Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults

NHLBI Obesity Education Initiative

National Heart, Lung, and Blood Institute

in cooperation with the

National Institute of Diabetes and Digestive and Kidney Diseases

National Institutes of Health

Background

Approximately 108 million American adults are overweight or obese.

Increased risk of:

- Hypertension
- Type 2 diabetes
- Coronary heart disease
- Gallbladder disease
- Certain cancers
- Dyslipidemia
- Stroke
- Osteoarthritis
- Sleep apnea

CDC/NCHS NHANES 1999

Purpose of the Guidelines

- To provide a thorough review of the scientific evidence on the effects of treatment of overweight and obesity
- To provide assistance to primary care practitioners on the identification, evaluation, and treatment of overweight and obese patients

Charge to the Panel

- Examine the scientific evidence regarding the issues pertaining to overweight and obesity in adults, particularly those issues related to:
  - other heart disease risk factors, such as hypertension, blood lipid levels, and diabetes;
  - the distribution and amount of body fat as it influences risk;
  - the independent relationship of obesity to coronary heart disease (CHD); and,
  - the relationship of obesity to sleep apnea.

Charge to the Panel (continued)

- Develop clinical practice guidelines, based on the evidence, for the practicing physician and other health care providers who are dealing with the problem of overweight in the high-risk adult.
- Make guidelines concise, comprehensive, and easy to use.

Obesity Expert Panel Members

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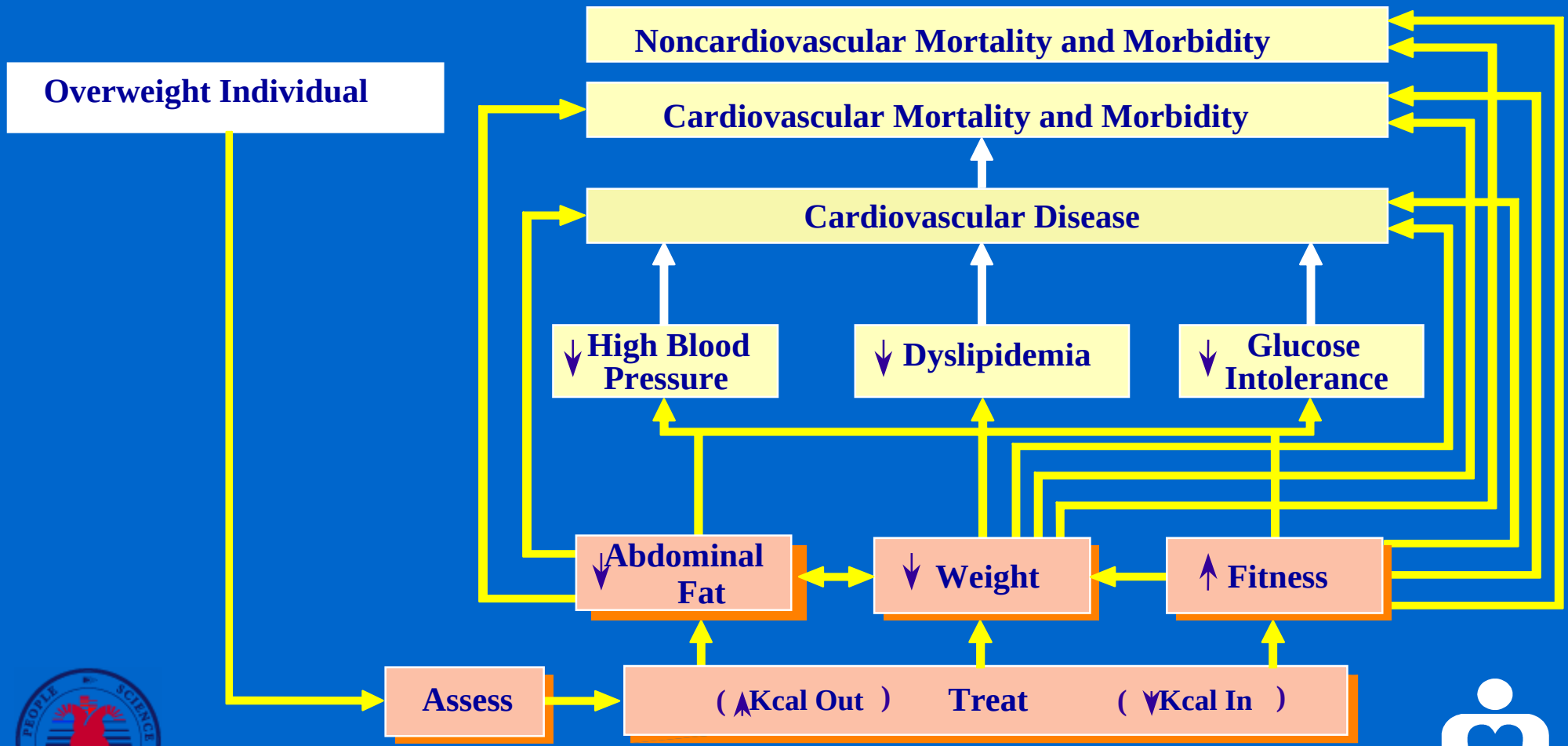
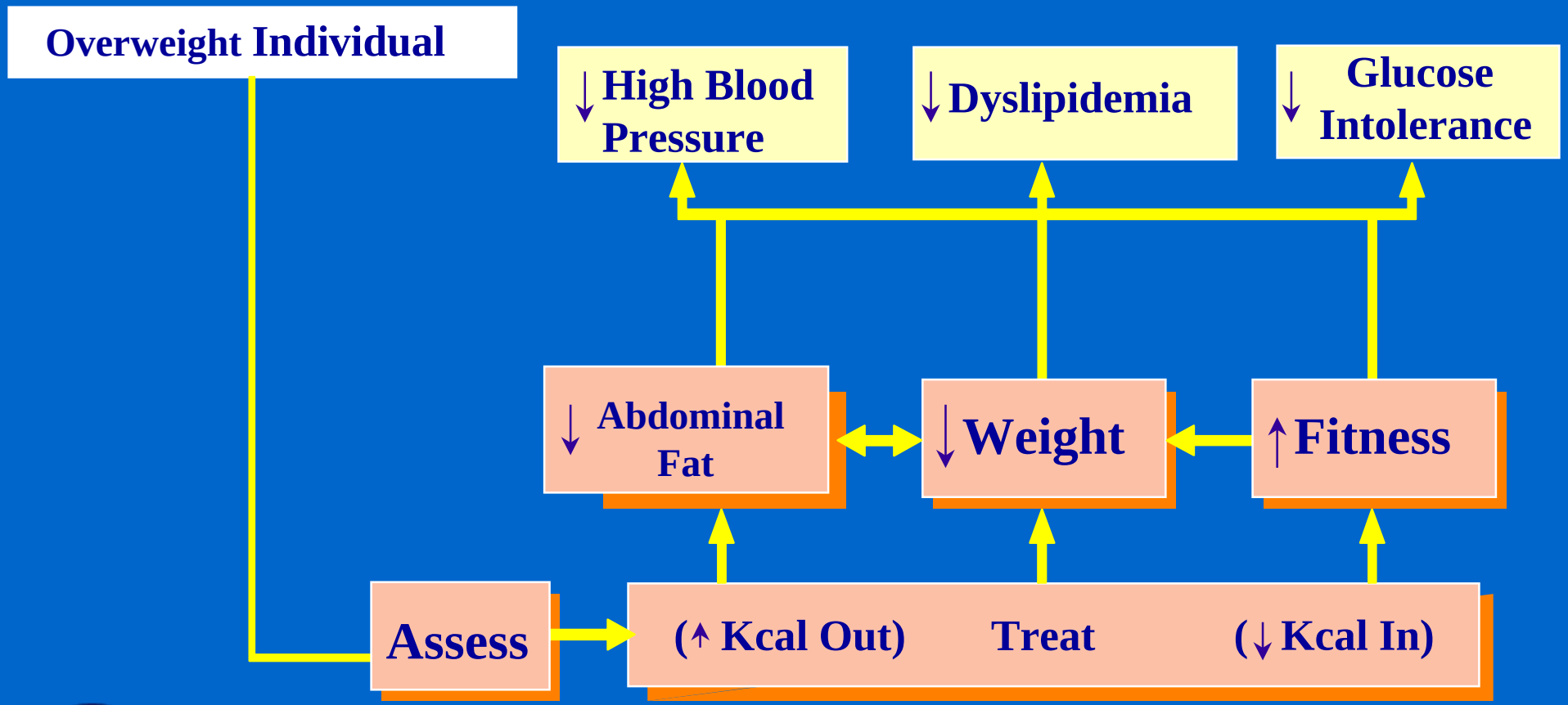
Evidence Model for Treatment of Overweight and Obesity



Evidence Model for Treatment of Overweight and Obesity



Literature Search

- Systematic review of published scientific literature in MEDLINE from 1980 through September 1997.
- English language.
- Priority: randomized controlled trials—394 reviewed.
- No editorials, letters, or case reports.

Inclusion and Exclusion Criteria

- Timeframe of the study—at least 4 months.
- For long-term maintenance—1 year or more.
- Excluded studies with self-reported weights, patients not overweight, dropout rate >35%, or no appropriate control group.

Criteria To Evaluate the Evidence

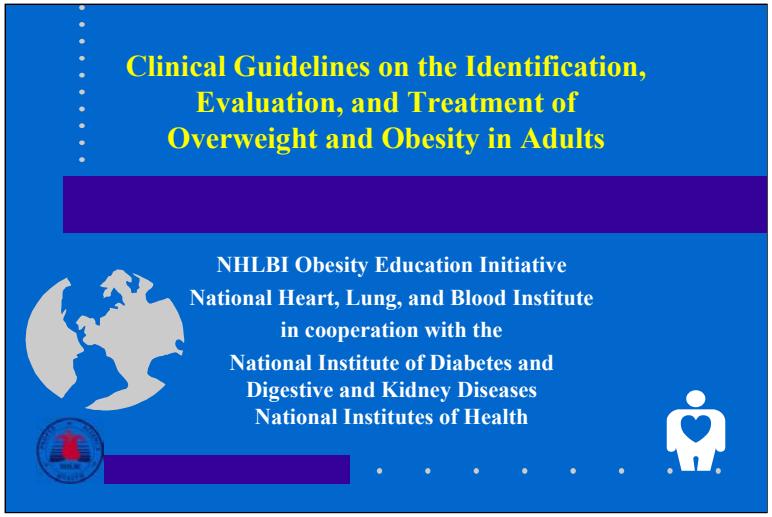
- A—Strong evidence: Evidence from well-designed randomized controlled trials (or trials that depart only minimally from randomization) that provides a consistent pattern of findings.
- B—Suggestive evidence (from randomized studies): Evidence as in A, but involving a smaller number of studies and/or a less consistent pattern of findings.

Criteria To Evaluate the Evidence (continued)

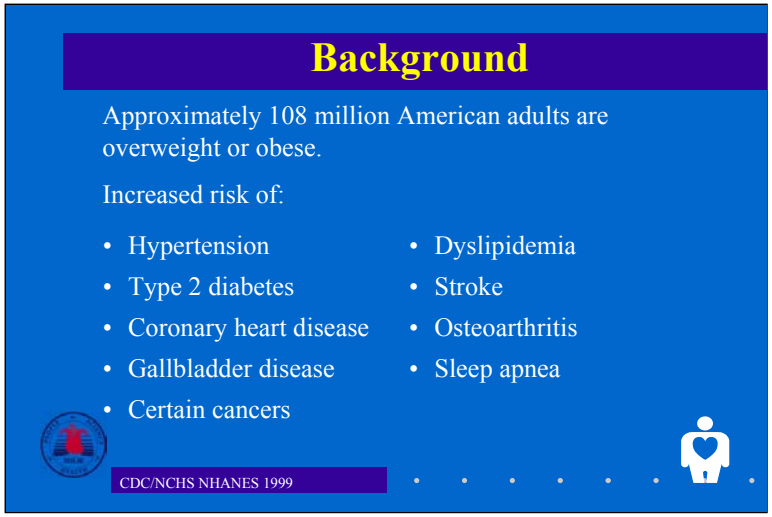
- C—Suggestive evidence (from nonrandomized studies): Evidence from the panel's interpretation of uncontrolled or observational studies.
- D—Expert judgment: Evidence from clinical experience or experimental research.

How Were the Guidelines Developed?

- NHLBI/NIDDK convened a 24-member expert panel in May 1995.
- Panel reviewed published scientific literature from January 1980 to September 1997. Evidence from 394 randomized controlled trials (RCTs) was considered.
- Data from 236 RCTs were abstracted, and data were compiled into evidence tables.
- Evidence statements and recommendations were categorized by level of evidence from A to D.

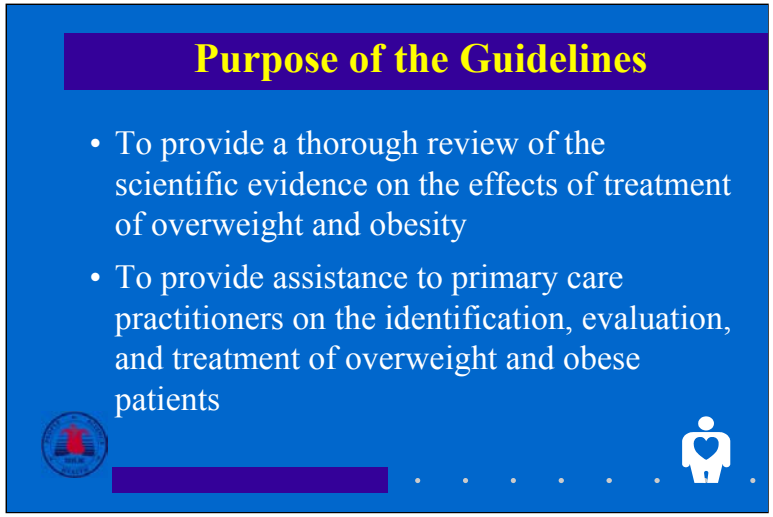


The expert panel that developed the *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults* was convened by the National Heart, Lung, and Blood Institute (NHLBI) in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The Clinical Guidelines are the first Federal guidelines released that deal with the issues related to the assessment and treatment of overweight and obesity in adults. They were officially released by NHLBI on June 17, 1998.



Based on the 1999 NHANES data, about 61 percent of adults, or an estimated 108 million adults, in the United States are overweight or obese, a condition that substantially increases their risk for hypertension, dyslipidemia, type 2 diabetes, stroke, coronary heart disease, osteoarthritis, gallbladder disease, sleep apnea and respiratory problems, and endometrial, breast, prostate, and colon cancers.

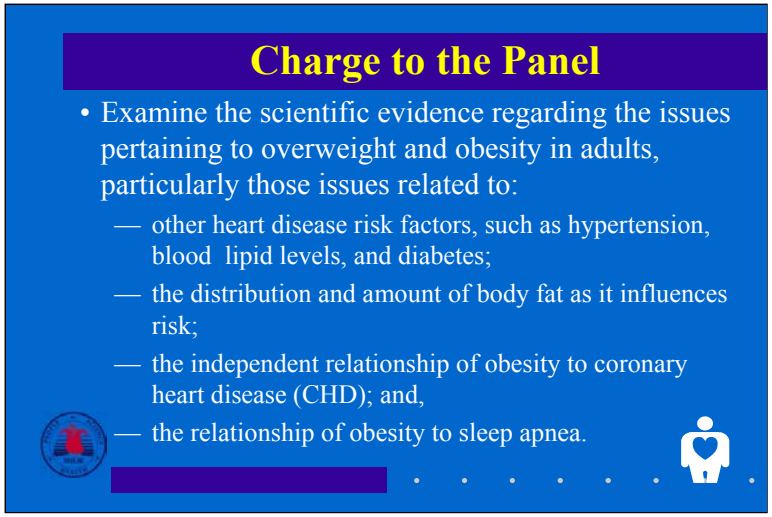
- Higher body weight is also associated with increases in all-cause mortality.
- Obese individuals may also suffer from social stigmatization and discrimination.



Development of the guidelines had to serve two distinct purposes:

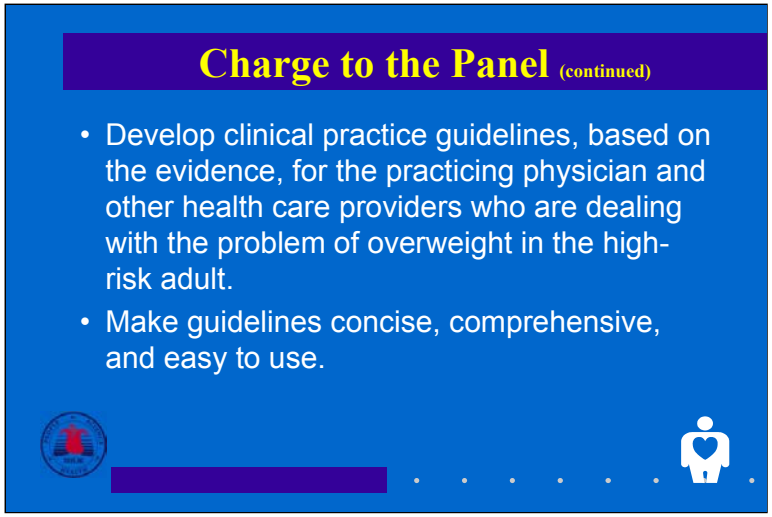
1. The guidelines had to be based on the best scientific evidence available to date. The expert panel had to conduct a thorough review of the scientific evidence related to various therapies for overweight and obesity and to critique that evidence on the basis of some very specific criteria. The panel used an evidence-based methodology to consider the evidence and ultimately come up with their recommendations.

2. The ultimate purpose was to provide primary care practitioners with standards for use when assessing and treating overweight and obese patients.



The specific charge given to the panel was to examine the scientific evidence regarding the issues pertaining to overweight and obesity in adults, particularly those issues related to:

- Other heart disease risk factors, such as hypertension, blood lipid levels, and diabetes.
- The distribution and amount of body fat as it influences risk.
- The independent relationship of obesity to CHD.
- The relationship of obesity to sleep apnea.



In addition to culling the scientific literature to come up with their recommendations, the panel was also charged to:

- Develop clinical practice guidelines that would be appropriate for the practicing physician and other health care providers who are dealing with the problem of overweight in the high-risk adult.
- Make the guidelines concise, comprehensive, and easy to use.

The expert panel was chaired by Dr. Xavier Pi-Sunyer, Director of the Obesity Research Center at St. Luke's/Roosevelt Hospital Center in New York City. The panel consisted of 24 members, 8 ex-officio members, and a methodologist consultant. Areas of expertise of panel members included primary care, epidemiology, clinical nutrition, exercise physiology, psychology, physiology, and pulmonary disease.

Obesity Expert Panel Members

Shiriki Kumanyika, Ph.D., M.P.H., R.D.

R. Dee Legako, M.D.

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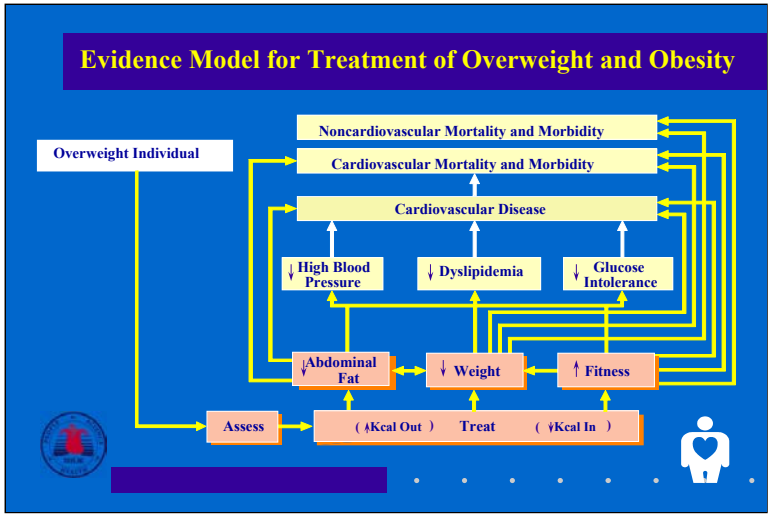
Michael Weintraub, M.D.

David F. Williamson, Ph.D., M.S.

G. Terence Wilson, Ph.D.

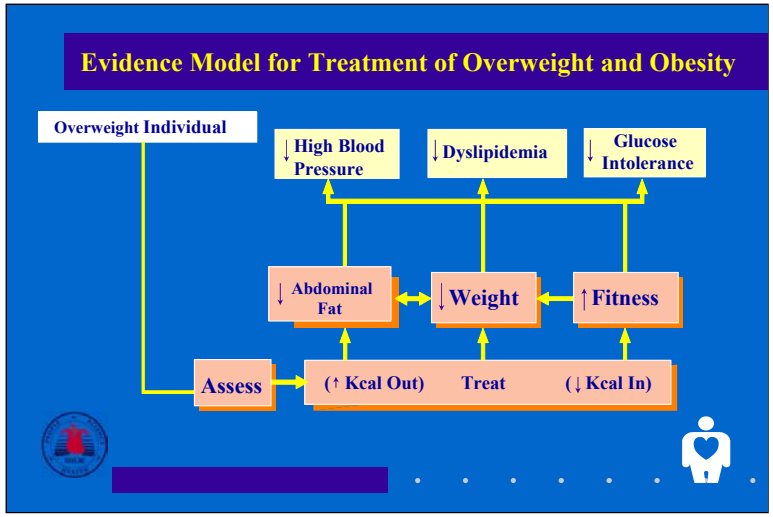
The ex-officio representatives to the panel were primarily NHLBI staff as well as Dr. Van Hubbard of NIDDK. Ms. Karen Donato served as executive director of the panel.



The panel had to first decide on the various topical areas where the evidence should be considered. The ***evidence model*** shown here points out those areas:

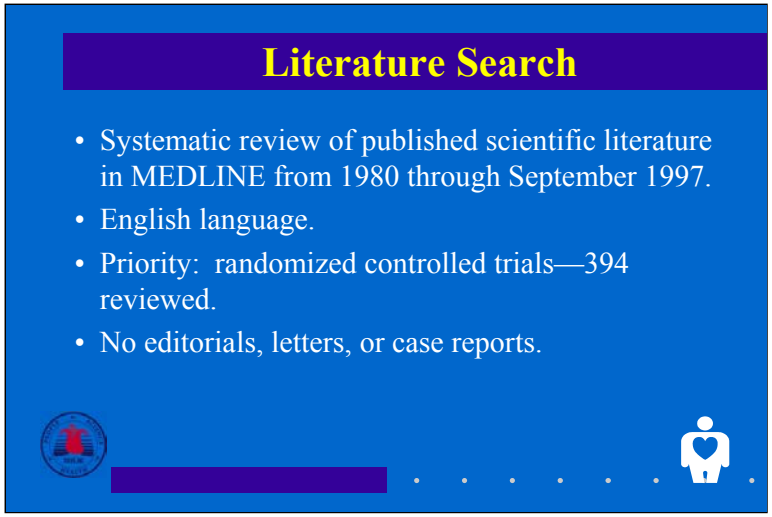
- This portion of the model pertains to the evidence on the effects of treatment strategies on the overweight patient. For example, as a result of treatment what happens to weight, abdominal fat, and fitness? And, consequently, do these changes affect cardiovascular disease (CVD) risk factors and ultimately cardiovascular morbidity and mortality?

- Each of the arrows represents particular questions that the panel wanted to consider.

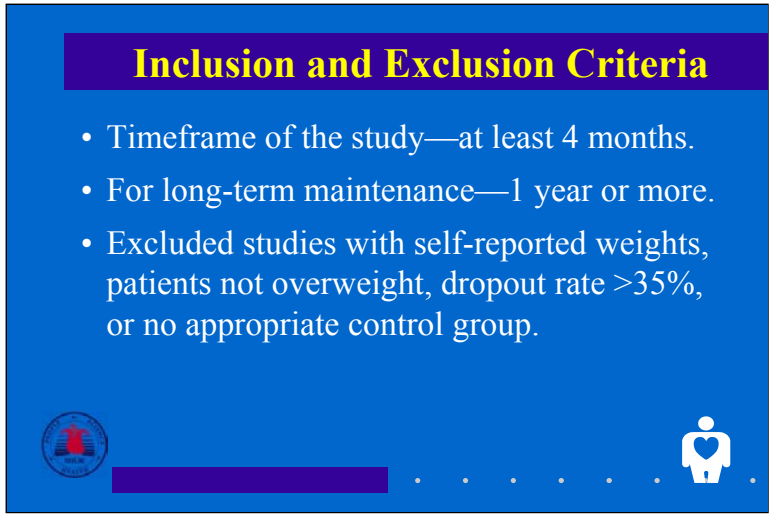


This slide illustrates the portion of the evidence model where the panel members spent most of their time considering the evidence:

1. Examining the various treatment strategies:
    - Dietary Therapy
    - Physical Activity
    - Behavior Modification
    - Combination Therapies
    - Pharmacotherapy
    - Surgery
2. Examining the effects of those treatments on weight loss as well as on changes in fitness and abdominal fat independent of weight loss.



The panel decided on the parameters for the literature search, particularly for the search dealing with the model linking treatment to weight loss. The search parameters included year of publication, country, language, and study design.

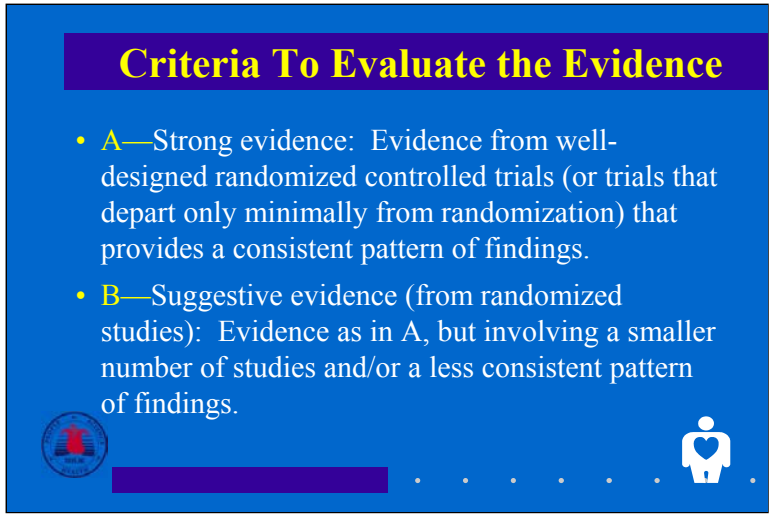


The panel used several criteria to determine whether a study should be accepted and included in the guidelines:

- The study's timeframe had to be at least 4 months, i.e., the minimum amount of time that must pass before the outcome measure is made.
- For considering long-term maintenance, studies had to have data collected after 1 year or more.

Studies were excluded from the guidelines if they :

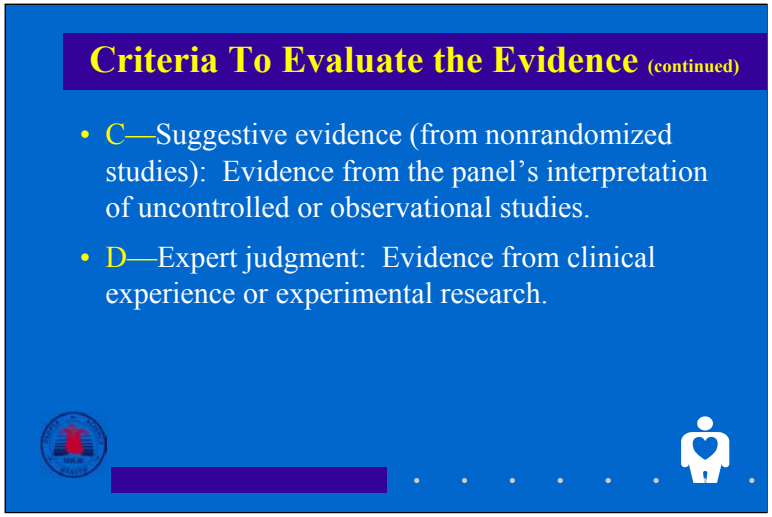
- Used self-reported weights.
- Had dropout rates greater than 35 percent.
- Had no control group.



The panel determined specific criteria to evaluate the evidence. The criteria ranged from A to D level and were used to rank each evidence statement and recommendation provided in the guidelines:

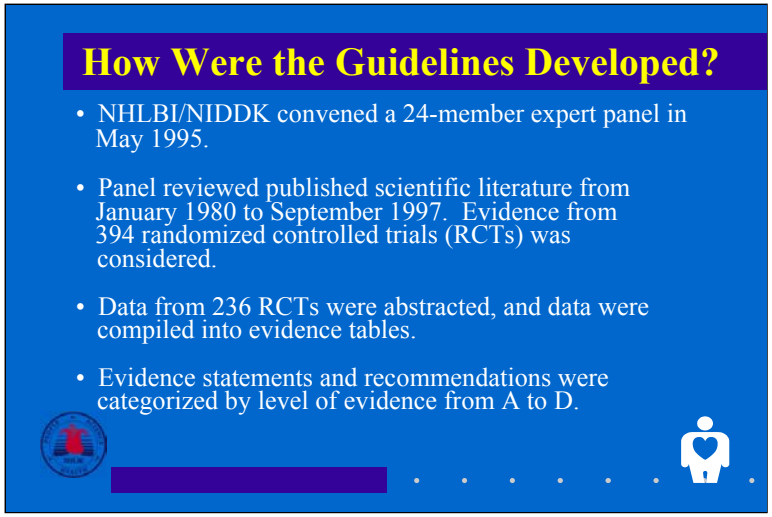
A. Strong evidence: Evidence from well-designed RCTs (or trials that depart only minimally from randomization) which provides a consistent pattern of findings. Category A therefore includes a substantial number of studies involving a substantial number of participants.

B. Suggestive evidence: Some evidence from RCTs supports the recommendation, but the scientific support is not optimal. For instance, either few randomized trials exist, they are small in size, they are somewhat inconsistent, or they were undertaken in a population which differs from the target population of the recommendation.



C. Suggestive Evidence: Evidence from nonrandomized studies or evidence from uncontrolled or observational studies.

D. Expert Judgment: Derived from the consensus of panel members on the basis of knowledge that does not meet the other criteria. This category was used only in cases where the provision of some guidance was deemed necessary but adequately compelling empirical literature addressing the subject of the recommendation did not yet exist.



- Twenty-four experts from the fields of cardiology, nutrition, epidemiology, genetics, and physiology were convened beginning in May 1995.
- The panel's charge was to examine the scientific evidence on the issues related to overweight and obesity in adults, such as the relationship of body weight and the amount of body fat to other risk factors including diabetes, high blood cholesterol, and hypertension as well as the relationship of obesity to cardiovascular and non cardiovascular morbidity and mortality.
- MEDLINE searches were conducted of the literature published from January 1980 to September 1997 related to overweight and obesity. The searches led to more than 43,000 articles. In order to best deal with the evidence regarding possible treatment strategies, the panel focused on randomized controlled trials (RCTs) because this type of evidence provides the strongest support for or against any particular treatment. A total of 394 RCTs were found in the literature and were critiqued using specific criteria. Ultimately 236 RCTs met the criteria; data were abstracted and compiled into evidence tables.
- The panel categorized the evidence using levels of evidence ranging from A to D.