO Country Office in Egypt

Requested by:

Egyptian Health Council

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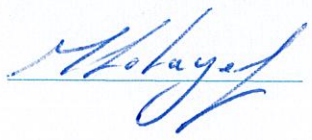

Contents:

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The roadmap was produced under the technical supervision of Dr Arash Rashidian (Director, Science, Information and Dissemination, WHO Regional Office for the Eastern Mediterranean) and policy direction of Professor Mohamed Lotayef (President of Egyptian Health Council).

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Abbreviations:

DOI	Declaration of Interest
EMRO	Eastern Mediterranean Regional Office of the WHO
EHC	Egyptian Health Council
EtD	Evidence to Decision Framework
GDG	Guideline Development Group
MOH	Ministry of Health and Population
PICO	Population, Intervention, Comparator, Outcome
TST	Technical Support Team
WHO	World Health Organization

Glossary:

Conflict of interests: Conflicts of interest (also known as competing interests) arise when "professional judgement concerning a primary interest (such as patients' welfare) is unduly influenced by a secondary interest (such as [personal] financial gains)" (1).

De novo guideline development: Refer to guideline development

Guideline recommendation: Guideline recommendation(s) are "systematically developed statements that recommend a particular course of action[s] often for citizens and professionals, and sometimes for organizations and governments" (1). Guideline recommendations may address clinical questions, public health concerns, managerial or health system questions. Guideline recommendations are developed based on research evidence syntheses and stakeholder expertise, and involve the evaluation of effectiveness, values, preferences, resource implications, and additional relevant factors.

Guideline adaptation: The systematic approach of customizing and modifying guideline recommendations produced in/for a setting or time (context), for their application in a different setting or time (context).

Guideline adoption: The process resulting in the decision to take up or use the recommendations of a guideline in a country or specific setting...

Guideline development: Guideline development is the transparent, systematic and collaborative process of producing a new guideline. The process involves several fundamental steps including formulating key questions, evidence retrieval and synthesis, and appraisal of the quality of the evidence...

Guideline implementation: The process of turning guideline recommendations into practice or action. It may be supported by an implementation plan (who should do what, by when), as well as implementation oversight and monitoring and evaluation of implementation.

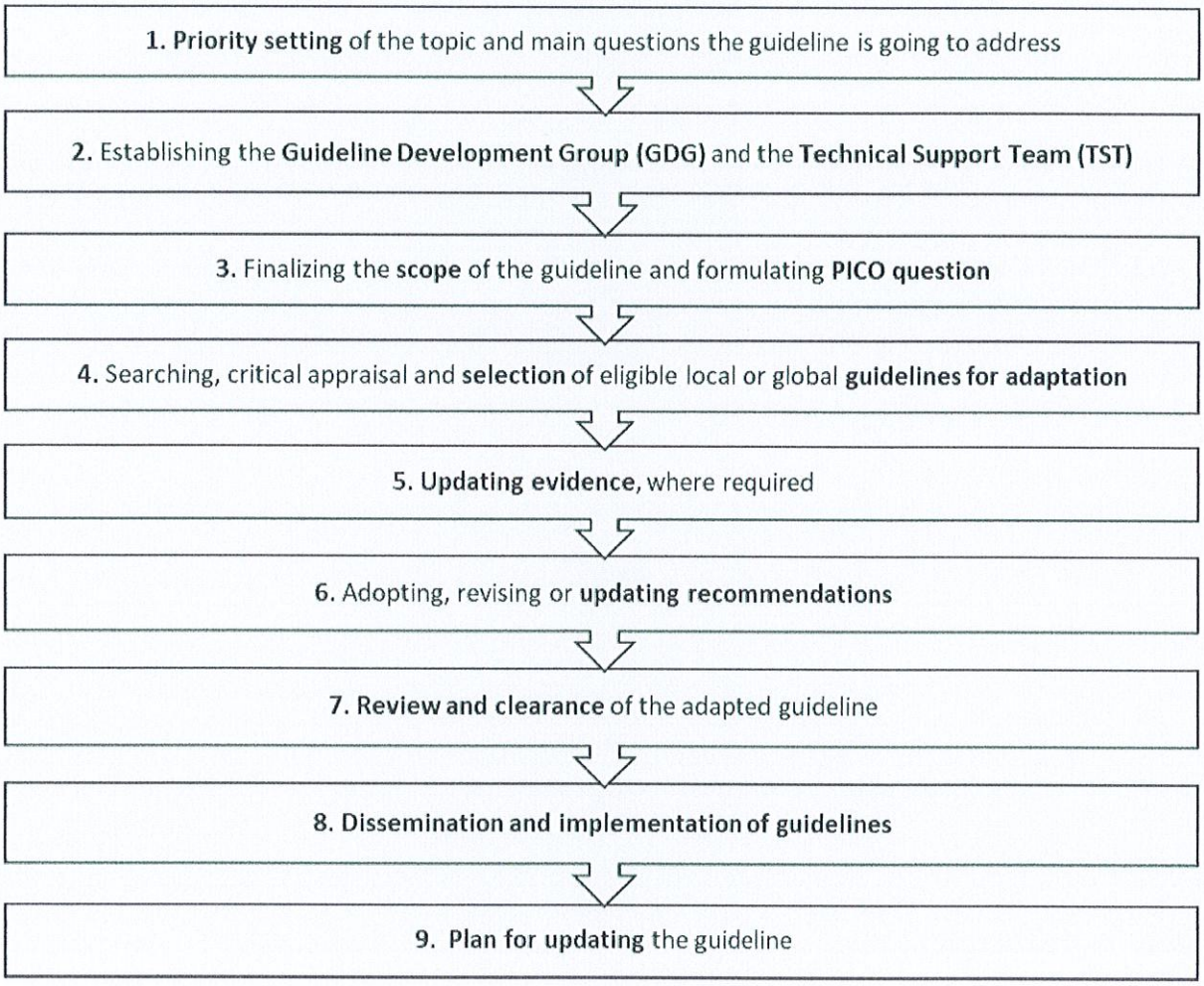
Background:

The development of the National Guidelines Program in Egypt is rooted in the country's ongoing efforts to transform its healthcare system to improve quality, accessibility, and patient safety.

This transformation aligns with Egypt's broader health sector reform initiatives aimed at achieving universal health coverage and strengthening public health services. The program emerged as part of a national strategy to standardize clinical practices and ensure safe healthcare delivery across public and private sectors. Following the launch of Egypt's Universal Health Insurance System, the government recognized the need for evidence-based national guidelines to address critical areas and to standardize care across the nation. Indeed, the transformed system called for the separation of the service provider, from the regulator and the payer. Along with this transformation came the mandate for quality service delivery. Supported by collaboration with WHO, Egypt developed these guidelines to provide healthcare professionals with standardized, high-quality protocols. The National Guidelines Program reflects Egypt's commitment to modernizing its healthcare system and improving health outcomes by adopting best practices and fostering a culture of safety and accountability across all levels of care.

Guideline Adaptation Flow Chart for Egypt

(World Health Organization Regional Office for the Eastern Mediterranean, 2024):



Roles and responsibilities for each step of guideline adaptation process:

Step 1: Priority setting of the topic and main questions the guideline is going to address:

The Higher Committee reviews the proposed topics submitted by different stakeholders and the priority topics will be identified by the committee using the three key criteria for prioritization including 1) health and cost burden of the disease, 2) practice variation or lack of established policies, and 3) potential impact of a guideline to improve health outcomes. The committee can apply any other relevant criteria in addition to these (see ANNEX 1). The list of the topics will guide development and adaptation of priority guidelines.

The key stakeholders representing diverse sectors of the health system should be engaged in proposing topics for development of the guidelines to the secretariat of the Higher Committee. Secretariat should ensure the regular meetings of the higher committee and announcement of the priority topics at least once a year.

Step 2: Establishing the Guideline Development Group (GDG) and the Technical Support Team (TST):

The Guideline Development Group (GDG) is the key multidisciplinary team responsible for the adaptation or development of each guideline and defining the recommendations. Relevant disciplines including the clinical specialties, nursing, pharmacy, laboratory and other health care groups that have roles and responsibilities related to the potential recommendations, as well as patient representatives and a methodologist. GDG members will be selected by the secretariat of the Higher Committee and approved by the board of directors of the Egyptian Health Council (EHC). Every GDG must have a chair. The GDG chair will be responsible for moderating GDG discussions and ensuring the views of all GDG members have been taken into account. Every individual selected to be part of a GDG must declare their potential conflicts of interest. Declaration of Interests (DOI) form should be signed by the chair and all the GDG members and submitted to the secretariat of the higher committee. The secretariat should evaluate the DOI forms and ensure there are no major conflicts of interest among GDG members.

The number of GDG members ideally should not exceed 15 members per group. Further details about the composition and qualification of GDG members can be found in ANNEX 2.

The secretariat of Higher Committee also assigns a Technical Support Team (TST) to support each GDG with methodological aspects of guideline development.

Step 3: Finalizing the scope of the guideline and formulating PICO question

A good scoping of the guideline is crucial to producing an effective and useful guideline.

The scope of the guideline should at minimum answer the following questions:

1. Why is the guideline is needed?
2. Who is the target group for the guideline? (i.e. Who is affected by it? Patient groups, Professional groups, etc.)
3. For what setting of care?
4. What areas of care are affected? (i.e. diagnosis, treatment, etc.)

The scope should also mention what will not be covered by the guideline. The scope and objective of the guideline should be defined by the GDG and submitted to the secretariat of the Higher Committee for approval.

The GDG, with TST support, will also create the list of PICO questions, and the corresponding PICO tables for the topic of interest.

Step 4: Searching, Critical Appraisal and Selection of Eligible Local and Global Guidelines for Adaptation:

Searching for the existing guideline should be conducted primarily by the TST, with guidance from the GDG. Guidelines from credible sources that cover all or most of PICO questions should be identified systematically. They then should be critically appraised using AGREE II tool. Critical appraisal should be conducted by at least 4 individuals from GDG and TST. The results will be shared with GDG for the final selection of eligible guideline(s) for adaptation.

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

[1] The copyright policies of the source of the original guideline to be adapted or the entity that owns the copyright (for example, publishers or development groups) must be checked and the source must be requested for permission to authorize the adaptation process.

Step 5: Updating evidence, where required:

TST and GDG should note whether the selected guideline for adaptation is up-to-date, noting the date of the release and the dates of systematic searches conducted during its development. Systematic searches should be updated where required to identify any relevant and high-quality evidence. GDG may also advise the search of local evidence, e.g. for assessing the applicability, cost, or implementation considerations of the relevant recommendations. The updating of evidence and systematic reviews is done by TST and presented to the GDG.

Step 6: Adopting, revising, and updating recommendations:

The updating and revising of recommendations should be based on evidence and national context, and informed by the Evidence to Decision (EtD) framework (ANNEX 3). Recommendations should be revised or defined after EtD is completed and discussed by the GDG.

The chair of the GDG must ensure that all the correct procedures are followed throughout the adopting, revising, and updating of recommendations and that all the recommendations are adequately discussed during the decision-making process. The chair should facilitate the group discussions to ensure all GDG members have expressed their opinions and the decisions are reached based on consensus. On occasion, decisions might be reached through voting if disagreements remain.

Further details on building consensus can be found in Chapters 3.8.2 and 10.5.1 of the WHO Handbook for Guideline Development (World Health Organization, 2014).

The following principles should be observed when documenting the guideline adaptation process:

- No video or audio recording
- Deliberations of GDG are confidential, but their decisions are public
- Main decisions, or concerns should be documented.
- If there are objections, these should be documented along with the respective reasons

Key action, decisions, and concerns also need to be documented but not the exact details (i.e. no attribution of the comments to the person who said these)

Step 7: Review and clearance of the adapted guideline:

The draft guideline should be submitted to EHC by the GDG chair. EHC will seek External Peer Review as needed to review the draft guideline, and ensure that the guidelines are free from any bias or influence. The results of the peer review will be shared with GDG for their consideration.

The final draft of the guideline will be published by the EHC. The template for writing and publication of a guideline, including all essential components can be found in ANNEX 4.

Step 8: Dissemination and Implementation of Guidelines:

The EHC, in consultation with the GDG, should develop the dissemination plan for the guideline, and contribute to the development of the implementation plan alongside relevant stakeholders.

The MOH, specialty societies, military and police health services, medical schools and teaching hospitals and the private sector have key roles and responsibilities in the monitoring and implementation of the guidelines according to their needs.

Further details on Implementation and monitoring and evaluation can be found in ANNEX 5 and ANNEX 6 respectively.

Step 9: Plan for updating the guideline:

EHC will be responsible for keeping their guidelines up to date.

Guidelines should be reviewed and to be updated whenever any new key evidence emerges that may require the revision of any published guidelines.

Key Stakeholders of National Guideline Program in Egypt:

The following section lists and describes the compositions and roles of the key stakeholders or "committees" that have a primary role in the adaptation of guidelines in Egypt.

a. Ministry of Health and Population, Egypt

The Ministry of Health plays a crucial role in ensuring the monitoring and effective implementation of guidelines, by executing robust and practical implementation for impact strategies and plans.

b. Egyptian Health Council

The Egyptian Health Council (EHC) provides overall leadership and direction for the development and adaptation of guidelines, ensuring that they are evidence-based, up-to-date and relevant to current health priorities. To oversee the development, review and update of clinical guidelines is at the heart of the EHC's mandate. EHC is the final approver of the guidelines submitted by guideline development groups. It is responsible for the development of a dissemination plan and dissemination of approved guidelines through the digital platform developed by EHC. The Council is also responsible for managing the budget for the national guideline program.

The Higher Committee is formed by EHC and includes representatives from the key stakeholders. The secretariat of the higher committee is located within the EHC. The secretariat is responsible for collecting suggestions for priority topics from various health stakeholders and conducting the priority setting for selection of topics for guidelines development or adaptation. The secretariat is also responsible for selection of the GDG members and assigning the Technical Support Team for each GDG In addition, it reviews and approves the scope and objective of each guideline.

c. Guideline Development Group (GDG):

The GDG is a multidisciplinary group made up of key experts whose central task is to adapt or develop evidence-based recommendations. The GDG also performs the important task of finalizing the scope and key questions of the guideline in PICO format. GDG should be established early in the guideline development process. GDG members are selected to encompass the technical skills, diverse perspectives and geographic representation needed. The group can hold online or teleconference meetings but will need to have at least one face-to-face meeting to formulate the recommendations based on the appraisal of the best available evidence.

GDG members are not commissioned and do not receive any financial compensation other than for direct expenses associated with their work on the guideline. GDG members participate in the guideline adaptation or development process and at meetings as individuals and not as

representatives of the institutions or organizations with which they are affiliated to or selected from (World Health Organization, 2014).

d. Technical Support Team (TST)

In most cases, GDG members may not have the time, resources or the methodological expertise to conduct thorough reviews of evidence. Hence the role of the Technical Support Team (TST) is crucial in support of all methodological aspects of guideline development. The TST will conduct the needful searches, critical appraisals, analyses and evidence syntheses and provide the results in a transparent and systematic approach to the GDG. TST does not have a decision-making role. Final decisions related to a guideline will be made by the GDG, while TST provides technical advice to ensure the methods are systematically followed and adhered to. The below table (Table 1) further describes the required qualifications in the TST and roles.

Table 1: Qualifications and role of Technical Support Team (TST)

Qualifications	**Functions**
Essential qualifications: critical appraisal, systematic review methods and guideline development (e.g. GRADE approach) Desirable qualifications: Experience in developing high-quality systematic reviews on clinical care or public health topics; past experience of developing evidence-based guidelines; ability to understand the guideline topic area	• Provide a comprehensive, objective synthesis of the evidence to support the GDG during their deliberations • Provide input into the key questions; perform systematic reviews of the evidence; assess the quality of the body of evidence and develop GRADE evidence profiles

e. Other key stakeholders

Other stakeholders such as Medical Specialty Societies, military and policy health services, academia, and the private sector, play important roles in the development and implementation of the national guideline program.

All the stakeholders can suggest areas of concern or priority topics for guidelines to the secretariat of the Higher Committee, and actively participate in guideline adaptation as part of peer review processor guideline development groups.

Once the guidelines are adapted, stakeholders can ensure their implementation by incorporating the recommendations into clinical practice, accreditation programs and quality assurance programs. They can also advocate for and support the implementation of guidelines, and provide feedback on their impact.

Key references

World Health Organization. (2014). *WHO handbook for guideline development, 2nd Edition*. Available from: https://www.who.int/publications/i/item/9789241548960. (The link provides further resources including additional chapters of the handbook.)

World Health Organization Regional Office for the Eastern Mediterranean. (2024). *Establishing a national programme for guideline adaptation: Key steps and functions*. Available from: https://iris.who.int/bitstream/handle/10665/376106/9789292741761-eng.pdf?sequence=1&isAllowed=y&ua=1&ua=1

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Pan American Health Organization. (2018). *Strengthening national evidence-informed guideline programs: A tool for adapting and implementing guidelines in the Americas*. Available from: https://iris.paho.org/bitstream/handle/10665.2/49145/9789275120163_eng.pdf

ANNEX 1: Criteria for Priority Setting of Guideline Topics

Once topics have been identified, there are many criteria that can be used for prioritization, the most common of which are the following:

- Prevalence of the clinical problem
- Health burden of the disease (mortality, morbidity, or functional impairment)
- Cost of managing the problem (cost per person)
- Practice variation
- Significant differences in utilization rates for prevention, diagnosis, or treatment options.
- Potential impact of a guideline to improve health outcomes
- Expected effect on health outcomes
- Potential of a guideline to reduce costs
- Professional or policy maker interest in the topic
- Availability of evidence or existing guidelines

There is no hard and fast rule for priority setting, however, it is important to select a few basic criteria and apply them well to the process. Below are the three key minimum criteria that should be used for priority setting in the Egypt National Guideline Program:

1. **Health and cost burden of the disease**: Not just in terms of number of patients, but also in terms of cost burden.
2. **Practice variation (or lack of established policies):** Different clinicians giving different treatment orders.
3. **Potential impact of a guideline to improve health outcomes:** The situation is improved through the application of the guideline.

ANNEX 2: Qualifications and Roles of GDG Members:

Stakeholder category*	Qualifications	Role
Chair of GDG	Essential qualification: Expert in facilitating groups that reach decisions based on consensus among people with different opinions Desirable qualifications: • May be an expert recognized in the guideline's subject area, but should not have strong views about interventions under consideration • Experience in guideline development, knowledge of basic issues related to evidence-based medicine, or evidence synthesis	• Ensures harmonious functioning of the group, and encourages participation of all team members (breaks the tie where needed) • Leads, coordinates, and manages the • group's integrity and transparency of internal processes and discussion • Summarizes group decision, and participates in dissemination process • Ensures compliance with the project timeline • Supports drafting of the document
Methodological coordinator or methods expert	• Professional with education and experience in guideline development and/or adaptation • Expert in systematic reviews, GRADE and the translation of evidence into recommendations • Usually has experience in formulating public health recommendations • • Must provide conflict of interest statement	• With the chairs' support, the coordinator determines the activities to carry out throughout the process • Trains team members in the development or adaptation process • Supports the formulation of clinical questions and ranking of outcomes • Conducts quality control of the products developed • Coordinates the formulation of recommendations • Ensures adherence to the method • Supports drafting of the document • Participates in the guideline implementation and dissemination processes

Stakeholder category*	Qualifications	Role
Technical or content experts	• Professionals with experience in the area of interest for the guideline • Clinical professionals involved with the patient care covered by the guideline (will be users of the guideline) • Must provide conflict of interest statement	• Participates in the meetings convened throughout the process • Helps with the decision to adapt or develop the guideline • Contributes to the formulation of clinical questions and the ranking of outcomes • Engages with the TST during evidence search and selection processes • Provides relevant contributions regarding retrieved evidence • Actively participates in the consensus that leads to the recommendations • Supports the drafting of the document
End-users *(Whenever possible or necessary)*	• Stakeholders expected to refer to, or use the guidelines • Can also refer to people with direct experience in managing the condition or problem addressed by the guideline and who will have a role in implementing the recommendations	• Provide input on acceptability of interventions under consideration, and implementation considerations through a formal stakeholder involvement process.
Patient, caregiver, consumer or people's representatives *(Whenever possible or necessary)*	• For clinical guidelines, these representatives belong to a patient support group on the guideline's subject • Must provide conflict of interest statement	• Participates in relevant meetings convened throughout the process

Stakeholder category*	Qualifications	Role
Other experts	• **Project manager or administrative support** – provides support to the GDG in terms of timeline management, meeting arrangement logistics, document management, etc. • **Economist** - can advise on economic efficiency, such as cost–effectiveness, and on any other resource implications of the interventions under consideration • **Expert on equity, human rights and gender** - can contribute to the analysis and interpretation of evidence and determine how the intervention might affect certain subpopulations	
* Modified from WHO Handbook (World Health Organization, 2014)		

Technical or content experts	• Professionals with experience in the area of interest for the guideline • Clinical professionals involved with the patient care covered by the guideline (will be users of the guideline) • Must provide conflict of interest statement	• Participates in the meetings convened throughout the process • Helps with the decision to adapt or develop the guideline • Contributes to the formulation of clinical questions and the ranking of outcomes • Engages with the TST during evidence search and selection processes • Provides relevant contributions regarding retrieved evidence • Actively participates in the consensus that leads to the recommendations • Supports the drafting of the document
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Patient, caregiver, consumer or people's representatives ***(Whenever possible or necessary)***	• For clinical guidelines, these representatives belong to a patient support group on the guideline's subject • Must provide conflict of interest statement	• Participates in relevant meetings convened throughout the process • •
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* modified from WHO Handbook (World Health Organization, 2014)		

ANNEX 3: Evidence-to-decision Framework

Source : BMJ 2016 ;353:i2016 http://dx.doi.org/10.1136/bmj.i2016

Table 1 | Criteria for EtD frameworks for five different types of decisions

	Clinical recommendations–individual perspective	Clinical recommendations–population perspective	Coverage decisions	Health system and public health recommendations/decisions	Diagnostic, screening, and other tests*
Priority of the problem	Is the problem a priority?				
Test accuracy	Not applicable				How accurate is the test?
Benefits and harms	How substantial are the desirable anticipated effects?				
	How substantial are the undesirable anticipated effects?				
Certainty of the evidence	What is the overall certainty of the evidence of effects?				What is the certainty of the evidence of: - Test accuracy? - Any critical or important direct benefits, adverse effects, or burden of the test? - Effects of the management that is guided by the test results? - Link between test results and management decisions? - Effects of the test?
Outcome importance	Is there important uncertainty about or variability in how much people value the main outcomes?				Is there important uncertainty about or variability in how much people value the main outcomes, including adverse effects and burden of the test and downstream outcomes of clinical management that is guided by the test results?
Balance	Does the balance between desirable and undesirable effects favour the intervention or the comparison?				Does the balance between desirable and undesirable effects favour the test or the comparison?
Resource use	—	How large are the resource requirements (costs)?			
	—	What is the certainty of the evidence of resource requirements (costs)?			
	Does the cost effectiveness of the intervention (the out-of-pocket cost relative to the net benefits) favour the intervention or the comparison?	Does the cost effectiveness of the intervention favour the intervention or the comparison?		Does the cost effectiveness of the option favour the option or the comparison?	Does the cost effectiveness of the test favour the test or the comparison?
Equity	—	What would be the impact on health equity?			
Acceptability	Is the intervention acceptable to patients, their care givers, and healthcare providers?	Is the intervention acceptable to key stakeholders?		Is the option acceptable to key stakeholders?	Is the test acceptable to key stakeholders?
Feasibility	Is the intervention feasible for patients, their care givers, and healthcare providers?	Is the intervention feasible to implement?		Is the option feasible to implement?	Is the test feasible to implement?

*Tests cover clinical and public health recommendations at individual and population perspectives.

ANNEX 4: Template for a Writing a Guideline:

Item	Description
1. Title and date of release	
2. Authors and acknowledgements	
3. Executive summary	Should include all the recommendations included in the guideline. Background, methods and other sections of the guideline should be briefly presented.
4. Abbreviations and acronyms	
5. Summary of the health problem	The main problem and its importance should be mentioned.
6. Aims and scope of the guideline and specific objectives, including target populations, end users and settings	
7. Health care and public health questions as applicable	Should be presented in PICO format as far as possible
8. Methods for guideline adaptation	should include the citation details of the guideline(s) that was used for adaptation, and the methods used by the GDG for decision-making
9. Evidence summaries as well as assessment of the certainty of body of evidence	
10. Recommendations and Rationale for recommendations	
11. Applicability and implementation	**Including:** - recommendation flow chart or implementation support algorithms. - key facilitators and potential barriers of the implementation of the guideline recommendations. - other key information such as medication safety considerations and other risks that should be

	considered and planned for as the result of implementing the recommendations
12. Further important information	Suggestions for further research; limitations of the guideline; audit and monitoring of implementation; plans for updating the guideline
ANNEXES	
1. Summary of the assessments that resulted in the selection of the original guideline for adaptation 2. Evidence to decision framework 3. Citations and references 4. Funding sources and roles of the funder 5. Declaration and management of interests GDG members and other contributors (including external reviewers if applicable)	

ANNEX 5: Implementation of Guideline

(From WHO Handbook for Guideline Development (World Health Organization, 2014))

Implementation of a guideline should be taken into account right from the beginning of the guideline development. Implementation strategies are context-specific. The basic steps for implementing a guideline are:

- Convene a multidisciplinary working group to analyse local needs and priorities (looking for additional data on actual practice);
- Identify potential barriers and facilitating factors;
- Determine available resources and the political support required to implement recommendations;
- Inform relevant implementing partners at all levels; and
- Design the implementation strategy (considering how to encourage the adoption of the recommendations and how to make the overall context favorable to the proposed changes).

Implementation or operational research can help inform field testing and rollout strategies to promote the uptake of recommendations. There is a range of derivative documents or tools that can be developed to facilitate implementation. These can be distributed with the guideline, or local guideline implementers can develop them. Such documents or tools may include a slide set reflecting the guideline content; a "how to" manual or handbook; a flowchart, decision aide or algorithm; fact sheets; quality indicators; checklists; computerized applications; templates, etc.

ANNEX 6: Monitoring and evaluation of the guideline impact

(From WHO Handbook for Guideline Development (World Health Organization, 2014))

Monitoring and evaluation systems are used to collect and analyze data to assess the effectiveness and impact of the guideline. The guideline should include outcome or performance measures that can be monitored for the main recommendations. Performance measures may be related to:

- Guideline dissemination;
- Adaptation and endorsement in the national context;
- Policy changes;
- Changes in end-user knowledge and understanding;
- Changes in practice performance;
- Changes in health outcomes and inequities (both by level and distribution);
- Economic or other social consequences.

Ideally, there should be baseline measures against which to assess performance in relation to the potential change induced by the guideline. Operational and implementation research can be performed to assess service providers' and end-users' perceptions, and the values and preferences related to guideline implementation. The guideline should propose a specific set of indicators to be monitored and evaluated, including relevant disaggregation of data. Each guideline should include at least 3 indicators to measure its implementation and 3 indicators to measure its impact.