AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS PROTOCOL FOR STANDARDIZED PRODUCTION OF CLINICAL PRACTICE GUIDELINES

AACE Ad Hoc Task Force
for Standardized Production of Clinical Practice Guidelines

Abbreviations:
AACE = American Association of Clinical Endocrinologists; **ACE** = American College of Endocrinology; **CPGs** = clinical practice guidelines

INTRODUCTION

The American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) have produced numerous clinical practice guidelines (CPGs) since 1995, which are available to the public free of charge over the Internet (Table 1). The intent of this activity is (*1*) to promote the general dissemination of information about endocrinology to endocrinologists, nonendocrinologist physicians, and interested laypersons and (*2*) to provide a consensus opinion about the appropriate management of certain clinical problems facing the practicing endocrinologist. The emergence of literature describing the effect of CPGs and the need to standardize the methods used in their creation prompted the AACE Publications Committee to form an ad hoc task force to address this issue. Moreover, AACE recognizes the primacy of evidence-based methods, especially when dealing with controversial topics. This current protocol on CPG standardization has been approved by the AACE Publications Committee and the AACE Executive Committee.

CHARACTERIZATION OF CPGs

CPGs are defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (1). Technical reviews are distinguished by an explicit method that describes the literature search, evidence rating, and recommendation grading. Such guidelines include not only consensus opinions and systematic technical reviews but also an assessment of the associated risks and benefits, cost-effectiveness, clinical outcomes, and patient preferences (2). In fact, inclusion of patient representatives in the CPG development process can be important when value judgments are integrated in final recommendations (3). CPGs generally have a broad scope and can yield consistent, specific, and practical recommendations (2). Moreover, the conclusions reached by CPGs must be compelling; CPGs must be persuasive.

ROLE OF CPGs

Philosophically, physicians uniformly act, and must act, on the basis of an incomplete set of information. As a result, subjectivity, bias, variability, and even creativity are introduced into the clinical decision-making process (4). Factors that can influence subjective physician behavior can be classified into four categories: social influence, adult learning, diffusion of innovation, and social marketing (5). These factors can facilitate the promulgation of adherence to CPGs or be a barrier to their use (6). In a survey of clinicians' attitudes, Farquhar et al (7) found high satisfaction rates with CPGs and a belief that they would improve the quality of medical care; however, concerns also existed about the practicality of CPGs, their ability to contain health-care costs, and their potential for increasing litigation. Provider education programs to promote implementation of CPGs have been advocated to improve health-care delivery (8). In addition, CPGs have been used to develop evidence-based patient education programs (9).

Evidence-based CPGs can identify which components of the decision-making process are objective. They can also enable the cohesive incorporation of traditional "standards" of care with scientific research paradigms. By systematic examination and analysis of prospective, randomized, controlled trials, other experimental studies, nonexperimental observational studies, anecdote, and consensus statements according to an a priori set of rules, the extant dynamic body of medical knowledge can be infused with new information. Technical reviews achieve this outcome without bias or subjectivity, and by production of high-quality CPGs, medical care will be optimized for society. This process reduces inappropriate and costly medical care (10-12). Several strength-of-evidence scales have been formulated and published (13-16), although no agreement exists about which is best (Table 2). Liberati et al (17) have argued against the use of a generic scale for

Table 1
American Association of Clinical Endocrinologists (AACE) Clinical Practice Guidelines*

Year	Title	Method	Reference
1995	AACE guidelines for the management of diabetes mellitus	Consensus opinion	*Endocr Pract*. 1995;1:149-157
1996	AACE clinical practice guidelines for the prevention and treatment of postmenopausal osteoporosis	Consensus opinion	*J Fla Med Assoc*. 1996;83:552-566
1996	AACE clinical practice guidelines for the diagnosis and management of thyroid nodules	Consensus opinion	*Endocr Pract*. 1996;2:78-84
1998	AACE clinical practice guidelines for the evaluation and treatment of male sexual dysfunction	Consensus opinion	*Endocr Pract*. 1998;4:219-235
1999	AACE medical guidelines for clinical practice for management of menopause	Consensus opinion	*Endocr Pract*. 1999;5:354-366
2000	AACE medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management—2000 update	Consensus opinion	*Endocr Pract*. 2000;6:42-84
2000	AACE medical guidelines for clinical practice for the diagnosis and treatment of dyslipidemia and prevention of atherogenesis	Consensus opinion	*Endocr Pract*. 2000;6:162-213
2001	AACE medical guidelines for clinical practice for the diagnosis and treatment of hyperandrogenic disorders	Consensus opinion	*Endocr Pract*. 2001;7:120-134
2001	AACE/AAES medical/surgical guidelines for clinical practice: management of thyroid carcinoma	Consensus opinion	*Endocr Pract*. 2001;7:202-220
2001	AACE 2001 medical guidelines for clinical practice for the prevention and management of postmenopausal osteoporosis	Consensus opinion	*Endocr Pract*. 2001;7:293-312
2002	AACE medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management—2002 update	Consensus opinion	*Endocr Pract*. 2002;8(Suppl 1):40-82
2002	AACE medical guidelines for clinical practice for the diagnosis and treatment of dyslipidemia and prevention of atherogenesis—2002 amended version	Consensus opinion	www.aace.com/clin/guidelines/lipids.pdf. Accessed February 14, 2004
2002	AACE medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients—2002 update	Consensus opinion	*Endocr Pract*. 2002;8:439-456
2002	AACE medical guidelines for clinical practice for the evaluation and treatment of hyperthyroidism and hypothyroidism	Consensus opinion	*Endocr Pract*. 2002;8:457-469
2003	AACE medical guidelines for clinical practice for growth hormone use in adults and children—2003 update	Consensus opinion	*Endocr Pract*. 2003;9:64-76
2003	AACE medical guidelines for clinical practice for the evaluation and treatment of male sexual dysfunction: a couple's problem—2003 update	Consensus opinion	*Endocr Pract*. 2003;9:77-95
2003	AACE medical guidelines for the clinical use of dietary supplements and nutraceuticals	Technical review	*Endocr Pract*. 2003;9:417-470
2003	AACE medical guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis: 2001 edition, with selected updates for 2003	Consensus opinion	*Endocr Pract*. 2003;9:544-564
2004	AACE medical guidelines for clinical practice for the diagnosis and treatment of acromegaly	Consensus opinion	*Endocr Pract*. 2004;10:213-225

*AAES = American Association of Endocrine Surgeons.

all disciplines because of subspecialty differences in patient populations, clinical contexts, and health-care settings.

MAINTENANCE OF QUALITY OF CPGs

Despite the growing acceptance of the need for CPGs, considerable variability prevails in the intent, organization, and overall quality of their production. Efforts have been made to remedy this shortcoming. The Institute of Medicine has issued the desirable attributes of CPGs (http://www.nap.edu/books/0309045894/html/): validity, reliability and reproducibility, clinical applicability, clinical flexibility, clarity, documentation, multidisciplinary development, and a review process (18). In addition, the National Guideline Clearinghouse disseminates these CPGs by providing their access over the Internet (www.guideline.gov). The National Guideline Clearinghouse lists inclusion criteria for organizations that wish to have their guidelines available on this Web-site (www.guideline.gov/contact/coninclusion.aspx). Additional methods exist in a seemingly never-ending attempt to standardize the practice of medicine (19-24). The American Medical Association (25) has outlined 13 attributes that serve as a model for future CPG development strategies (Table 3). Nevertheless, many CPGs that do not adhere to these various "guidelines for guidelines" continue to be published (26-29). Shaneyfelt et al (30), who evaluated 279 CPGs published from 1985 through June 1997, found that only 43.1% adhered to published standards advanced by the American Medical Association, the Institute of Medicine, and the Canadian Medical Association (1,31-35). In response to these insufficiencies, the Conference on Guideline Standardization published a report defining a methodologic standard for CPG quality and implementation (36) (Table 4). This "checklist" provides a starting point for guideline development and represents a step in the evolution of standardizing CPGs.

AACE CPG DEVELOPMENT STRATEGIES AND PRINCIPLES

AACE has established its own CPG development strategies, consistent with the published recommendations of the aforementioned organizations and individual clinicians. The AACE Protocol for the Standardized Production of Clinical Practice Guidelines incorporates features previously endorsed in publications. The purpose of stipulated a priori components is to facilitate the "reproducibility" of guideline production. The format for the CPGs must be clear and user-friendly. The CPGs must be comprehensive for the condition discussed but, at the same time, must provide specific, relevant recommendations that can be cited in review articles and in performance or quality measurements. Outcomes must be specified for each recommendation (for example, cure, delayed morbidity or mortality, symptomatic relief, improved quality of life, conservation of resources, or effect on patient and physician behavior). Similarly, outcome measures must be specified for assessment of each outcome (for example, duration of life, quality of life, length of hospital stay, or efficiency of control of overhead factors).

The following six principles, as developed by the AACE Ad Hoc Task Force for Standardized Production of Clinical Practice Guidelines, have been adopted by the AACE Publications Committee:

1. The prime mission for the development of AACE CPGs is the improvement of patient outcome. This priority outweighs any methodologic concerns and is consistent with the philosophic mission of AACE and ACE.
2. The methodology for CPG development must be an evidence-based technical review. The evidence-rating and recommendation-grading scales must be developed and implemented a priori. Evidence and recommendation grade scales may be tailored to specific problems, but the a priori scale must be approved by the AACE Publications Committee before performance of the technical review. Any a priori changes proposed to the AACE Publications Committee must be supported by a rationale based on the unique clinical context of the endocrine problem.
3. Evidence must be rated on the basis of the a priori rating scale approved by the AACE Publications Committee. Likewise, recommendations must be graded on the basis of the a priori grading scale approved by the AACE Publications Committee. Recommendation-grading scales incorporate evidence ratings, patient preferences, risk-benefit analysis, expert opinions from the CPG development clinicians, and, if applicable, preferences on the part of the patient representative.
4. CPG development and the final document must conform to the templates outlined in Tables 5 and 6. The rationale is to adhere to attributes previously described in the literature and adopted by other medical societies and organizations, while at the same time meeting the unique needs of AACE, the endocrinologist, and the endocrine patient.
5. All clinicians or other members appointed for development of specific CPGs must have appropriate credentials. This qualification can be expertise in the specific topic as an academic researcher, an experienced clinician, a practitioner in a related field, or a patient representative with direct experience with the topic.
6. Potential conflicts of interest must be disclosed by all members involved in the development of the specific CPGs. These conflicts will be reviewed by the CPG chairperson and AACE Publications Committee before development of the CPGs. Corporate sponsorship must be approved by the AACE Publications Committee before actual CPG development.

Table 2
Various Strength-of-Evidence Scales Reported in the Medical Literature

Level of evidence	Recommendation grade	Description	References
1		Well-controlled, generalizable, randomized trial	13-15
		Adequately powered	13,14
		Well-controlled multicenter trial	13,14
		Large meta-analysis with quality ratings	13,14
		All-or-none evidence	13,14
2		Randomized controlled trial—limited body of data	14,15
		Well-conducted prospective cohort study	13,14
		Well-conducted meta-analysis of cohort studies	13,14
3		Methodologically flawed randomized clinical trials	13-15
		Observational studies	13-15
		Case series or case reports	13,14
		Conflicting evidence with weight of evidence supporting the recommendation	13
4		Expert consensus	13-15
		Expert opinion based on experience	13-15
		"Theory-driven conclusions"	14
		"Unproven claims"	14
	A	Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power	16
		Homogeneous evidence from multiple well-designed cohort controlled trials with sufficient statistical power	16
		≥1 conclusive level 1 publications demonstrating benefit >> risk	14
	B	Evidence from at least one large well-designed clinical trial, cohort or case-controlled analytic study, or meta-analysis	16
		No conclusive level 1 publication; ≥1 conclusive level 2 publications demonstrating benefit >> risk	14
	C	Evidence based on clinical experience, descriptive studies, or expert consensus opinion	16
		No conclusive level 1 or 2 publication; ≥1 conclusive level 3 publications demonstrating benefit >> risk	14
		No conclusive risk at all and no conclusive benefit demonstrated by evidence	14
	D	Not rated	16
		No conclusive level 1, 2, or 3 publication demonstrating benefit >> risk	14
		Conclusive level 1, 2, or 3 publication demonstrating risk >> benefit	14

Table 3
Evaluation of Clinical Practice Guidelines (CPGs), as Recommended by the American Medical Association

Topic	Assessment factor
Involvement of physician organization(s)	Provide participant names and professional affiliations
Review of literature	Include references, inclusion and exclusion criteria for the literature search, databases searched, years of published material reviewed, and search terms used
Credentials of experts	Document expertise by providing curricula vitae and academic positions
Appropriateness	Ensure appropriateness of recommendations for the stated specific clinical conditions and settings
Generalizability	Include disclaimers, discussion of the limitations, and discussion of the degree of generalizability
Currency	Indicate date when CPGs were last developed, reviewed, or updated
Update mechanism	Describe the update mechanism
Dissemination mechanism	Ensure that CPGs are readily available to all physicians affected by the recommendations
Importance of issue	Include appropriate section on prevalence, incidence, cost, and controversies
Outcomes	Describe expected measurable outcomes for evaluation of the CPGs
Patient preferences	Include available data regarding patient preferences
Cost	Discuss methods to track cost of implementing the CPGs
Conflicts of interest	Address whether the authors or sponsors have any conflicts of interest

Adapted from the American Medical Association (25).

MEMBERS OF THE AD HOC TASK FORCE

The AACE Ad Hoc Task Force for Standardized Production of Clinical Practice Guidelines consists of the following members: Jeffrey I. Mechanick, MD, FACP, FACE, FACN (Chairperson), Donald A. Bergman, MD, FACP, FACE, Susan Shapiro Braithwaite, MD, FACP, FACE, and Pasquale J. Palumbo, MD, MACE, MACP.

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Table 4
Conference on Guideline Standardization "Checklist" for Reporting Clinical Practice Guidelines (CPGs)

Topic	Description
Overview material	Provide a structured abstract containing release date, status, and sources
Focus	Describe the clinical problem
Goals	Specify the goals and rationale
Users and setting	Describe the intended audience and the setting for implementation
Target population	Outline the target patients and the exclusion criteria
Developers	Describe the society or organization and persons involved in CPG development, including names, credentials, and potential conflicts of interest
Funding and sponsor	Identify funding sources, describe the role of the sponsors, and indicate any potential conflicts of interest
Collection of evidence	Specify the method of literature search, the database(s) and dates searched, and the method of filtering retrieved evidence
Recommendation grading criteria	State the method of rating the quality of evidence and describe the recommendation grades; describe how risks and benefits were incorporated into recommendation grades
Method of synthesizing evidence	Clarify how the evidence is actually used to create specific recommendations
Prerelease review	Discuss how the developers evaluated the CPGs before release
Update plan	Indicate the status of the plan to update and the expiration date for current CPG version
Definitions	Define terms that are unfamiliar, critical, or subject to misinterpretation
Recommendations and rationale	State each recommendation precisely and specifically; indicate the evidence basis for the recommendation
Potential benefits and harms	Discuss the potential risks and benefits associated with each recommendation
Patient preferences	Describe the role of patient preferences when personal choice or values are factored into a recommendation
Algorithm	Provide a graphical depiction of the decision algorithm used in the CPGs
Implementation considerations	Describe anticipated barriers to implementation; provide references that can facilitate implementation; suggest review criteria for evaluation of CPG implementation

Adapted from Shiffman et al (36).

13. **American Diabetes Association.** Introduction. *Diabetes Care*. 2004;27(Suppl 1):S1-S2.
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Table 5
American Association of Clinical Endocrinologists (AACE)
Template for Development of Clinical Practice Guidelines (CPGs)

Step	Description
1	Assignment of CPG topic by AACE president
2	Appointment of CPG chairperson by AACE president and charge to conform to the AACE Protocol for the Standardized Production of CPGs
3	Appointment of CPG Development Committee (which may include a patient representative), reviewers, and special reviewer* (optional) by CPG chairperson
4	Preliminary literature search by CPG chairperson
5	Assignment of CPG section topics and provision of timeline by CPG chairperson to members of CPG Development Committee
6	Notification of assignments and timeline to AACE Communications Director
7	Ongoing communication between CPG chairperson and members of CPG Development Committee to ensure adherence to timeline
8	Assembly of CPGs into a first draft by CPG chairperson, using materials submitted by members of CPG Development Committee
9	Redistribution of first draft to members of CPG Development Committee for review per timeline (copy to AACE Communications Director for file; members of CPG Development Committee sign AACE review sheet)
10	Incorporation of comments from members of CPG Development Committee into second draft by CPG chairperson
11	Distribution of second draft to reviewers and special reviewer per timeline (copy to AACE Communications Director for file; reviewers sign AACE review sheet)
12	Incorporation of comments from reviewers into third draft by CPG chairperson
13	Distribution of third draft to AACE Publications Committee per timeline (copy to AACE Communications Director for file; members of Publications Committee sign review sheet)
14	Incorporation of comments from AACE Publications Committee into fourth draft by CPG chairperson
15	Distribution of fourth draft to AACE Executive Committee and AACE president for final review per timeline (copy to AACE Communications Director for file)
16	Incorporation of comments from AACE Executive Committee and AACE president into a fifth and final draft by CPG chairperson
17	Submission of final draft to AACE Communications Director for publication in *Endocrine Practice*

*A non-AACE expert in the field directly addressed by the CPGs.

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21. **Cluzeau FA, Littlejohns P, Grimshaw JM, Feder G, Moran SE.** Development and application of a generic methodology to assess the quality of clinical guidelines. *Int J Qual Health Care*. 1999;11:21-28.
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Table 6
American Association of Clinical Endocrinologists
Template for Final Document for Clinical Practice Guidelines (CPGs)

Component	Description
1	Title, which must use the following wording: "American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for…[topic]"
2	Context for selection of CPG topic, explanation of how these CPGs differ from previously published CPGs, objectives for CPGs
3	Importance of targeted clinical problem or technology, definition of terms, identification of targeted population, list of objectives
4	Detailed discussion of the theoretical nature of the clinical problem a. Background clinical, preclinical, and other experimental studies b. Commentary and consensus opinion c. Not subject to evidence ratings
5	Methods (cite this protocol) a. Strategy for ongoing review, updates, and distribution; include expiration date, methods to evaluate outcome performance, and methods to measure effect of CPGs b. Strategy for implementation c. Credentials of CPG Development Committee d. Explicit a priori evidence-rating and recommendation-grading scales (see Table 2), including methods for inclusion and exclusion of evidence, database(s) searched, dates of publications searched, and search terms used e. Rationale for any deviations from previously published scales f. Specification of outcomes and outcome measures g. Methods and quantification of risk-benefit analyses h. Methods and quantification of cost-benefit analyses i. Methods of incorporating patient preferences and other subjective biases and value judgments; specification of recommendation flexibility j. Intended audience or users of the CPGs
6	Executive summary: state the issue, the recommendation, and the recommendation grade; indicate principal preventive, diagnostic, and therapeutic options
7	Appendix: discuss each issue in detail; identify each citation as being clinical, preclinical, or otherwise; assign each clinical study an evidence level or a group of studies an overall evidence level; explain how the final recommendation grade is derived from the provided evidence levels; describe and discuss any subjectivity
8	Disclaimer
9	References
10	Figures and tables

24. **Altman DG, Schulz KF, Moher D, et al (CONSORT Group [Consolidated Standards of Reporting Trials]).** The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med*. 2001;134:663-694.
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