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Proposed Framework for MENA-SINO Guidelines adaptation and Practice Parameters development

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Abstract

Evidence-based guidelines tailored to the Middle East and North Africa (MENA) region are critical for improving stroke and neurointerventional outcomes, given varied epidemiological profiles, resource disparities, and cultural factors. This manuscript outlines a comprehensive framework established by the Middle East North Africa Stroke and Interventional Neurotherapies Organization (MENA-SINO) to develop, adapt, and update guidelines. The framework incorporates recognized methodologies (e.g., GRADE), encourages multidisciplinary collaboration, and addresses region-specific needs through "Resource-Limited" tags and novel Expert Opinion (EO) processes. "Mini Updates" function as a rapid mechanism to integrate high-impact new evidence into existing guidelines. By embedding robust stakeholder engagement, conflict-of-interest safeguards, and transparent publication procedures, this approach aims to unify practices and enhance the quality of stroke and neurointerventional care across diverse MENA healthcare settings.

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INTRODUCTION

Stroke is a leading cause of morbidity and mortality worldwide, and the MENA region faces particular challenges due to distinct socioeconomic demographic, countries torn by war with refugee status in neighboring countries and cultural contexts. Despite the availability of general international guidelines, discrepancies in resource availability—from access to advanced imaging facilities to reliable medication supplies—underscore the necessity for region-specific adaptations. Recognizing these unique challenges, MENA-SINO has endeavored to build a structured yet flexible system that guides clinicians, policymakers, and researchers in generating and implementing evidence-based recommendations effectively.[1]

To address these unique conditions, the Middle East North Africa Stroke and Interventional Neurotherapies Organization (MENA-SINO) has established a process to develop, adapt, and periodically refine evidence-based guidelines. This document:

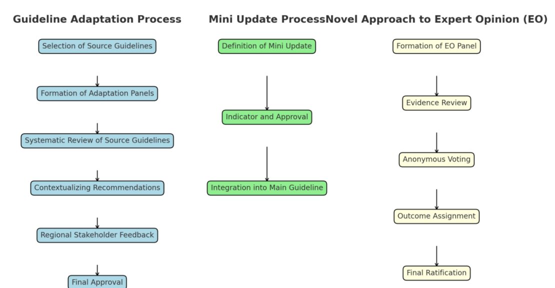
1. Provides a systematic process for guideline development aligned with recognized evidence-based methods (e.g., GRADE).[2,3]
2. Outlines a method for adapting existing, high-quality guidelines to MENA-specific contexts.
3. Introduces “Mini Updates” for rapid recommendation revisions.
4. Incorporates resource-limited tags, expert consensus categories, and clear conflict-of-interest management.
5. Emphasizes robust stakeholder engagement and transparent publication practices.

1. PROCESS FOR GUIDELINE DEVELOPMENT (Figure 1)

1. TOPIC SELECTION AND PRIORITIZATION

• Solicit potential guideline topics from MENA-SINO members, focusing on high-impact clinical questions in stroke and neurointerventional care, neurocritical care and neurorehabilitation (e.g., acute ischemic stroke, bleeding risk management, advanced endovascular devices). • Collect suggestions at least annually through open calls or internal MENA-SINO channels. Evaluate potential topics based on epidemiological importance, feasibility, degree of controversy, and potential impact on patient outcomes. • The MENA-SINO Guidelines and Practice Parameters Committee (G&PPC) selects topics for guideline drafting, subject to approval by the MENA-SINO Board of Directors.

Figure 1: flowchart for the steps for MENA-SINO Framework for writing Guidelines



2. FORMATION OF WRITING GROUPS

• Each guideline is developed by a writing group of 5–10 members, representing

Journal of Vascular and Interventional Neurology, Vol. 15

multiple MENA countries. • MENA-SINO encourages a diverse, multidisciplinary group, including physicians (interventional neurologists, interventional neuroradiologists, vascular neurologists, neurosurgeons, Neurocritical , ..etc) and nonphysician experts (e.g., nurses, pharmacists, research methodologists , etc). • Members submit conflict-of-interest (CoI) disclosures following recommendations from the International Committee of Medical Journal Editors (ICMJE). The G&PPC and MENA-SINO Board assess declared CoIs for severity (e.g., "significant" vs. "moderate"). • Group leaders (or co-leaders) must be experienced in both the guideline topic and the chosen methodological approach (e.g., GRADE). • The G&PPC finalizes the writing group composition by majority vote. Typically, each member addresses 1–3 PICO questions, ensuring workload balance.

3. DEFINING SCOPE

• Each guideline's scope is defined via the PICOTS framework (Population, Intervention, Comparator, Outcomes, Timeframe, and Setting). • All important outcomes for each clinical question are labeled as "critical," "important," or "limited" in importance. • Potential health-economic considerations may be identified but are typically beyond the depth of these guidelines (left to health policymakers).

4. EVIDENCE REVIEW

• The writing group conducts a systematic review of peer-reviewed literature, existing reputable organizational guidelines (e.g., ACC/AHA, SVIN), and relevant meta-analyses. • Searches generally encompass multiple databases (PubMed/MEDLINE, Embase, Cochrane Library) and are executed or overseen by individuals with methodological expertise. • Data extraction uses a transparent workflow (e.g., PRISMA chart). Critically appraised sources inform the final evidence rating, which follows established tools (e.g., Cochrane RoB2 for RCTs, ROBINS-I for observational studies).

5. DRAFTING RECOMMENDATIONS

• MENA-SINO's "Modified Applying ACC/AHA Class of Recommendation (COR)[4] and Level of Evidence (LOE)" model provides the basis for recommendation grading, in parallel with recognized GRADE practices:

– Class of Recommendation (COR): 1. Strong (Benefit >>> Risk) 2. Moderate (Benefit >> Risk) and 2a. Weak (Benefit ≥ Risk) 3. No Benefit or Harm > Benefit

– Level of Evidence (LOE): A. High-quality (multiple RCTs/meta-analyses) B. Moderate-quality (one RCT or multiple observational studies) C. Expert opinion or small patient series

• If robust region-specific data is unavailable, an Expert Opinion (EO) statement may be added. EO statements employ a secret-ballot (Delphi) approach within the writing group to ensure consensus. • Local resource limitations, epidemiologic profiles (e.g., higher prevalence of certain comorbidities, younger stroke populations), and cultural factors may warrant re-weighting or downgrading initially higher-level recommendations.

6. COMMITTEE REVIEW AND APPROVAL

• The draft guideline undergoes two main review stages:

Preliminary review by the MENA-SINO G&PPC, possibly with input from external consultants.

Final review and ratification by the MENA-SINO Board of Directors.

Journal of Vascular and Interventional Neurology, Vol. 15

• MENA-SINO may consult external experts for additional insights on crucial methodology or content gaps. • Once approved, the guideline is published in open-access format (e.g., MENA-SINO's official website, relevant journals), maximizing visibility across the MENA region.

2. PROCESS FOR GUIDELINE ADAPTATION (Figure 1)

Recognizing that established international guidelines (e.g., ACC/AHA, SVIN) may not fully capture MENA-specific circumstances, MENA-SINO uses an adaptation process:

1. SELECTION OF SOURCE GUIDELINES

• Select prominent guidelines demonstrating robust methodology and evidence strengths. • Assess alignment with MENA priorities (common stroke etiologies, real-world resource constraints, cultural considerations).

2. FORMATION OF ADAPTATION PANELS

• A 5–10 member panel (similar in structure to a writing group) meets to adapt a given guideline. At least one member should be highly knowledgeable about the source guideline. • Aim for broad representation within MENA to capture variable healthcare infrastructures and practices.

3. SYSTEMATIC REVIEW OF SOURCE GUIDELINES

• The panel reviews the methodology of the original guideline, focusing on COR/LOE assignment and potential biases. • It highlights areas reliant on expert consensus or observational data that may require re-evaluation for MENA settings. • Supplementary literature searches may be performed if newer data have emerged since the guideline's publication.

4. CONTEXTUALIZING RECOMMENDATIONS

• Recommendations are modified to account for resource constraints (e.g., limited advanced imaging, cost barriers) and regionally prevalent comorbidities. • An "Adapted for MENA" tag distinguishes recommendations that have changed based on local factors. • If insufficient data exist, the panel may produce an Expert Consensus statement specific to MENA.

5. REGIONAL STAKEHOLDER FEEDBACK

• The draft adaptation is presented to relevant MENA stakeholders (clinicians, ministries of health, patient advocacy groups) for comments on feasibility and cost implications. • Any major concerns may prompt additional revisions or lead to an EO-based recommendation.

6. FINAL APPROVAL

• The adaptation receives final endorsement from the MENA-SINO G&PPC and Board of Directors. • The adapted guideline is disseminated through MENA-SINO websites, professional societies, and local conferences to ensure uptake.

3. "MINI UPDATE" PROCESS (Figure 1)

Occasionally, major new studies may alter a recommendation before a guideline's scheduled revision. MENA-SINO addresses such developments via Mini Updates:

1. DEFINITION OF "MINI UPDATE"

• A short update publication that affects only one or a few sections of an existing guideline. • Typically spurred by pivotal new evidence (e.g., a recently published

RCT or meta-analysis) that could change clinical practice.

2. INDICATOR AND APPROVAL

• Any MENA-SINO member or recognized external expert can request a Mini Update if data substantially modifies the benefit-risk calculation. • The original writing or adaptation panel rapidly reviews and grades the new data. • Following expedited approval by MENA-SINO's Executive Committee, the Mini Update is published.

3. INTEGRATION BACK INTO THE MAIN GUIDELINE

• Content from the Mini Update is incorporated during the next scheduled full revision. • Maintaining clarity and consistency across all recommendations ensures guidelines remain up-to-date yet cohesive.

4. MODIFIED APPLYING ACC/AHA CLASS OF RECOMMENDATION AND LEVEL OF EVIDENCE

MENA-SINO endorses a combined approach based on ACC/AHA COR/LOE and recognized GRADE frameworks:

Class of Recommendation (COR)

- (1) Strong (Benefit >>> Risk)
- (2) Moderate (Benefit >> Risk), (2a) Weak (Benefit ≥ Risk)
- (3) No Benefit / Harm > Benefit

Level of Evidence (LOE)

- (A) High-quality (≥2 RCTs or robust meta-analyses)
- (B) Moderate-quality (single RCT or multiple observational studies)
- (C) Expert Opinion / small case series

RESOURCE-LIMITED CONSIDERATIONS

• Many MENA countries operate under constrained circumstances (e.g., limited specialized facilities, certain pharmaceuticals). • A therapy rated Class I/LOE A in well-resourced settings might be impractical or inaccessible regionally, necessitating a Resource-Limited (RL) tag or potential downgrading.

"Resource-Limited" (RL) Tag : If the recommended therapy or diagnostic strategy may be challenging to implement in certain MENA settings (e.g., advanced imaging or specialized devices), the recommendation acquires an (RL) tag.

• If no practical alternative exists, the recommendation may be shifted to Expert Opinion status.

5. NOVEL APPROACH TO EXPERT OPINION (EO)

EO CATEGORY AND APPLICATION

EO–Strong Agreement : ≥75% of the panel endorses the recommendation following review of available evidence. (implies that more than 75% of the panel a solid majority endorses the recommendation.)

EO–Partial Accord: ≥50% but <75% endorsement, reflecting partial agreement or limited data. (indicates that over half the panel supports it, but not to the point of strong consensus.)

Process for Determination of EO

1. **Formation of EO Panel**
   a. A subset of 5–10 experts with ≥5 years of clinical and/or research experience in the guideline topic.

b. At least one member from the guideline's original writing team and additional MENA-based experts to represent regional diversity.

2. **Evidence Review**
   a. Each EO panelist reviews the relevant data (up to five key articles or documented experience).
   b. Identify alignment or gaps between the current global guidelines and actual MENA practice.

3. **Anonymous Voting**
   a. To avoid groupthink, voting occurs anonymously via electronic survey.
   b. Experts vote "Yes" or "No" on a proposed recommendation, followed by ≥50 words explaining rationale.

4. **Outcome Assignment**
   a. If ≥75% vote "Yes," the recommendation is EO–Consensus.
   b. If ≥50% but <75% vote "Yes," the recommendation is EO–Variance.
   c. Results are then integrated into the final guideline or Mini Update with an explicit mention of the EO rating. Or discuss it for consensus for an example

5. **Final Ratification**
   a. The EO determination is presented to the MENA-SINO Guidelines and Practice Parameters Committee for acceptance by majority vote (>50%).
   b. The Board of Directors confirms final adoption.
   c. EO-based recommendations are noted as potentially evolving if new data become available.

CONCLUSION

By blending a structured guideline-development process with specific adaptations for MENA-related priorities, MENA-SINO upholds best practices that are both methodologically sound and attainable within diverse healthcare environments across the Middle East and North Africa. "Mini Updates" offer a rapid mechanism to incorporate high-impact new evidence, ensuring guidelines remain contemporary. Employing a careful balance of rigorous data appraisal and expert consensus fosters clarity, cultural sensitivity, and realistic recommendations, ultimately enhancing stroke and neurointerventional care within MENA.[5]

This coordinated approach aims to raise clinical standards, unify practices, and create flexible yet authoritative guidelines that evolve in step with scientific progress, improving patient outcomes across the MENA region.

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Journal of Vascular and Interventional Neurology, Vol. 15