AAFP Clinical Practice Guidelines: Championing Science and Evidence in Your Practice

David O'Gurek, MD, FAAFP
Bellinda K. Schoof, MHA, CPHQ, CAE
Melanie Bird, PhD

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All individuals in a position to control content for this session have indicated they have no relevant financial relationships to disclose.

The content of my material/presentation in this CME activity will not include discussion of unapproved or investigational uses of products or devices.

David O'Gurek, MD, FAAFP

Associate Professor, Department of Family and Community Medicine, Lewis Katz School of Medicine at Temple University, Philadelphia, Pennsylvania; Director of Urban Community Health, Center for Bioethics, Urban Health, and Policy, Temple University, Philadelphia, Pennsylvania

Dr. O'Gurek earned his medical degree from the Pennsylvania State University College of Medicine, Hershey, and completed a family medicine residency at Lancaster General Health in Pennsylvania. He practices comprehensive outpatient family medicine, as well as coordinating an office-based opioid treatment (OBOT) program for patients who have opioid use disorder. In his role as Director of Urban Community Health, he coordinates undergraduate and graduate medical education programs on social determinants of health and community health advocacy. He also serves as the director of Begin the Turn, a community-based, trauma-informed public health solution to address the overdose crisis. Dr. O'Gurek collaborates with Temple University’s faculty practice and the Temple Center for Population Health on creative methods to address the university’s community health needs assessment. Notably, he has partnered with the City of Philadelphia and its agencies to address the overdose crisis. He is a former chair of the AAFP’s Commission on Health of the Public and Science.
Bellinda K. Schoof, MHA, CPHQ, CAE

Director, Health of the Public and Science Division, American Academy of Family Physicians, Leawood, Kansas

Schoof has 20 years of experience in evidence-based clinical guideline development, clinical and population health policy development and promotion, and implementation of evidence-based interventions at the family medicine practice level. Her previous roles in the AAFP’s Health of the Public and Science Division have included acting director and clinical policies manager. Prior to her career at the AAFP, she served as director of the Health Care Quality Improvement Program at the Kansas Foundation for Medical Care in Topeka. Schoof earned her Bachelor of Science degree in public health and her Master of Health Administration (MHA) degree from Indiana University, Bloomington. She is certified in grant writing through the Grantsmanship Center, a Certified Professional in Healthcare Quality (CPHQ) through the National Association for Healthcare Quality, and a Certified Association Executive (CAE) through the American Society of Association Executives.

Melanie Bird, PhD

Clinical Policies Strategist, American Academy of Family Physicians, Leawood, Kansas

Bird earned a Bachelor of Science (BS) degree in microbiology from Kansas State University in Manhattan and a doctoral degree in experimental pathology from the University of Texas Medical Branch Graduate School of Biomedical Sciences in Galveston. She completed her postdoctoral training at the Loyola University Stritch School of Medicine in Maywood, Illinois. Bird has more than 20 years of research experience and has participated in or led multiple funded projects that have resulted in numerous peer-reviewed journal articles. In her current role at the AAFP, she participates in the review and development of clinical guidelines that are based on independent systematic reviews of the evidence and adhere to a rigorous methodology for grading the evidence and developing recommendations. She also aids in the development of additional clinical resources for family physicians, including policies, clinical recommendations, quality improvement resources, and point-of-care toolkits.
Learning Objectives

1. Describe the process used by the AAFP to review clinical practice guidelines for potential endorsement.

2. Articulate key steps in the AAFP’s grading of recommendations and development of evidence-based clinical practice guidelines.

3. Assimilate the AAFP’s practical approach to evaluating literature to remain up to date as well as evidence-based in practice.

4. Identify best practices for implementation of key recommendations to manage chronic conditions based on recent guidelines developed by the AAFP.

Audience Engagement System

Step 1
Step 2
Step 3
Clinical Practice Guidelines (CPGs)
Characteristics of Trustworthy* CPGs

- Informed by a systematic review of the evidence & assessment of benefits and harms of alternative care options
- Follow sound, transparent methodology to translate evidence into practice
- Patient-oriented outcomes are prioritized
- Feasible, measurable, and attainable
- Sound enough to consider development of clinical performance measures from recommendations

*National Academy of Medicine (IOM) Standards for Trustworthy Guidelines
**CPC Guideline Development in Action**

**Screening and Treatment of Depression Following Acute Coronary Syndrome**

Topic Generation

Subcommittee on Clinical Recommendations & Policies (SCRP)

- The AAFP Guideline for the Detection and Management of Post-Myocardial Infarction Depression was reviewed and designated for an update.
- Topic was nominated to the Agency for Healthcare Research and Quality (AHRQ) for an systematic review/evidence report
- Key questions were developed to guide the systematic review
  - Informs the literature search and eventual recommendations

Table 1. American Academy of Family Physicians Grading System†

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AAFP Board of Directors
Commission on Health of the Public & Science

Evidence Synthesis & Review

Guideline Creation

- AAFP Approval
- Publication
- Dissemination
- 5 year update
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<td>Indication of low confidence in the net benefit for patient-oriented outcomes.</td>
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**Guideline Creation**

- AAFP Approval
- Publication
- Dissemination
- 5 year update

**RECOMMENDATIONS & GUIDELINE DEVELOPMENT**

**Key Question Development**

| P | Population | age, condition, ethnicity, sex/gender, etc |
| I | Intervention | Treatment or diagnostic tool |
| C | Comparison | Placebo, no treatment, standard of care |
| O | Outcome | Mortality, symptoms, quality of life, diagnostic accuracy, |

**Disease-oriented outcomes**

- Intermediate, physiologic or surrogate end points

**Patient-oriented outcomes**

- Outcomes that matter to patients
### Key Question Development

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**Disease-oriented outcomes**
- Intermediate, physiologic or surrogate end points

**Patient-oriented outcomes**
- Outcomes that matter to patients

### Poll Question #1

Which of the following would be considered patient-oriented outcomes?

A. Lower systolic blood pressure  
B. Reduced blood hemoglobin A1c  
C. Increased LDL  
D. Increased risk of stroke
AHRQ 2017 Evidence Report

- **KQ1**: What is the accuracy of depression screening instruments or screening strategies compared to a validated criterion standard in post-ACS patients?

- **KQ 2**: What are the comparative safety and effectiveness of pharmacologic and nonpharmacologic depression treatments in post-ACS patients?

Evidence for KQ1

- **Instruments Evaluated**: Beck Depression Inventory II [BDI-II], Geriatric Depression Scale [GDS], Hospital and Anxiety Depression Scale [HADS], and Patient Health Questionnaire [PHQ]

- Screening in post-ACS patient populations was comparable to general populations.
  - All instruments produced generally acceptable sensitivity, specificity, and negative predictive values but had low positive predictive values.

- One or two specific items from validated screening scales (BDI-II, PHQ) may be almost as accurate for diagnostic screening as using the full instrument

The BDI-II studies indicated a sensitivity of 90% and specificity of 80% based on 4 studies with over 1500 patients. Strength of evidence was rated moderate to high quality.

### Evidence for KQ2

- **Antidepressants alone** = small positive effect of antidepressants

- **Cognitive behavioral therapy (CBT) plus antidepressants**
  - Improved depression symptoms, mental health–related function, and overall life satisfaction
  - No consistent difference on MACE, cardiac mortality, all-cause mortality, repeat ACS, revascularization, or cardiac hospitalization
  - Other adverse events not reported

- **In summary** = Strength of evidence was stronger for depression than for cardiovascular outcomes, and stronger for CBT with antidepressants than for enhanced care strategies or antidepressant treatment.
## CBT/Antidepressants vs Usual Care

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<th>Outcome</th>
<th>Number of Studies/ Number of Patients</th>
<th>Effect Estimate (95% CI)</th>
<th>Strength of Evidence</th>
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<tr>
<td>Depression symptoms</td>
<td>1 study 2,481 patients</td>
<td>Mean difference -2.7 (CI -3.7 to -1.7) BDI SMD -0.31 (CI -0.42 to -0.20)</td>
<td>High</td>
</tr>
<tr>
<td>Mental health–related function</td>
<td>1 study 2,481 patients</td>
<td>Mean difference 2.2 (CI 1.2 to 3.2) SF-12 MCS SMD 0.24</td>
<td>High</td>
</tr>
<tr>
<td>MACE</td>
<td>1 study 2,481 patients</td>
<td>HR 1.01 (CI 0.86 to 1.18) for death or nonfatal MI</td>
<td>Moderate</td>
</tr>
<tr>
<td>Adverse effects</td>
<td>Not reported 331 patients</td>
<td>--</td>
<td>Insufficient</td>
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## Antidepressants vs Usual Care

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<td>Depression symptoms</td>
<td>1 study 331 patients</td>
<td>Mean BDI 11.0 vs 10.2 SMD 0.12 (CI -0.10 to 0.34)</td>
<td>Moderate</td>
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<tr>
<td>Mental health–related function</td>
<td>1 study 331 patients</td>
<td>Mean at 18 months 44.5 vs 43.4 SF-36 MCS SMD 0.14</td>
<td>Low</td>
</tr>
<tr>
<td>MACE</td>
<td>1 study 331 patients</td>
<td>OR 1.07 (0.57 to 2.0) for MACE</td>
<td>Low</td>
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Guideline Panel Development

- Following the completion of the independent systematic review, a guideline panel is formed consisting of a chair and 5-6 other members
  - FPs
  - Collaborator reps (other medical specialties)
  - Patient/Patient Advocacy
Conflict of Interest Management

• Financial COI
  – Material influence that could influence, or be perceived as influencing, an individual's point of view

• Intellectual COI
  – Activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation

Conflict of Interest Management

• Whenever possible guideline members should not have COI
• Chair or co-convener should not have COI and remain free of COI for 1 year following publication
• Members with COI should not represent more than 50% of panel
• Funders should have no role in development of the guideline recommendations
Review & Management of COI

• Disclosures reviewed prior to placement on panel
  – Potential for exclusion from panel or limits from discussion or voting on related recommendations

• COI updated at each meeting

Poll Question #2

Which of the following would be considered an intellectual conflict of interest?

A. Listed on a speakers bureau for a pharmaceutical company
B. Journal articles and editorials on the guideline topic
C. Stock options in a pharmaceutical company
D. Expert Witness Testimony
**Recommendation Development**

- AAFP uses a modified GRADE method to systematically examine research
  
  – GRADE – Grading of Recommendations Assessment, Development, and Evaluation

http://www.gradeworkinggroup.org/
Recommendation Development

- GRADE has been adopted by many groups including AAFP, ACP, AHRQ, and CDC.
- This is different from the Strength of Recommendation Taxonomy (SORT) used by the American Family Physician journal.
- Both are valid systems, but AAFP’s work in guideline development is separate from the review articles published in American Family Physician.

GRADE Methodology

- Provides a transparent process or framework to:
  - Assess the quality of the evidence (estimate of effect)
    - High quality: further research is very unlikely to change our confidence
    - Moderate quality: further research is likely to have an important impact on our confidence
    - Low quality: further research is very likely to have important impact on our confidence
    - Very low quality: any estimate of effect is very uncertain
  - Develop structured recommendations based on the evidence
    - Strong and weak (conditional) recommendations
    - Rationale for the recommendation and factors (values/considerations) influencing the recommendation
GRADE—Evaluating the Evidence

- RCTs start off as high quality (high certainty) but can be lowered if concerns:
  - Risk of bias (individual study)
  - Inconsistency across studies
  - Indirectness (not relevant to PICO)
  - Imprecision (relative to effect estimate)
  - Publication bias
- Observational studies start as low quality (low certainty) and can be raised for:
  - Large effect
  - Dose response
  - Residual Confounders (see an effect “despite” confounders)

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Table 1. American Academy of Family Physicians Grading System

*The AAFP uses a modified version of Grading of Recommendations Assessment, Development and Evaluation (GRADE)

*Recommendations can be either for or against an intervention or testing modality.

**The strength of the recommendation should be consistent with the quality of the evidence such that strong recommendations are based on high quality evidence, whereas weak recommendations are based on low to moderate quality evidence. Very low-quality evidence should be considered insufficient for a recommendation unless there are highly unusual circumstances and the benefits would greatly outweigh the harms.
Recommendation Development

KQ1: What is the accuracy of depression screening instruments or screening strategies compared to a validated criterion standard in post-ACS patients?

Recommendation 1: The AAFP recommends that clinicians consider screening for depression, using a standardized depression screening tool, in patients who have recently experienced acute coronary syndrome (weak recommendation, low quality evidence).

Recommendation 1

- The panel determined that the quality of evidence was low due to the following:
  - Lack of direct association of screening and outcomes in this population (chain of evidence)
  - Only BDI-II had enough data to support a strength of evidence assessment
  - While the screening tools were comparable, they had low predictive values
Recommendation Development

KQ 2: What are the comparative safety and effectiveness of pharmacologic and nonpharmacologic depression treatments in post-ACS patients?

**Recommendation 2**: The AAFP strongly recommends that clinicians prescribe antidepressant medication, preferably selective serotonin reuptake inhibitors (SSRIs) or serotonin and neurotin reuptake inhibitors (SNRIs), and/or cognitive behavioral therapy (CBT) to improve symptoms of depression in patients who have a history of ACS and have been diagnosed with depression (**strong recommendation, moderate quality evidence**).

Recommendation 2

- The panel determined that the quality of evidence was **moderate** due to the following:
  - Moderate (SSRI alone) to high (SSRI/CBT) quality evidence for treatment of depressive symptoms
  - Consistent with previous recommendation and evidence report
Guideline writing process

• Includes intent, rationale, and scope in all guidelines
• Recommendations should be specific and clear, keeping number to a minimum
• Consider implementation (at point of care through EMR, tools/resources needed)
• Discuss updating/review practices*

Updating and Review Process

• All AAFP guidelines undergo review every 5 years
  – Literature monitored routinely so updates may occur sooner than 5 years
• Determine if systematic review needed
• Guideline can be reaffirmed or sunsetted
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<td>A recommendation that is not supported by evidence but may be important for patients and practitioners.</td>
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Guideline Creation
- AAFP Approval
- Publication
- Dissemination
- 5 year update

AAFP Guideline Review Form

CLARITY AND PRESENTATION
- Recommendations specific, unambiguous
- Different options for management of condition clearly presented
- Key recommendations identifiable
- Evidence gaps and research needs detailed

APPLICABILITY
- Applicable to Family Medicine practice
- Application / Risk assessment tool available
- Guidelines describe facilitators & barriers to its application
- Potential cost implications considered
- Monitoring/audit criteria presented

EDITORIAL INDEPENDENCE
- Content of guideline not influenced by funding body
- Competing interests of guideline panel members reported & addressed
- Fewer than 50% of panel members with COI: Chair of panel is free of COI

OVERALL ASSESSMENT OF GUIDELINE QUALITY

Adapted from the AGREE II tool
Endorsement of Non-AAFP Guidelines

• Development of clinical practice guidelines is time and resource intensive, limiting the number that are developed
• Starting in 2008, the AAFP began using endorsement as a way to increase the number of clinical practice guidelines available to members
• It is important to note that guidelines endorsed by the AAFP are separate from guideline summaries in the *American Family Physician (AFP)* journal.
  – If a guideline or clinical recommendation is in the *AFP* journal, this does not make it AAFP policy.

Endorsement of Non-AAFP Guidelines

• Six Domains to Assess:
  – Scope and Purpose
  – Stakeholder involvement
  – Rigor of Development
  – Clarity and Presentation
  – Applicability
  – Editorial Independence

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<tr>
<td>Good</td>
<td>well described and meets criteria/considerations</td>
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<tr>
<td>Fair</td>
<td>information reported but not meet full criteria (lacking detail or insufficiently addressed)</td>
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<tr>
<td>Poor</td>
<td>no information or poorly reported</td>
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• **Endorsed** = criteria met, overall rating of good
• **Affirmation of Value** = most criteria met, some flaws, overall rating of good or fair
• **Not Endorsed** = criteria not met, major flaws, overall rating of fair or poor
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Key Question Development

Evidence Report

Evidence Synthesis & Review

Guideline Creation

- AAFP Approval
- Publication
- Dissemination
- 5 year update

Recommendations & Guideline Development

Approval Process

AAFP BOD

Publication

Dissemination

5-year review

SCRP

CHPS

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RECOMMENDATIONS & GUIDELINE DEVELOPMENT

Panel

Guideline

TOPIC GENERATION

(topic)
Moving Guideline to Practice

- Recommendations are written clearly and are actionable
  - Incorporation into EMRs
- Algorithms and supporting resources provided
- Considerations for cost
- Barriers and facilitators to implementation

Poll Question #3

Do you plan to implement screening for depression in patients with a recent ACS event?

A. Yes
B. No
C. Will consider after further reading/discussion
Resources

- National Academy of Medicine
- AAFP Guidelines
- AAFP Guideline Development video
- GRADE
Questions