Development Process for Practice Guidelines of the American Psychiatric Association - Revised

Background and Overview

The guideline development process described in this document was initially approved by the American Psychiatric Association (APA) Steering Committee on Practice Guidelines on September 8, 2011 and revised by the Committee on Practice Guidelines (CPG) on August 04, 2017. This is a living document that will be updated as new processes are implemented and tested. The process used to develop individual guidelines will be described in their publication. Because of continuous innovation and improvement, the process used may not necessarily match exactly what is described here.

APA's guideline development process is intended to meet standards for the development of "trustworthy" practice guidelines recommended by the National Academy of Medicine, formerly the Institute of Medicine (IOM), in a report published in March 2011. The standards address transparency, management of conflicts of interest, composition of writing groups, use of systematic reviews of evidence, articulation and rating of recommendations, external review, and updating.

Other recent reports also provide standards or principles for development of guidelines, including the American Medical Association's (AMA's) Physician Consortium for Performance Improvement² and the Council of Medical Specialty Societies.³ APA's process has been informed by these reports as well as by innovative development processes used by other medical specialty societies.

The process also builds upon APA's previous guideline development process,⁴ which was designed to be aligned with principles described in early IOM^{5,6} and AMA⁷ reports. Approved guidelines are available through APA Publishing at www.psychiatryonline.org/guidelines, as well as the APA Clinical Practice Guidelines page and the National Guideline Clearinghouse.

The following elements of APA's pre-2011 development process continue to be included in the current process as described in this document:

- Appointment of writing groups that are balanced with respect to expertise, geographical location, and demographic background
- Disclosure of potential financial conflicts of interest by writing groups on appointment, during development, and on publication
- Limits on the participation of individuals with potential conflicts of interest, e.g., from significant financial relationships with industry
- Rigorous review of supporting evidence
- Broad review of guideline drafts
- Approval of guidelines by the APA Assembly and Board of Trustees

In addition, the current process includes the following elements intended to make APA guideline development more transparent, rigorous, and in line with the 2011 IOM recommended standards:

- Guidelines are organized around clinical questions, which may be in PICO(TS) format, i.e., population, intervention, comparison, outcome, and when applicable, timing and setting.
- Subject matter experts from multiple disciplines and patient/family advocates provide input.
- Guideline statements are separately rated according to strength of supporting research evidence and strength of recommendation.⁸
- Strength of supporting research evidence is determined through systematic review of the evidence, determinations of the risk of bias of individual studies, and assessment of the overall quality of the body of research evidence.
- In the absence of high quality research evidence, APA has chosen to use expert opinion as determined by formal survey of large panels of research and clinical experts.
- Consensus about guideline statements and ratings is determined by modified Delphi method through blind iterative voting.
- Guidelines are published as sets of recommendations or suggestions, each addressing a clinical question or related set of clinical questions.
- Literature searches are conducted on a regular basis after guideline publication with updating of guideline statements and text, as needed, to maintain all guidelines as current.

The flow chart below shows the current development process.

APA Practice Guideline Development Process

	Committee on Practice Guidel		Guideline Writing Group	Stakeholders	APA Assembly and Board of Trustees	Expert Survey Panel
Step 1 ~4 months	Selects relevant experts for GWG				Review COI information and approve new GWG members	
Step 2 ~ 2 months		Formulates clinical questions	Review clinical que	estions		
Step 3 ~12 months		Assesses literature and determines level of evidence				
Step 4 (as needed, concurrent with Step 3) ~12 months		Draft expert opinion survey		Nominate experi	ts for expert opinion survey	Completes survey
Step 5 ~8 months	Oversees guideline process		Reviews conclusions from evidence and survey and drafts recommendations			
			Delphi			
Step 6 ~2 months			Reviews and approves draft guideline modules		Review draft guidelines modules	
Step 7 ~1 month			Reviews comments			
			Delphi			
Step 8 ~4 month			Finalizes guideline modules			
Step 9 ~1 month	Reviews and approves guidelines for Assembly/BOT submission	for				
Step 10 ~2 months					Review and approve guideline modules for publication	

Organizational Structure

The following groups participate in approval, development, and review of APA practice guidelines:

Approval

- APA Board of Trustees
- APA Assembly

Development

- Committee on Practice Guidelines (CPG)
- Guideline Writing Group (GWG)
- Systematic Review Advisors (SRAs)
- APA staff and consultants

Review

- Stakeholders
- Expert Survey Panels
- APA Assembly and BOT

Individuals in each group are subject to different participation rules, as described in the following. These rules are intended to minimize potential bias from conflicts of interest and are considered by APA to be consistent with the 2011 IOM standards and with principles recommended by the Council of Medical Specialty Societies.⁹

APA Board of Trustees and Assembly

The APA Assembly and Board of Trustees are composed of APA members elected by the APA membership. The Assembly is a deliberative body consisting of representatives from district branches/state associations of the association as well as representatives of minority/underrepresented groups, resident-fellows, early career psychiatrists, and representatives from allied organizations. The Assembly advises on and recommends actions to the Board of Trustees. The Board is composed of 14 voting members, who govern the association through an executive process.

The Assembly and the Board provide input to the CPG at multiple steps of the guideline development process, including identification of experts for consensus panels and substantive review of draft guidelines.

The Assembly recommends and the Board of Trustees votes to approve publication of new practice guidelines under the imprimatur of APA.

The Conflict of Interest Committee reviews disclosures by candidates for the CPG and GWGs before their appointment by the APA President and approval by the APA Board of Trustees. The conflict of interest policy, which is approved by the Board of Trustees, is determined by the Conflict of Interest Committee for all APA activities including for the CPG and for GWGs.

This document summarizes the current policy; the full policy is described in the APA Operations Manual, which is available from the APA Department of Governance at https://www.psychiatry.org/about-apa/read-apa-organization-documents-and-policies.

Committee on Practice Guidelines

The role of the CPG is to define the APA guideline development process and ensure adherence to the process, including use of methods established a priori to determine ratings of strength of research evidence and strength of guideline statements as well as procedures established a priori to determine consensus. Based on fidelity to process, the CPG approves the submission of finalized guidelines to the APA Assembly and Board for association approval.

The CPG is comprised of six members plus consultants and seven liaisons from the APA Assembly Areas. Members of the CPG are vetted by the Conflict of Interest Committee and appointed by the APA President. They serve 5-year terms with the possibility of one renewal. All members of the CPG must make disclosures on appointment and at regular intervals during their terms. The chairs must not have any conflicts of interest. The rest of the CPG should not have any conflicts of interest as well. Per APA policy, individuals and their spouses may not receive more than \$5,000 per year in direct payments from industry–related work. All other forms of financial support, commercial involvements, or other financial involvements must be disclosed as specified in the APA Disclosure of Interest Policy. Currently, all members have zero ties with industry. Any member of the CPG who has a financial conflict is asked to recuse him- or herself from voting on decisions about the development process or relevant guidelines.

Guideline Writing Group

The role of the GWG is to write and determine the ratings of the strength of the guideline statements. The GWG receives authorial credit for published guidelines, with the chair of the GWG serving as first author.

The group consists of 8–10 volunteer APA members who are psychiatrists with general research and clinical expertise, plus ad hoc members who are specialists in the topic area. Ad hoc members may or may not be APA members and can include individuals with various professional backgrounds (e.g., psychiatrists, other physicians, psychologists, nurses, etc.). In addition to diversity of expertise, the GWG aims to have diversity with respect to characteristics such as geographical location and demographic background. GWG members are identified by the CPG and GWG chair, vetted by the Conflict of Interest Committee, and appointed by the APA President. Each member serves a 5-year term, with the possibility of one reappointment.

All members of the GWG must make disclosures on appointment, at regular intervals during their terms, and at the time of guideline publication. The GWG chair and vice-chair must not have any conflicts of interest. The rest of the GWG should not have any conflicts of interest as well, except in cases where it may not be possible to find specialists without conflicts. Per APA policy, individuals and their spouses may not receive more than \$5,000 per year in direct payments from industry—related work. All other forms of financial support, commercial involvements, or other financial involvements must be disclosed as specified in the APA Disclosure of Interest Policy. Members of the GWG who have a financial conflict are asked to recuse themselves from discussion of and voting on relevant recommendations/statements and ratings.

Systematic Review Advisors

The role of the SRAs is to perform systematic reviews of evidence, including determining clinical questions and ratings of quality of evidence. The SRAs also determine whether systematic reviews available from other sources including the Cochrane Collaborative and AHRQ are appropriate for use in APA guidelines, when relevant. The SRAs also nominate topics for AHRQ development of systematic reviews and develop the expert surveys, as needed.

The SRAs include a methodologist who also serves as vice-chair of the GWG, acts as a resource on methodological matters, and does not vote on guideline statements. SRAs may also include contractors, such as Doctor Evidence, as well as other individuals, such as APA members, APA staff or contract employees, who have specific training or experience in systematic review methodology. The number of SRAs depends on the amount of work required to search, screen, and review available evidence, or analyze survey data for guidelines under development. Other members of the SRAs and the GWG do not overlap.

SRAs must make disclosures on appointment, at regular intervals during their terms, and on guideline publication. No one who serves as a SRA may have a conflict of interest.

SRAs are acknowledged on guideline publication.

APA Staff

APA staff implement the guideline development process and publish the guidelines under the imprimatur of APA. They include managerial, administrative, and publications staff.

Stakeholders

Draft clinical questions (except when AHRQ reviews are used) and guidelines may be made available for review by the following groups: APA members including APA Councils, patient/family advocacy groups, medical/professional groups, experts, and the general public. Stakeholders are asked to disclose relevant conflicts of interest and may choose to be acknowledged on guideline publications. Their acknowledgement does not imply endorsement of the guideline.

Expert Survey Panels

Expert opinion about interventions that may be recommended/suggested in APA guidelines may be determined by a formal survey of experts. Panels include two categories of experts, research experts and clinical experts:

Research experts are individuals who have made substantial contributions with respect to research in and scholarly writing on a guideline topic. These individuals may also serve on review panels and editorial boards. These individuals may be psychiatrists but may also be researchers or scholars in disciplines other than psychiatry, including other medical specialties, psychology, nursing, social work, or pharmacology.

Expert clinicians are psychiatrists and other health professionals who are expert in the clinical care of patients, especially "real world" patients whose primary disorder may be complicated by features such as pregnancy, treatment resistance or nonadherence, or co-occurring substance use, other psychiatric disorders, or other medical conditions. Such expertise may also include knowledge of patient preferences and values, including those related to ethnic and cultural considerations.

These groups are not mutually exclusive. An individual may be considered an expert in both categories.

The experts are identified through a blind nomination process that is based on a "snowball" sampling method, which is used in research studies to identify hidden populations. ^{10,11} The nomination process begins with the following groups:

• Current and past APA writing groups include psychiatrists and other providers who are expert in specific psychiatric disorders and conditions.

- Chairs of academic departments of psychiatry head complex clinical and research programs. They are therefore familiar with the research and scholarly experts both within their region and nationally. Additionally, they are frequently called upon by members of their larger academic communities to make clinical referrals. There are approximately 200 chairs in the United States.
- Directors of psychiatric residency training programs are involved in the care of a variety of
 patients and are responsible for the training of resident psychiatrists on a variety of treatment
 modalities to satisfy competency requirements of the Residency Review Committee. Directors
 are well connected to a large number of psychiatrists in their communities who serve as clinical
 faculty and are therefore expected to have contacts with experts across the spectrum of
 psychiatric care. There are approximately 180 directors in the United States, Canada, and Puerto
 Rico.
- The APA Assembly is a geographically representative sample of American psychiatrists who have
 diverse interests and areas of expertise. Because of their political role within the APA, Assembly
 members are socially connected with clinicians across the United States, both within and
 outside of academia. There are approximately 244 members in the APA Assembly.

Depending on the guideline topic, presidents and/or executive directors of subspecialty organizations may also be asked to nominate research and clinical experts.

Experts nominated by the above groups are asked to nominate additional experts, and this process is repeated, i.e., "snowballed," until a large number of experts is identified who are diverse with respect to geography, training, research and scholarly contributions, clinical experience, and treatment orientation.

The following nomination rules apply:

- Nominators may not nominate themselves.
- Nominated individuals may be from anywhere in the world.
- Nomination is anonymous (i.e., nominated individuals are not informed as to who nominated them).

Research and clinical experts are combined to form one panel and depending on the size, their number may be narrowed. Individuals not selected remain on a wait list to replace dropouts. If an individual who is nominated declines to participate, or does not respond to surveys, another individual may be randomly selected from the pool of nominated and screened individuals.

Because of their oversight role for the guidelines project, members of the CPG and the APA Board of Trustees are not eligible to participate if nominated.

In addition to the survey, expert survey panel members are invited to review the draft guideline during public comment. Experts are asked to disclose relevant conflicts of interest at that time, and may choose to be acknowledged on guideline publications. Their acknowledgement does not imply endorsement of the guideline.

Development Process

The following steps describe the development process from topic selection to publication. The steps are illustrated in the flow chart. The process requires approximately 2 years from start to approval.

Step 1: The CPG selects topics for guideline development.

The CPG selects topics for development of a practice guideline according to the following criteria:

- Degree of public importance (prevalence and seriousness)
- Relevance to psychiatric practice
- Availability of systematic reviews of available evidence
- Likelihood that a guideline would improve practice and patient care
- Time since publication of practice guidelines on the topic by APA or other organizations

To help prioritize topics, the CPG may seek input from stakeholders, the APA Assembly, and others about potential "quality gaps," i.e., areas where usual care may not be aligned with best practice as supported by evidence or expert opinion. Topics for potential guideline development may also be nominated by any APA member. Topic prioritization is reviewed annually, or as needed.

Step 2: The SRAs formulate clinical questions.

After the CPG chooses a topic for guideline development, the SRAs formulate clinical questions on the topic, which may follow a PICO(TS) format, i.e., population, intervention, comparison, outcome, and if applicable, timing and setting. If too many questions are needed, the GWG, in consultation with the CPG, considers narrowing the overall scope of the guideline. In the case when an existing systematic review, such as those by AHRQ, is used, the clinical questions are defined within that review.

Step 3. The GWG and stakeholders review the draft questions.

Input from the GWG, CPG, and stakeholders, including patient/family advocate organizations, ensures that the clinical questions are informed by availability of evidence, are relevant to psychiatrists in clinical practice, include outcomes that are important to patients, and address areas where quality of care may be improved.

Stakeholder groups that are invited to comment on draft questions include allied and subspecialty organizations and patient and family advocacy groups. The APA membership and the general public are also invited to comment.

The SRAs revise the questions based on comments received.

In the case when the GWG uses an existing systematic review, such as those by AHRQ, the clinical questions will have already been reviewed by stakeholders and an additional review of draft questions will not be needed.

Step 4: The SRAs perform a systematic review of available evidence.

After the clinical questions are finalized, the SRAs perform a search of the main relevant databases, including MEDLINE (PubMed), Cochrane, PsycINFO, and other databases as indicated. Each citation retrieved in the search is screened by at least two independent raters according to APA's general screening criteria (i.e., RCT, systematic review or meta-analysis, or observational study with a sample of at least 50 individuals; human; study of the effects of a specific intervention or psychiatric disorder or symptoms) and then for relevance to the clinical questions. In the case of needing to update or supplement an existing review, the original search criteria will be followed to the extent possible.

If, during the review period, subject matter experts or stakeholders indicate that unpublished data exist on a specific intervention, the SRAs may perform gray literature searches to try to confirm this and, if possible, obtain unpublished study protocols and data.

After search results are screened, the SRAs extract the data from the studies and determine the risk of bias for each study outcome according to the AHRQ methodology guide (https://effectivehealthcare.ahrq.gov/topics/methods-bias-update/methods). Evidence tables are developed for all randomized controlled trials (RCTs) and for observational studies that meet a priori criteria. For the benefits and harms of each treatment, the SRAs assess the strength of the body of supporting research evidence, which considers factors such as the risk of bias (includes study design and aggregate quality), consistency, directness, and precision of the evidence. This is distinct from the magnitude of the effect of the intervention. For example, evidence can have high strength but show no effect of the intervention, indicating a high degree of confidence that the intervention is ineffective. The definitions for strength of evidence are:

Table 1 (from AHRQ review). Definitions of the grades of overall strength of evidence					
Grade	Definition				
High	High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.				
Moderate	Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of the effect and may change the estimate.				
Low	Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate.				
Insufficient	Evidence either is unavailable or does not permit estimation of an				

effect. (outcomes only)

Source: Owens et al., 2010¹²

When systematic reviews are available from external sources such as the Cochrane Collaborative or AHRQ, the SRAs use these reviews. The SRAs may agree with the ratings of quality of evidence of the external review, or they may draw independent conclusions using evidence tables from the external review in combination with internally developed evidence tables.

Step 5: The GWG reviews the conclusions of the SRAs and, as needed, surveys the Expert Survey Panel.

The process for forming an Expert Survey Panel is described above (pages 6-8). Results from the survey inform the GWG's grading of strength of recommendation, as described in step 6.

The survey questions specifically evaluate the Expert Survey Panel's opinions about the benefits and harms of interventions as well as potential practical barriers. Questions are generally in Likert scale format but may also include some free text questions. The survey asks for demographic information, so that opinion of subgroups may be characterized, e.g., according to practice setting.

After the distribution of responses is determined for each question, appropriate measures of central tendency are calculated. Depending on sample size and response rate, data from subgroups of respondents may be compared.

Step 6: Based on survey data and the SRAs' systematic review of evidence, the GWG drafts guideline statements and rates the strength of the guideline statement.

Each statement is separately graded according to both strength of supporting research evidence and strength of recommendation. Strength of recommendation describes the level of confidence that potential benefits of an intervention outweigh potential harms. This level of confidence is informed by available evidence, which includes evidence from clinical trials as well as expert opinion and patient values and preferences.

There are two possible ratings: recommendation or suggestion. A "recommendation" (denoted by the numeral 1 after the guideline statement) indicates confidence that the benefits of the intervention clearly outweigh harms. A "suggestion" (denoted by the numeral 2 after the guideline statement) indicates greater uncertainty. Although the benefits of the statement are still viewed as outweighing the harms, the balance of benefits and harms is more difficult to judge, or either the benefits or the harms may be less clear. For clinicians, a recommendation implies that most patients should receive the intervention, and a suggestion implies that different choices may be appropriate for different patients. These strengths of recommendation correspond to ratings of "strong" or "weak" (also termed "conditional") as defined under the GRADE method for rating recommendations in clinical practice guidelines (described in publications such as Guyatt et al. 2008 [general information] 14, Andrew et al. 2013 [specific information] 15, and others available on the website of the GRADE Working Group at http://www.gradeworkinggroup.org/).

When a negative statement is made, ratings should be understood as meaning the inverse of the above (e.g., "recommendation" indicates confidence that harms clearly outweigh benefits). If clinical trial evidence and expert opinion are judged to be insufficient to support a suggestion, the APA makes no statement for or against the intervention, and instead, further research may be recommended.

As a general principle, interventions to be recommended must be viewed very favorably by the GWG. Such interventions may or may not be supported by high-quality evidence, but, if there is very strong expert opinion that benefits outweigh harms, may nevertheless receive a recommendation. (Separately, the evidence supporting the recommendation would be rated as "low quality.") For example, some interventions may be endorsed as a recommendation if they have strong face validity, but for ethical or practical reasons, no RCTs exist or are ever likely to be conducted. ¹⁶

Because suggestions are less directive than recommendations, the interventions they describe require a lesser degree of support. Usually, such interventions will be supported by moderate- or low-quality rather than high-quality evidence, but exceptions may occur.

In weighing potential benefits and harms, the GWG considers the strength of supporting research evidence, their own clinical experiences and opinions, and patient preferences. Particularly when interventions are supported by low-quality evidence, patient values and preferences and survey data, when available, guide the GWG in determining ratings of strength of recommendation.

The GWG reaches consensus on the wording and rating of each recommendation or suggestion using a modified Delphi method, i.e., through iterative blind voting. For recommendations, all members except one must vote to "recommend" the intervention or assessment, and at most one member may vote other than "recommend" the intervention or assessment. On the basis of the discussion among the GWG members, adjustments to the wording of recommendations can be made between the voting rounds. If this level of consensus is not achieved, the GWG can agree to make a "suggestion" rather than

a "recommendation." No suggestion or statement can be made if three or more members vote "no statement." Differences of opinion within the group about ratings of strength of recommendation, if any, may be described under "Balancing of Potential Benefits and Harms in Rating the Strength of the Guideline Statement."

Each will also be rated on the strength of its supporting research evidence. This is determined by the methodologist/vice-chair, and reviewed by the SRAs and GWG chair, based on literature identified in the systematic review and reflects the level of confidence that the evidence reflects a true effect based on consistency of findings across studies, directness of the effect on a specific health outcome, precision of the estimate of effect and risk of bias in available studies. Confidence is enhanced by factors such as rigorous study design and minimal potential for study bias. Ratings are determined, in accordance with the AHRQ's *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* (Agency for Healthcare Research and Quality, 2014)¹⁷, and are defined as follows:

- A = High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- B = Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- C = Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.

Evidence tables and survey data are included and reviewed in the appendices, allowing readers to judge for themselves the credibility of a rating based on their own assessment of the data and the methodology used to obtain it.

During this step, the GWG also identify statements appropriate for development as performance measures and highlight this in discussion sections. Statements not appropriate for performance measures, e.g., because of implementation barriers may also be highlighted.

Step 7: The supporting text and appendixes for the guideline are drafted.

The medical editor, with support from APA staff and other SRAs, draft the rest of the document, which includes: the supporting text under each guideline statement, including sections on implementation, balancing potential benefits and harms, and quality measurement considerations; the rationale; the introduction; areas for further research; the development process; glossary; and appendixes, including the clinical questions, search strategies, the review of research evidence, the review of survey results, and other sections as needed. The draft is reviewed by the GWG and edits are made as needed.

Step 8: The draft guideline is reviewed.

The draft guideline is made available for review by the Expert Survey Panel, all APA Councils, the APA Assembly and Board of Trustees, the APA general membership, the general public, and stakeholders including other professional associations and patient advocacy/consumer groups.

Step 9: The GWG finalizes the guideline.

The GWG reviews comments and considers whether revisions to the guideline text are needed. After any revisions are incorporated, the guideline is reviewed by the CPG including Assembly liaisons and by the chair of the Council on Quality of Care. The main purpose of this step is to provide a final check to ensure that policies and procedures for the guideline development process have been followed and that statements are unlikely to be misinterpreted or misused by the field.

If any revisions to the wording or rating of a statement are necessary, the GWG will reach consensus using the modified Delphi method described in step 6. Such revisions must be consistent with the evidence and any available survey data, as described in steps 4 and 6.

Step 10: The CPG submits the finalized guideline for approval to the APA Assembly and Board of Trustees.

After revisions are completed, the CPG votes to approve submission of the guideline to the APA Assembly and Board of Trustees. The Assembly liaisons on the CPG may facilitate Assembly approval, e.g., by reporting to the Assembly that the development process has been followed.

The APA Assembly and Board of Trustees review and approve the guideline for publication under the imprimatur of APA. As in step 9, if either group requests a revision to any statement, the proposed revision must go back to the GWG for a new consensus determination using the modified Delphi method. Such revisions must be consistent with the evidence and any available survey data, as described in steps 4 and 6.

The approved guideline is disseminated in a variety of formats, including online and in print.

Review and Revision Process

Guidelines remain published and are considered "current" for five years. They may be re-affirmed after completion of an updated systematic review of the evidence if the SRAs and the GWG agree that new findings will not have changed the recommendations or ratings. Depending on any changes in the evidence base, it is possible that only one or more statements (and supporting material) may warrant an update.

If the SRAs recommends revising a rating, the GWG considers if this should change the wording or rating of a recommendation or suggestion. The GWG also considers if expert opinion may have changed, e.g., because of changing practice patterns, potentially affecting the rating of a statement.

Revisions to the wording or rating of a statement require re-doing steps 4 through 9 of the development process. Revisions to a discussion section require re-doing steps 8–9 only.

Guideline development is funded and supported by the APA's general operating fund without any involvement of industry or external funding.

¹ Institute of Medicine. (2011). *Clinical Practice Guidelines We Can Trust.* Washington, DC: National Academies Press.

² American Medical Association. (2009). *Physician Consortium for Performance Improvement (PCPI) position statement: The evidence base required for measures development*. Chicago: Author. http://www.ama-assn.org/ama1/pub/upload/mm/370/pcpi-evidence-based-statement.pdf.

³ Council of Medical Specialty Societies. (2012). *Principles for the Development of Specialty Society Guidelines*. Chicago: Author. https://cmss.org/wp-content/uploads/2016/02/CMSS-Principles-for-the-Development-of-Specialty-Society-Guidelines-September-20122.pdf

- ¹⁰ For a description of "snowball" sampling, see Heckathorn DD. Respondent-driven sampling: a new approach to the study of hidden populations. Social Problems. 1997; 44:174–99.
- ¹¹ For an example of a "snowball" process used to identify experts for a consensus report, see Hogan et al. Development of geriatric competencies for emergency medicine residents using an expert consensus process. Acad Emerg Med 2010; 17: 316-324.
- ¹² Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions--Agency for Healthcare Research and Quality and the Effective Health-Care Program. J Clin Epidemiol. 2010 May;63(5):513-23. PMID: 19595577.
- ¹³ Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, Schünemann HJ; GRADE Working Group. Rating quality of evidence and strength of recommendations: Going from evidence to recommendations. BMJ 2008; 336: 1049–1051.
- ¹⁴ Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, Schünemann HJ; GRADE Working Group. Rating quality of evidence and strength of recommendations: Going from evidence to recommendations. BMJ 2008; 336: 1049–1051.
- ¹⁵ Andrews J, Guyatt G, Oxman, AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. J Clin Epidemiol. 2013 July;66(7):719-725.
- ¹⁶ Smith GCS, Pell JP. Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. BMJ 2003 Dec; 327(7429):1459–1461.
- ¹⁷ Agency for Healthcare Research and Quality. Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication No. 10(14)-EHC063-EF. Rockville, MD: Agency for Healthcare Research and Quality. January 2014. Chapters available at: https://effectivehealthcare.ahrq.gov/topics/cer-methods-guide/overview/.www.effectivehealthcare.ahrq.gov

⁴ American Psychiatric Association. (2006). "Appendix: Practice Guideline Development Process." Arlington, VA: Author. http://psychiatryonline.org/content.aspx?bookid=28§ionid=1674966#58558

⁵ Institute of Medicine. (1990). *Clinical Practice Guidelines: Directions for a New Program.* Washington, DC: National Academies Press.

⁶ Institute of Medicine. (1992). *Guidelines for Clinical Practice: From Development to Use.* Washington, DC: National Academies Press.

⁷ American Medical Association. (1990). *Attributes to Guide the Development and Evaluation of Practice Parameters/Guidelines.* Chicago: Author.

⁸ The GRADE method is described at http://www.gradeworkinggroup.org.

⁹ Council of Medical Specialty Societies. *Code for Interactions with Companies*. April 2010. Chicago, IL: Author. Available at https://cmss.org/wp-content/uploads/2016/02/CMSS-Code-for-Interactions-with-Companies-Approved-Revised-Version-4.13.15-with-Annotations.pdf.