Opportunities and Barriers for Clinical Practice Guidelines

ADULT GUIDELINES

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School of Medicine

Disclosures

Research support	Nestle Healthcare Nutrition, Eli Lilly, Boehringer Ingelheim, Epitomee, Inc., UnitedHealth Group R&D, KVKTech, Weight Watchers
Consulting	Nestle Healthcare Nutrition, Eli Lilly, Optum Labs R&D, Novo Nordisk, Intuitive, Regeneron, Brightseed
Advisory Board	Novo Nordisk, Nestle Healthcare Nutrition, Eli Lilly, Level2, Weight Watchers, Boehringer Ingelheim, Regeneron
Memberships	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

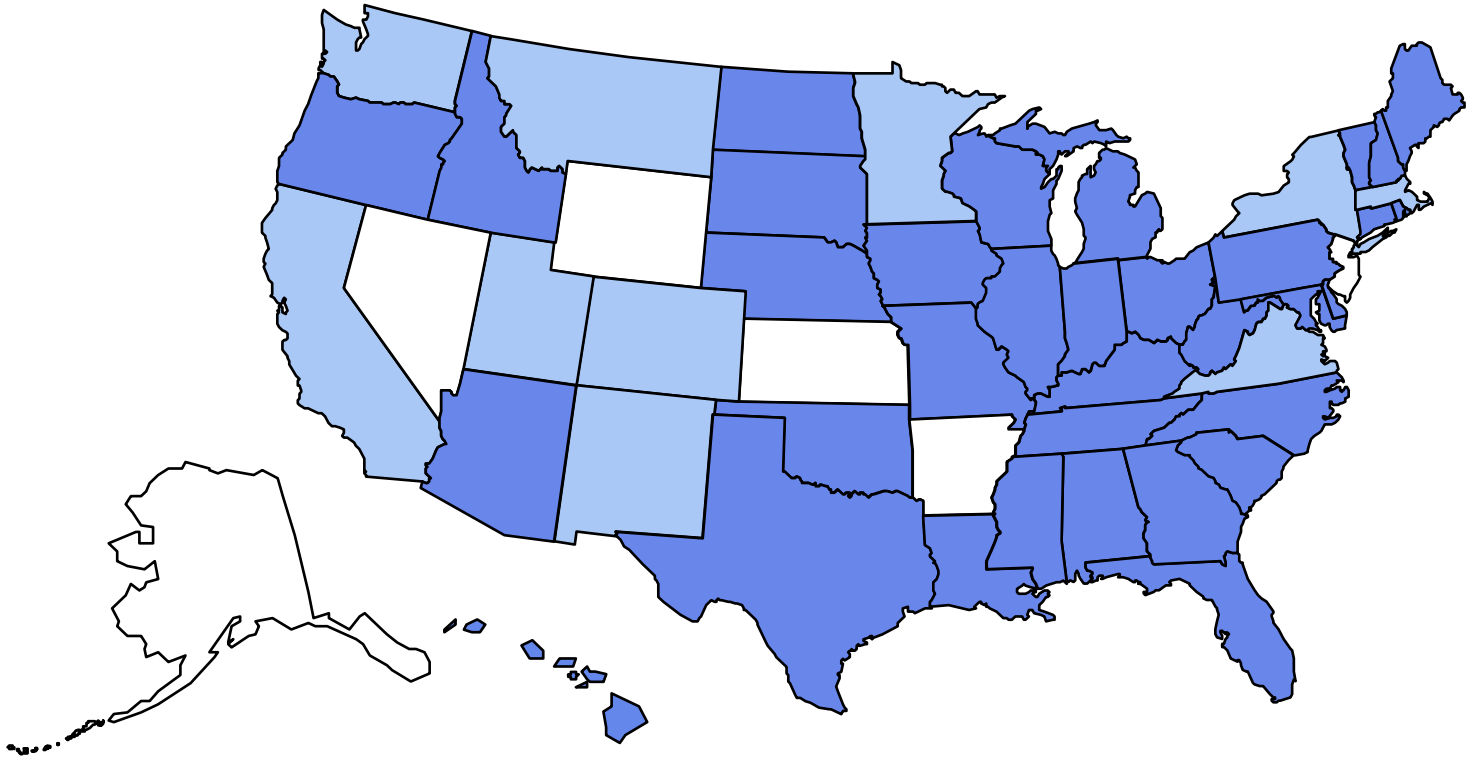
- Clinical practice guidelines (CPG) are a function of
  - The questions asked
  - The evidence available
  - Resources available
  - The people writing them

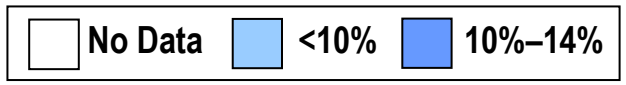
- CPG can be used in a variety of ways that improve or hinder obesity care
- CPG need to be living documents and supplemented by Standards of Care

Obesity Trends* Among U.S. Adults

BRFSS, 1990

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)





Source: Behavioral Risk Factor Surveillance System, CDC.

1991 NIH Consensus Statement

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

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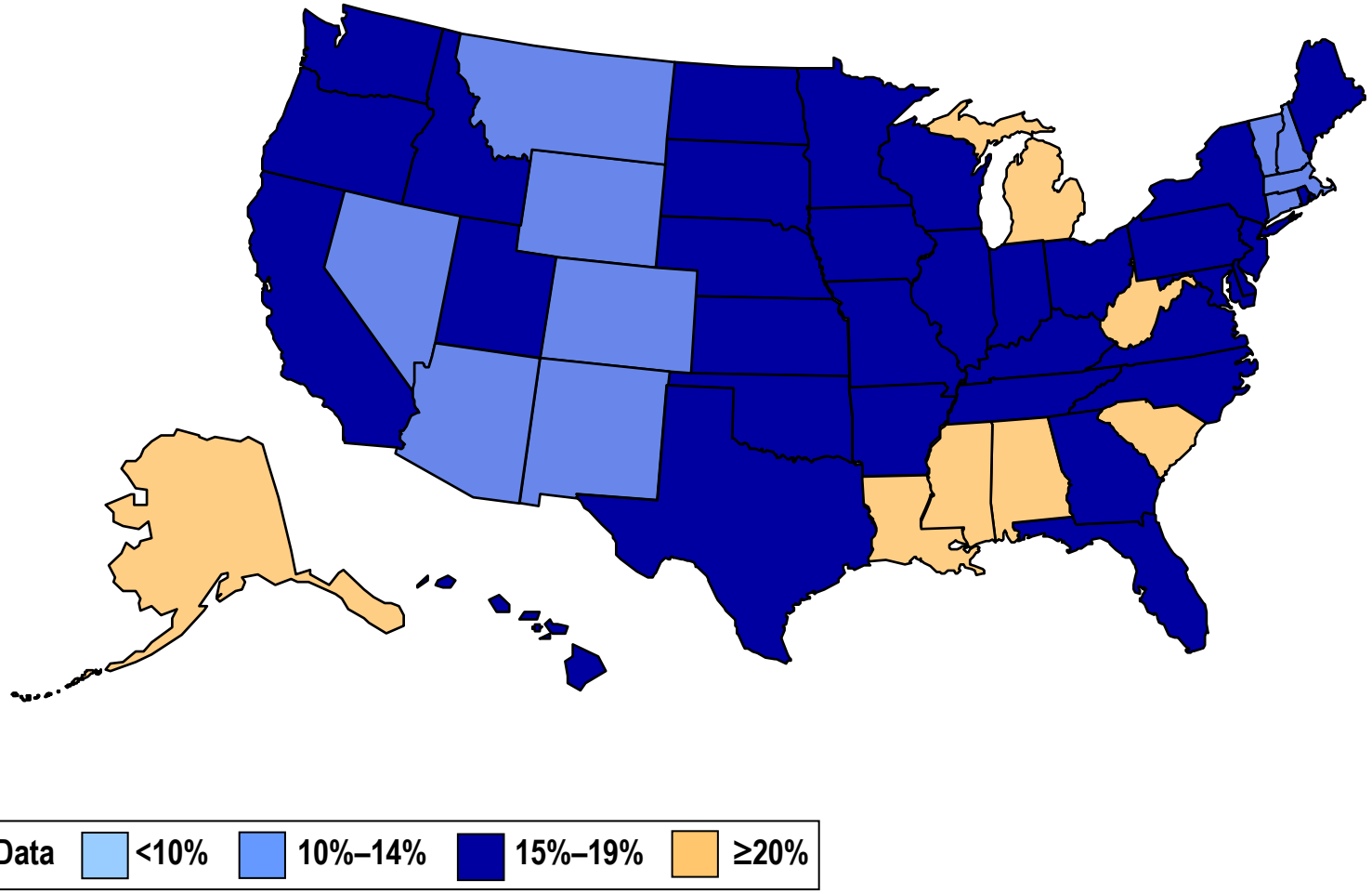
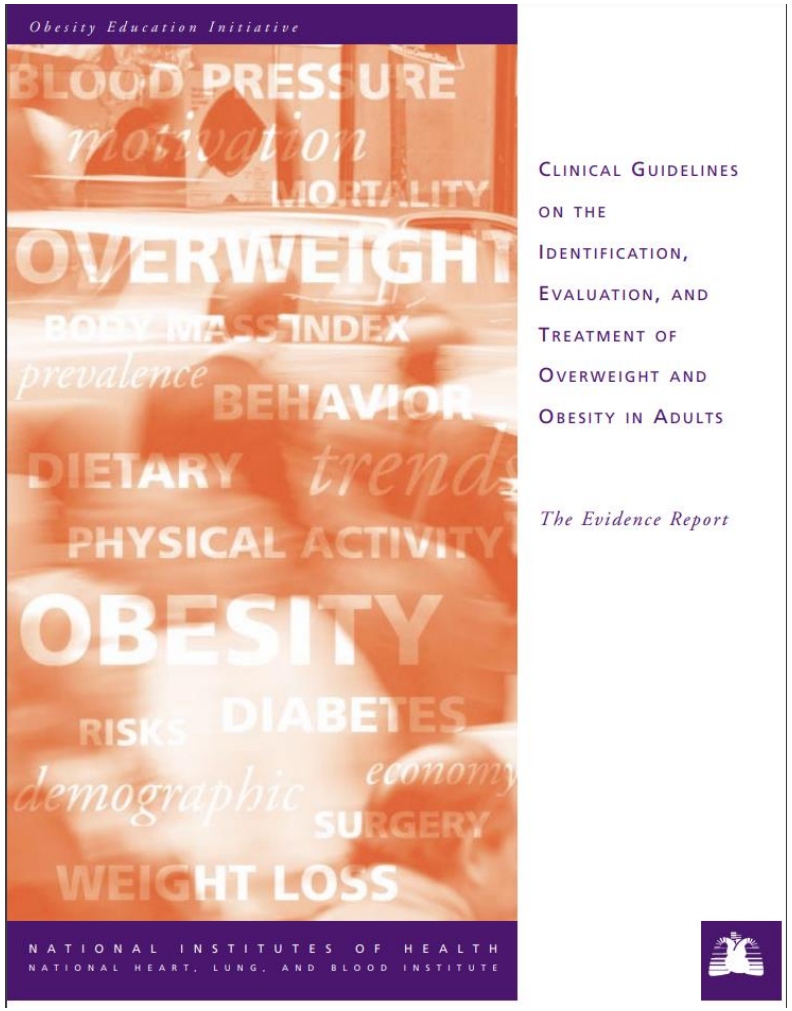
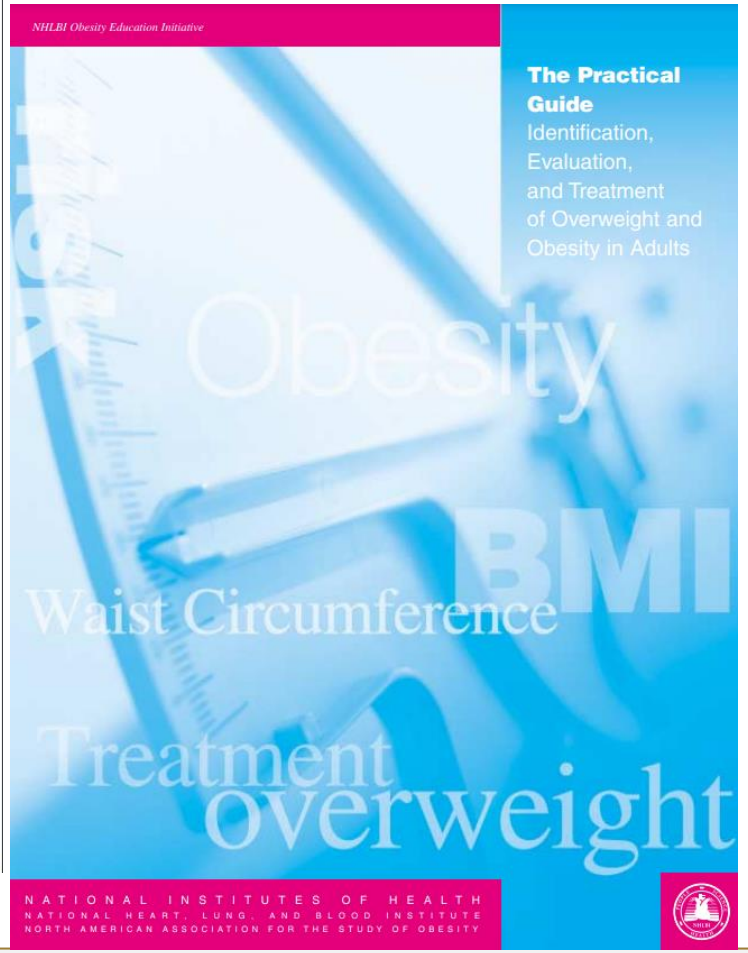


Source: Behavioral Risk Factor Surveillance System, CDC.

CPGs on Obesity in the US





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

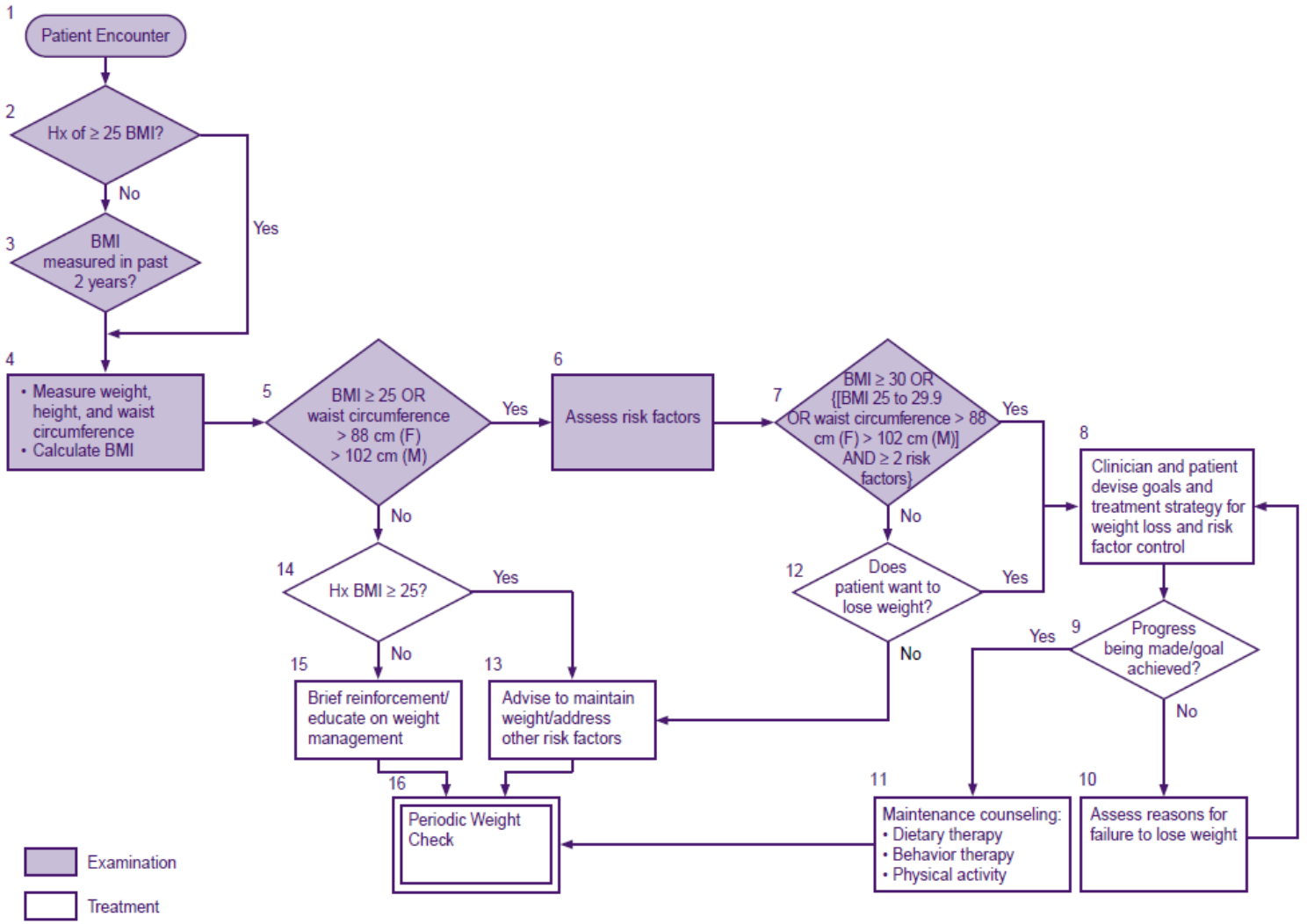
Evidence Report and Practical Guide published 1998

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

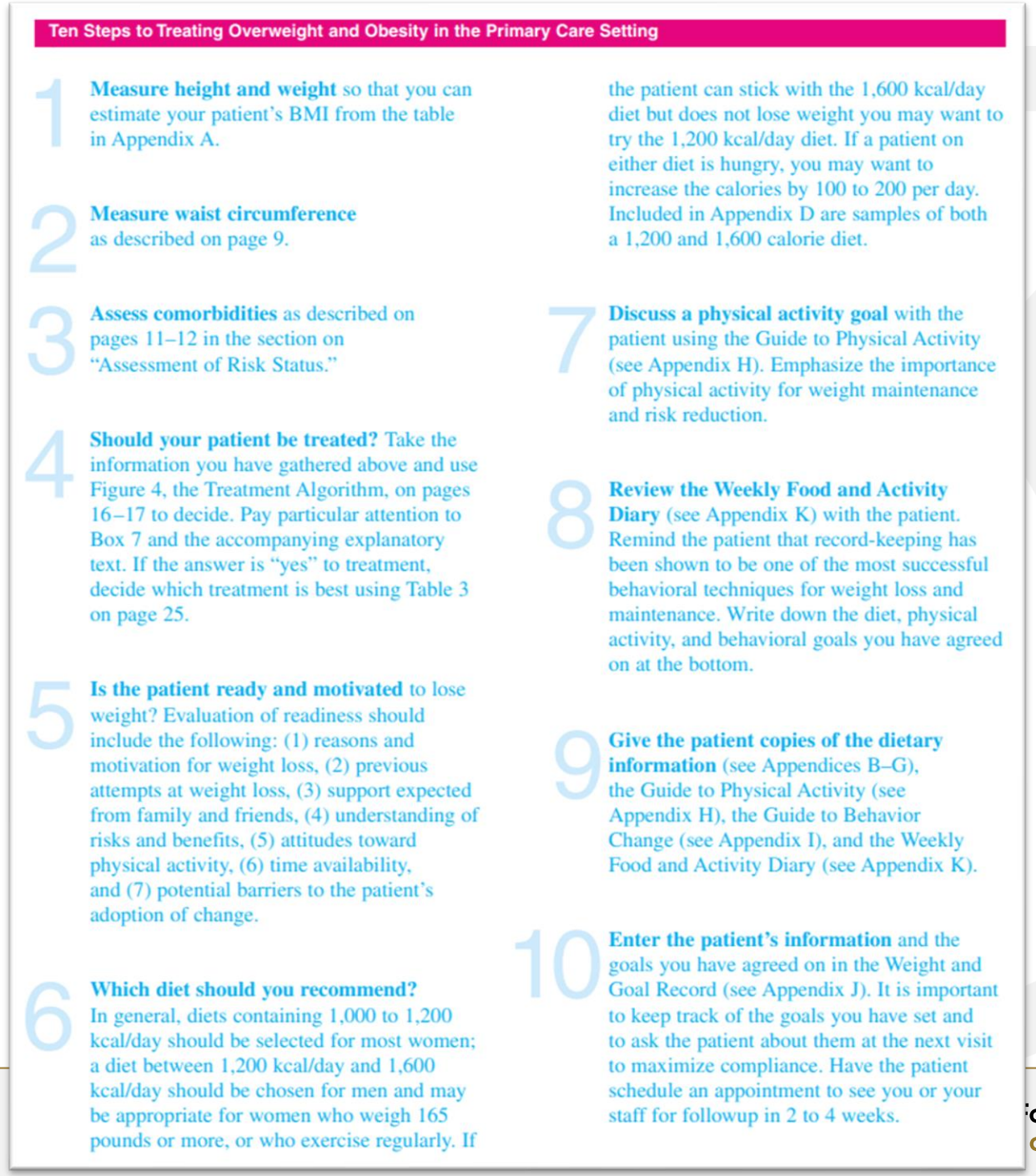
*Note: sibutramine was approved by FDA; orlistat approval was pending at the time of publication; dexfenfluramine and fenfluramine had just been removed in 1997

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.

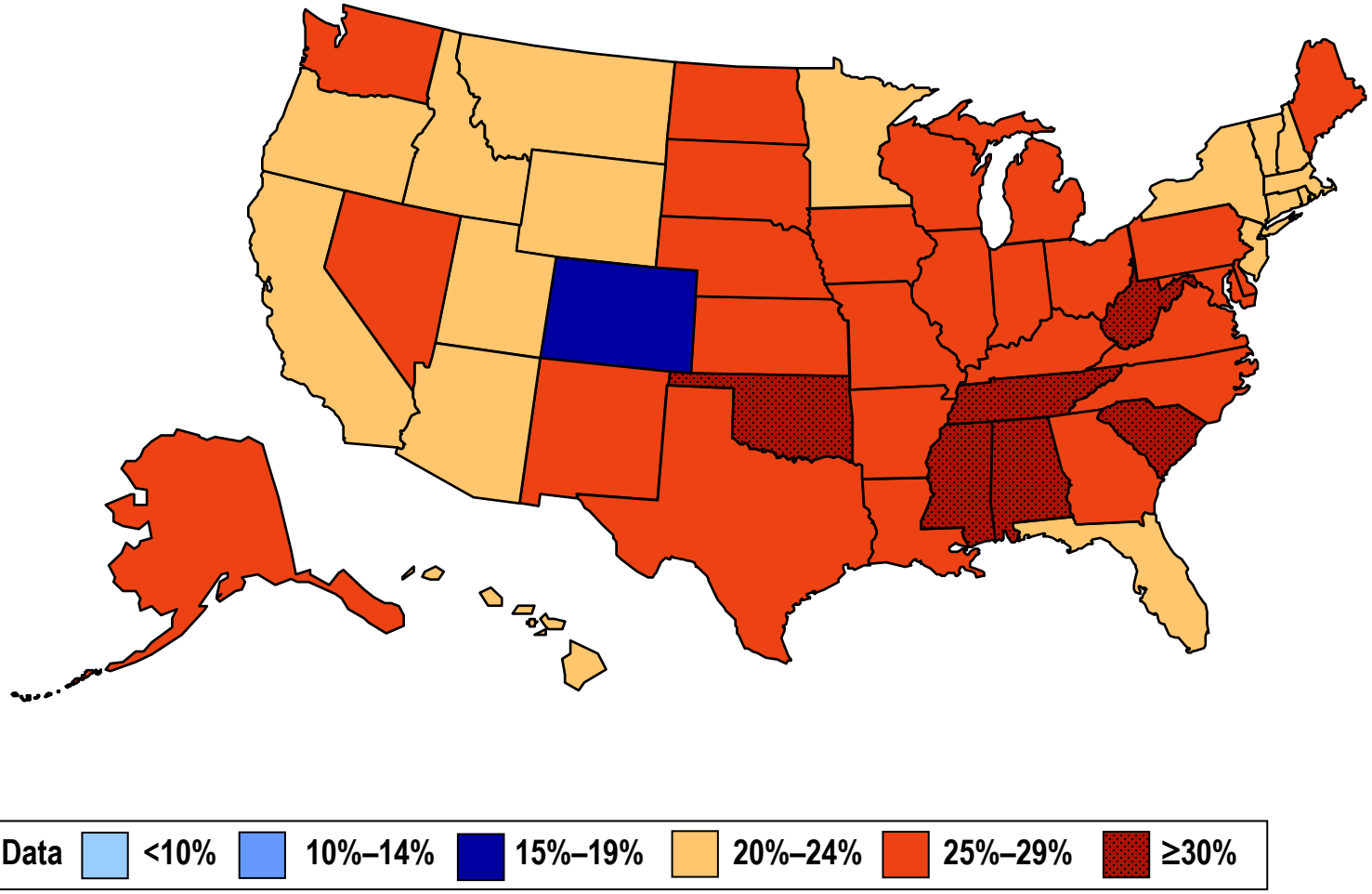
9 **Give the patient copies of the dietary information** (see Appendices B–G), the Guide to Physical Activity (see Appendix H), the Guide to Behavior Change (see Appendix I), and the Weekly Food and Activity Diary (see Appendix K).

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 ≥30, or ~ 30 lbs. overweight for 5’ 4” person)



Source: Behavioral Risk Factor Surveillance System, CDC.

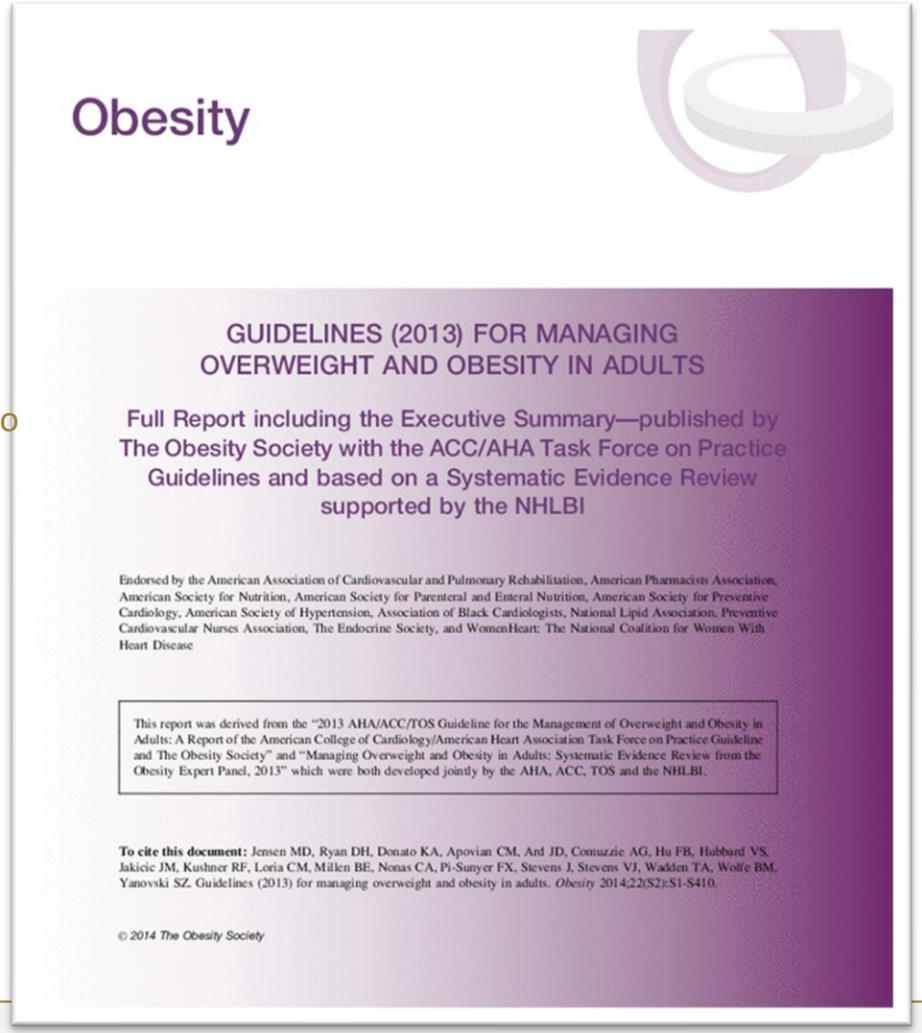
2013 AHA/ACC/TOS Obesity Guideline

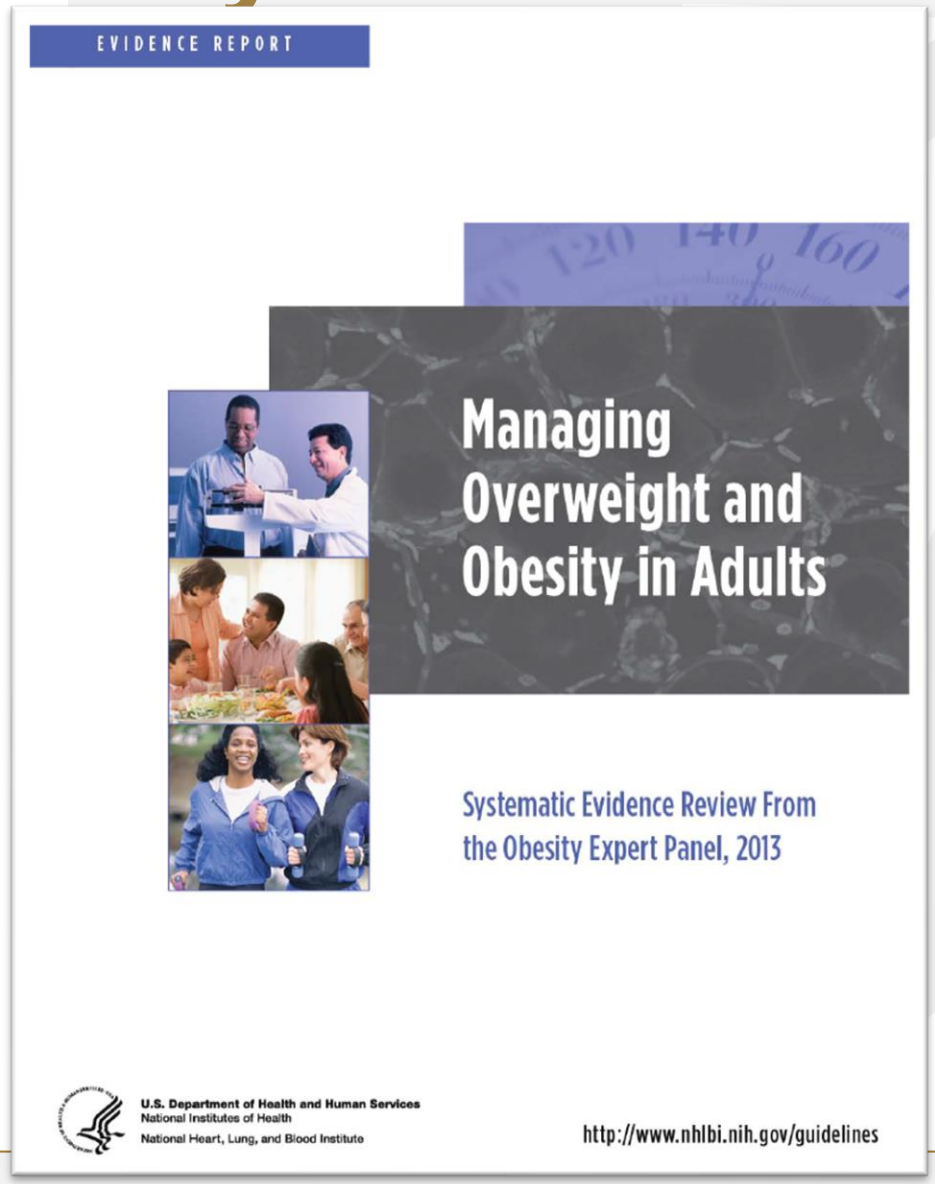
NHLBI convened expert panel in 2008

- 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

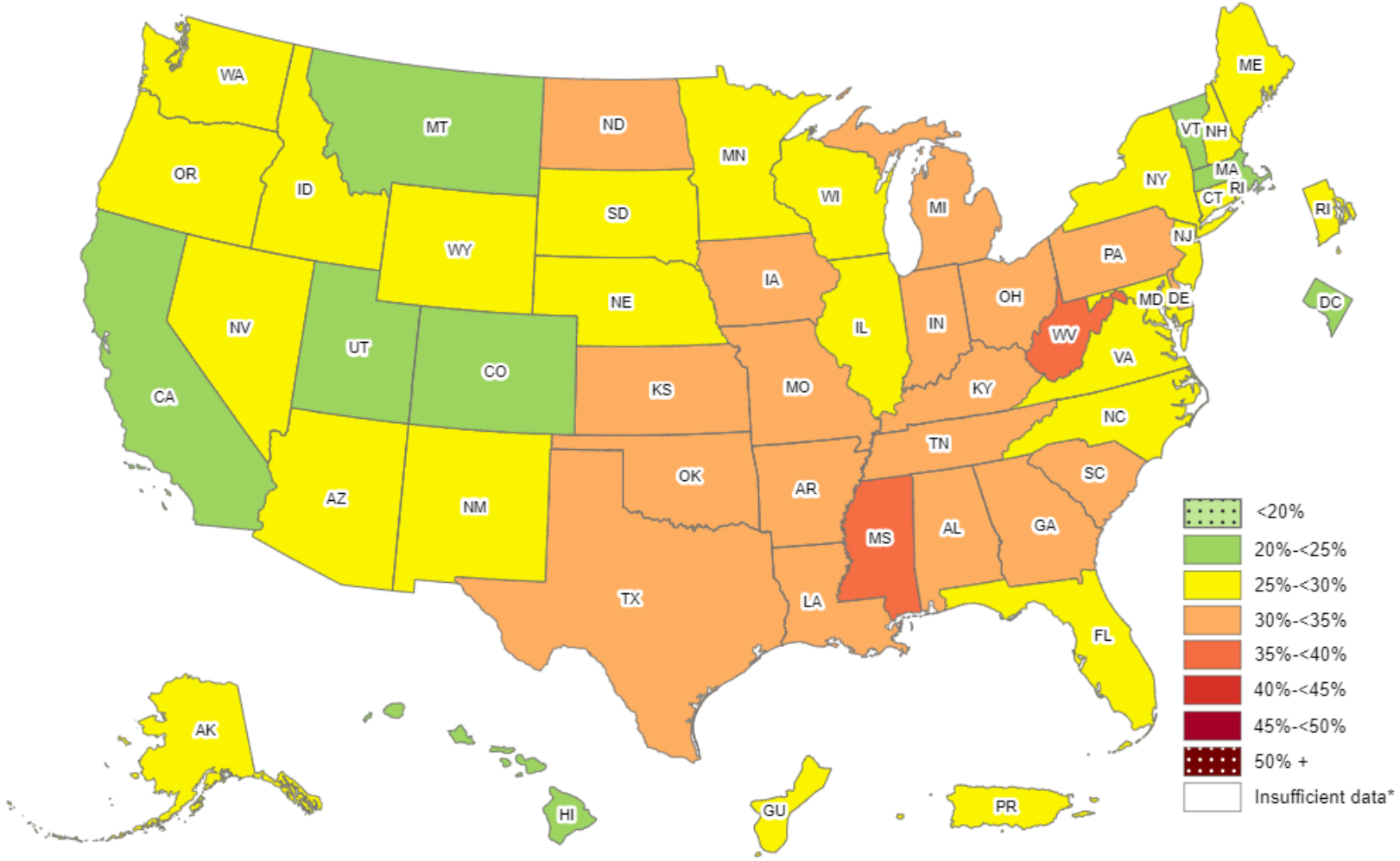
- CQ2: added systematic reviews/meta-analyses up to 10/2011
- CQ3/4: added major RCTs after 2009 if > 100 people per treatment arm
- CQ5: added major studies after 2009 that met I/E criteria

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¶ of Self-Reported Obesity Among U.S. Adults by State and Territory, BRFSS, 2013

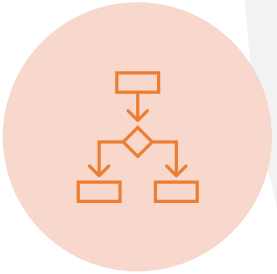
¶ Prevalence estimates reflect BRFSS methodological changes started in 2011. These estimates should not be compared to prevalence estimates before 2011.



***Sample size <50, the relative standard error (dividing the standard error by the prevalence) ≥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

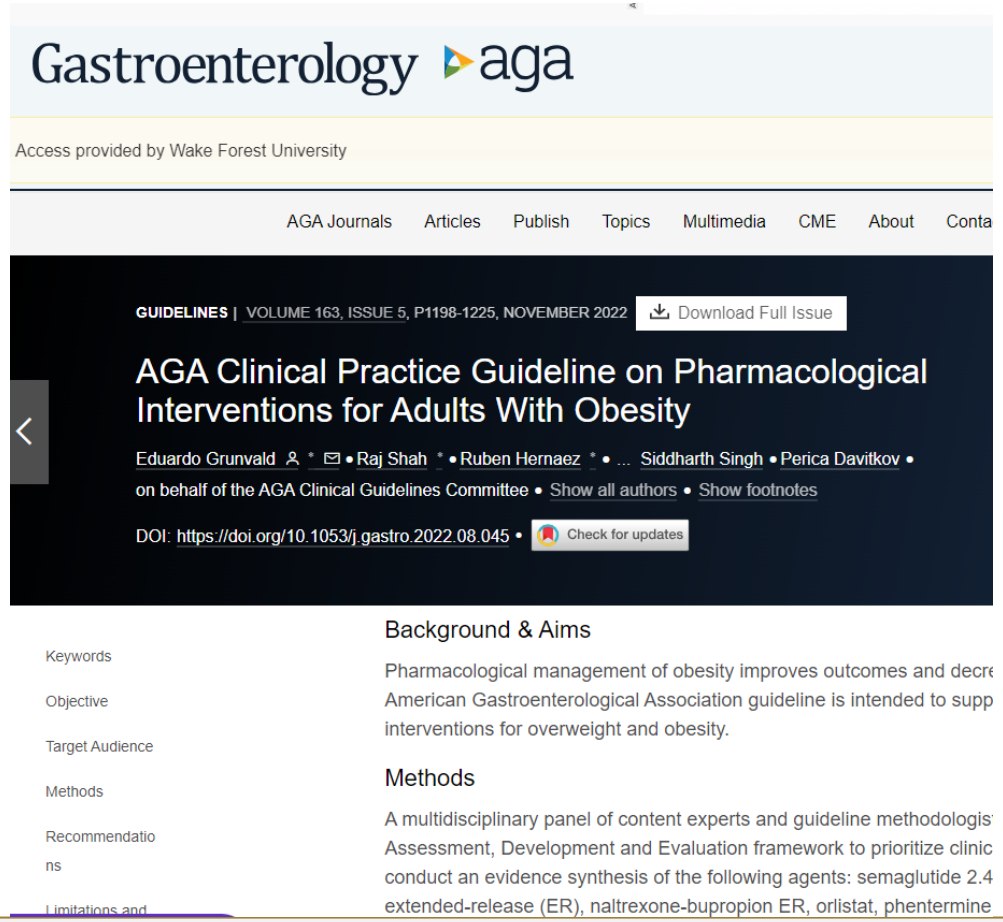
Pharmacological Management of Obesity Guideline Resources

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

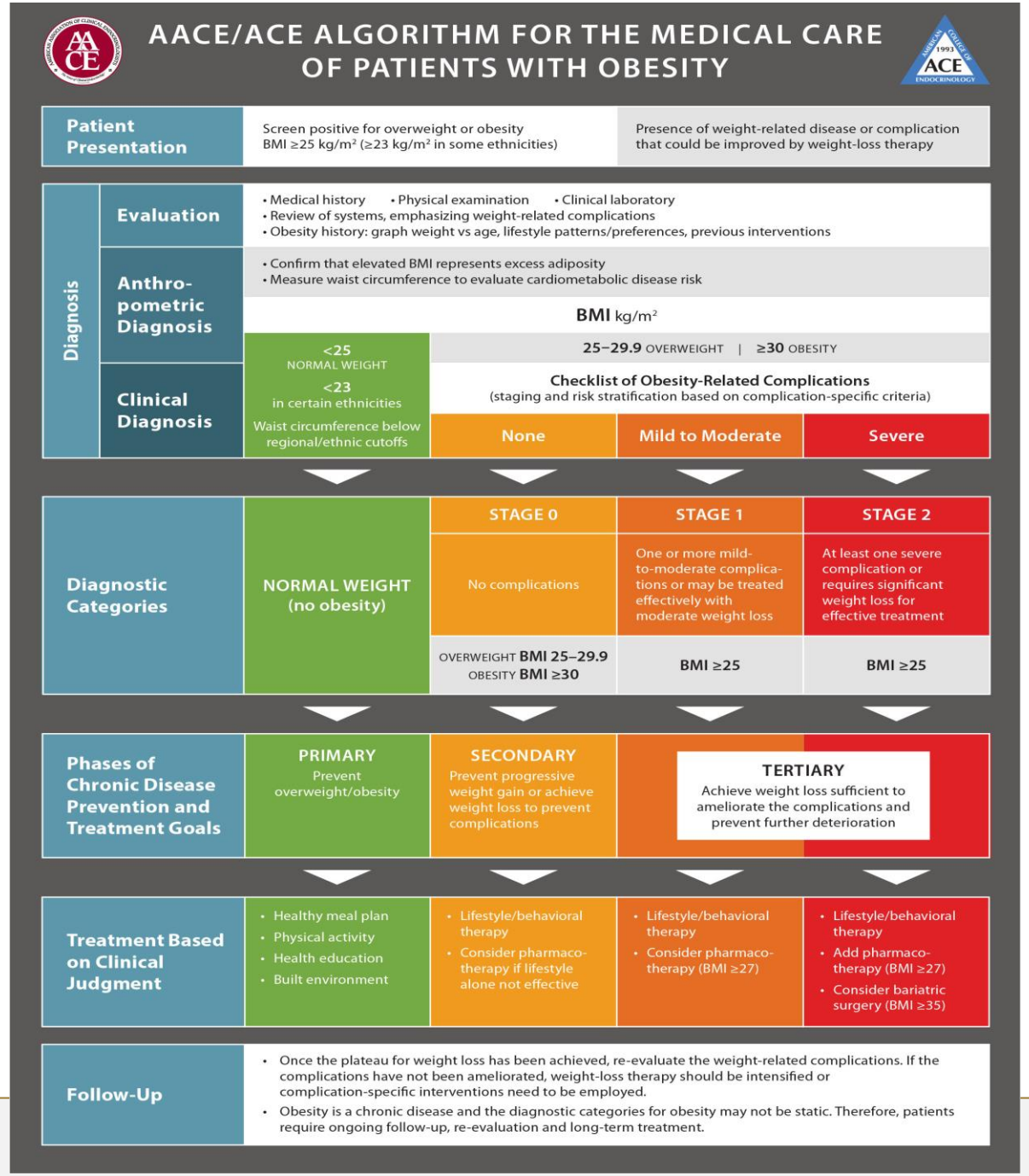
The 2016 guideline on the pharmacological management of obesity addresses:

- 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



Shift to Professional Societies

AACE/ACE ALGORITHM FOR THE MEDICAL CARE OF PATIENTS WITH OBESITY



Guidelines to Shift Practice

For Immediate Release
October 21, 2022

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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

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

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?