

# Opportunities and Barriers for Clinical Practice Guidelines

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ADULT GUIDELINES



Wake Forest University  
School of Medicine



# Disclosures

<b>Research support</b>	Nestle Healthcare Nutrition, Eli Lilly, Boehringer Ingelheim, Epitomee, Inc., UnitedHealth Group R&D, KVKTech, Weight Watchers
<b>Consulting</b>	Nestle Healthcare Nutrition, Eli Lilly, Optum Labs R&D, Novo Nordisk, Intuitive, Regeneron, Brightseed
<b>Advisory Board</b>	Novo Nordisk, Nestle Healthcare Nutrition, Eli Lilly, Level2, Weight Watchers, Boehringer Ingelheim, Regeneron
<b>Memberships</b>	International Food Information Council- Assembly, The Obesity Society- president, American Diabetes Association, Society of Behavioral Medicine, Roundtable on Obesity Solutions, American Society for Nutrition, American Society for Nutrition Foundation- Board of Trustees Executive Committee

# Objectives

- Brief history of clinical practice guidelines in North America
- Who develops guidelines?
- What are guidelines good for?
- What are the limitations of guidelines, particularly in adult obesity care?



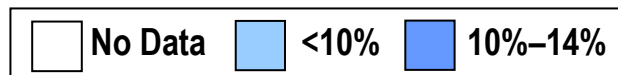
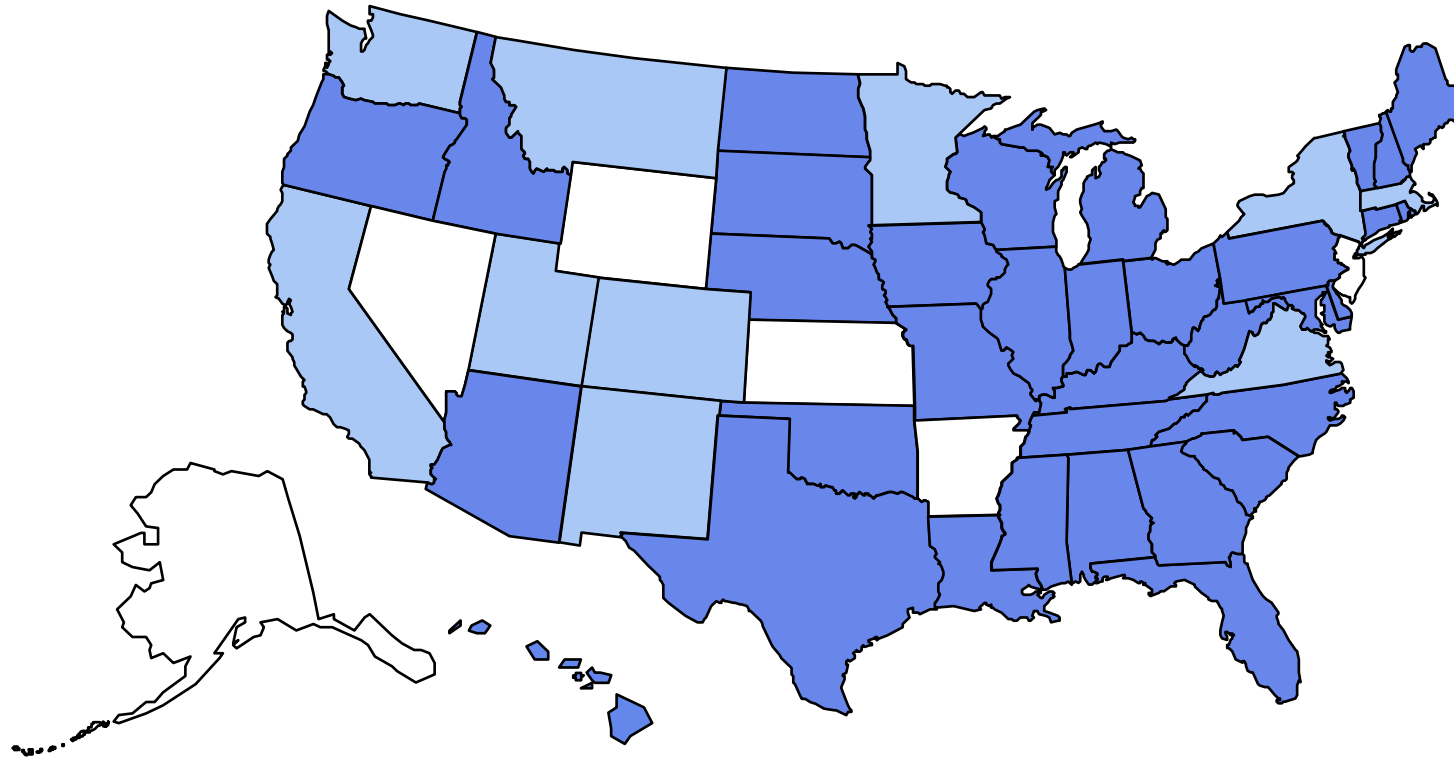
# Key Take Aways

- Clinical practice guidelines (CPG) are a function of
  - The questions asked
  - The evidence available
  - Resources available
  - The people writing them
- CPG can be used in a variety of ways that improve or hinder obesity care
- CPG need to be living documents and supplemented by Standards of Care

# Obesity Trends\* Among U.S. Adults

## BRFSS, 1990

(\*BMI  $\geq 30$ , or  $\sim 30$  lbs. overweight for 5' 4" person)

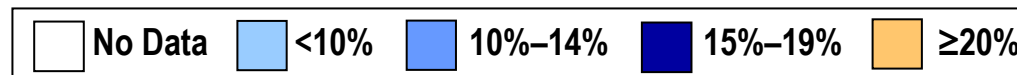
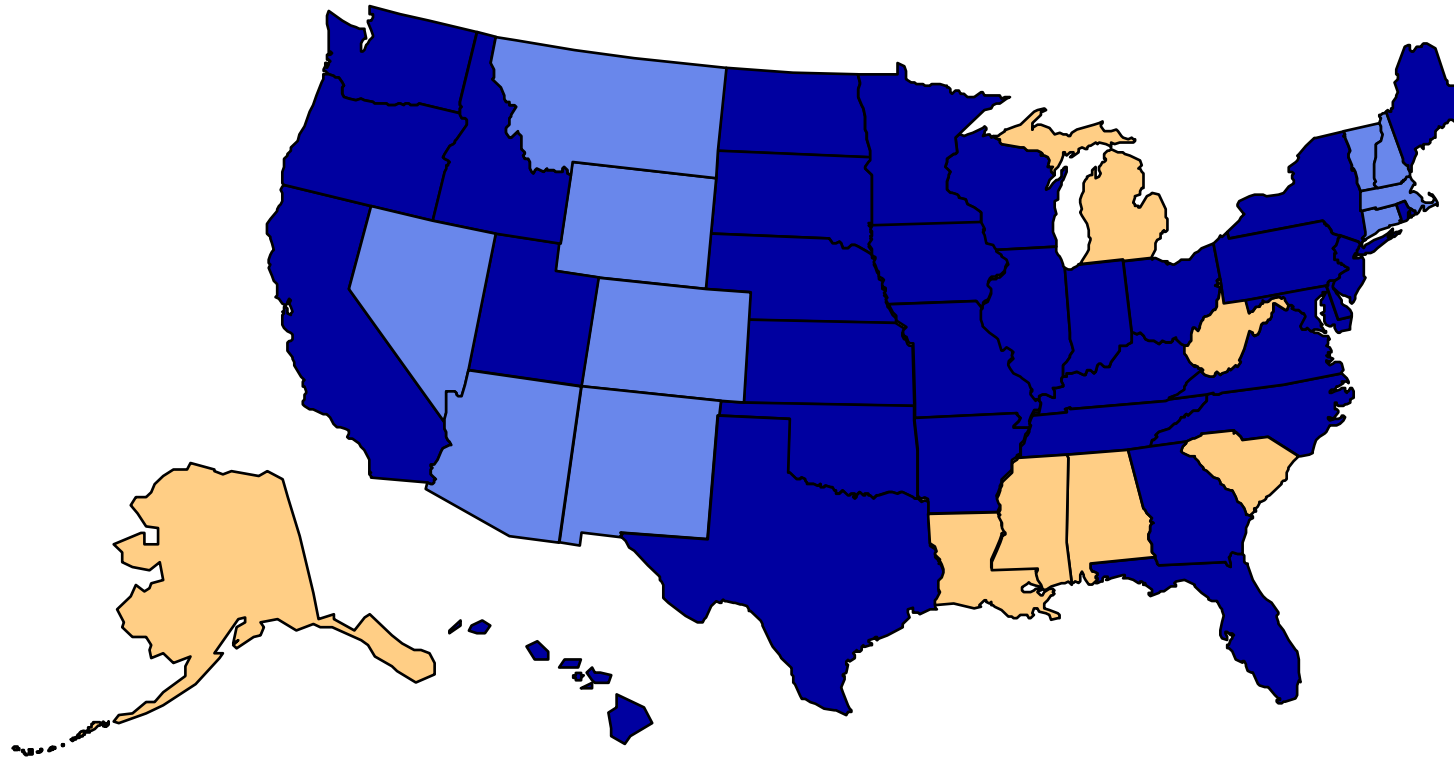


# 1991 NIH Consensus Statement

- Gastrointestinal surgery for severe obesity
- Becomes standard rationale for indication for bariatric surgery at BMI  $\geq 40$  kg/m<sup>2</sup> or 35-39.9 kg/m<sup>2</sup> with complications of obesity
- Recommends that patients have comprehensive evaluation and preparation
- Suggests that surgery be performed by experienced surgeon; multidisciplinary team support

## Obesity Trends\* Among U.S. Adults BRFSS, 1998

(\*BMI  $\geq 30$ , or  $\sim 30$  lbs. overweight for 5' 4" person)



# CPGs on Obesity in the US



CLINICAL GUIDELINES  
ON THE  
IDENTIFICATION,  
EVALUATION, AND  
TREATMENT OF  
OVERWEIGHT AND  
OBESITY IN ADULTS

*The Evidence Report*



Convened expert panel  
in May 1995

Sponsored by NIH  
(National Heart, Lung,  
and Blood Institute)

Covered literature from  
Jan 1980 to Sept 1997

- 236 RCT articles reviewed

Evidence Report and  
Practical Guide  
published 1998

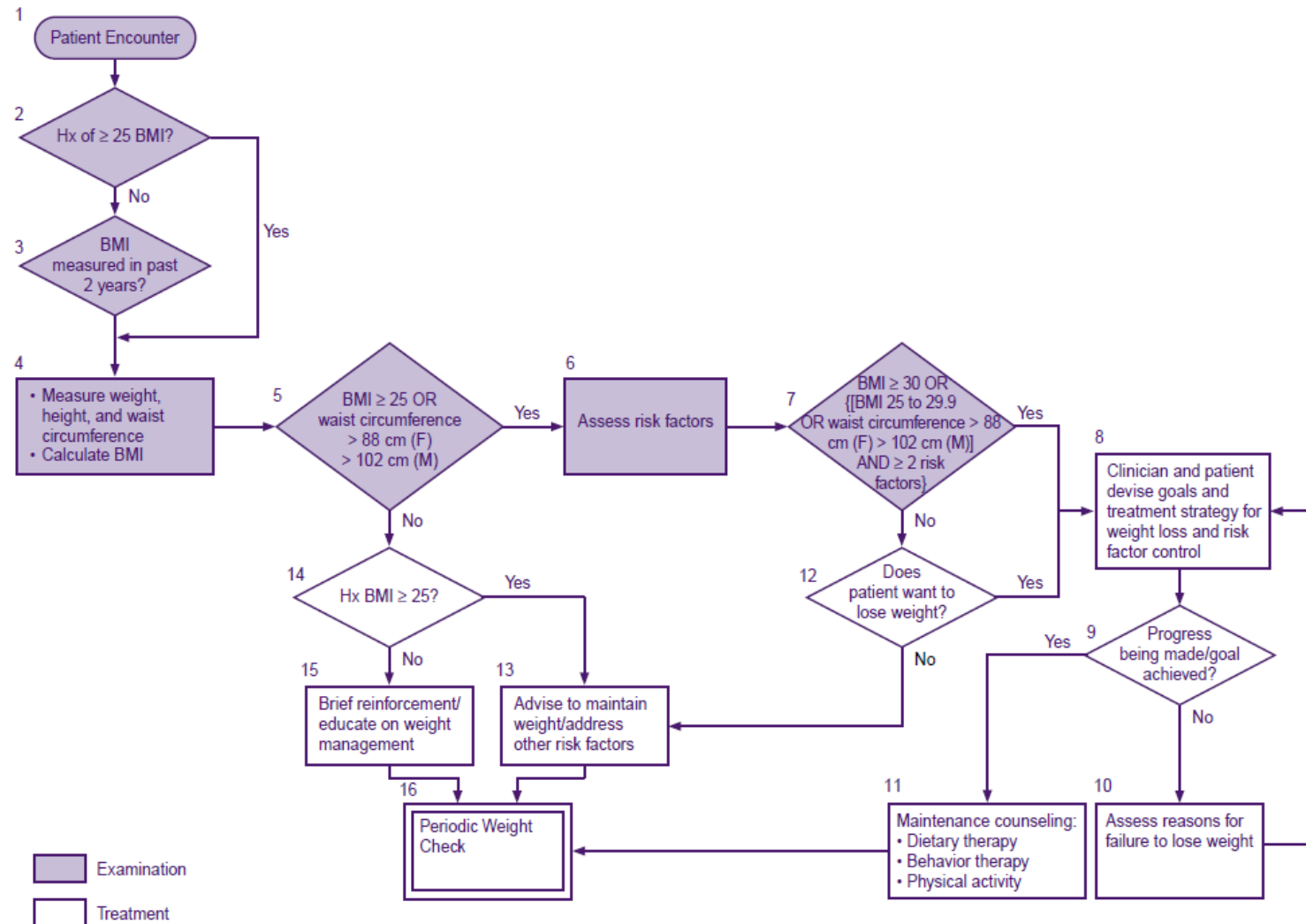


# Topics Addressed

- Who is at risk?
- Why treat overweight and obesity?
- What treatments are effective?
- Clinical guidelines
  - Assessment- BMI, waist circumference, risk status, patient motivation
  - Evaluation and treatment- goals of weight loss and management, strategies for weight loss and maintenance\*
  - Adapt weight loss programs to meet the needs of diverse patients

\*Note: sibutramine was approved by FDA; orlistat approval was pending at the time of publication; dexfenfluramine and fenfluramine had just been removed in 1997

## Treatment Algorithm\*



\* This algorithm applies only to the assessment for overweight and obesity and subsequent decisions based on that assessment. It does not include any initial overall assessment for cardiovascular risk factors or diseases that are indicated.

# Practical Guidance for Primary Care

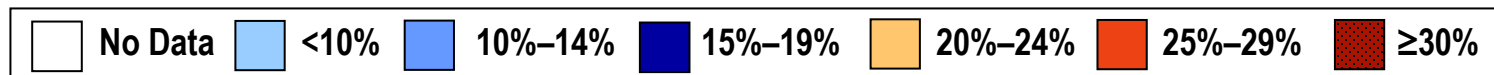
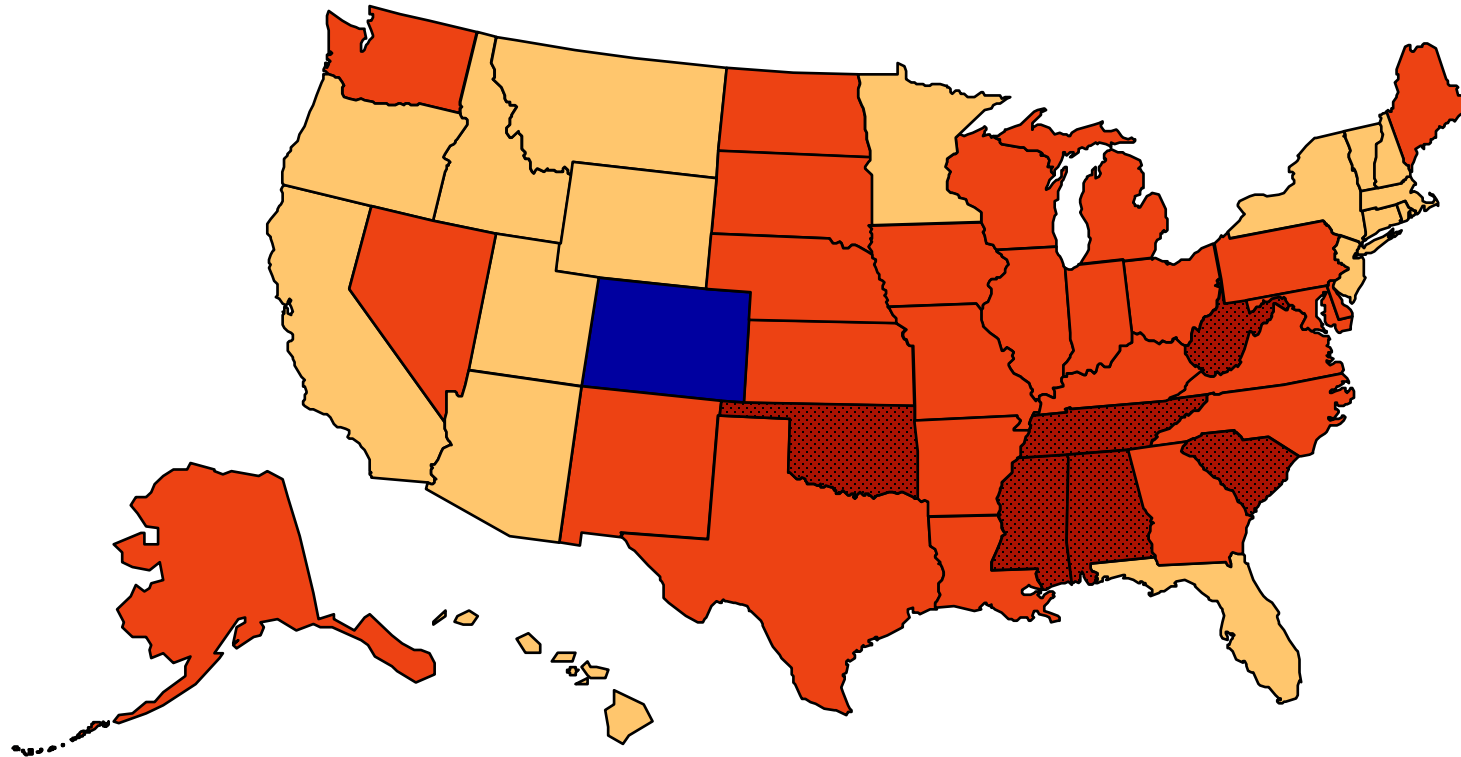
## Ten Steps to Treating Overweight and Obesity in the Primary Care Setting

- 1 Measure height and weight** so that you can estimate your patient's BMI from the table in Appendix A.
- 2 Measure waist circumference** as described on page 9.
- 3 Assess comorbidities** as described on pages 11–12 in the section on “Assessment of Risk Status.”
- 4 Should your patient be treated?** Take the information you have gathered above and use Figure 4, the Treatment Algorithm, on pages 16–17 to decide. Pay particular attention to Box 7 and the accompanying explanatory text. If the answer is “yes” to treatment, decide which treatment is best using Table 3 on page 25.
- 5 Is the patient ready and motivated** to lose weight? Evaluation of readiness should include the following: (1) reasons and motivation for weight loss, (2) previous attempts at weight loss, (3) support expected from family and friends, (4) understanding of risks and benefits, (5) attitudes toward physical activity, (6) time availability, and (7) potential barriers to the patient's adoption of change.
- 6 Which diet should you recommend?** In general, diets containing 1,000 to 1,200 kcal/day should be selected for most women; a diet between 1,200 kcal/day and 1,600 kcal/day should be chosen for men and may be appropriate for women who weigh 165 pounds or more, or who exercise regularly. If the patient can stick with the 1,600 kcal/day diet but does not lose weight you may want to try the 1,200 kcal/day diet. If a patient on either diet is hungry, you may want to increase the calories by 100 to 200 per day. Included in Appendix D are samples of both a 1,200 and 1,600 calorie diet.
- 7 Discuss a physical activity goal** with the patient using the Guide to Physical Activity (see Appendix H). Emphasize the importance of physical activity for weight maintenance and risk reduction.
- 8 Review the Weekly Food and Activity Diary** (see Appendix K) with the patient. Remind the patient that record-keeping has been shown to be one of the most successful behavioral techniques for weight loss and maintenance. Write down the diet, physical activity, and behavioral goals you have agreed on at the bottom.
- 9 Give the patient copies of the dietary information** (see Appendices B–G), the Guide to Physical Activity (see Appendix H), the Guide to Behavior Change (see Appendix I), and the Weekly Food and Activity Diary (see Appendix K).
- 10 Enter the patient's information** and the goals you have agreed on in the Weight and Goal Record (see Appendix J). It is important to keep track of the goals you have set and to ask the patient about them at the next visit to maximize compliance. Have the patient schedule an appointment to see you or your staff for followup in 2 to 4 weeks.

# Obesity Trends\* Among U.S. Adults

## BRFSS, 2008

(\*BMI  $\geq 30$ , or  $\sim 30$  lbs. overweight for 5' 4" person)



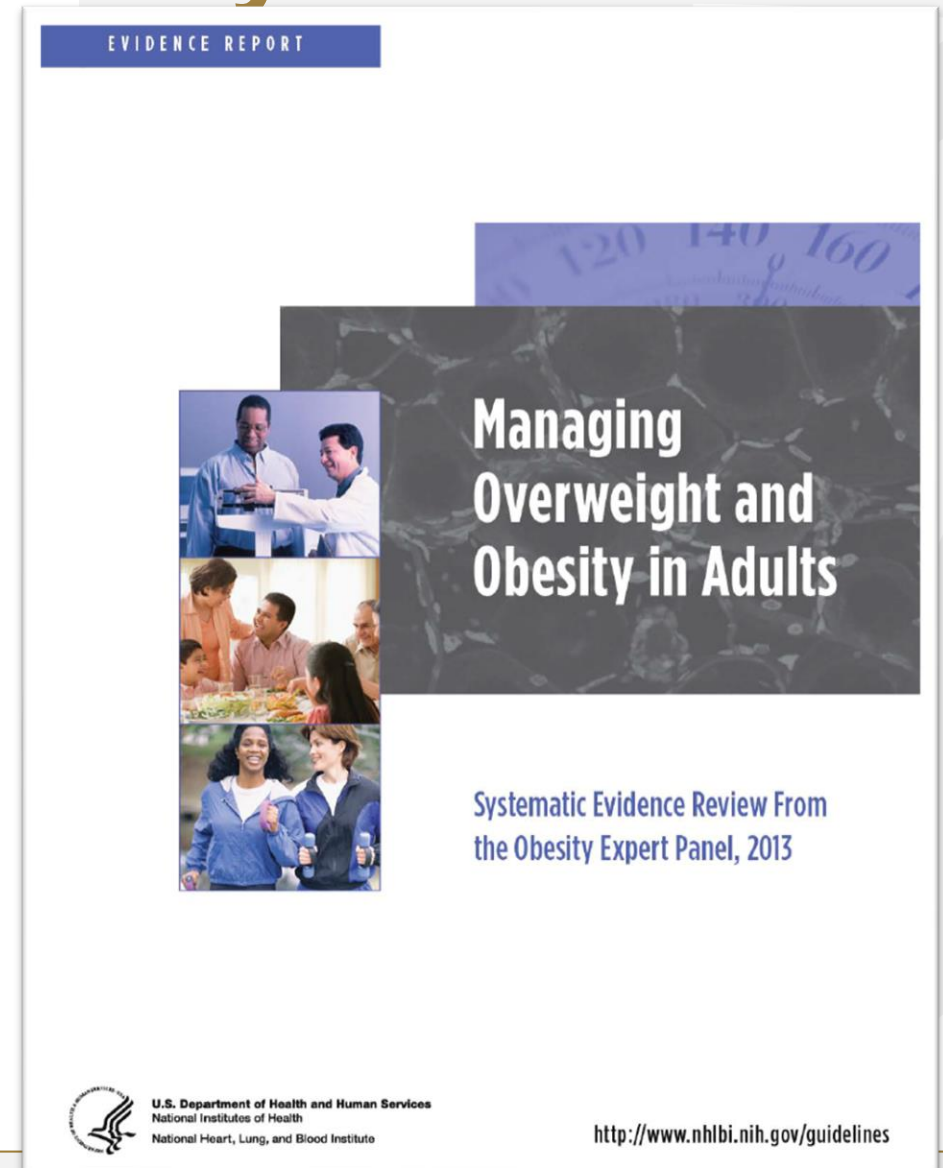
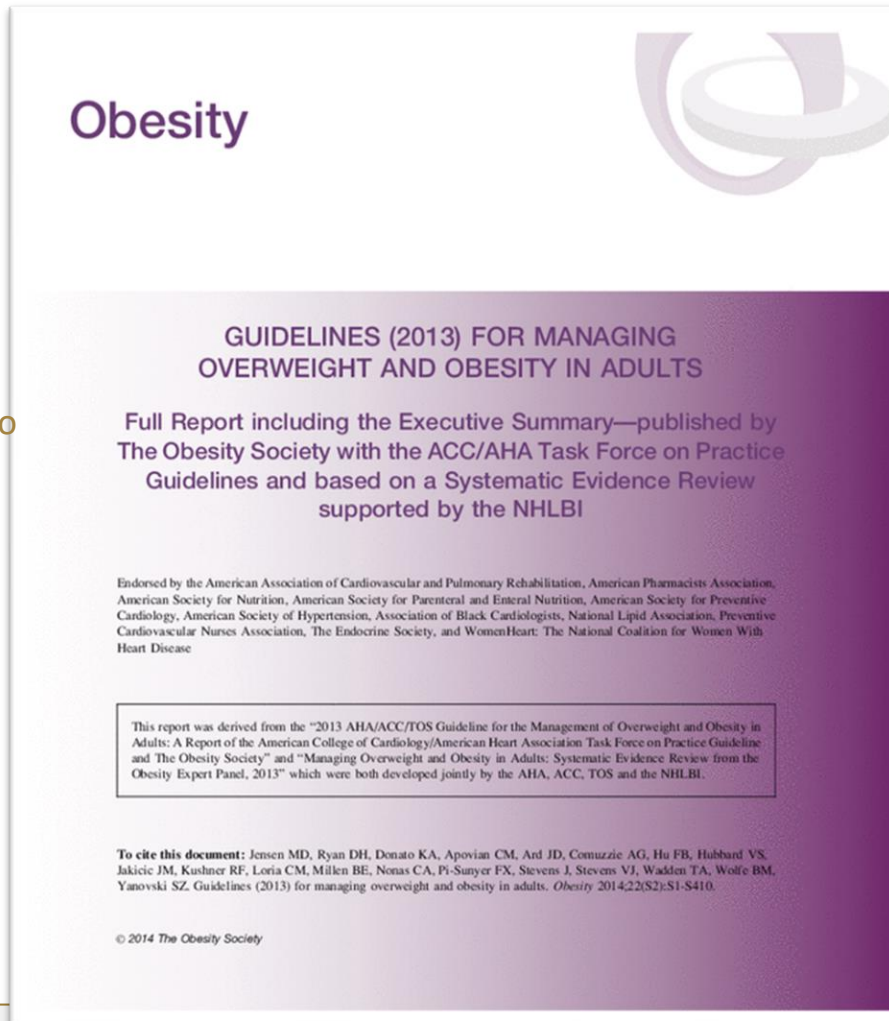
# 2013 AHA/ACC/TOS Obesity Guideline

NHLBI convened expert panel in 2008

- NIH took on systematic evidence review (SER)

- Shifted clinical guideline to professional societies

Published in 2013





# 5 Critical Questions

CQ1: Expected health benefits of weight loss

CQ2: Health risks associated with overweight and obesity (cut points for waist and BMI)

CQ3: Which dietary strategies are effective

CQ4: Effectiveness of comprehensive lifestyle approach for weight loss and maintenance

CQ5: Efficacy and safety of bariatric surgery

Literature search: Jan 1998 to December 2009

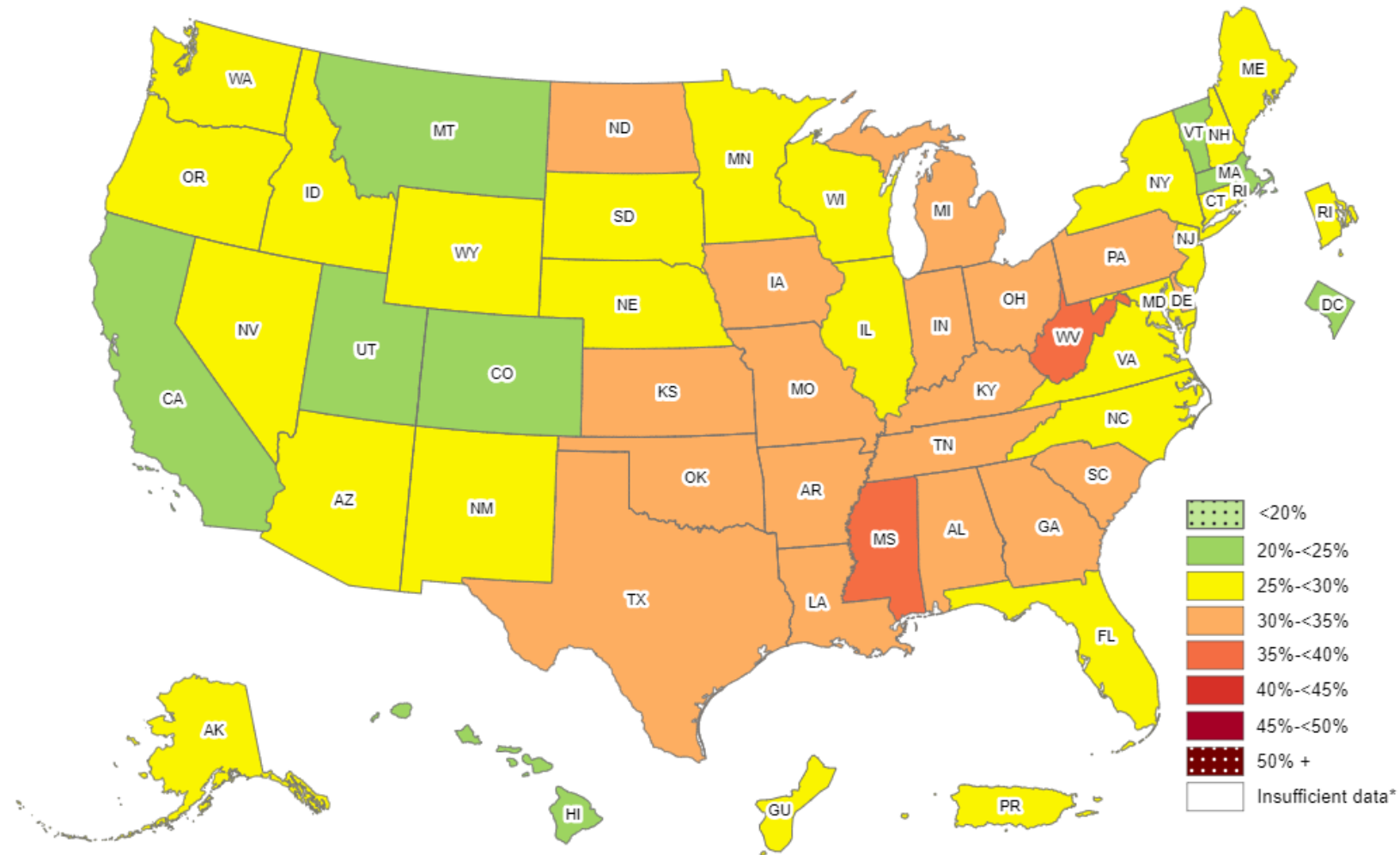
- CQ2: added systematic reviews/meta-analyses up to 10/2011
- CQ3/4: added major RCTs after 2009 if > 100 people per treatment arm
- CQ5: added major studies after 2009 that met I/E criteria

# Challenges

- No focus on pharmacotherapy
  - At the initial convening (2009):
    - Sibutramine was soon to be withdrawn (2010)
    - Rimonabant had been withdrawn (2007)
    - Lorcaserin and phentermine/topiramate were ~2 years from completing phase 3 study programs (both approved in 2012)
- 4-year gap in literature review
- Shift in ownership and strategy

# Prevalence<sup>†</sup> of Self-Reported Obesity Among U.S. Adults by State and Territory, BRFSS, 2013

<sup>†</sup> Prevalence estimates reflect BRFSS methodological changes started in 2011. These estimates should not be compared to prevalence estimates before 2011.



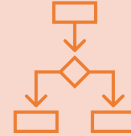
\*Sample size <50, the relative standard error (dividing the standard error by the prevalence)  $\geq 30\%$ , or no data in a specific year.



# Clinical Implications



Payers are making decisions about treatment coverage using guidelines



Clinicians are basing practice patterns on evidence that is not the latest



Policy makers take the lack of discussion about AOM as indication of decreased significance



Carry forward bariatric surgery indication

# Other Focused CPG- Filling the Gap

CLINICAL PRACTICE GUIDELINE

## Pharmacological Management of Obesity Guideline Resources

February 19, 2016

Full Guideline: [Pharmacological Management of Obesity](#)

*JCEM* | February 2016

Caroline M. Apovian (Chair), Louis J. Aronne, Daniel H. Bessesen, Marie E. McDonnell, M. Hassan Murad, Uberto Pagotto, Donna H. Ryan, and Christopher D. Still

The 2016 guideline on the pharmacological management of obesity addresses:

- › Management of chronic obesity, including managing comorbid conditions
- › Monitoring progress of weight loss using medication
- › Choosing alternative medications that are weight-losing or weight-neutral in the management of other medical conditions such as T2D, depression and other

The screenshot shows the top portion of a web page for the AGA Clinical Practice Guideline on Pharmacological Interventions for Adults With Obesity. The header includes the 'Gastroenterology' journal title and the 'aga' logo. Below the header, it states 'Access provided by Wake Forest University'. A navigation bar contains links for 'AGA Journals', 'Articles', 'Publish', 'Topics', 'Multimedia', 'CME', 'About', and 'Contact'. The main content area has a dark background with white text. It displays 'GUIDELINES | VOLUME 163, ISSUE 5, P1198-1225, NOVEMBER 2022' and a 'Download Full Issue' button. The title 'AGA Clinical Practice Guideline on Pharmacological Interventions for Adults With Obesity' is prominently displayed. Below the title, the authors are listed: 'Eduardo Grunwald', 'Raj Shah', 'Ruben Hernaez', 'Siddharth Singh', and 'Perica Davitkov', followed by 'on behalf of the AGA Clinical Guidelines Committee'. There are links for 'Show all authors' and 'Show footnotes'. The DOI is provided as 'https://doi.org/10.1053/j.gastro.2022.08.045', and there is a 'Check for updates' button.

Keywords

Objective

Target Audience

Methods

Recommendations

Limitations and

### Background & Aims

Pharmacological management of obesity improves outcomes and decreases the burden of obesity-related complications. The American Gastroenterological Association guideline is intended to support interventions for overweight and obesity.

### Methods

A multidisciplinary panel of content experts and guideline methodologists used the Assessment, Development and Evaluation framework to prioritize clinical questions and conduct an evidence synthesis of the following agents: semaglutide 2.4 extended-release (ER), naltrexone-bupropion ER, orlistat, phentermine



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# Shift to Professional Societies

AACE/ACE GUIDELINES | [VOLUME 22, SUPPLEMENT 3, 1-203, JULY 2016](#)

 [Download Full Issue](#)

## American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines For Medical Care of Patients with Obesity

[W. Timothy Garvey, MD, FACE](#) • [Jeffrey I. Mechanick, MD, FACP, FACE, FACN, ECNU](#) •

[Elise M. Brett, FACE, CNSC, ECNU](#) • ... [Rachel Pessah-Pollack, MD](#) • [Raymond Plodkowski, MD](#) •

Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines \* • [Show all authors](#)

DOI: <https://doi.org/10.4158/EP161365.GL>



# AAACE/ACE ALGORITHM FOR THE MEDICAL CARE OF PATIENTS WITH OBESITY



Patient Presentation		Screen positive for overweight or obesity BMI $\geq 25$ kg/m <sup>2</sup> ( $\geq 23$ kg/m <sup>2</sup> in some ethnicities)	Presence of weight-related disease or complication that could be improved by weight-loss therapy		
Diagnosis	Evaluation	<ul style="list-style-type: none"><li>• Medical history</li><li>• Physical examination</li><li>• Clinical laboratory</li><li>• Review of systems, emphasizing weight-related complications</li><li>• Obesity history: graph weight vs age, lifestyle patterns/preferences, previous interventions</li></ul>			
	Anthropometric Diagnosis	<ul style="list-style-type: none"><li>• Confirm that elevated BMI represents excess adiposity</li><li>• Measure waist circumference to evaluate cardiometabolic disease risk</li></ul>			
	Clinical Diagnosis	BMI kg/m <sup>2</sup>			
		<div>&lt;25 NORMAL WEIGHT</div> <div>&lt;23 In certain ethnicities</div> <div>Waist circumference below regional/ethnic cutoffs</div>	<div>25–29.9 OVERWEIGHT   <math>\geq 30</math> OBESITY</div> <div>Checklist of Obesity-Related Complications</div> <div>(staging and risk stratification based on complication-specific criteria)</div>		
		None	Mild to Moderate	Severe	
Diagnostic Categories	NORMAL WEIGHT (no obesity)	STAGE 0	STAGE 1	STAGE 2	
		No complications	One or more mild-to-moderate complications or may be treated effectively with moderate weight loss	At least one severe complication or requires significant weight loss for effective treatment	
		OVERWEIGHT BMI 25–29.9 OBESITY BMI $\geq 30$	BMI $\geq 25$	BMI $\geq 25$	
Phases of Chronic Disease Prevention and Treatment Goals	PRIMARY Prevent overweight/obesity	SECONDARY Prevent progressive weight gain or achieve weight loss to prevent complications	TERTIARY Achieve weight loss sufficient to ameliorate the complications and prevent further deterioration		
Treatment Based on Clinical Judgment	<ul style="list-style-type: none"><li>• Healthy meal plan</li><li>• Physical activity</li><li>• Health education</li><li>• Built environment</li></ul>	<ul style="list-style-type: none"><li>• Lifestyle/behavioral therapy</li><li>• Consider pharmacotherapy if lifestyle alone not effective</li></ul>	<ul style="list-style-type: none"><li>• Lifestyle/behavioral therapy</li><li>• Consider pharmacotherapy (BMI <math>\geq 27</math>)</li></ul>	<ul style="list-style-type: none"><li>• Lifestyle/behavioral therapy</li><li>• Add pharmacotherapy (BMI <math>\geq 27</math>)</li><li>• Consider bariatric surgery (BMI <math>\geq 35</math>)</li></ul>	
Follow-Up	<ul style="list-style-type: none"><li>• Once the plateau for weight loss has been achieved, re-evaluate the weight-related complications. If the complications have not been ameliorated, weight-loss therapy should be intensified or complication-specific interventions need to be employed.</li><li>• Obesity is a chronic disease and the diagnostic categories for obesity may not be static. Therefore, patients require ongoing follow-up, re-evaluation and long-term treatment.</li></ul>				



# Guidelines to Shift Practice

For Immediate Release  
October 21, 2022

**CONTACT:** Roger Kissin  
[rkissin@compartersny.com](mailto:rkissin@compartersny.com)

## Medical Groups Replace Outdated Consensus Statement that Overly Restricts Access to Modern Day Weight-Loss Surgery

**NEWBERRY, FL – Oct. 21, 2022** – Two of the world's leading authorities on bariatric and metabolic surgery have issued new evidence-based clinical guidelines that among a slew of recommendations expand patient eligibility for weight-loss surgery and endorse metabolic surgery for patients with type 2 diabetes beginning at a body mass index (BMI) of 30, a measure of body fat based on a person's height and weight and one of several important screening criteria for surgery.

The [ASMBS/IFSO Guidelines on Indications for Metabolic and Bariatric Surgery – 2022](#), published online today in the journals, Surgery for Obesity and Related Diseases (SOARD) and Obesity Surgery, are meant to replace a consensus statement developed by National Institutes of Health (NIH) more than 30 years ago that set standards most insurers and doctors still rely upon to make decisions about who should get weight-loss surgery, what kind they should get, and when they should get it.

# Canadian Guidelines



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Guideline

## Obesity in adults: a clinical practice guideline

Sean Wharton, David C.W. Lau, Michael Vallis, Arya M. Sharma, Laurent Biertho, Denise Campbell-Scherer, Kristi Adamo, Angela Alberga, Rhonda Bell, Normand Boulé, Elaine Boyling, Jennifer Brown, Betty Calam, Carol Clarke, Lindsay Crowshoe, Dennis Divalentino, Mary Forhan, Yoni Freedhoff, Michel Gagner, Stephen Glazer, Cindy Grand, Michael Green, Margaret Hahn, Raed Hawa, Rita Henderson, Dennis Hong, Pam Hung, Ian Janssen, Kristen Jacklin, Carlene Johnson-Stoklossa, Amy Kemp, Sara Kirk, Jennifer Kuk, Marie-France Langlois, Scott Lear, Ashley McInnes, David Macklin, Leen Naji, Priya Manjoo, Marie-Philippe Morin, Kara Nerenberg, Ian Patton, Sue Pedersen, Leticia Pereira, Helena Piccinini-Vallis, Megha Poddar, Paul Poirier, Denis Prud'homme, Ximena Ramos Salas, Christian Rueda-Clausen, Shelly Russell-Mayhew, Judy Shiau, Diana Sherifali, John Sievenpiper, Sanjeev Sockalingam, Valerie Taylor, Ellen Toth, Laurie Twells, Richard Tytus, Shahebina Walji, Leah Walker and Sonja Wicklum

CMAJ, August 04, 2020 192 (31) E875-E891; DOI: <https://doi.org/10.1503/cmaj.191707>



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# Canadian Process

Inclusion of the patient voice

“assessed well over 550,000 published peer-reviewed articles”

“built consensus on a wide range of clinical and scientific issues to identify 80 key recommendations”

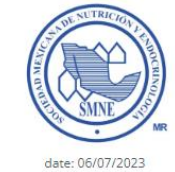
Adoption/adaptation by other countries

Living document with regular updates



# Endorsed by Others

## Adult Clinical Practice Guideline Endorsements:



# Summary and Key Questions

- Even the most comprehensive guidelines will be limited by the availability of high-quality evidence
- Clinical decision making still has to be informed by best practice standards in the absence of a guideline (i.e., standard of care)
  - Especially true in obesity medicine where non-science-based therapies abound, and we have little comparative effectiveness evidence
- Who is the authoritative body that defines the predominant guideline?
- Will US policy makers, payers, etc use an international guideline?