Randomized Controlled Trial to Reduce Obesity in the Context of Primary Care

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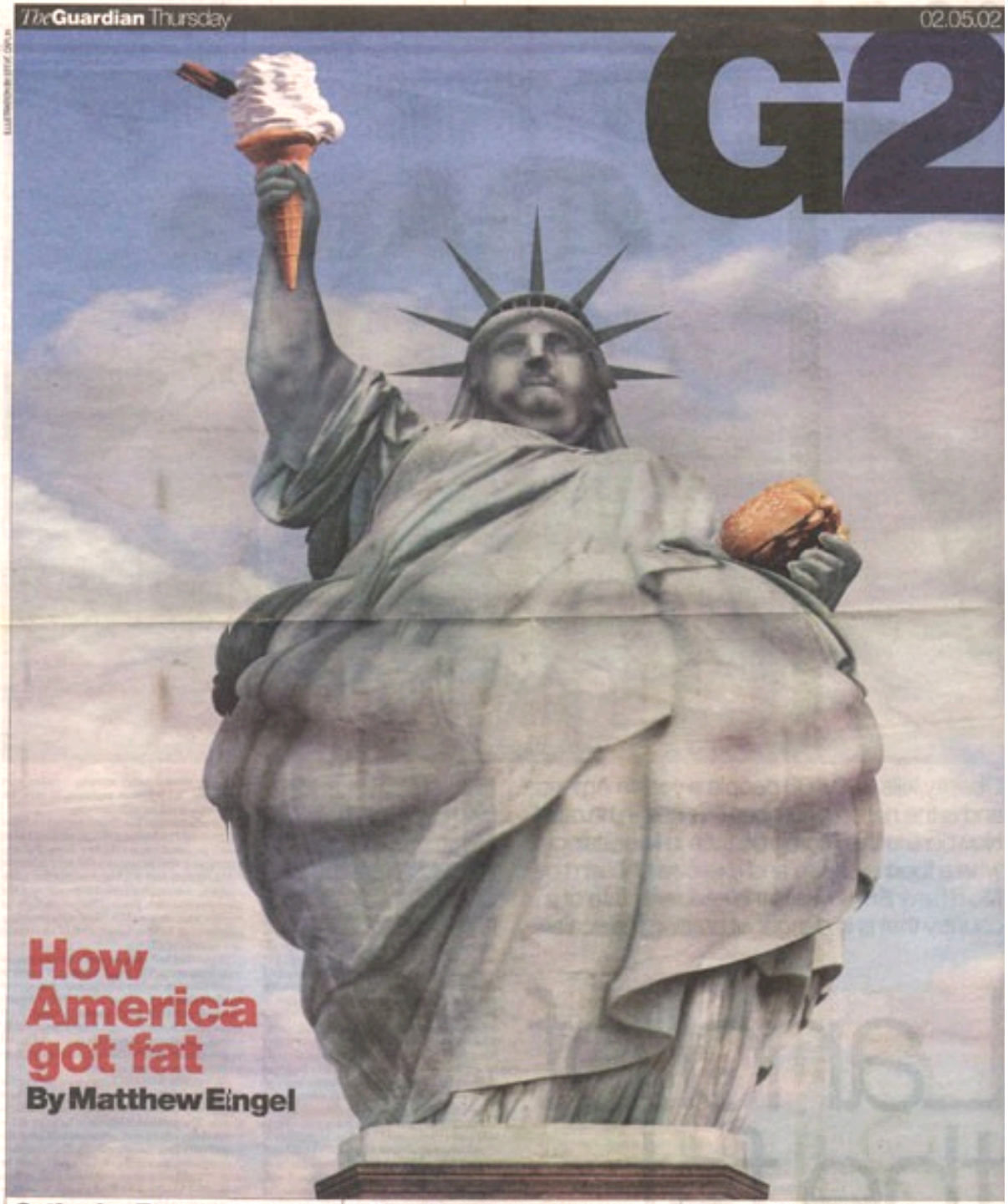


How America got fat

By Matthew Engel

Catherine Bennettt A cheat's guide to good schools. Page 5

Libby Brooks A day training with Fulham Ladies. Page 8

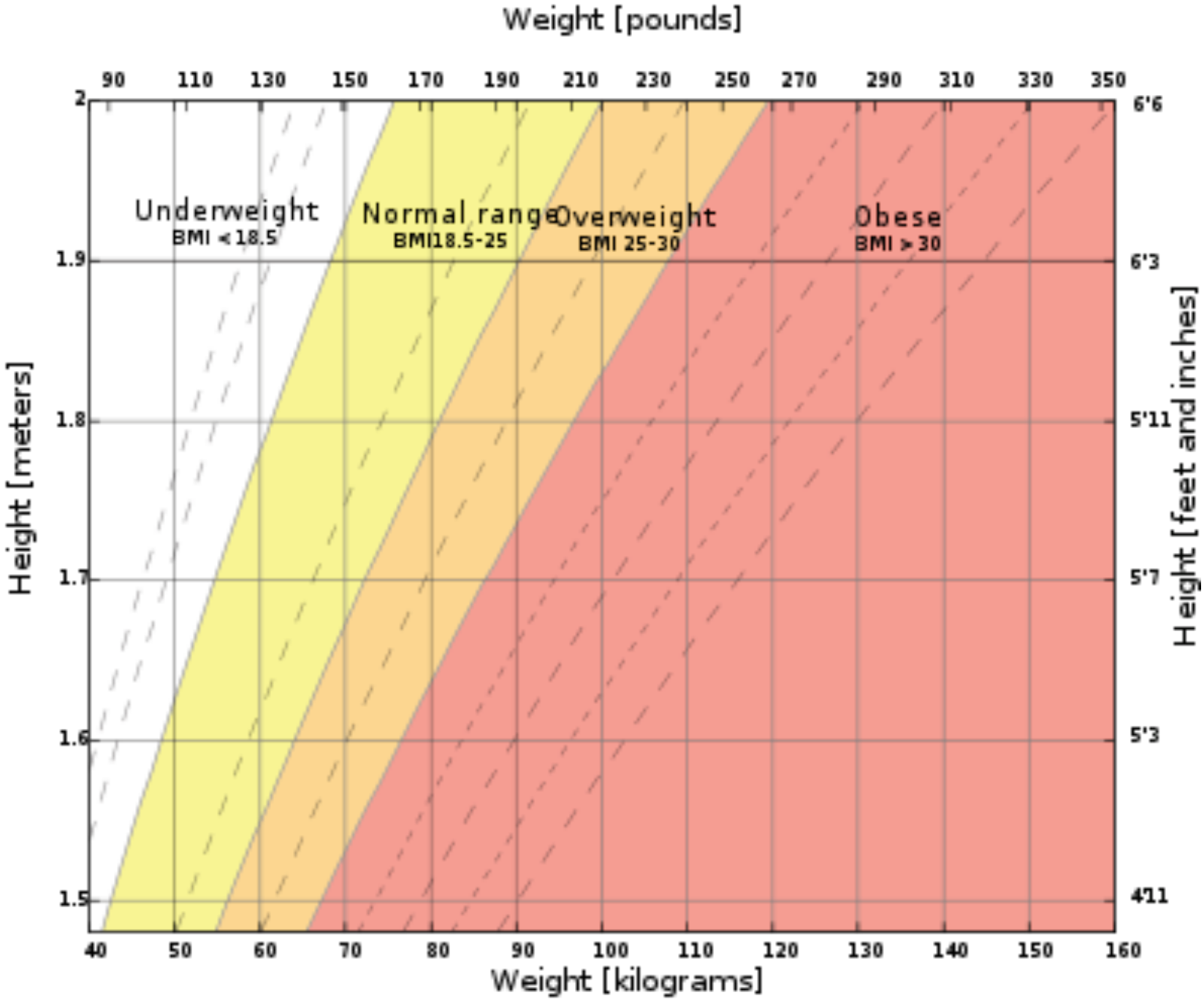
Derek Malcolm The genius of Satyajit Ray. Page 10

Outline

- Define and measure obesity
- Epidemiology of obesity
- Physiology of obesity
- Determinants of obesity
- Health consequences
- Clinical trial for obesity treatment

Obesity: a definition

- Excess adiposity (fat)
- Measured as excess weight:
  - Body Mass Index (BMI)
- BMI = mass (kg) / height (m) ^{2}
- Used for adults over 18 years
  - Underweight $\leq$ 18.5
  - Normal range 18.6-24.9
  - Overweight 25-29.9
  - Obese $\geq$30 ➔
    - Class I: 30.0-34.9
    - Class II: 35.0-39.9
    - Class III: $\geq$ 40.0


Weight [pounds]
90 110 130 150 170 190 210 230 250 270 290 310 330 350
Underweight
BMI < 18.5
Normal range
BMI 18.5-25
Overweight
BMI 25-30
Obese
BMI > 30
Height [meters]
2
1.9
1.8
1.7
1.6
1.5
Height [feet and inches]
6'6
6'3
5'11
5'7
5'3
4'11
40 50 60 70 80 90 100 110 120 130 140 150 160
Weight [kilograms]

Considerations: BMI

- Where might BMI be misleading?
- Less reliable with muscular individuals
- Need for different cut points for Asians and South Asians vs. European ancestry
  - Overweight = 23-27.4 kg/m^2
  - Obesity ≥ 27.5 kg/m^2
- Height loss with aging or injury
- Anything that changes weight to height relationship

Body Fat Distribution

- Not just “how much” but WHERE the fat is deposited is important
- Men and women *tend* to increase body mass differently when developing overweight
- Two specific shapes are often characterized
  - “Pear” or gynoid = peripheral, subcutaneous
  - “Apple” or android = central

Body Fat Distribution

- Apple-shaped (male-like) fat pattern
  - Large waist, deposits of intra-abdominal fat
  - ↑ CHD and obesity-related CHD risk factors
    - ↑ blood pressure
    - ↑ type 2 diabetes
    - ↑ triglycerides
    - ↓ HDL cholesterol (“good” cholesterol)
  - ↑ gall bladder disease
  - ↑ obesity-related cancers
- Pear-shaped (female-like) fat pattern
  - Subcutaneous fat deposited on hips and thighs

Other Measurement Methods

- Waist circumference
- Skin fold thickness (standard locations for assessing subcutaneous fat)
  - Less accurate, particularly in the obese
- Underwater weighing (density measurement)
- Imaging
  - DEXA
  - MRI
  - CT Bioelectrical impedance

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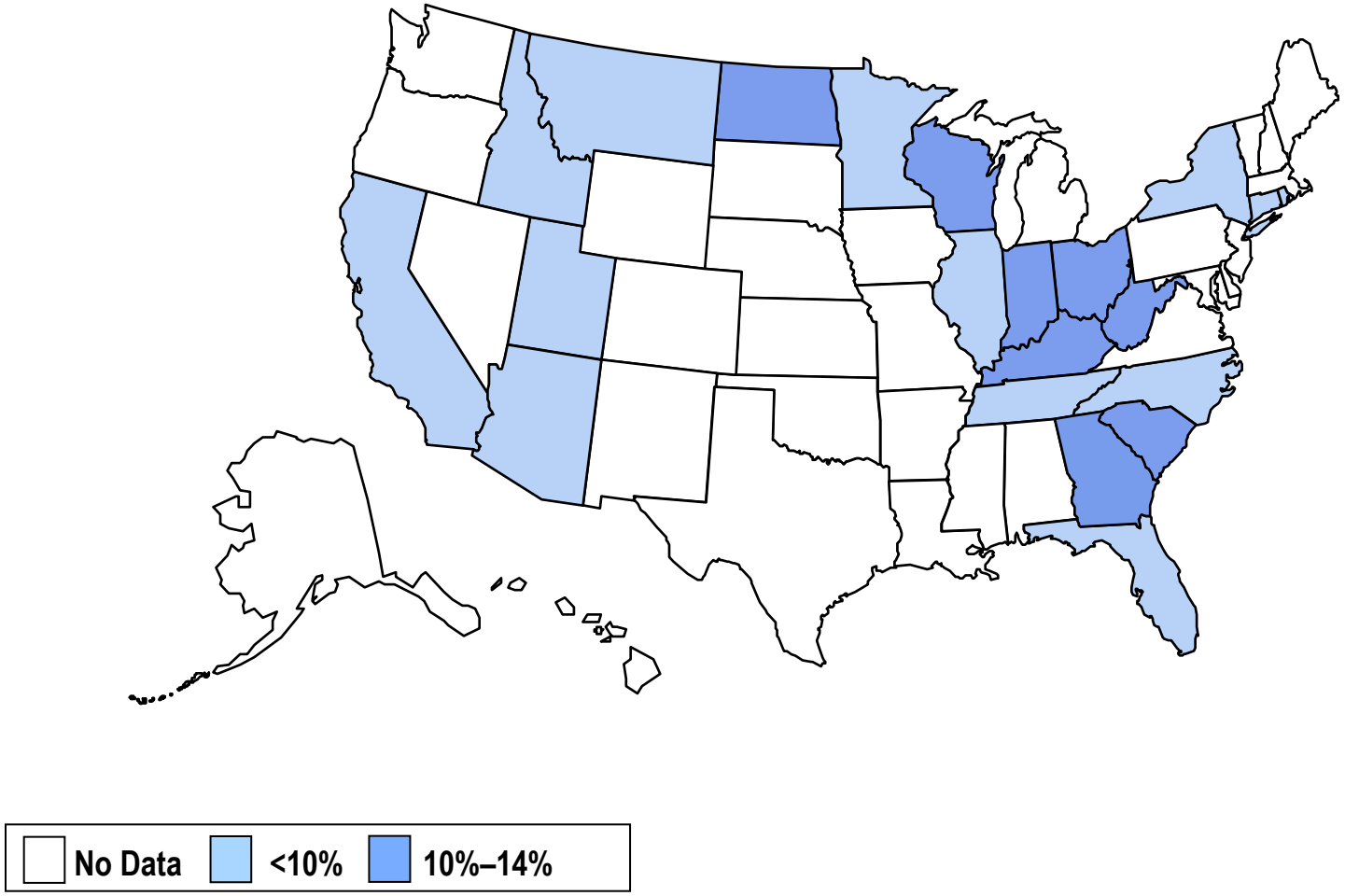
Trends in Obesity

- Behavioral Risk Factor Surveillance System (BRFSS)
- Organized at a state level by the Centers for Disease Control and Prevention
- Began in 1984 with 15 states, now all 50
- Phone Interviews
- Self-reported height and weight
- About 200,000 adults surveyed annually

Obesity Trends Among U.S. Adults

BRFSS, 1985

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



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BRFSS, 1986

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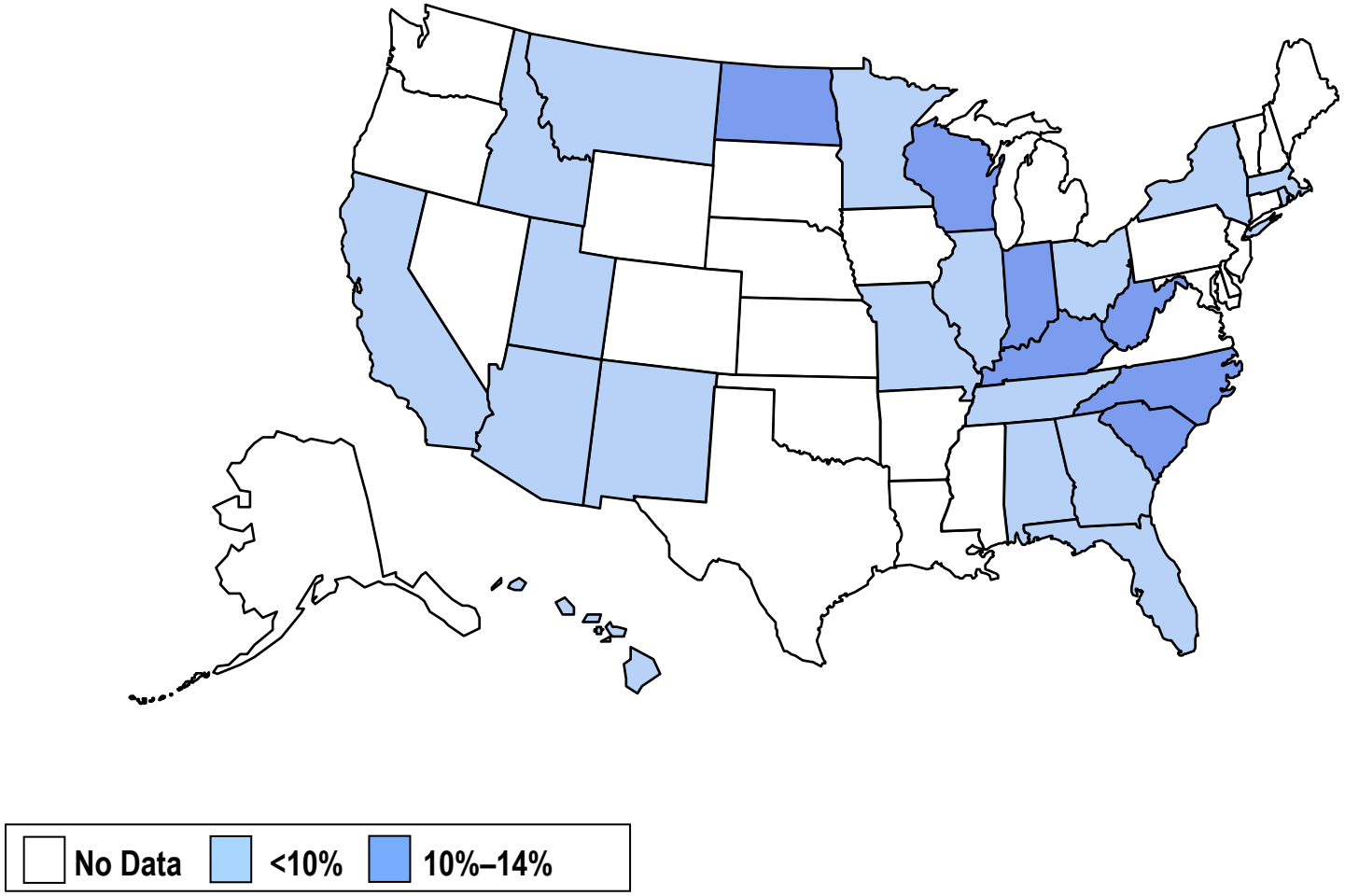

Obesity Trends Among U.S. Adults

BRFSS, 1987

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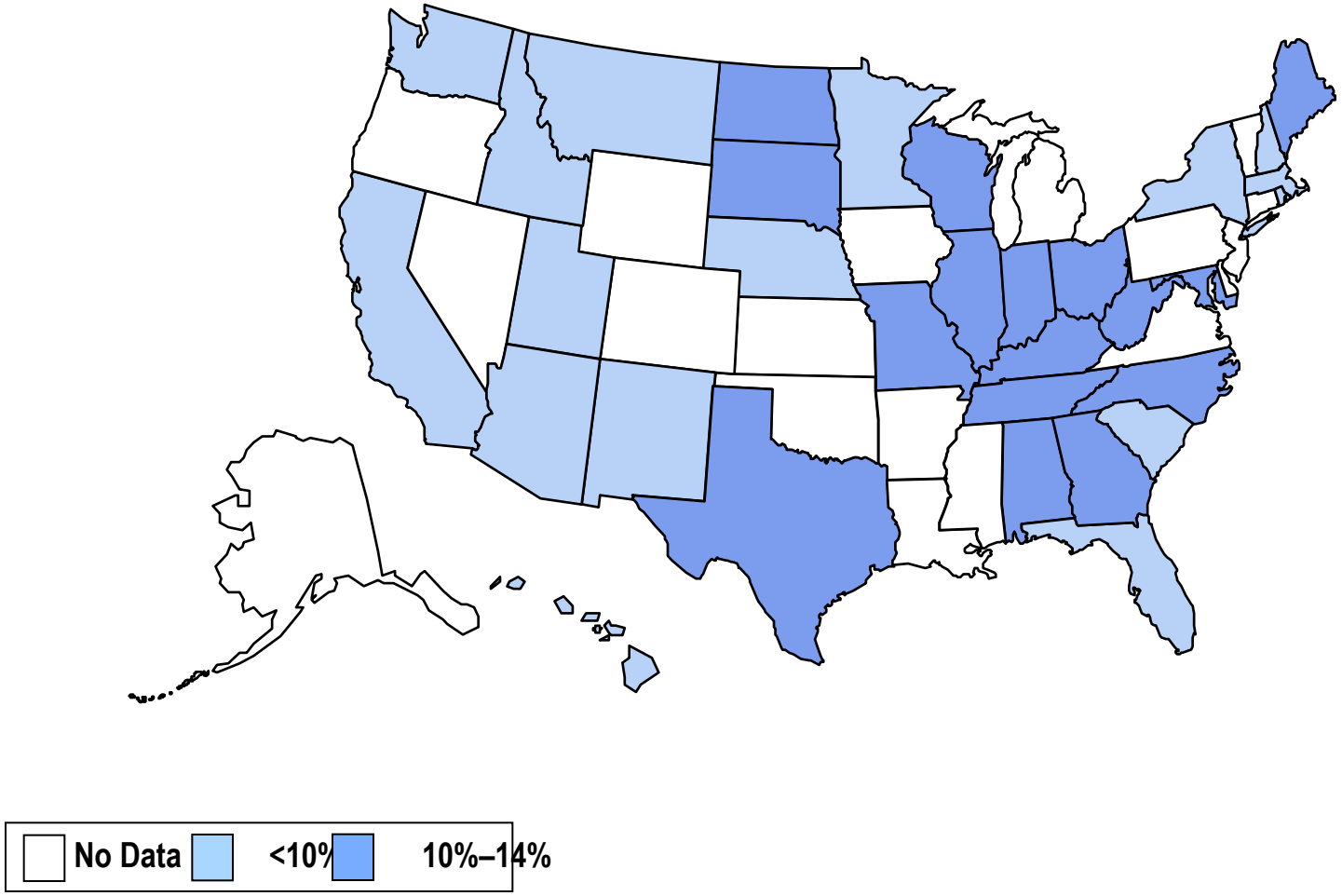

Obesity Trends Among U.S. Adults

BRFSS, 1988

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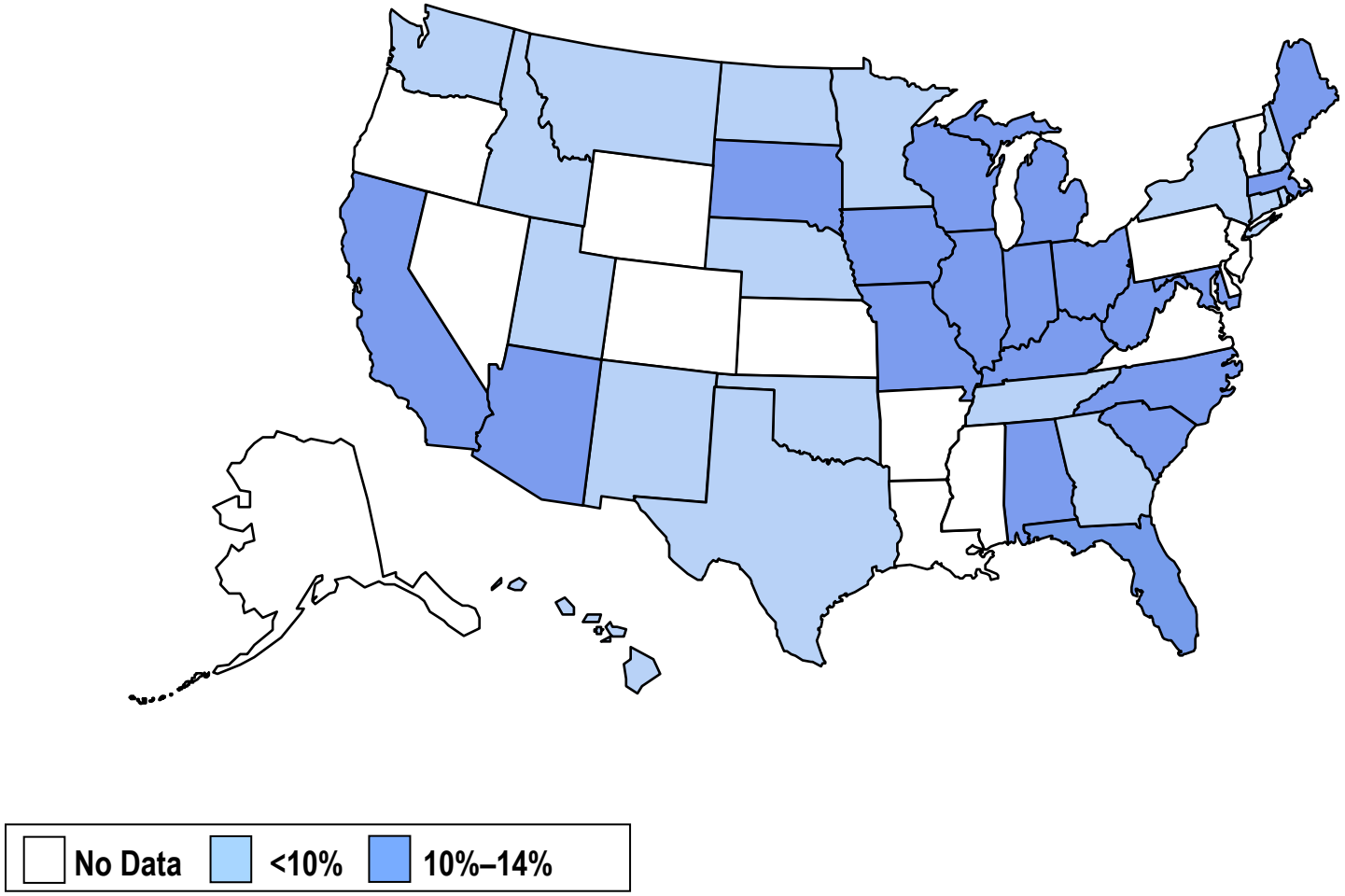
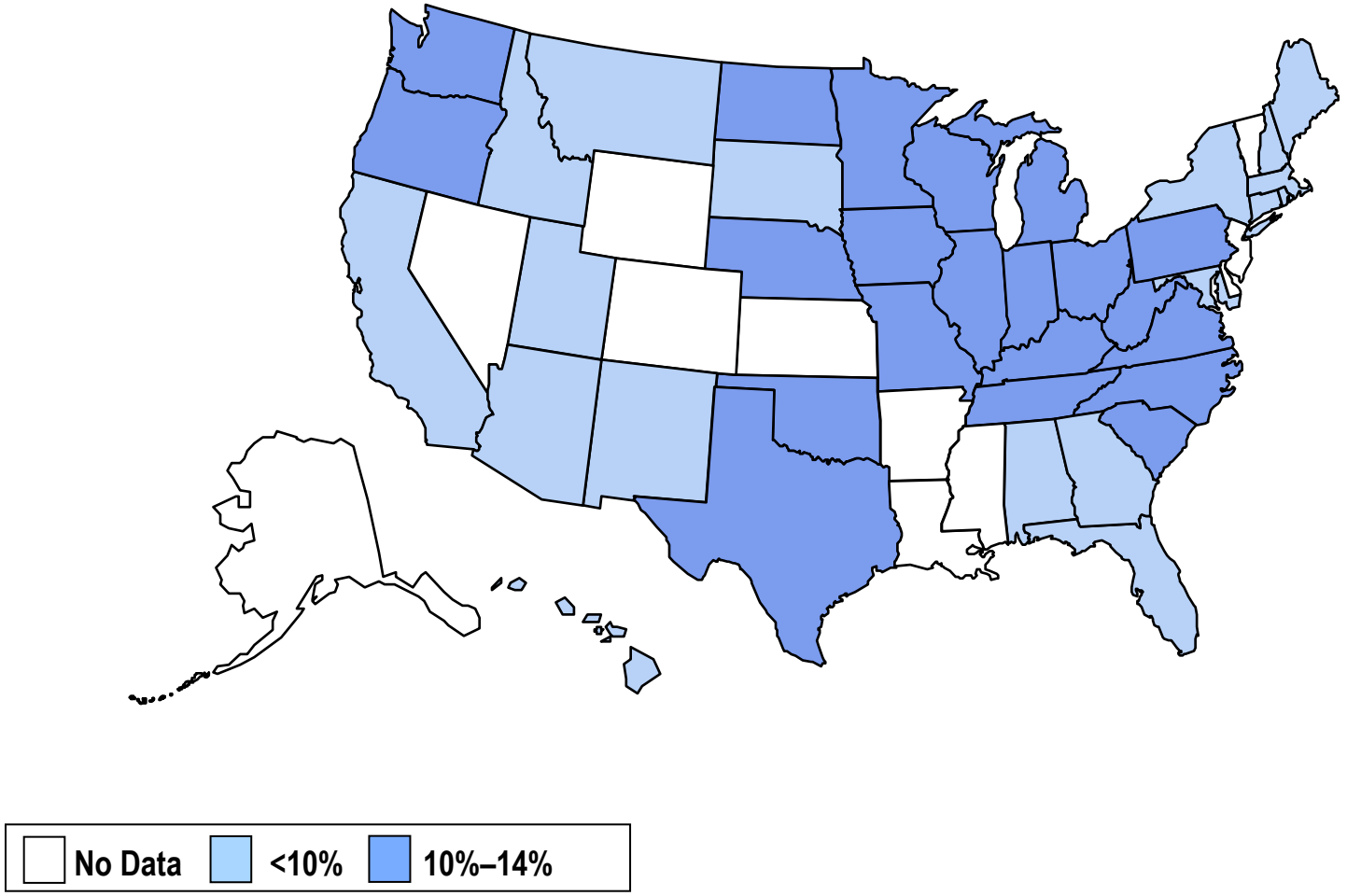


Obesity Trends Among U.S. Adults

BRFSS, 1989

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



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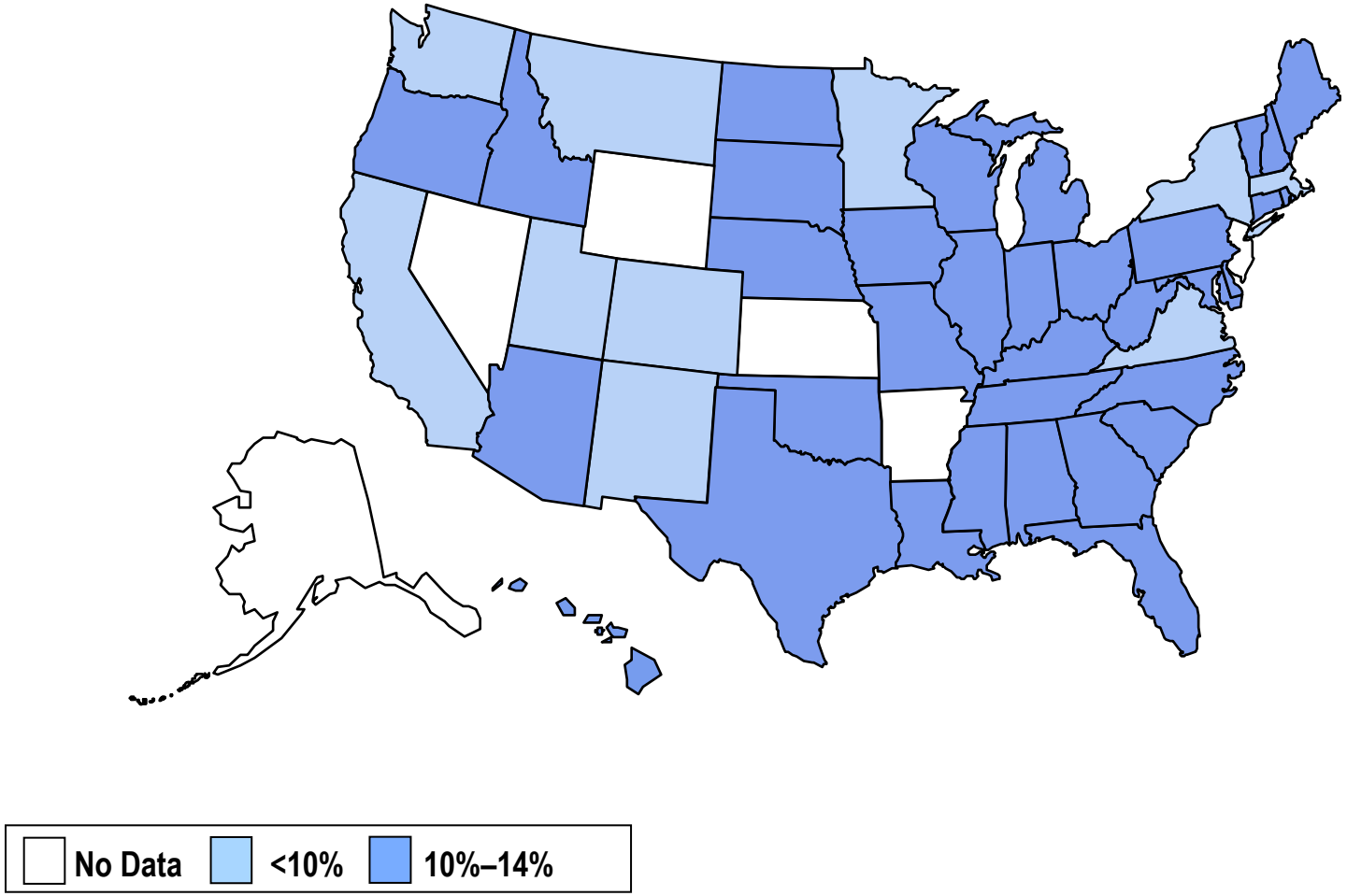

Obesity Trends Among U.S. Adults

BRFSS, 1991

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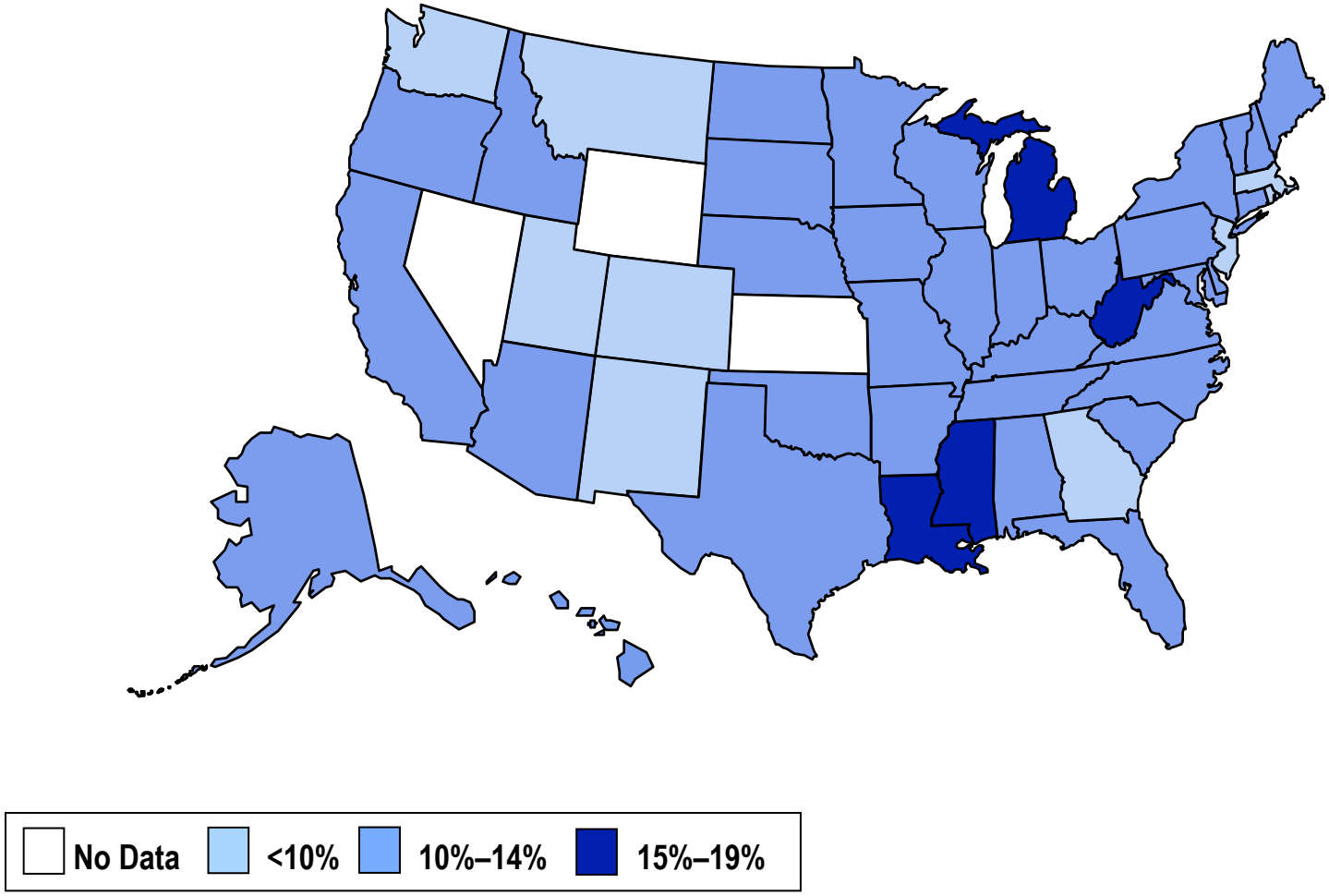

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BRFSS, 1992

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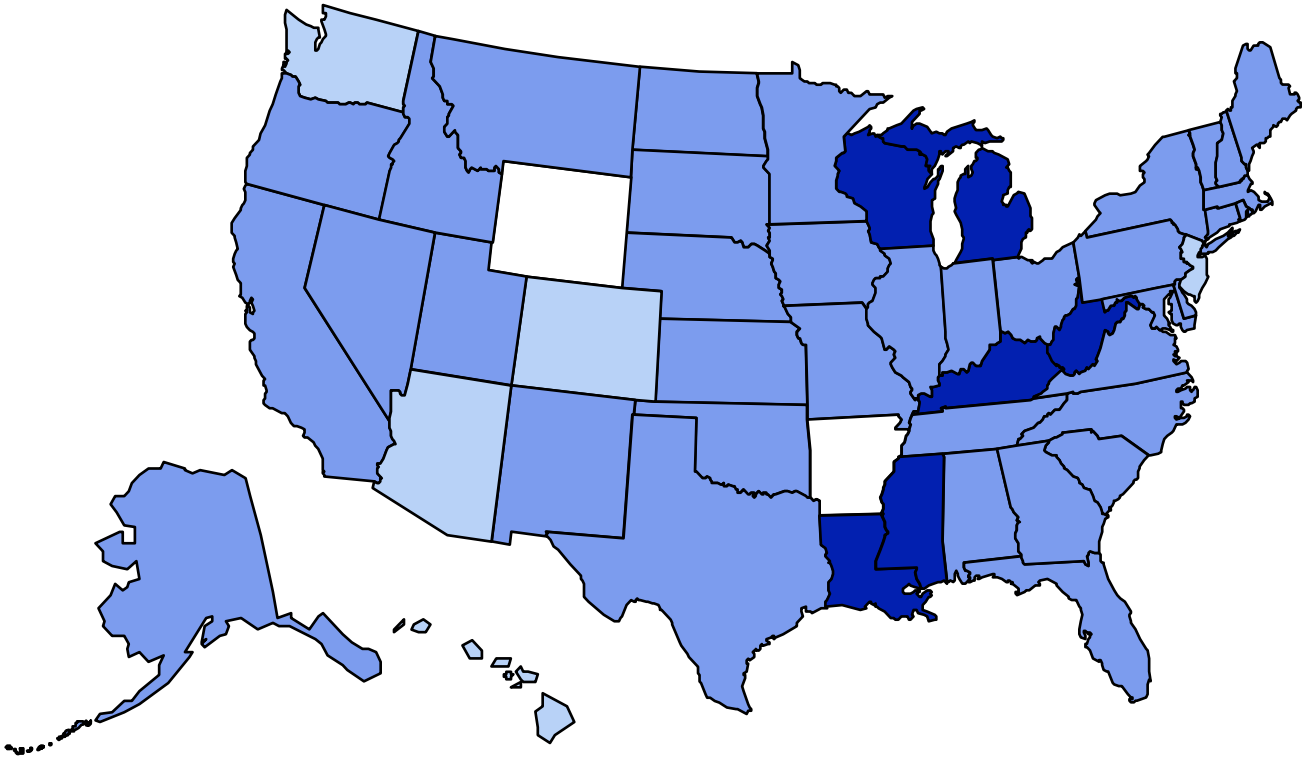
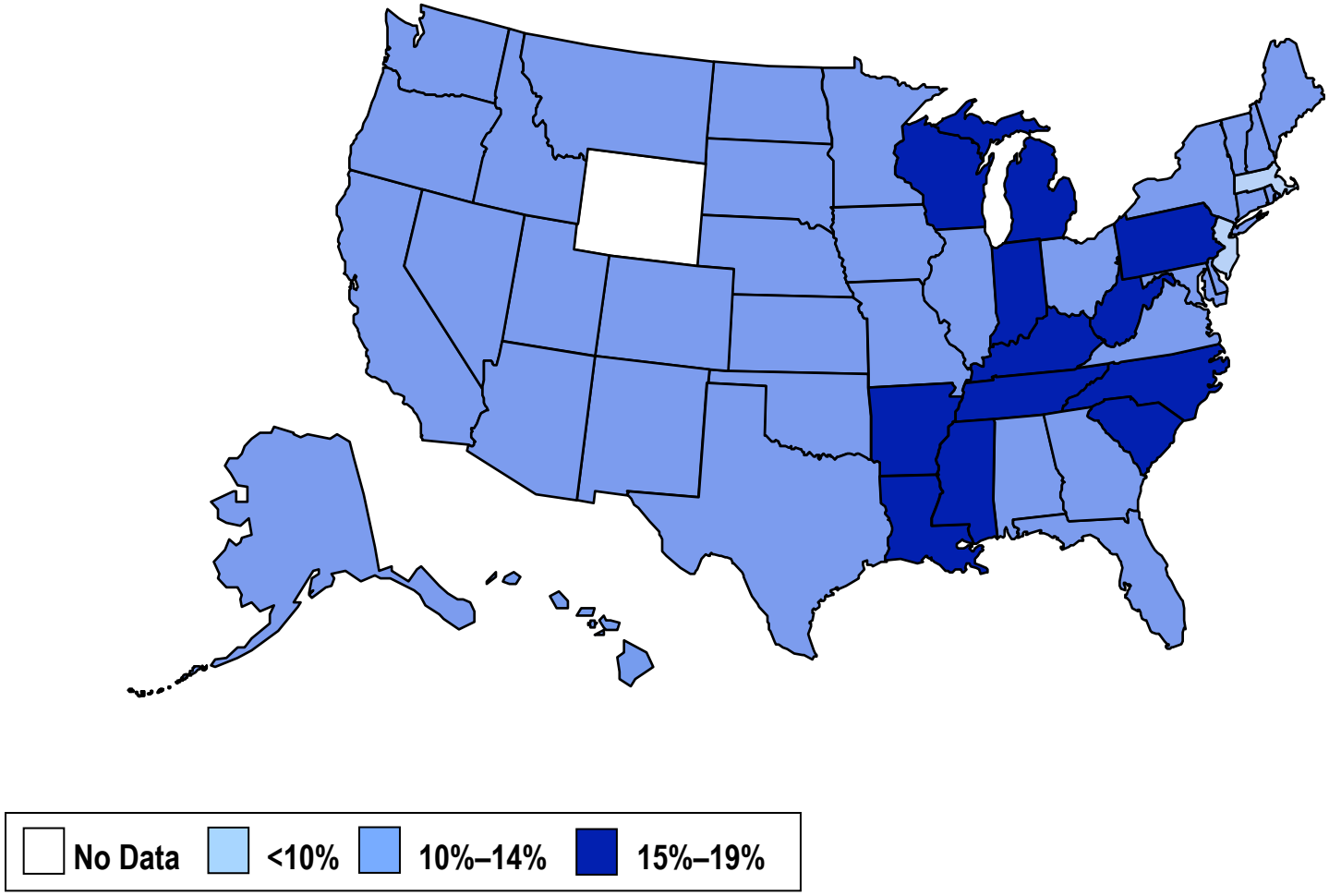


No Data | <10% | 10%–14% | 15%–19%

Obesity Trends Among U.S. Adults

BRFSS, 1993

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



Obesity Trends Among U.S. Adults

BRFSS, 1994

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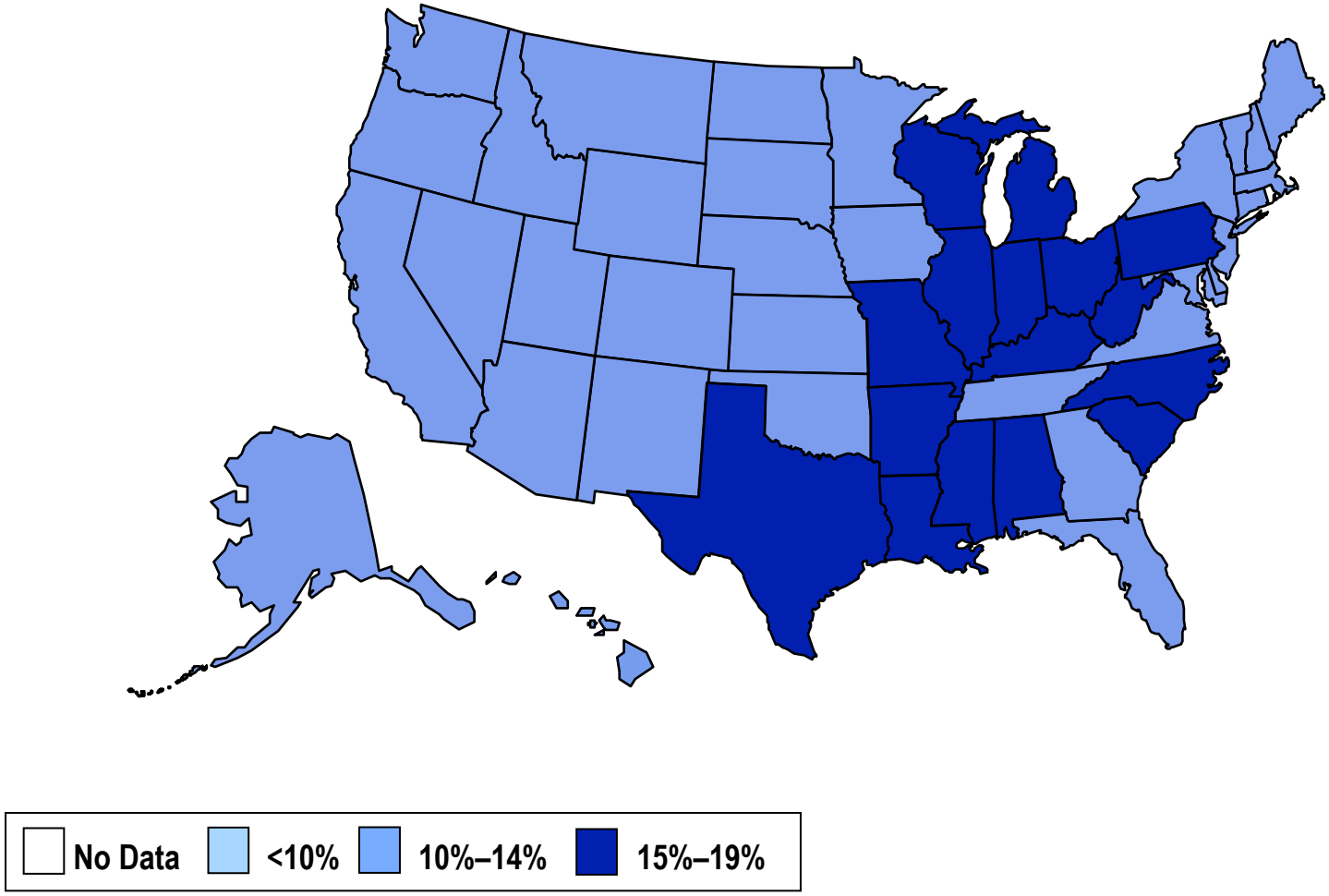

Obesity Trends Among U.S. Adults

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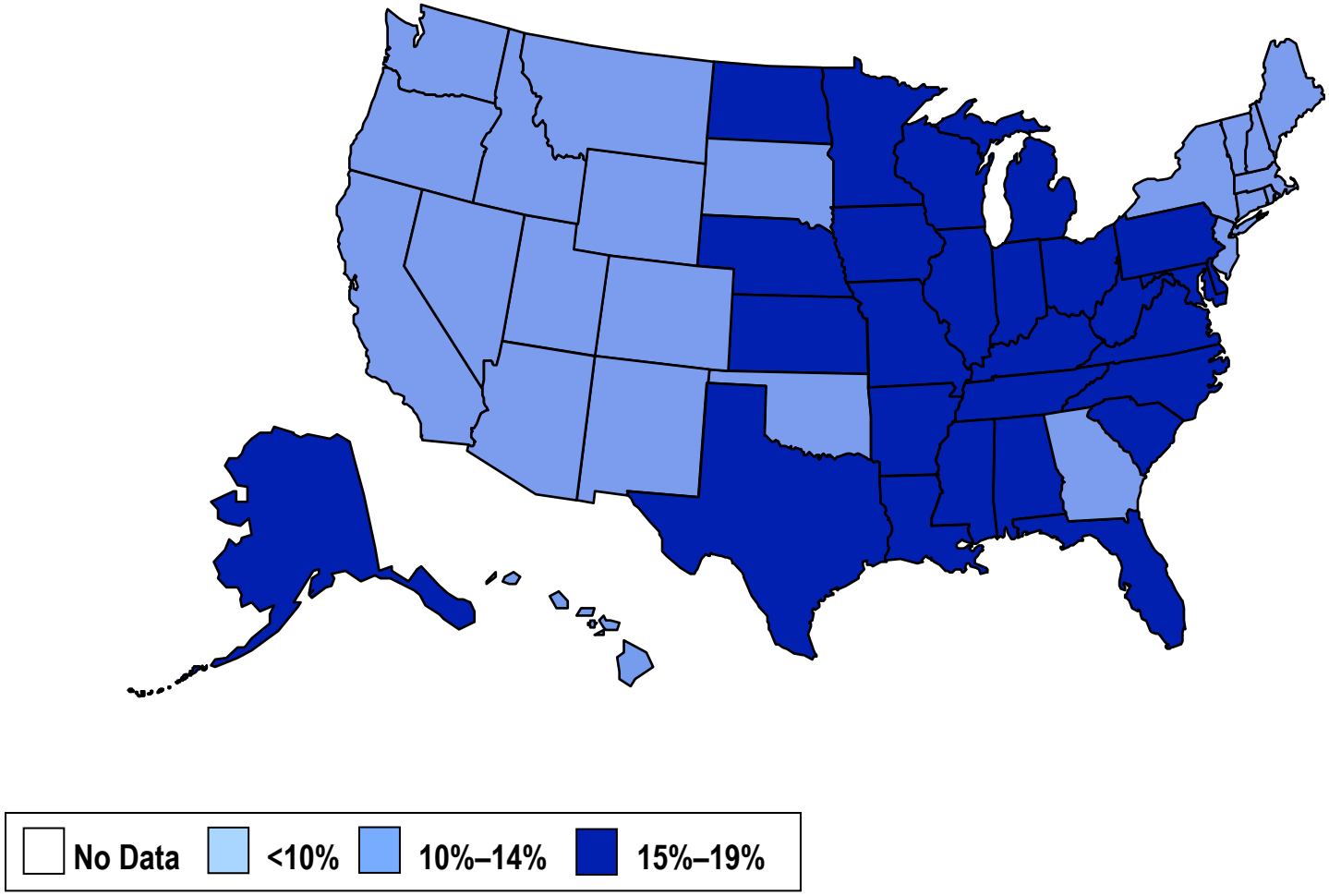

Obesity Trends Among U.S. Adults

BRFSS, 1996

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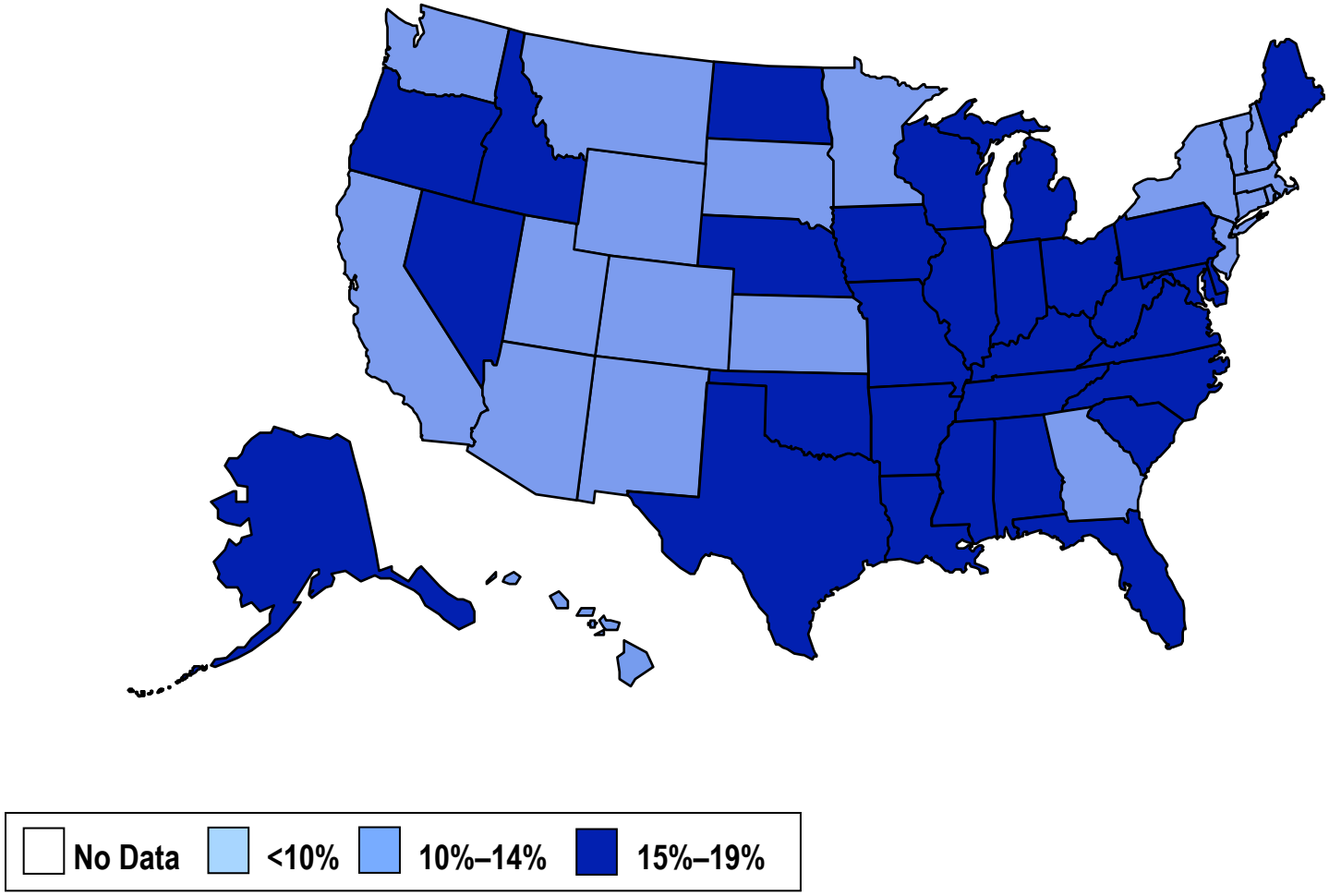

Obesity Trends Among U.S. Adults

BRFSS, 1997

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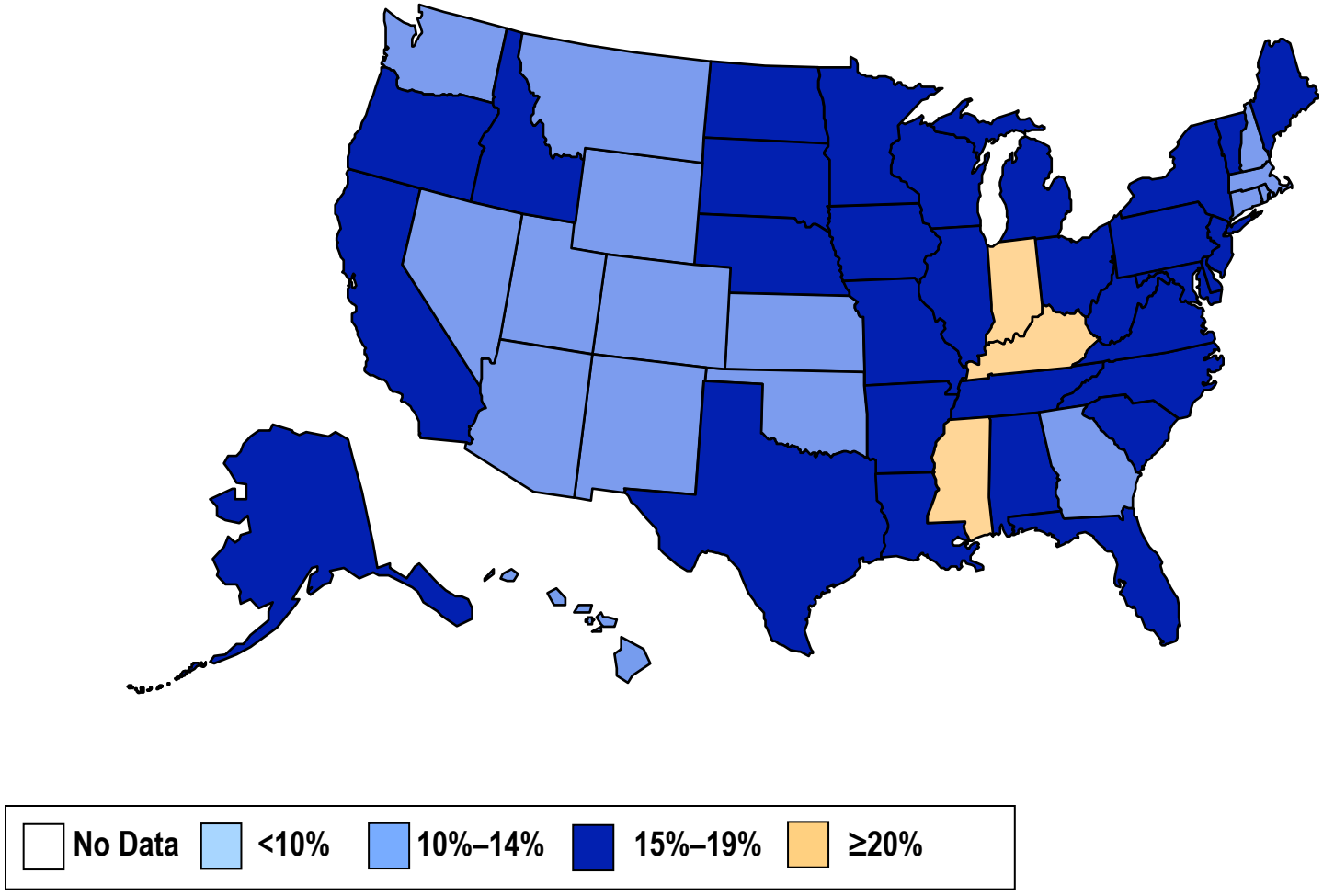

Obesity Trends Among U.S. Adults

BRFSS, 1998

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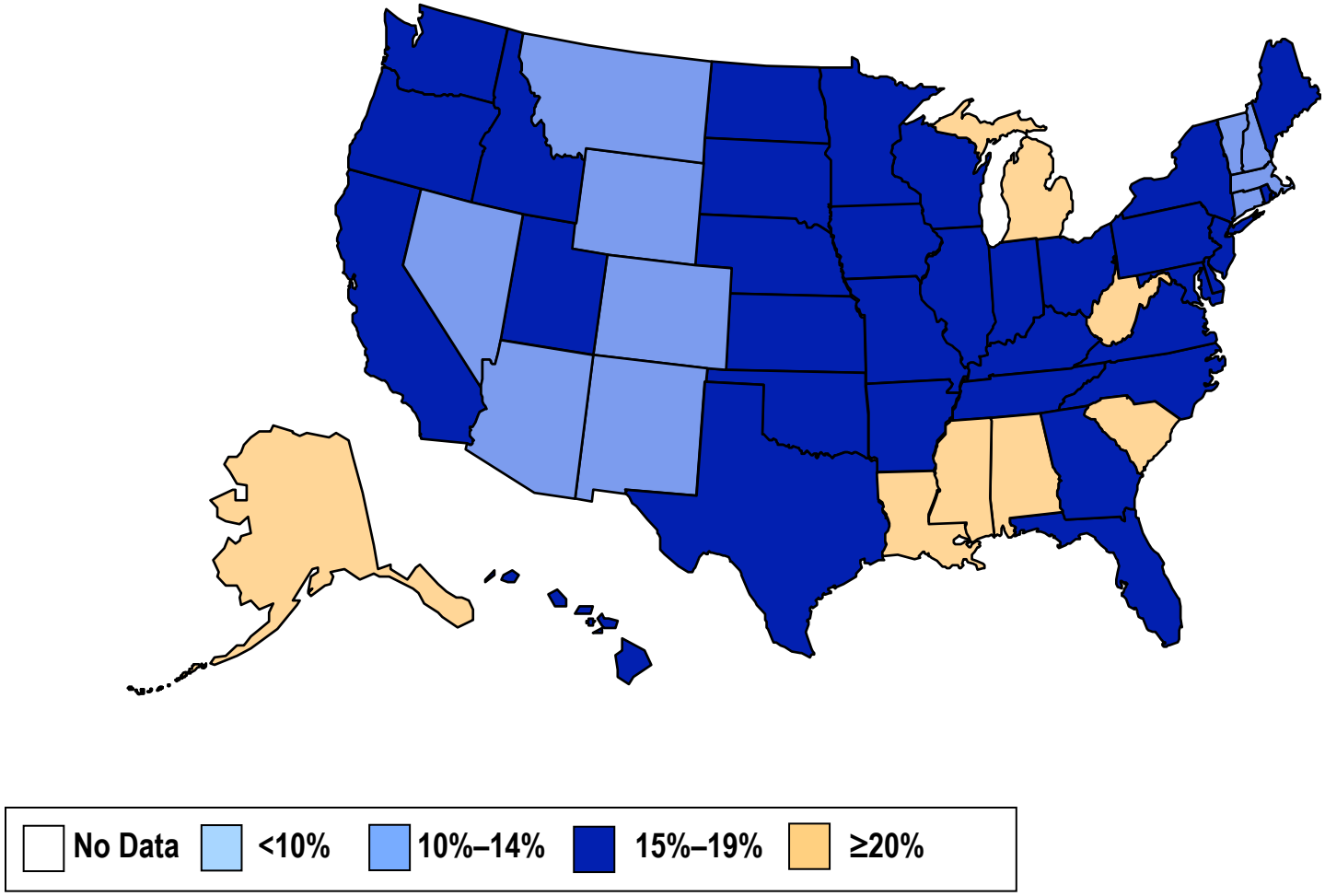

Obesity Trends Among U.S. Adults

BRFSS, 1999

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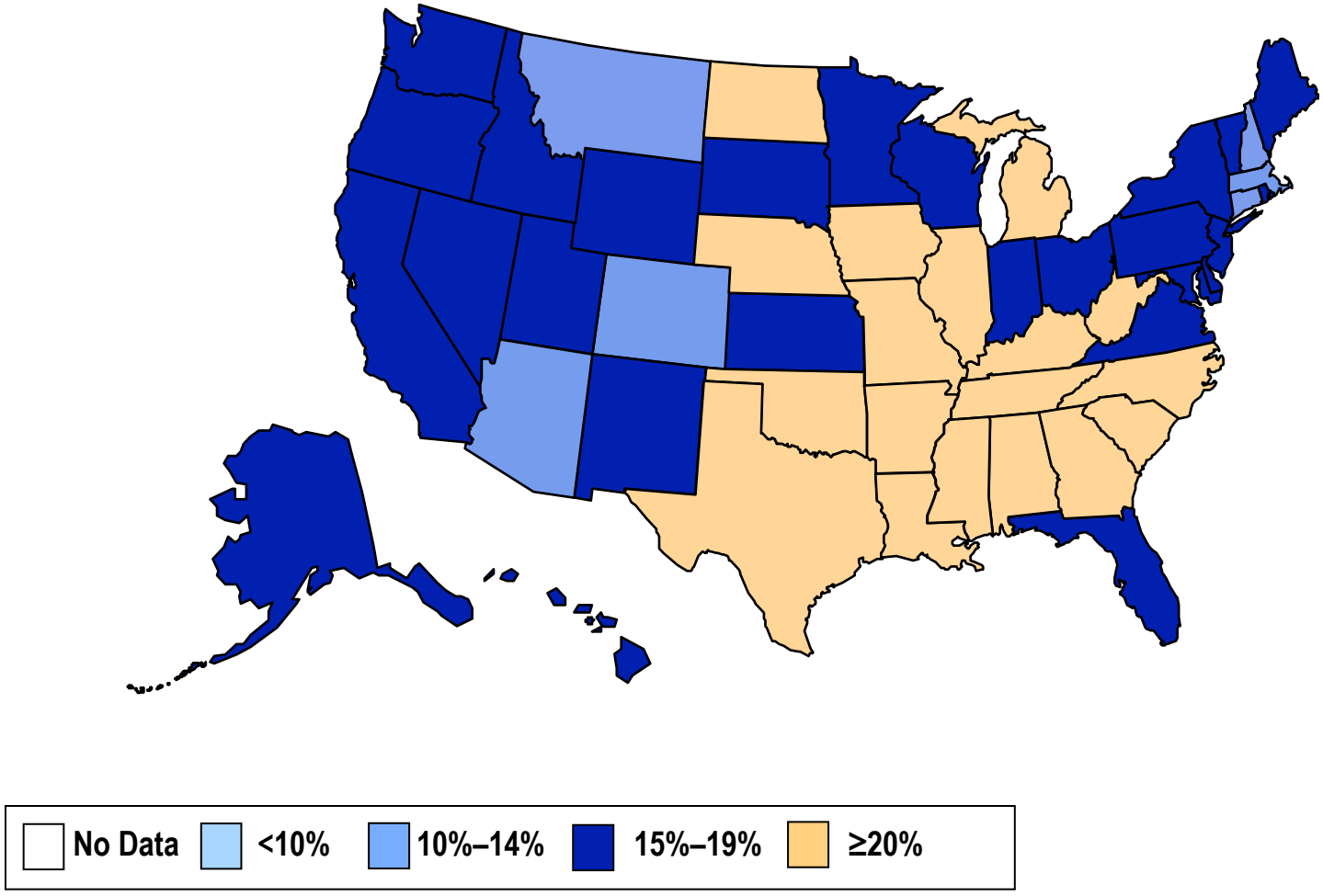
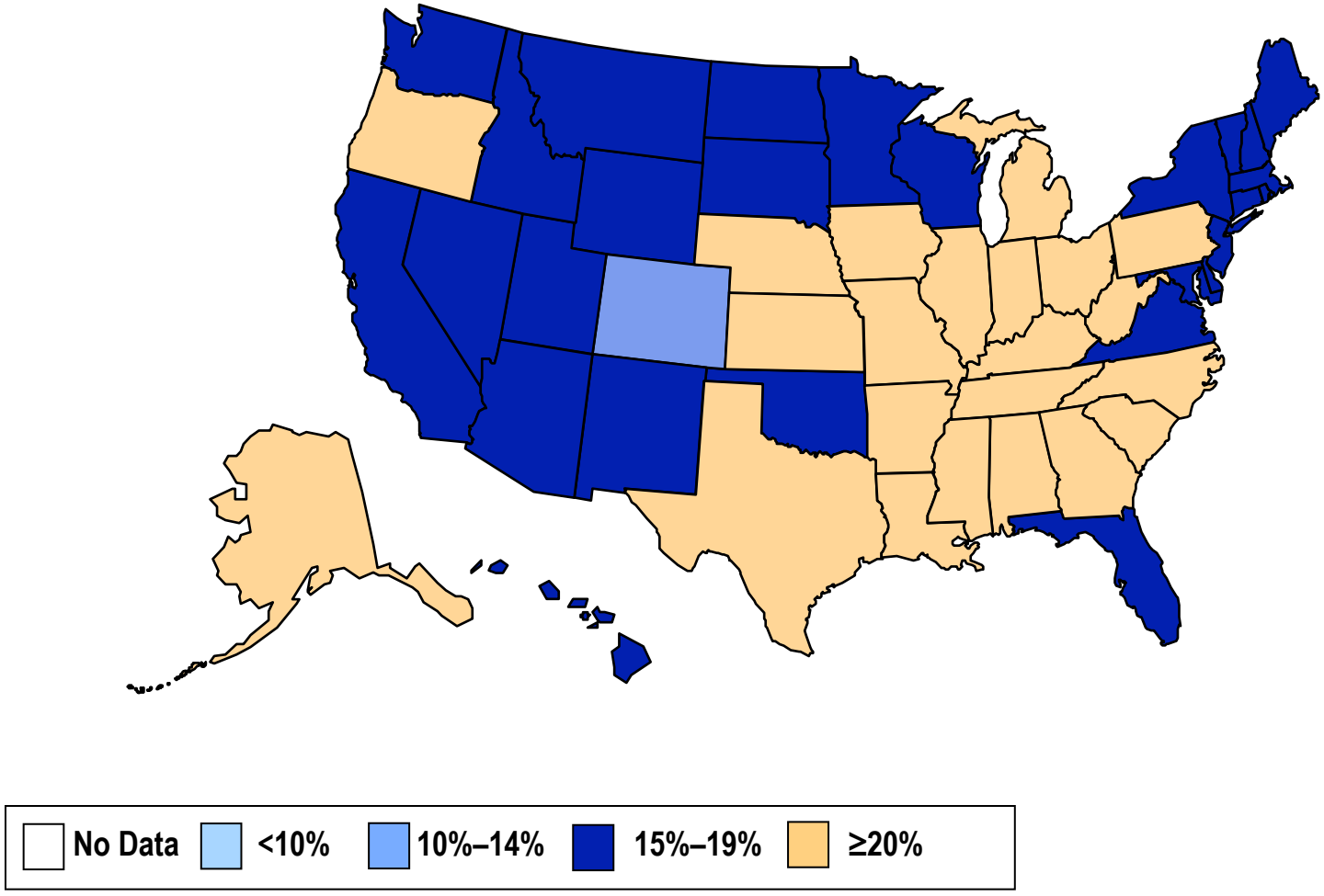


Obesity Trends Among U.S. Adults

BRFSS, 2000

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



Obesity Trends Among U.S. Adults

BRFSS, 2001

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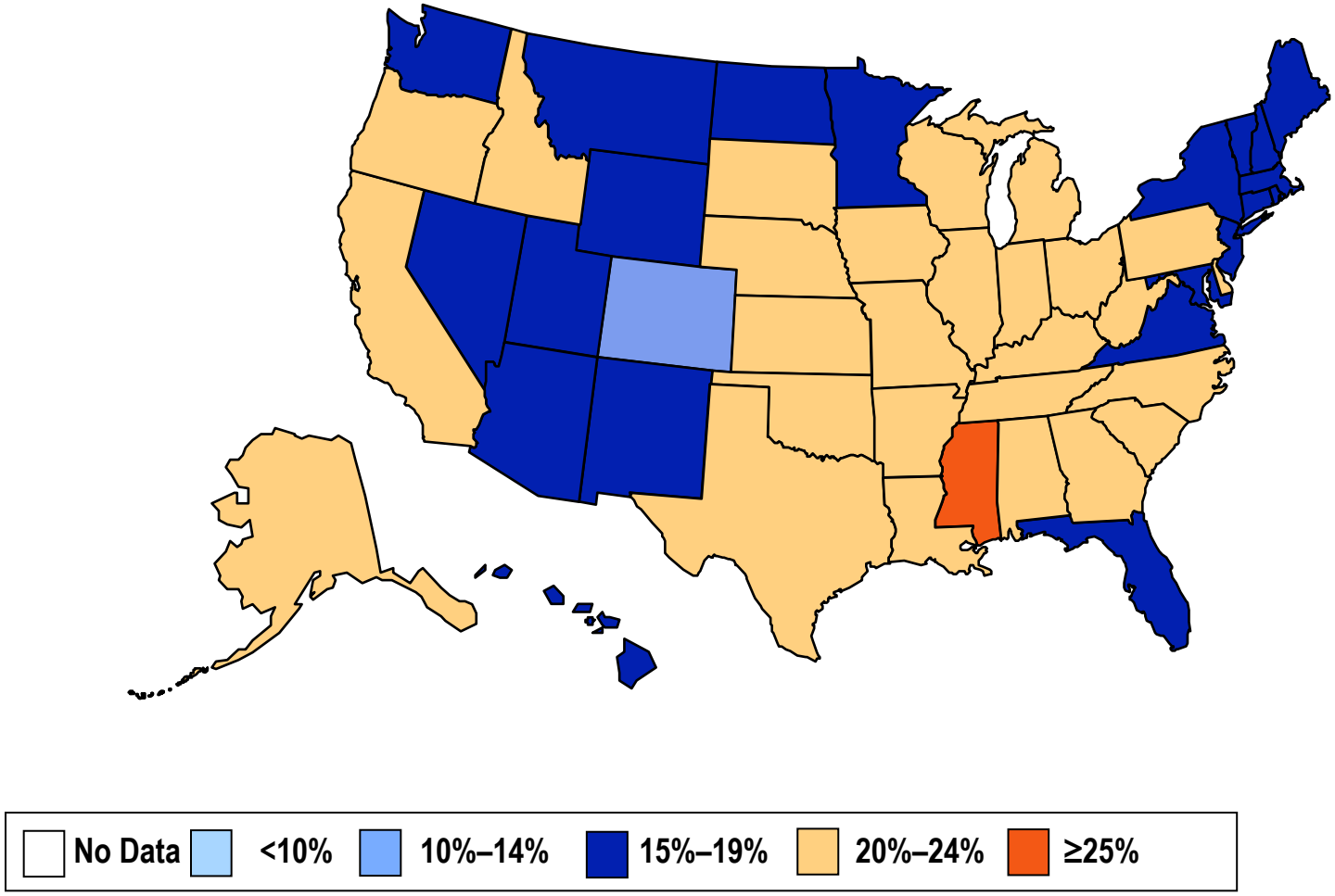
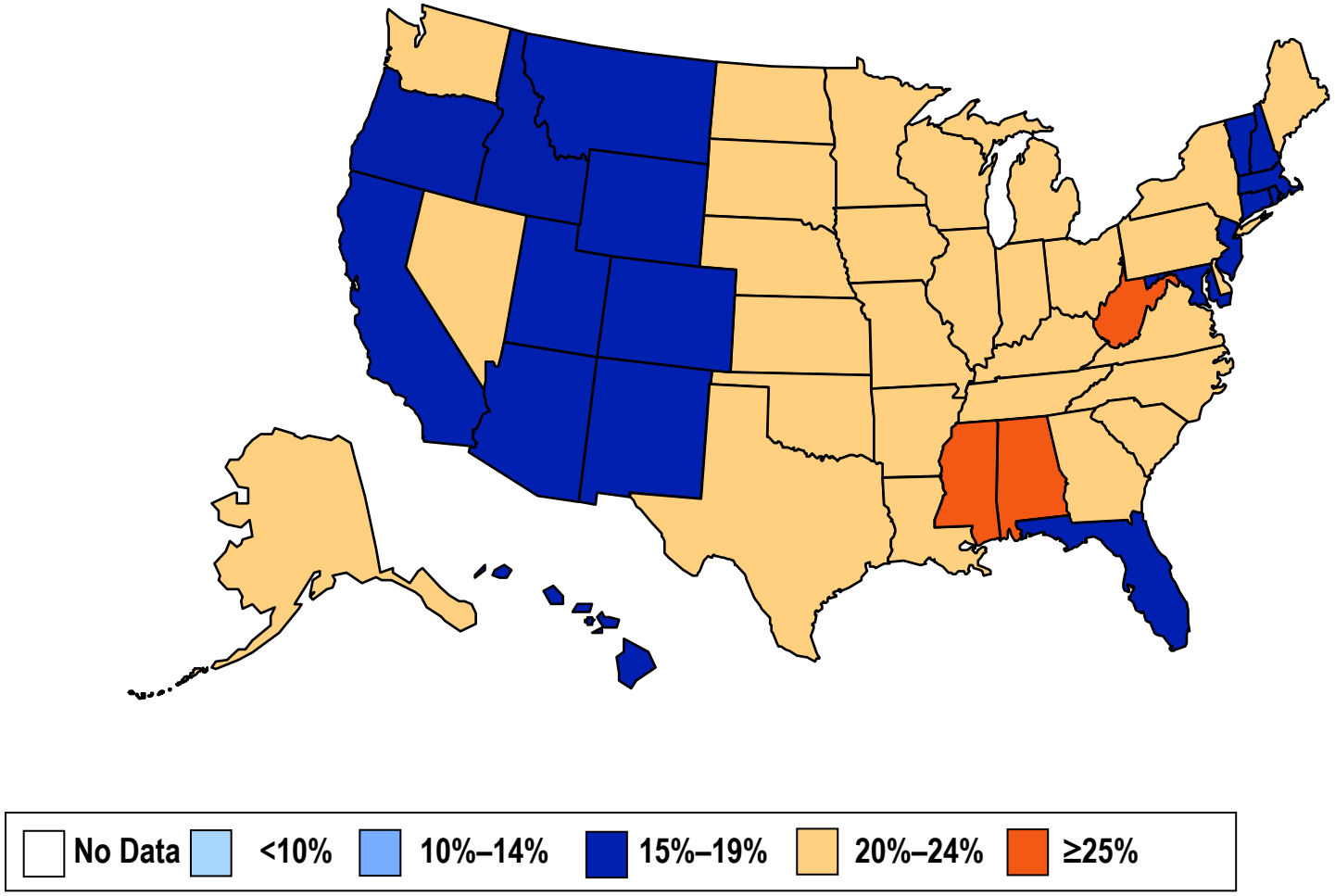


Obesity Trends Among U.S. Adults

BRFSS, 2002

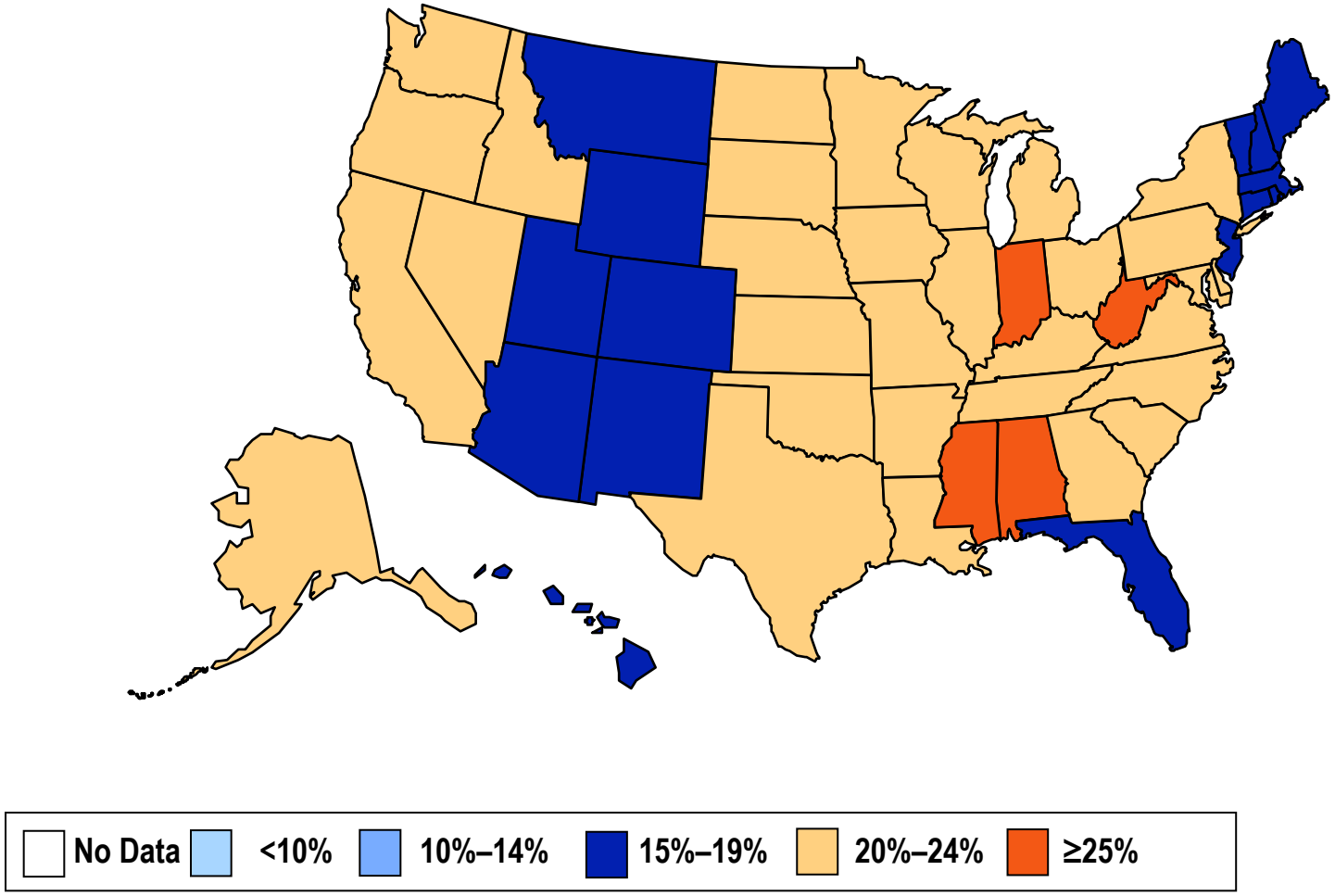
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)



Obesity Trends Among U.S. Adults

BRFSS, 2003

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



Obesity Trends Among U.S. Adults

BRFSS, 2004

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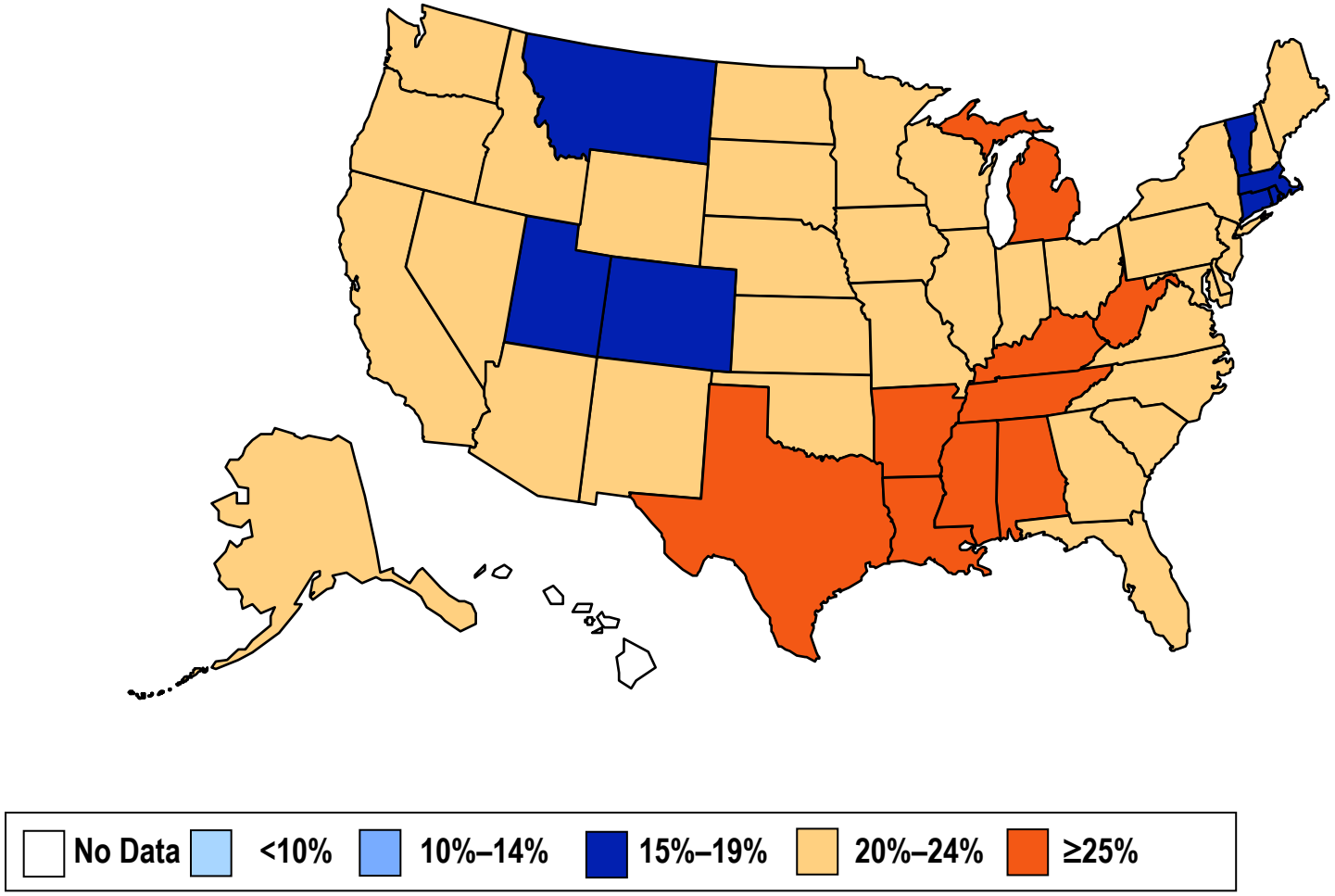
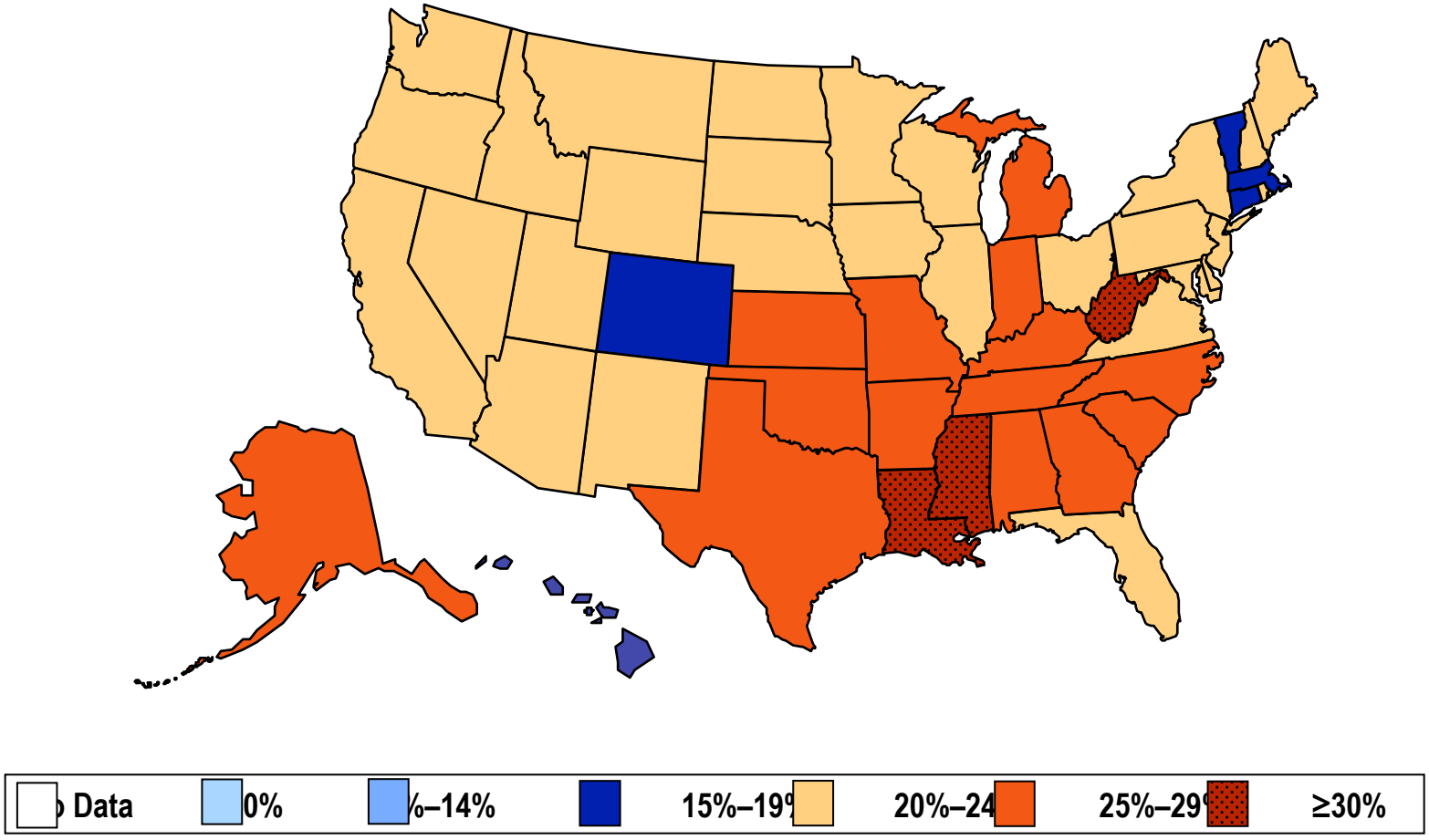


Obesity Trends Among U.S. Adults

BRFSS, 2005

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



Obesity Trends Among U.S. Adults

BRFSS, 2006

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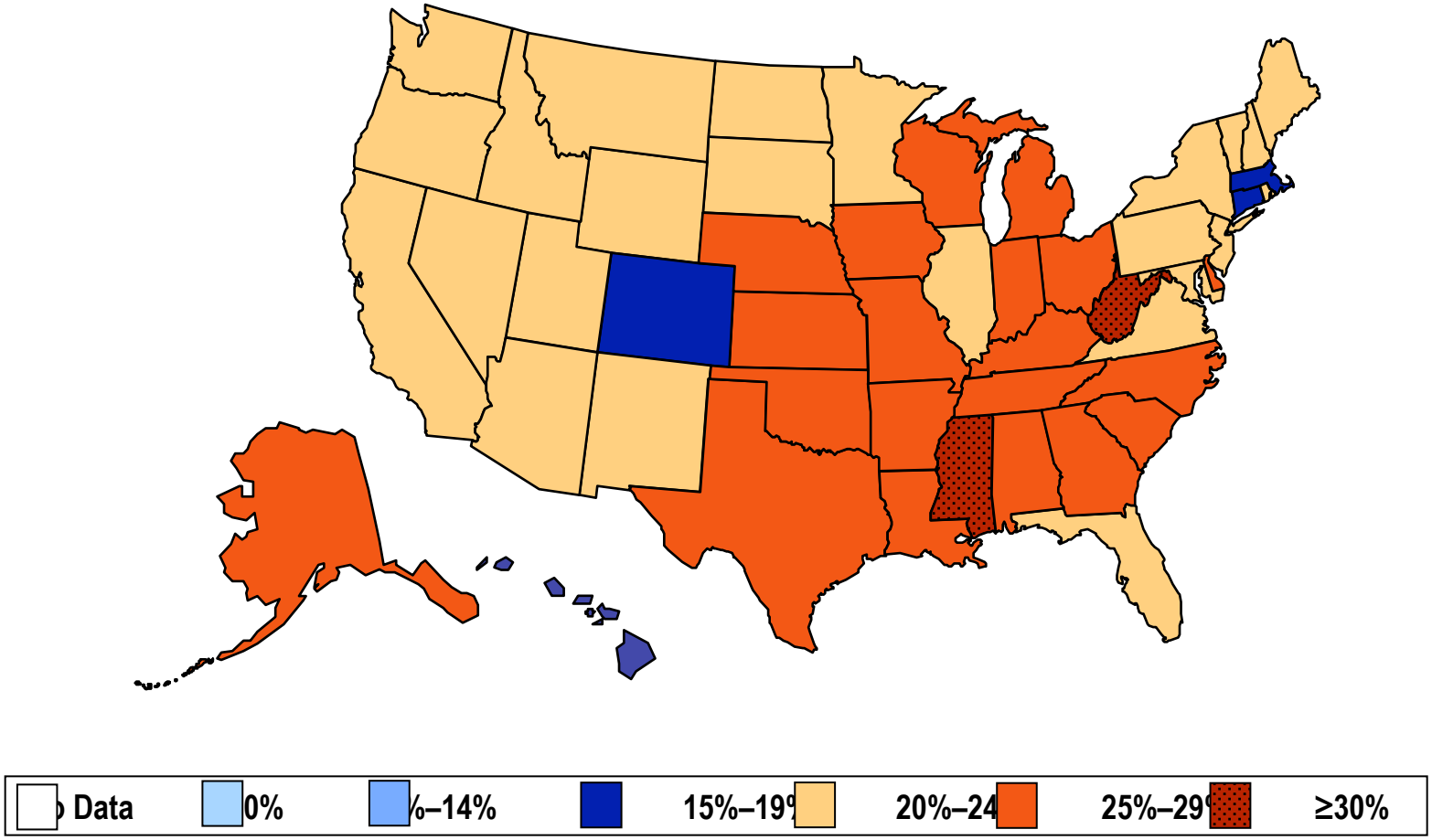
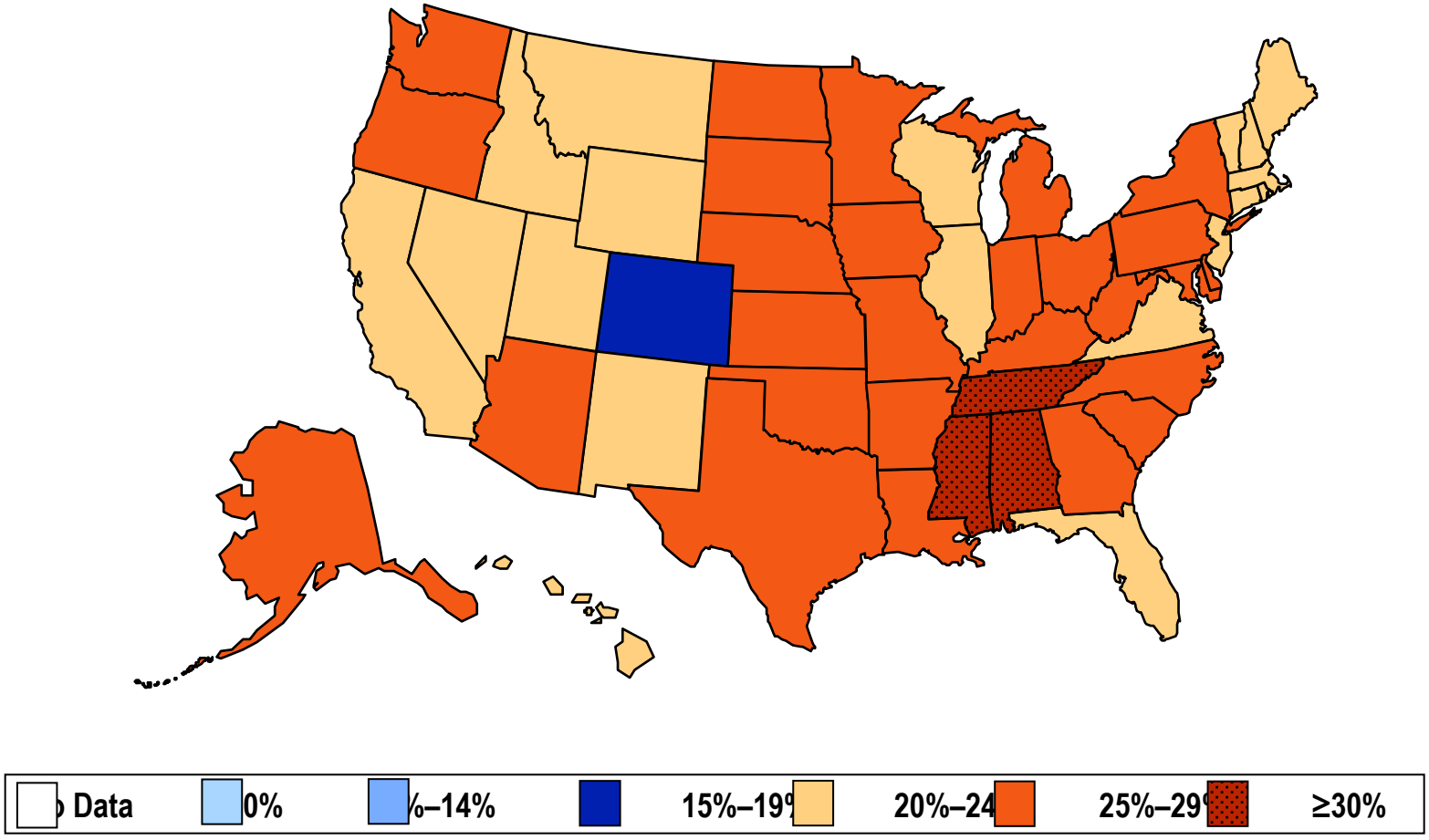


Obesity Trends Among U.S. Adults

BRFSS, 2007

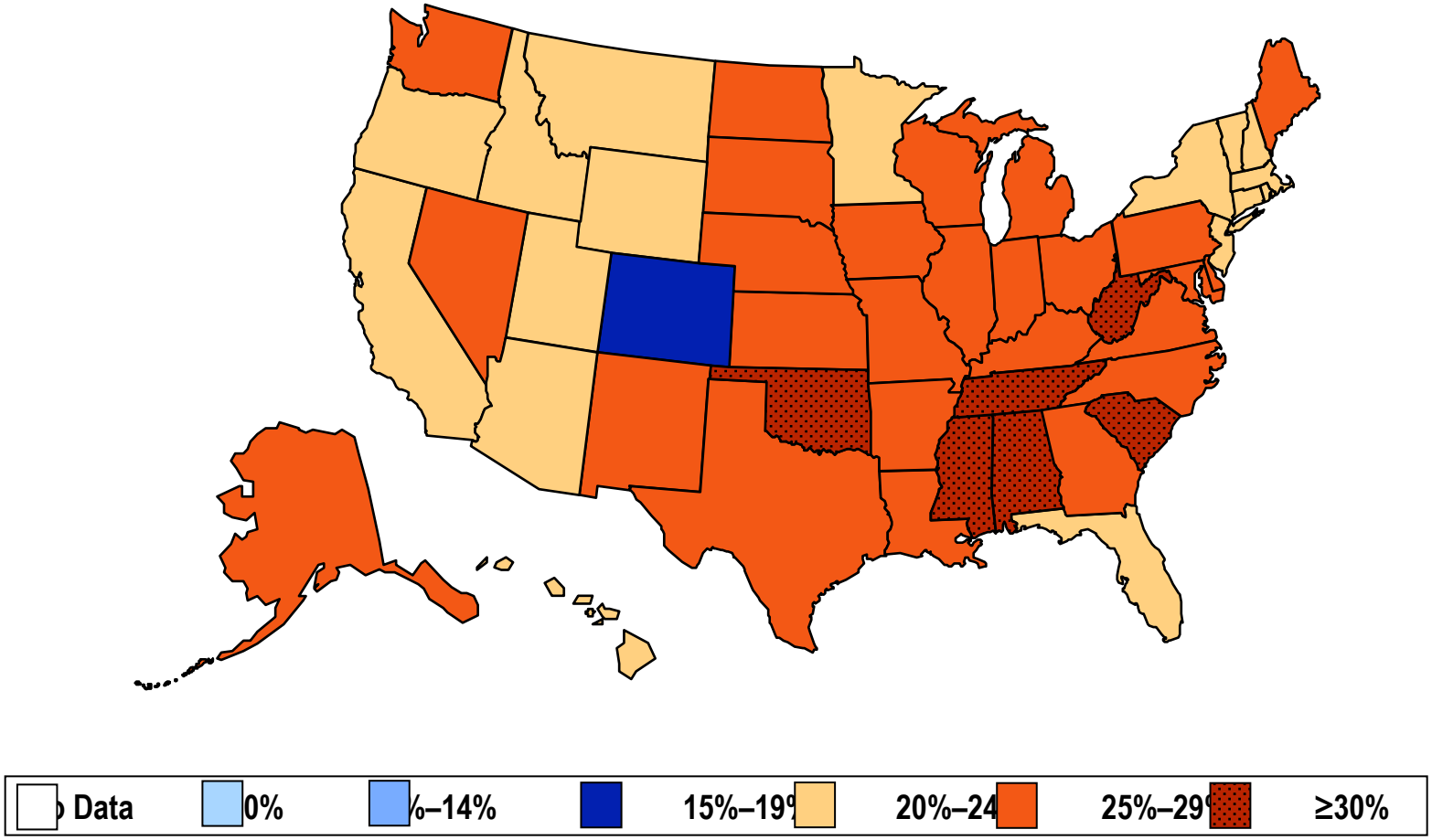
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)



Obesity Trends* Among U.S. Adults

BRFSS, 2008

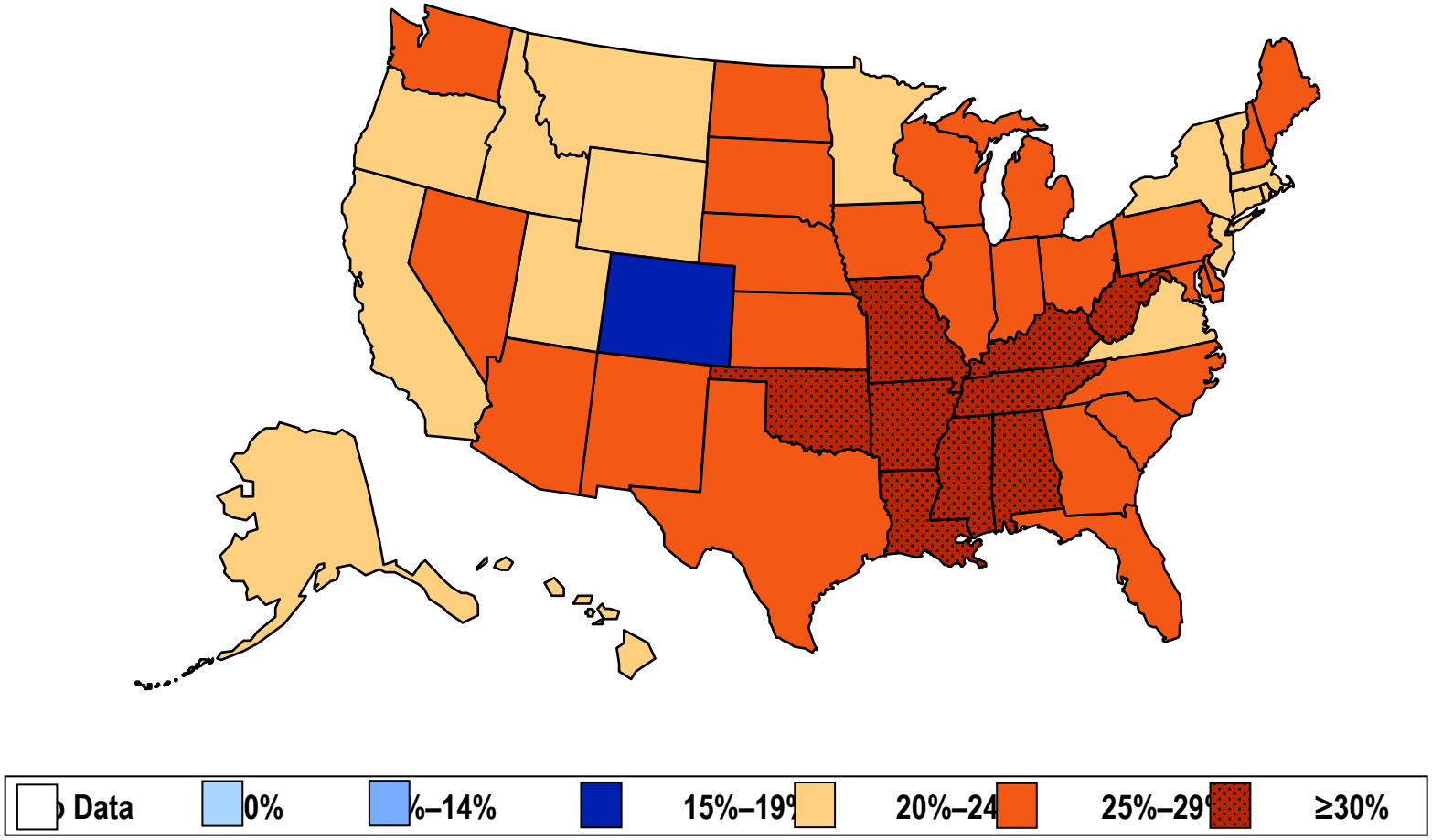
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)



Obesity Trends* Among U.S. Adults

BRFSS, 2009

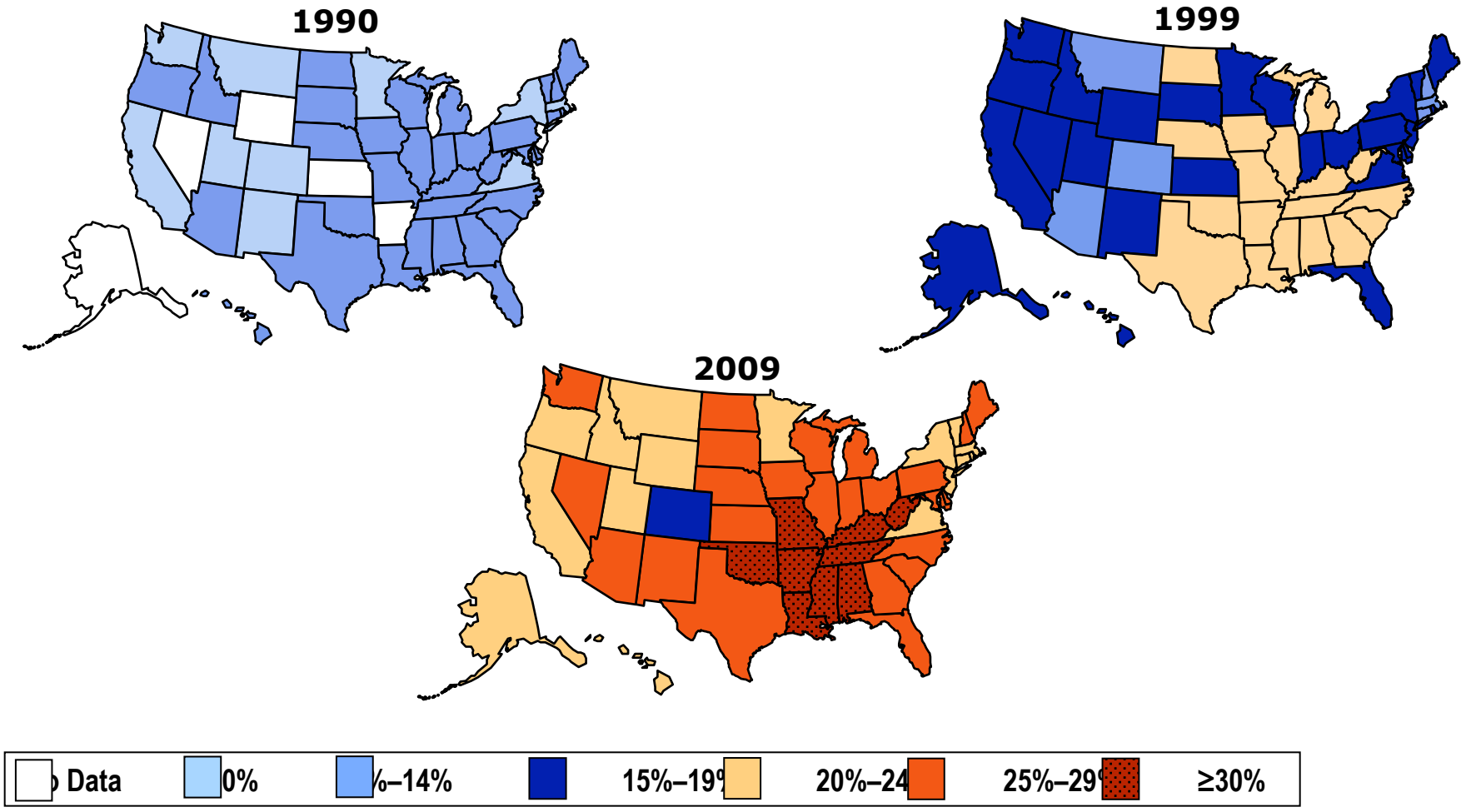
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)



Obesity Trends* Among U.S. Adults

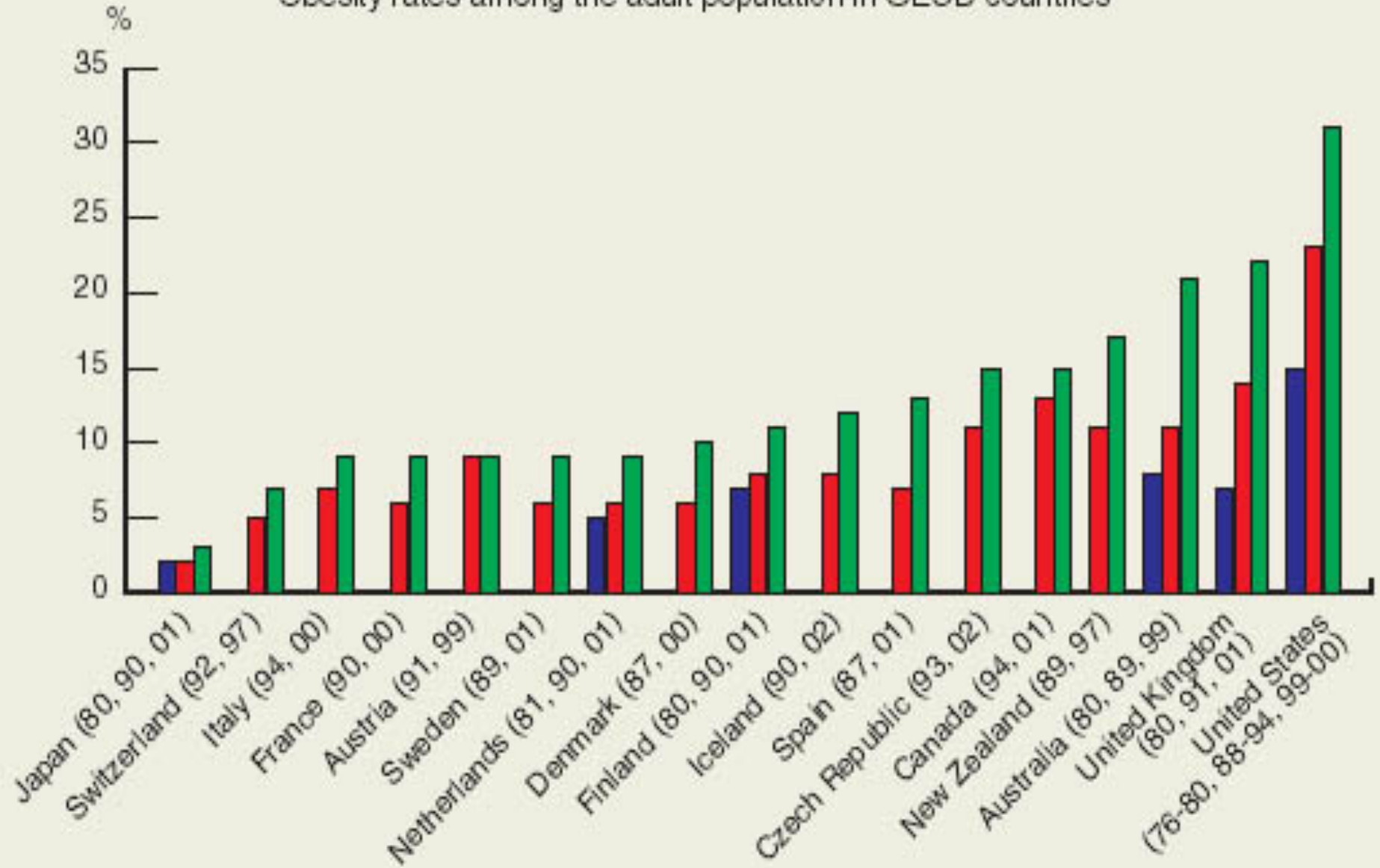
BRFSS, 1990, 1999, 2009

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



Rising obesity

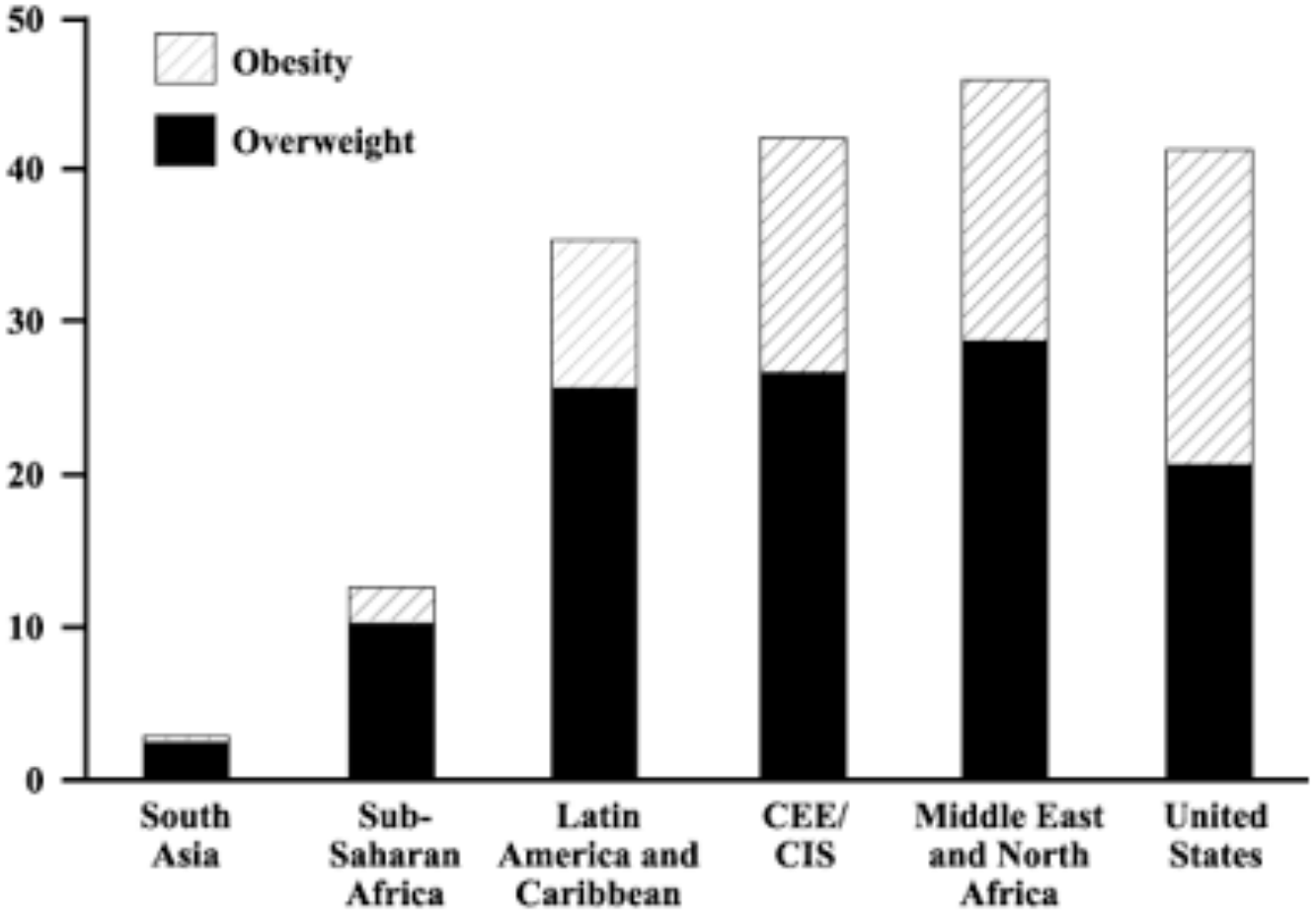
Obesity rates among the adult population in OECD countries



Note : For Australia, UK and US figures are based on health examination surveys, rather than health interview surveys.

Source: OECD Health Data 2003

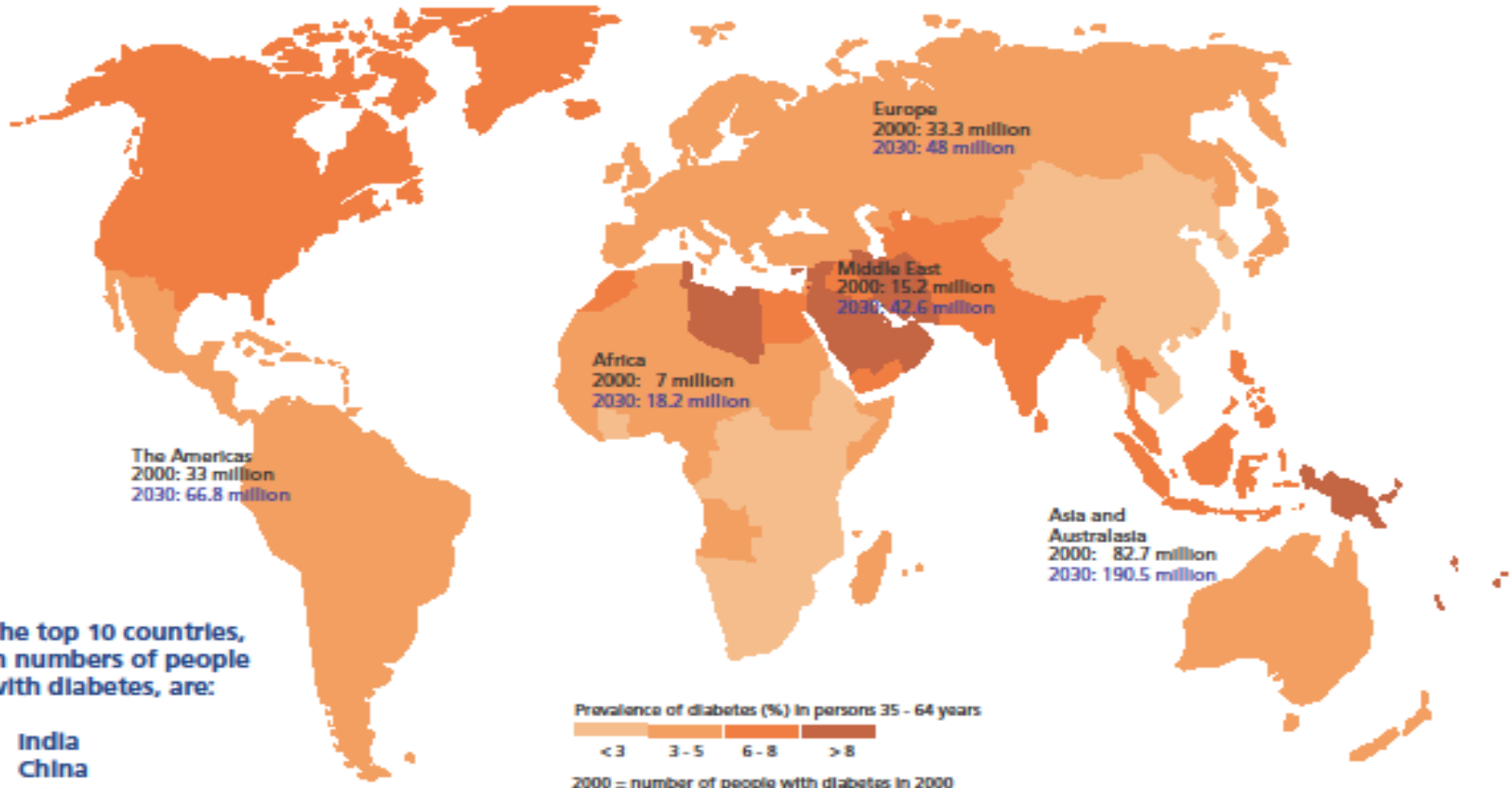
Figure 1
Overweight and Obesity in Women 15 to 49 Years Old in Developing Countries and the United States



Source: See suggested readings at the end of this brief.

Note: CEE/CIS stands for Central Eastern Europe/Commonwealth of Independent States.

Prevalence of diabetes



The top 10 countries, in numbers of people with diabetes, are:

India
China
USA
Indonesia
Japan
Pakistan
Russia
Brazil
Italy
Bangladesh

Year		2000	2030
Ranking	*Country*	*People with diabetes (millions)*	
1	India	31.7	79.4
2	China	20.8	42.3
3	United States of America	17.7	30.3

Source: World Health Organization

Nutritional Status in Mexico

Figura 6.1

Comparativo de la prevalencia nacional de bajo peso, baja talla y emaciación en menores de cinco años por grupos de edad de la ENN 1988, ENN 1999 y ENSANUT 2006. México

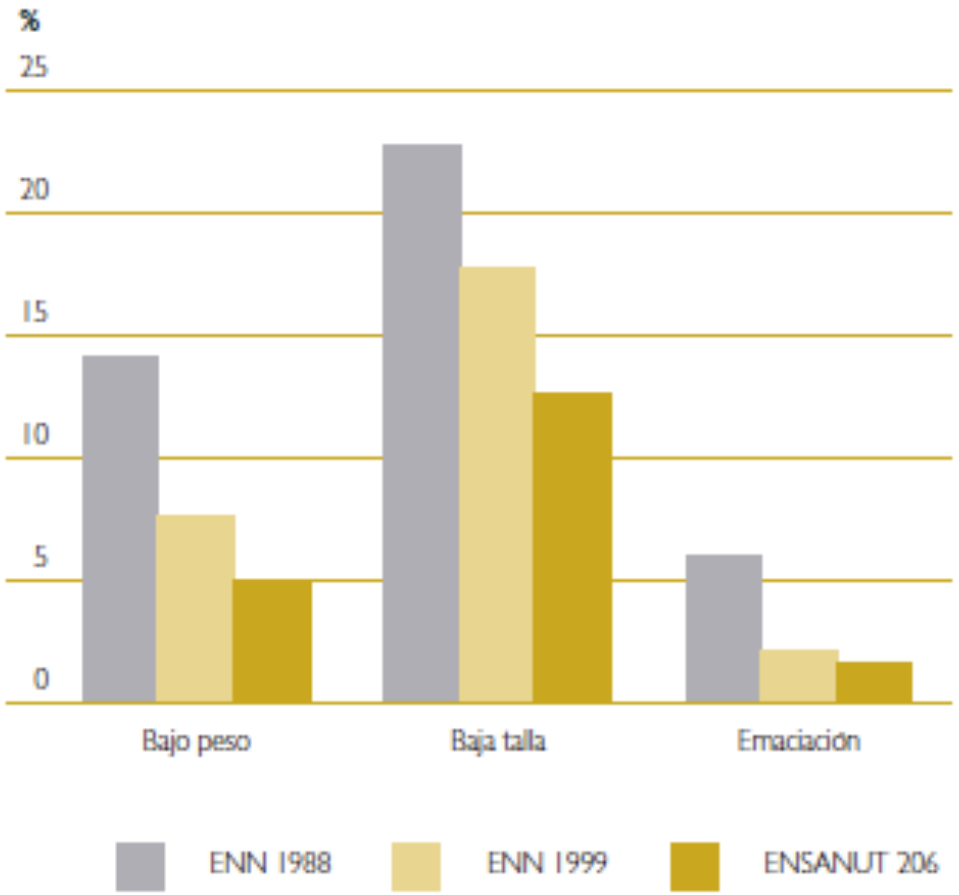


Figura 6.10

Distribución del estado nutricio, de acuerdo con el IMC, por sexo ENSANUT 2006. México

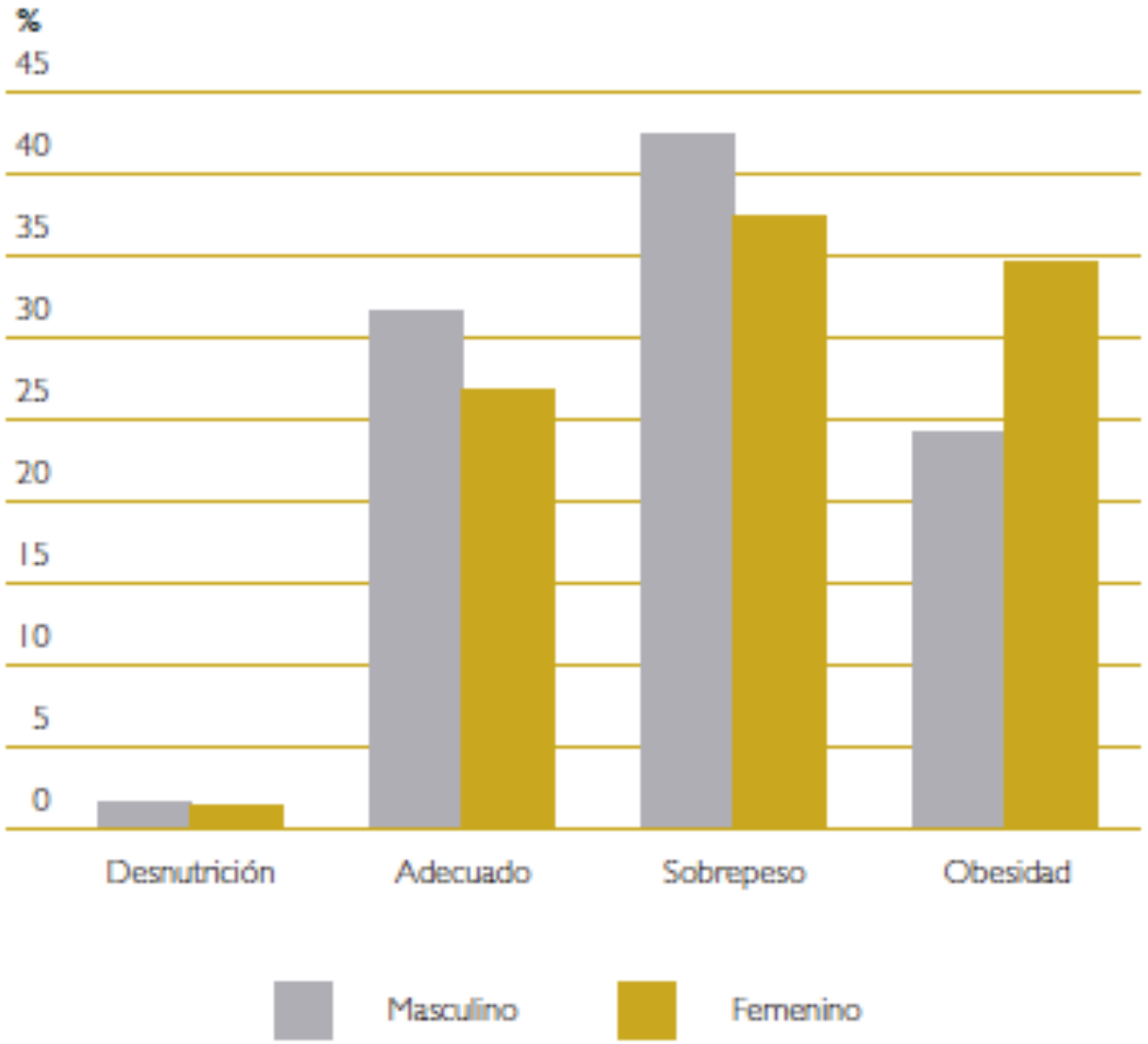
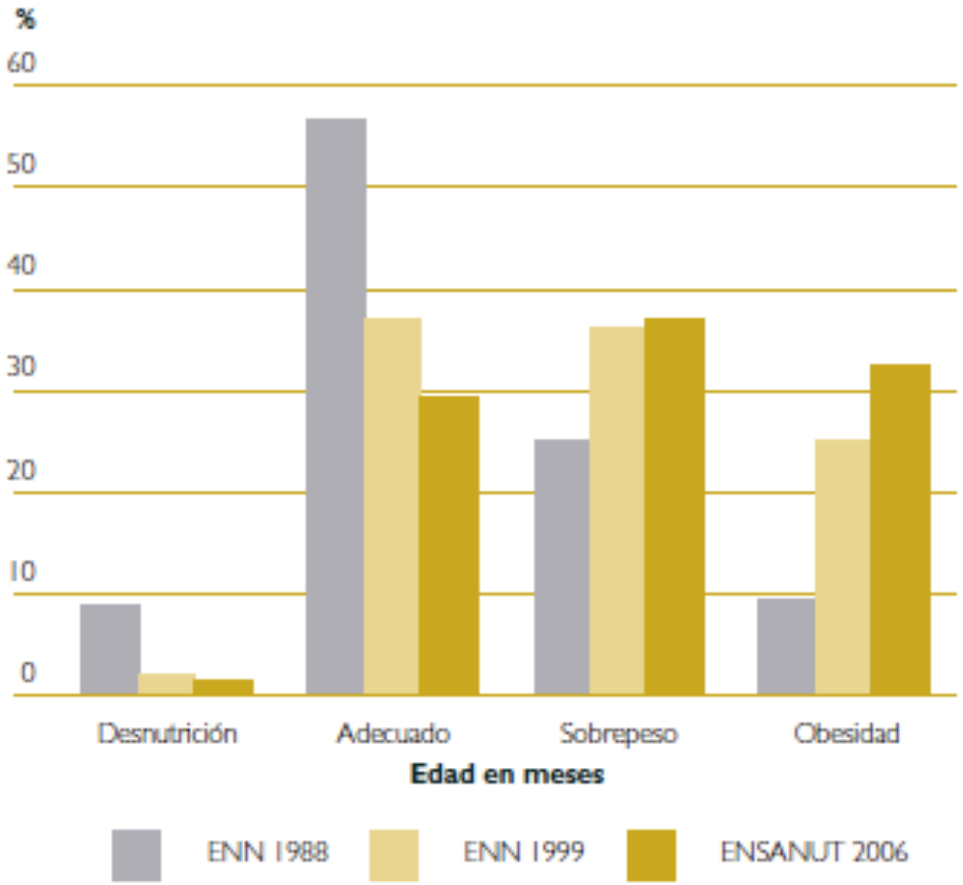
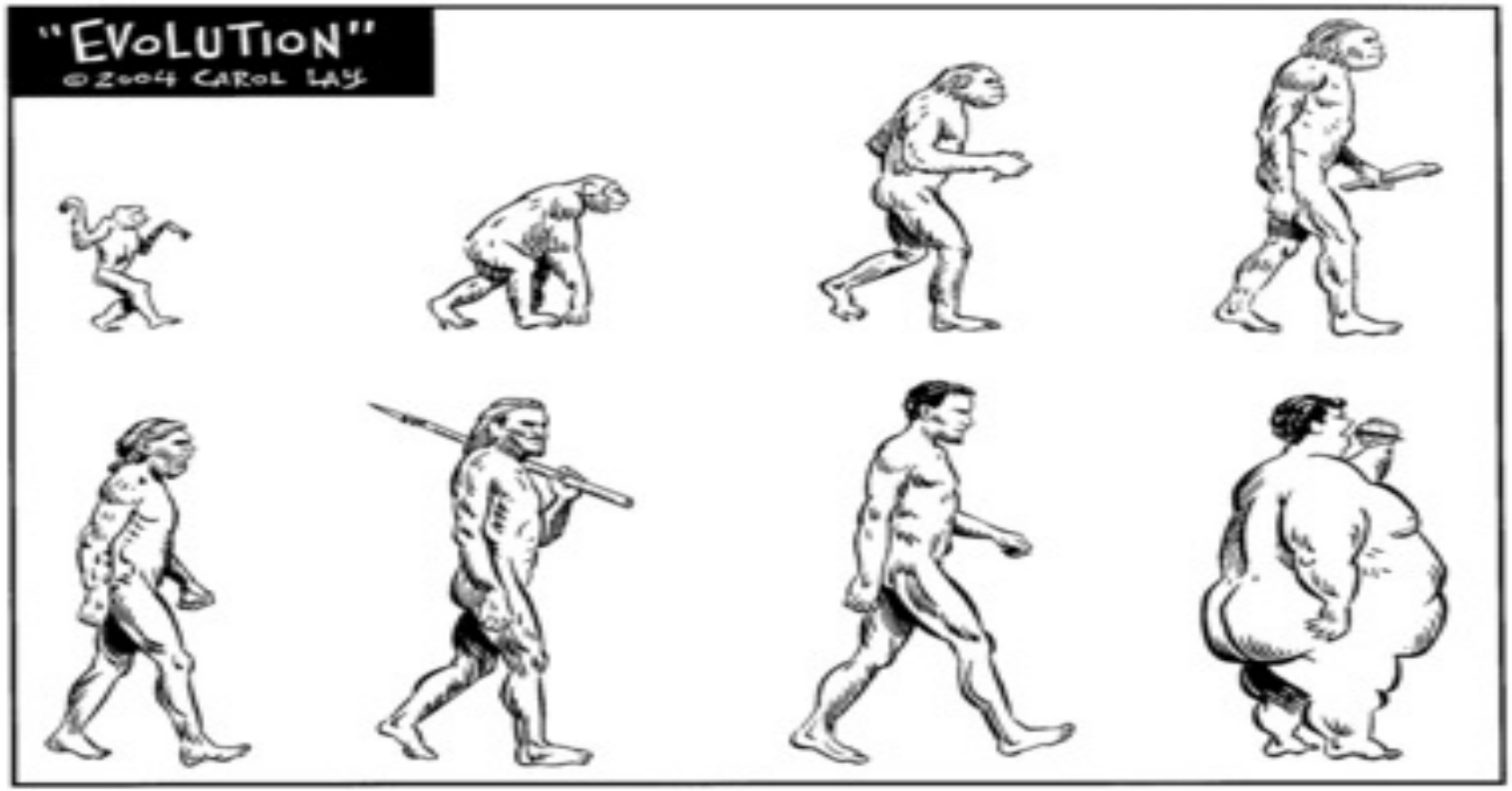


Figura 6.12

Comparación de la distribución de estado nutricio de acuerdo con el IMC, en mujeres de 20 a 49 años de edad de la ENN 1988, ENN 1999 y ENSANUT 2006. México



Evolution?



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Physiology of Obesity

- Overweight/obesity is the result of *CALORIC IMBALANCE*

Energy Balance

- Weight Gain: Calories Consumed > Calories Used
- Weight Loss: Calories Consumed < Calories Used
- Maintenance: Calories Consumed = Calories Used

- 3500 Calories (kcal) = 1.0 pounds of body weight
- Walking 3 mph burns 240 kcal/hour (150 lb. person)

Potential for Weight Loss or Gain

- Typical resting metabolism: 24-26 kcal/day/kg
- Women slightly less than men
- 150 lb (68 kg) man = 1800 kCal/day

- Reduced Consumption or Increased Activity
- (-)300 kcal/day = loss of 2.5 lbs/month or 30 lbs/yr

- Increased Consumption or Decreased Activity
- (+)100 kcal/day = gain of 0.9 lbs/month or 10 lbs/yr

FRENCH FRIES

20 Years Ago

210 Calories

2.4 ounces

Today

How many calories are in today's portion of fries?

FRENCH FRIES

20 Years Ago

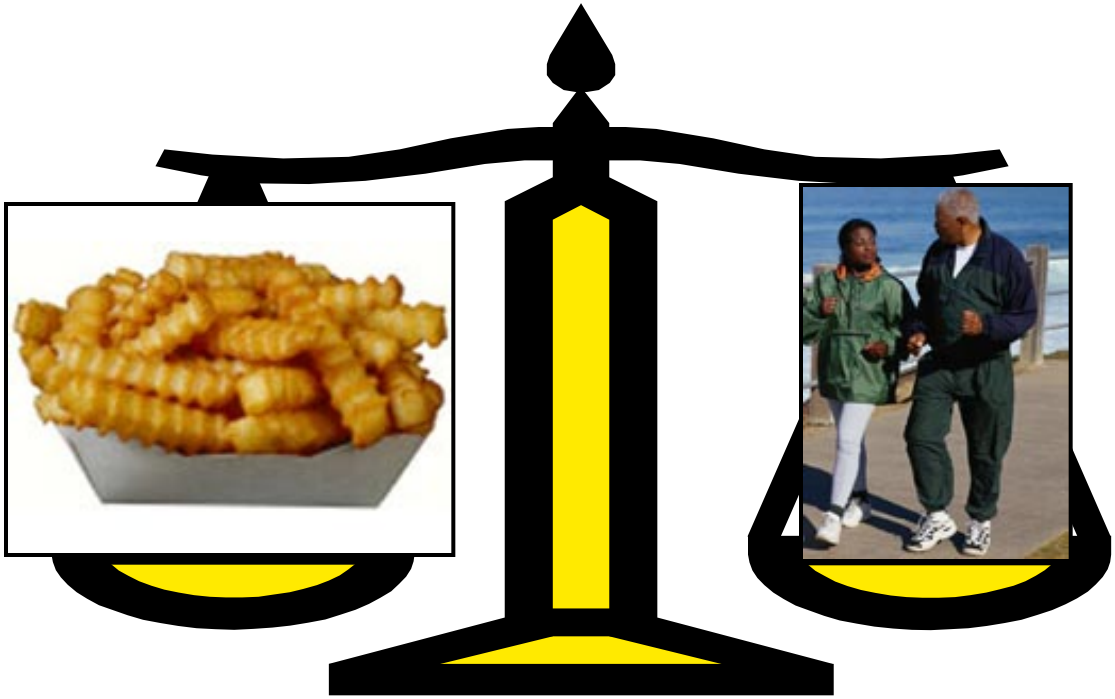
210 Calories
2.4 ounces

Today

610 Calories
6.9 ounces

Calorie Difference: 400 Calories

Maintaining a Healthy Weight is a Balancing Act
Calories In = Calories Out



How long will you have to walk leisurely in order to burn those extra 400 calories?*

***Based on 150-pound person**

Calories In = Calories Out

If you **walk leisurely for 1 hour and 40 minutes** you will burn approximately **400 calories.***

***Based on 150-pound person**

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- Define and measure obesity
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Factors that Affect BMI

- Increasing Age
- Gender
- Race/Ethnicity
  - Asian < White < Latino < Blacks and Native American
- Lower socioeconomic status
- Health behaviors
- Access to Health Care
- Environment
- For immigrants, length of time living in the US

*Note: Important to distinguish association from causation

Prevalence of obesity and diabetes by gender, BRFSS, 2001

Gender	% Obese	% Diabetes
Male	21.0	6.8
Female	20.8	8.9

Mokdad et al. JAMA 2003;289:76-79.

Prevalence of obesity and diabetes by race/ethnicity, BRFSS, 2001

Race/Ethnicity	% Obese	% Diabetes
White	19.6	7.2
African American	31.1	11.2
Latino	23.7	9.0
Other	15.7	8.2

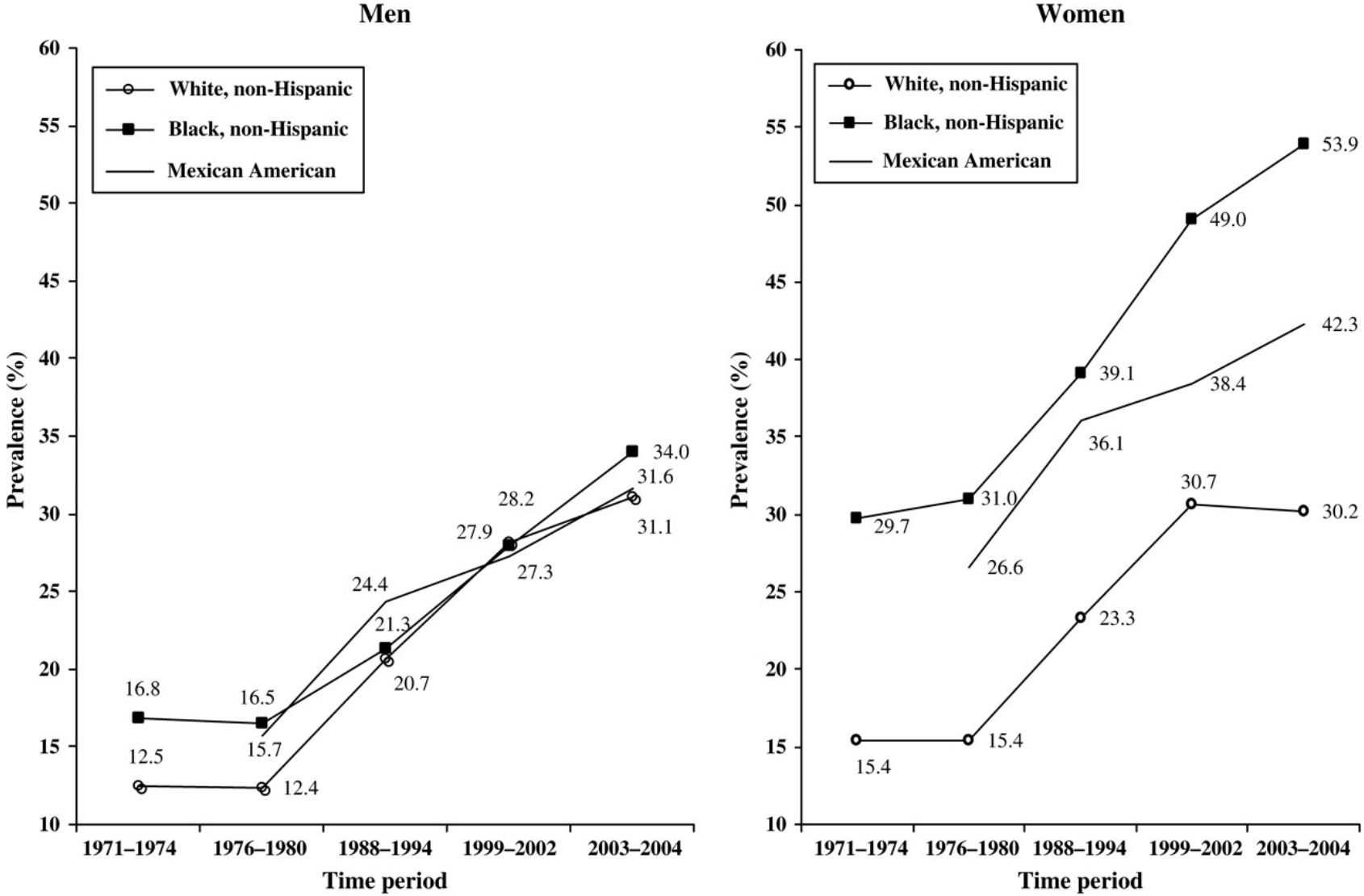
Mokdad et al. JAMA 2003;289:76-79.

Prevalence of obesity and diabetes by education level, BRFSS, 2001

Education Level	% Obese	% Diabetes
< High School	27.4	13.0
High School	23.2	8.2
Some College	21.0	7.5
College +	15.7	5.5

Mokdad et al. JAMA 2003;289:76-79.

Trends in obesity prevalence (BMI ≥30), US adults, NHANES, 1971-2004



Source: Wang, Y. et al. Epidemiol Rev 2007 29:6-28

Prevalence (%) of overweight (BMI ≥25) and obesity (BMI ≥30) in different Asian-American groups, 1992–1995 National Health Interview Survey, United States

	Men		Women	
Ethnicity	Overweight	Obesity	Overweight	Obesity
Total NHIS	60	15	40	15
Asian Indian	33	4	25	4
Chinese	26	3	9	2
Filipino	40	5	22	4
Japanese	42	7	18	3
Korean	31	3	10	1
Vietnamese	17	0	9	1

Source: Wang, Y. et al. Epidemiol Rev 2007 29:6-28

Nature vs. Nurture

Pima Indians early 1900s

Pima Indians today

- Pima Indians today have a much more serious obesity problem and the highest incidence of diabetes in the world
- “Thrifty gene” hypothesis
- Susceptible individuals in a permissive environment

Source: Marx J, Science 2002; 296:686-689

Genetic Influences on Obesity

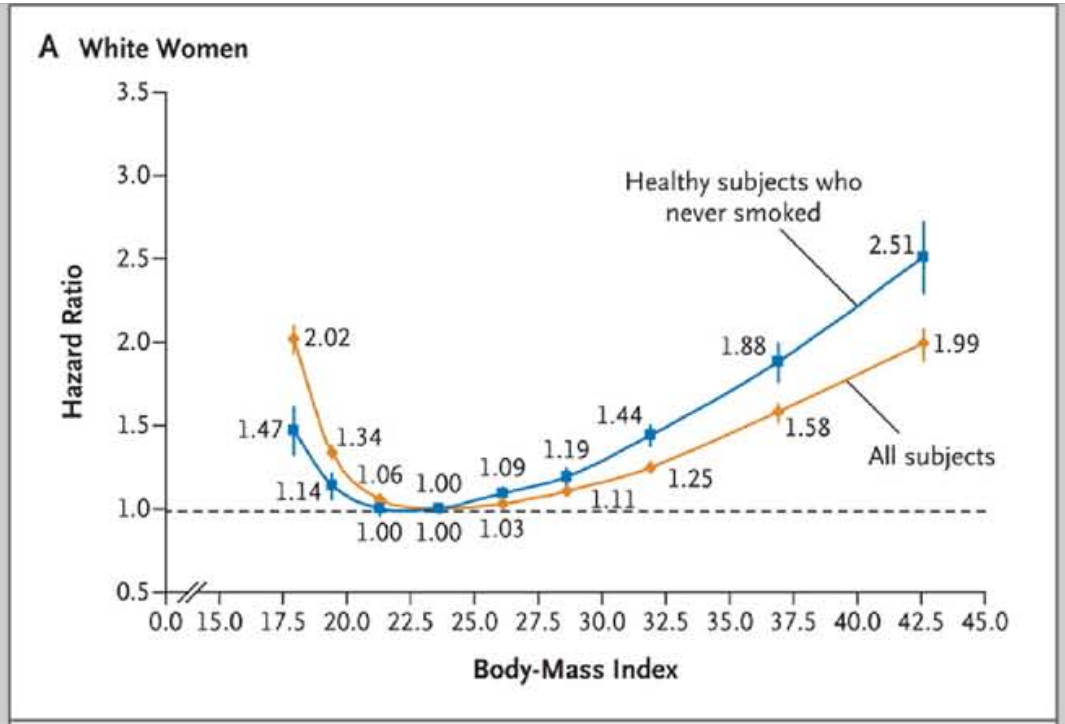
- Known clustering of obesity in families
- Twin studies
  - greater concordance in MZ twins vs. DZ twins
- Statistical linkage studies suggest genetic associations
- Dramatic increase in obesity argues against a dominant influence of genetics

Outline

- Define and measure obesity
- Epidemiology of obesity
- Physiology of obesity
- Determinants of obesity
- Health consequences
- Clinical trial for obesity treatment

Health Consequences of Obesity

- Mechanical: Increased fat mass leads to anatomical problem or increased stress
  - Osteoarthritis, Obstructive Sleep Apnea
- Metabolic: Altered physiology leads to abnormal cardiovascular complications
  - Diabetes Type 2, hypertension, elevated lipids
- Hormonal: Altered hormonal signals lead to increased cancer risk and reproductive problems
  - Breast cancer, fertility, pregnancy complications
- Social: Stigma associated with body size has negative consequences, potential relationship to depression



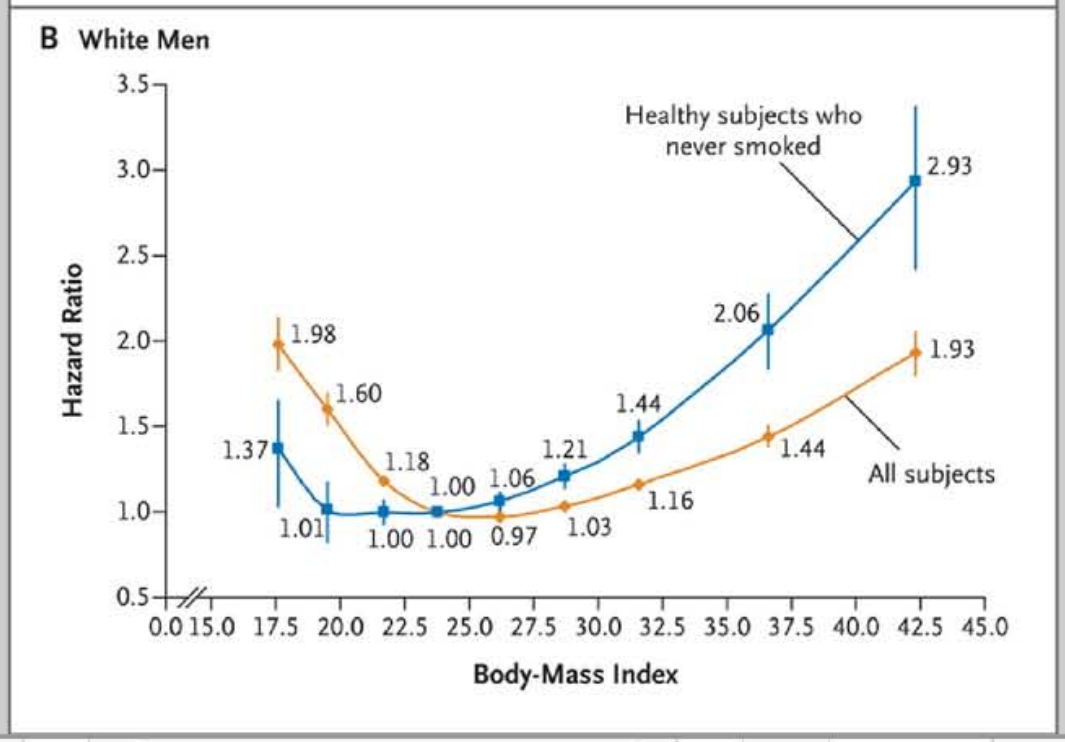
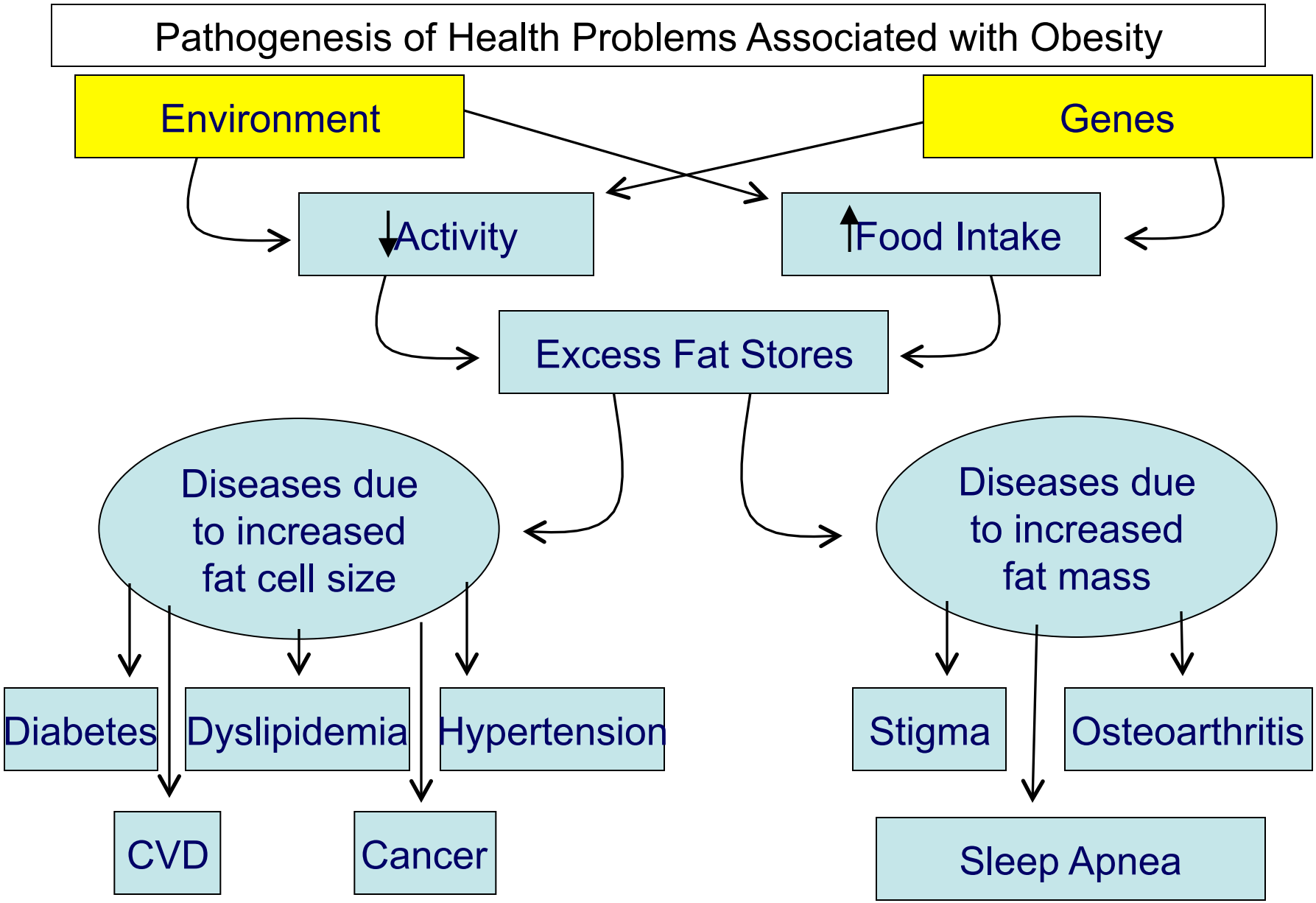


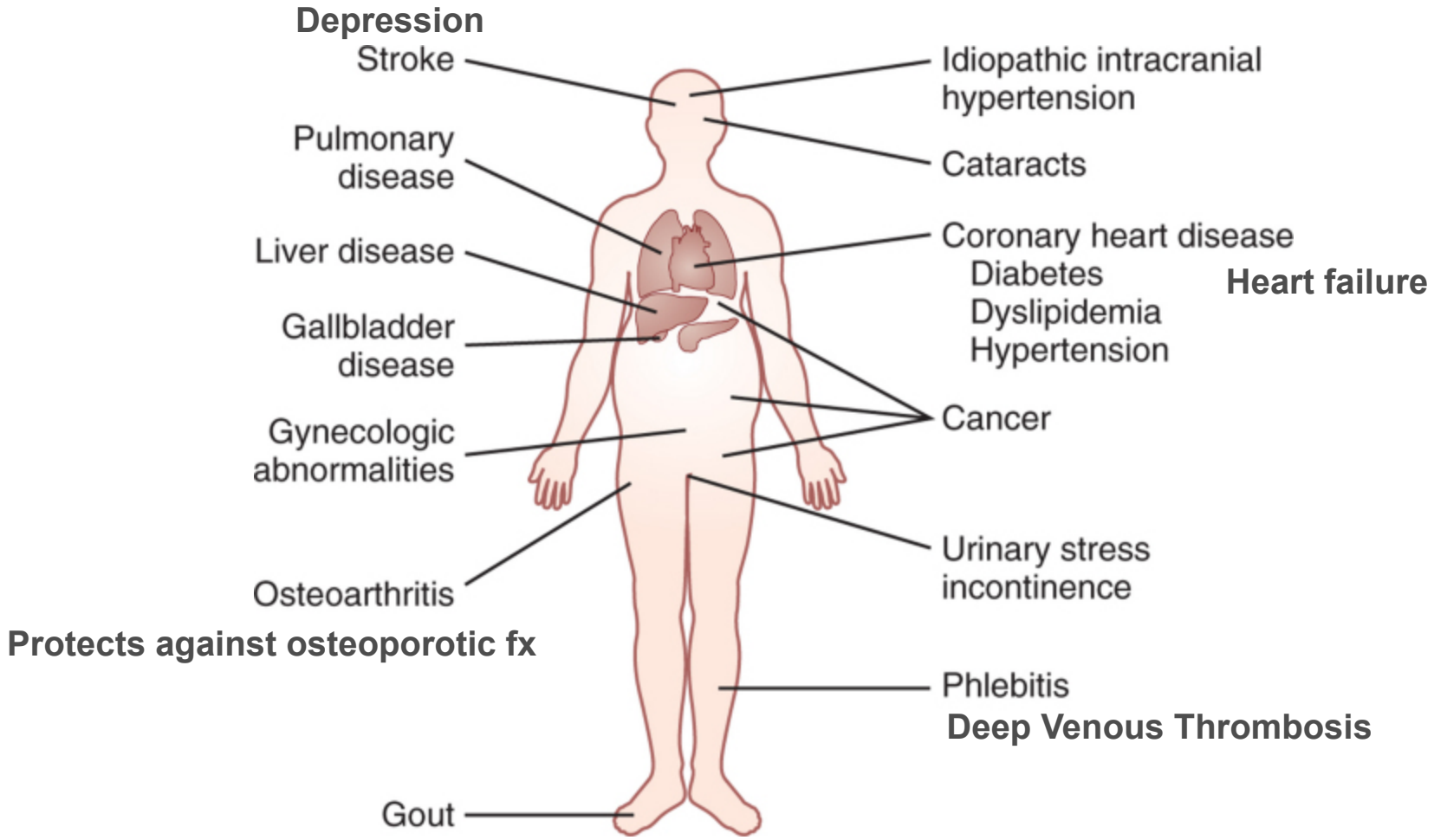
Figure 1. Estimated Hazard Ratios for Death from Any Cause According to Body-Mass Index for All Study Participants and for Healthy Subjects Who Never Smoked.

Hazard ratios and 95% confidence intervals are shown for white women (Panel A) and white men (Panel B). The hazard ratios were calculated with the use of age as the underlying time scale, were stratified by study, and were adjusted for alcohol intake (grams per day), educational level, marital status, and overall physical activity. Subjects were deemed healthy if they had no cancer or heart disease at baseline.



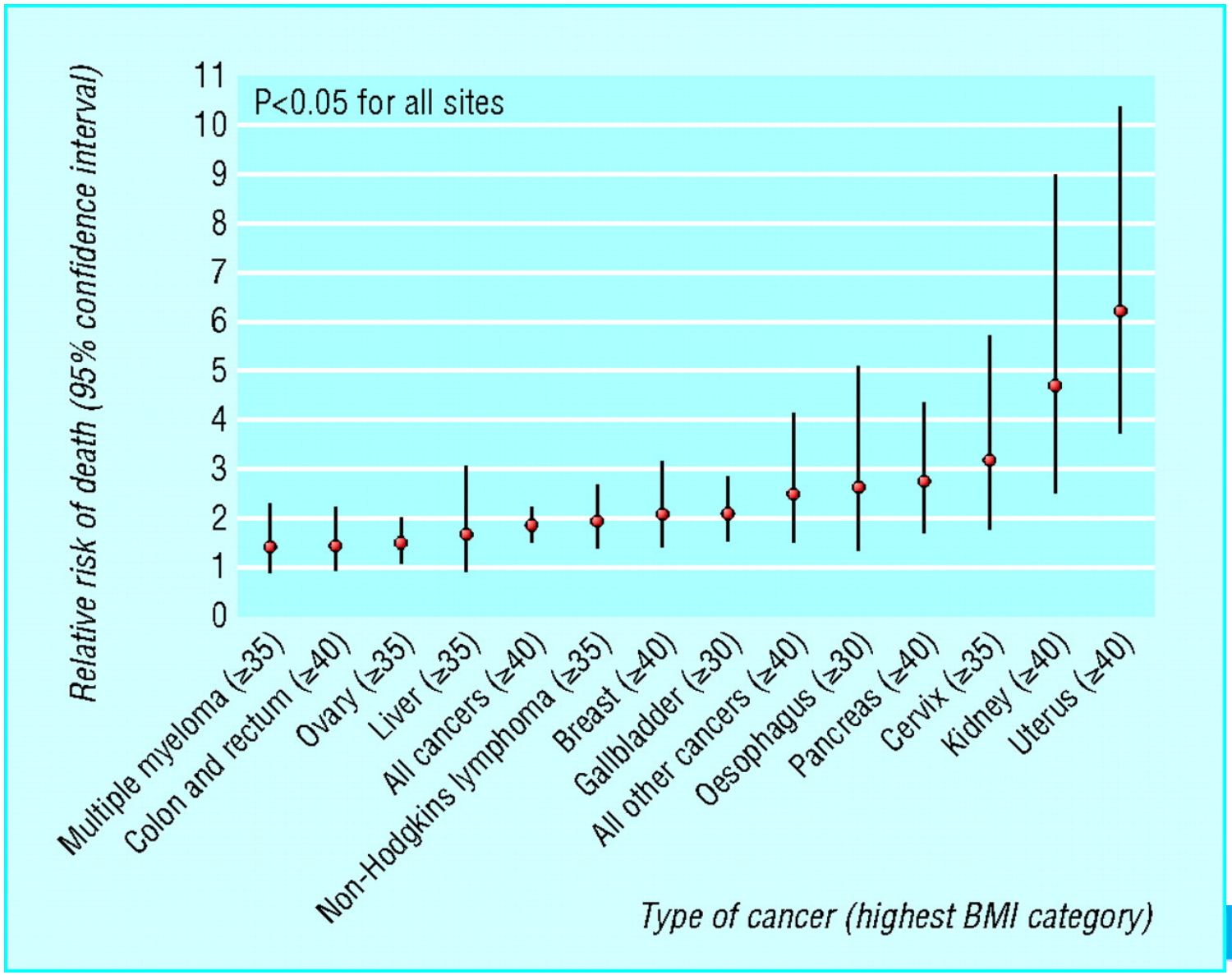
Bray, George A. J Clin Endocrinol Metab 2004; 89(6):2583

Other Health Consequences



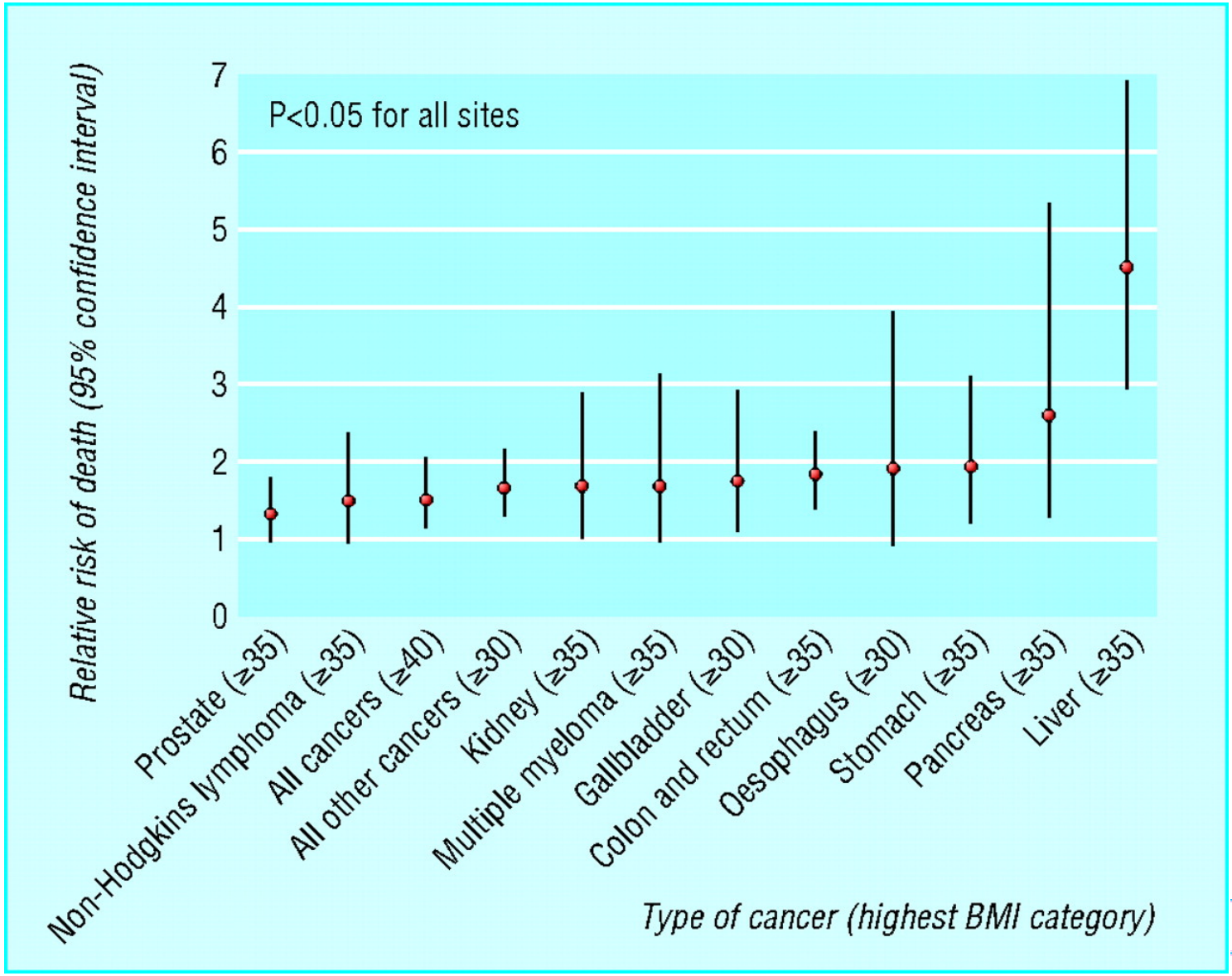
Source: Kronenberg: Williams Textbook of Endocrinology, 11th ed.

Mortality from cancer for US women, 1982-98, by body mass index (BMI). For each relative risk, the comparison was between women in the highest BMI category and women in the reference category (18.5 to 24.9). Adapted from Calle et al.



McMillan, D. C et al. BMJ 2006;333:1109-1111

Mortality from cancer for US men, 1982-98, by body mass index (BMI). For each relative risk, the comparison was between men in the highest BMI category and men in the reference category (18.5 to 24.9). Adapted from Calle et al.



BMJ

McMillan, D. C et al. BMJ 2006;333:1109-1111

Summary

- Although BMI dominates measurement, other strategies are very important
- Obesity is a very prevalent condition and increasing in many populations
- Obesity results from caloric imbalance
- Obesity is associated with a number of metabolic, endocrine, and cardiovascular complications

Outline

- Define and measure obesity
- Epidemiology of obesity
- Physiology of obesity
- Determinants of obesity
- Health consequences
- Clinical trial for obesity treatment

What solutions exist?

- Prevention and treatment
- Interventions
  - Individual
    - Behavioral
    - Medical (meds, surgical)
  - Environmental
    - Built environment
    - Food environment
    - Health care systems
    - Public policy

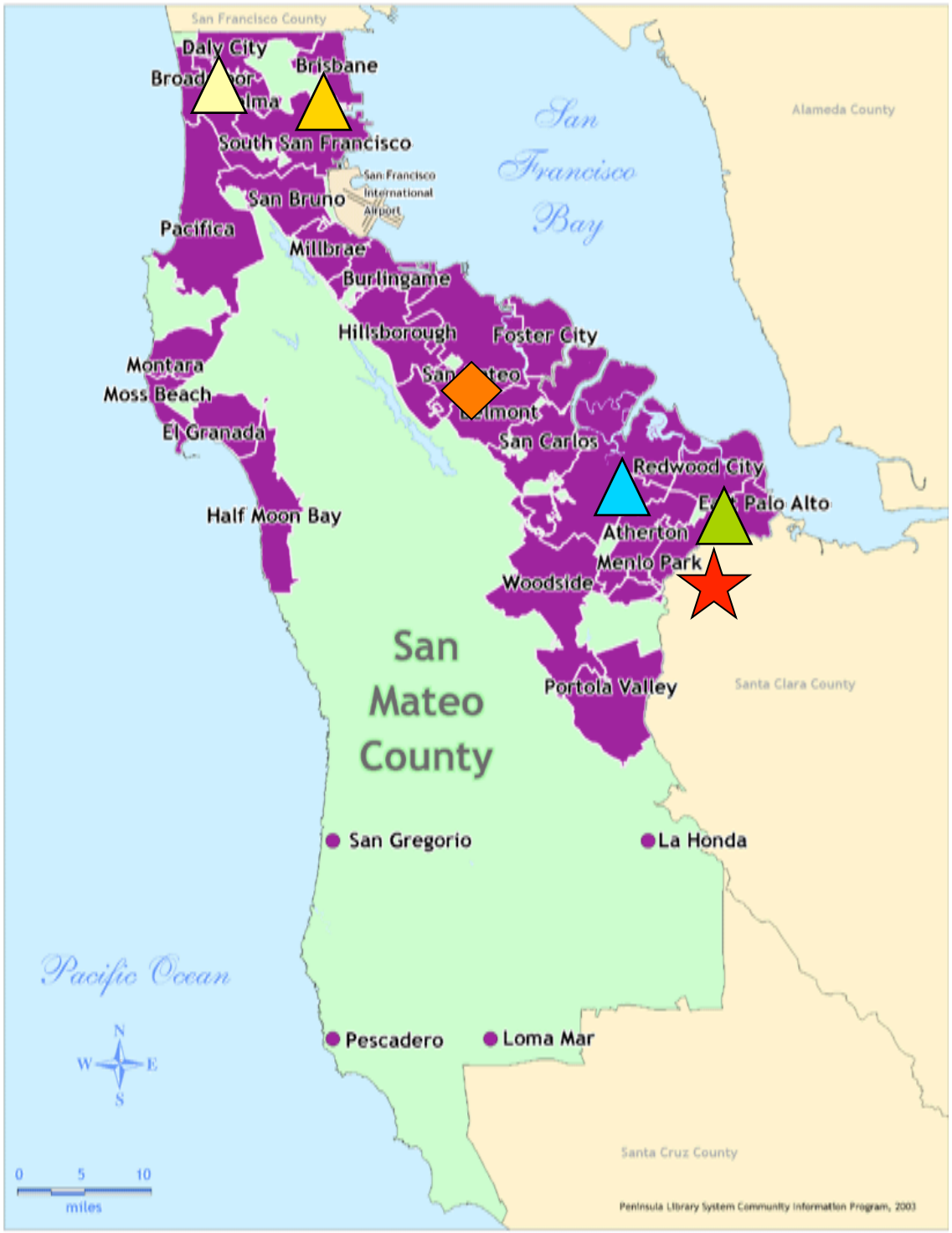
Vivamos Activos: Obesity Management in a Low-income Latino Neighborhood

PI: Randall S. Stafford, MD, PhD

Program on Prevention Outcomes and Practices
Stanford Prevention Research Center

Stanford Prevention
Research Center


OREGON
IDAHO
NEVADA
CALIFORNIA
PACIFIC OCEAN
NORTH COAST
Medford
Crescent City
Eureka
Arcata
McKinleyville
Redwood Nat. Park
Yreka
Mt. Shasta
Redding
Burney Falls
Lassen Volcanic Nat. Park
Susanville
Red Bluff
Corning
Chico
Paradise
Oroville
Fort Bragg
Mendocino
Ukiah
Clearlake
Yuba City
Nevada City
Olympic Valley
Truckee
Reno
Carson City
Lake Tahoe
South Lake Tahoe
Auburn
Rocklin
Roseville
Folsom
Rancho Cordova
Sacramento
Davis
Napa
Fairfield
Vallejo
Concord
Stockton
Healdsburg
Calistoga
Santa Rosa
Sonoma Valley
Petaluma
San Rafael
Novato
Berkeley
SAN FRANCISCO
Oakland
Hayward
Manteca
Modesto
Turlock
South San Francisco
San Mateo
Half Moon Bay
Fremont
Palo Alto
SAN JOSE
Morgan Hill
Merced
Santa Cruz
Watsonville
Gilroy
Hollister
Marina
Monterey
Seaside
Carmel Valley
Big Sur
Salinas
Soledad
Pinnacles Nat. Mon.
Fresno
Madera
Clovis
Reedley
Hanford
Visalia
Tulare
Porterville
Avenal
Delano
Hearst Castle
San Simeon
Paso Robles
Atascadero
Morro Bay
San Luis Obispo
Pismo Beach
Santa Maria
Wasco
Oildale
Bakersfield
Arvin
Lompoc
Solvang
Orcutt
Goleta
Santa Barbara
Ventura
Oxnard
Santa Barbara Channel
Channel Islands Nat. Park
Santa Rosa I.
Santa Cruz I.
Santa Monica
LOS ANGELES
Long Beach
Huntington Beach
Laguna Beach
Catalina I.
San Nicolas I.
San Clemente I.
Palmdale
Lancaster
Victorville
Apple Valley
Hesperia
Sta. Clarita
Simi Valley
Pomona
San Bernardino
Riverside
Disneyland
Anaheim
Santa Ana
Palm Springs
Indio
Palm Desert
Temecula
San Clemente
Oceanside
Carlsbad
Escondido
Encinitas
Chula Vista
SAN DIEGO
TIJUANA
MEXICALI
MEXICO
Brawley
El Centro
Yuma
Blythe
Salton Sea
Anza-Borrego Desert State Park
Joshua Tree National Park
Mojave Nat. Preserve
MOJAVE DESERT
Barstow
Ridgecrest
Las Vegas
Henderson
Death Valley National Park
Manzanar Nat. Hist. Site
Giant Sequoia Nat. Mon.
Sequoia Nat. Park
Kings Canyon Nat. Park
Sierra Summit
Bishop
Oakhurst
Mariposa
Yosemite Nat. Park
Jamestown
Mammoth Lakes
Devils Postpile Nat. Mon.
Mono Lake
Bodie State Historic Park
COUNTRY
GOLD
Miles
0 20 40 60 80



San Mateo County

2008 Population 713,000

Med. family Income $79K

- Urban / Suburban
- Rural / Open Space
- Fair Oaks Clinic
- South SF Clinic
- Willow Clinic
- Daly City Clinic
- San Mateo Med Ctr
- Stanford Prevention Research Center

STANFORD

Rationale for Case-Management

- Medical care system not designed to provide chronic disease management services
- Physicians' emphasizes acute health issues
- For many conditions, we do not apply known evidence to reduce risk of adverse outcomes
- Shortfalls disproportionately affect low-income populations
- Compelling need for new models of delivering disease management services
- Meager evidence for effectiveness of new models, esp. in low-income patients

What is Case Management

- Address the barriers to good chronic disease management services
- Nurses, dietitians, health educators may manage routine disease management with:
  - More continuity
  - Greater patient engagement
  - Appropriate focus on behavior change
  - Potential for greater cultural congruence
- Patient outreach
- Team-based approach including PCP

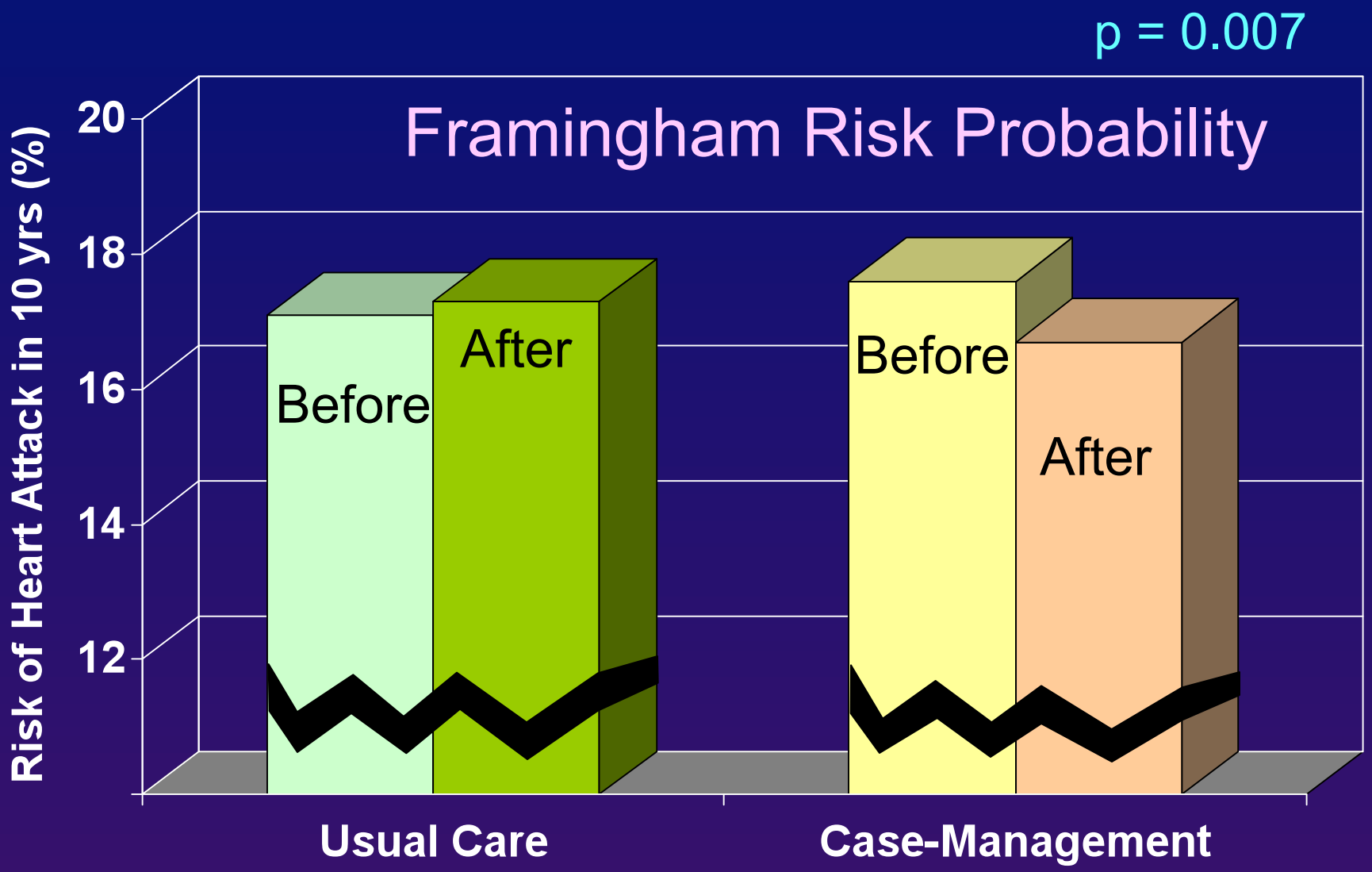
Obstacles to Case Management in Low Income Populations

- Most trials of CM for risk factors and obesity in employed populations, not low income
- Increased obstacles to prevention services:
  - Organizations with limited resources
  - Multiple non-health concerns (financial, legal)
  - Limited family resources for prevention
  - Neighborhoods less conducive to prevention: less access to fresh vegetables, less walkable
  - Increased cultural and language “barriers”
  - Problems with health literacy and numeracy

Opportunities for Success in Low Income Populations

- Challenges to CM in low income populations may be opportunities
- Value of CM in low income populations:
  - Greater preventable disease burden
  - Advantageous model for overcoming health literacy problems and cultural divisions
  - Receptivity to new prevention messages not effectively delivered in past
  - Health care organizations without incentives to maintain high cost acute services

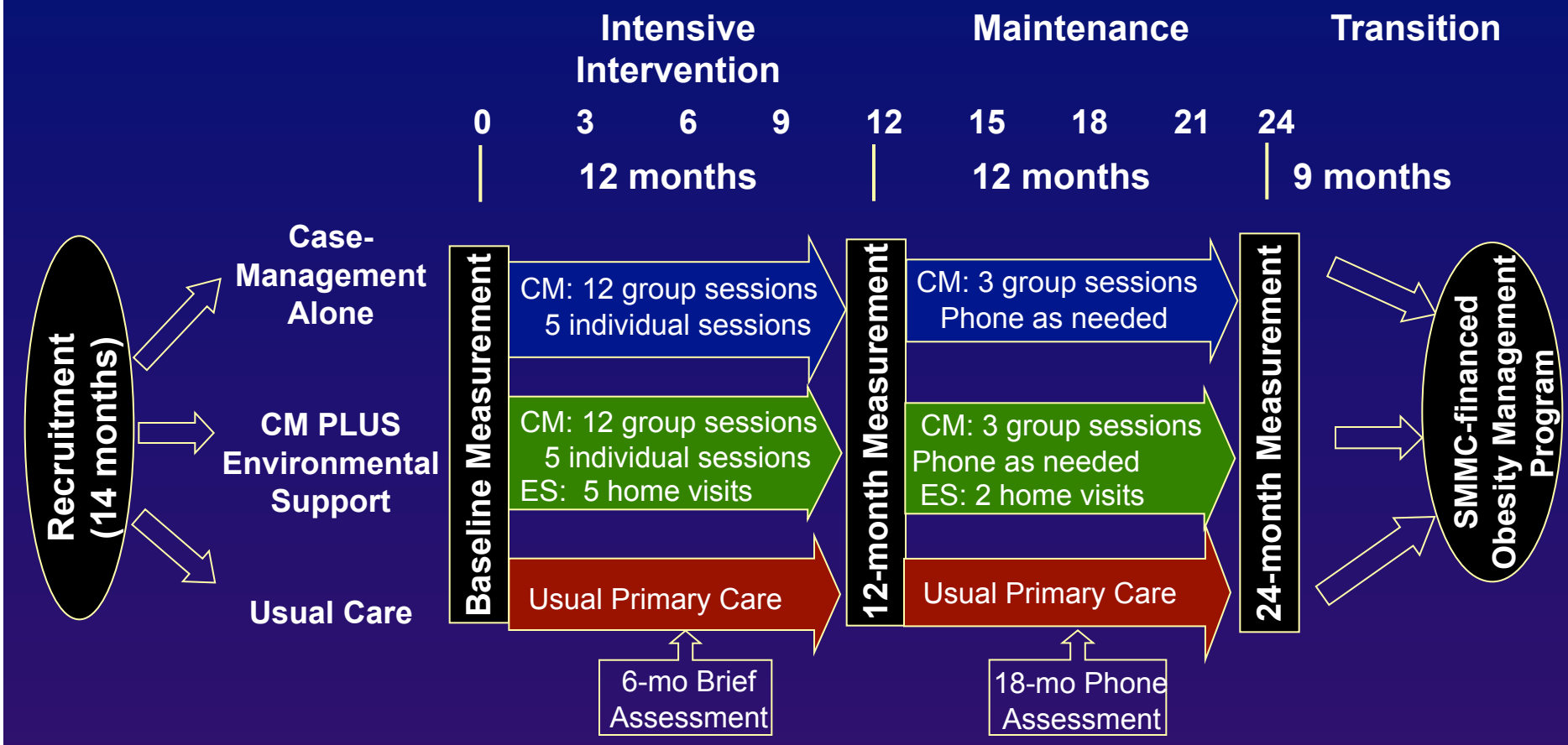
Change in Risk of Heart Attack



Vivamos Activos Objectives

- Use participatory methods to develop case management intervention for the Latino population of North Fair Oaks CA
- Integrate program into health care center
- Conduct RCT to evaluate effectiveness of two weight loss strategies vs. usual care
- Estimate intervention cost-effectiveness
- Transition to ongoing County program

Vivamos Activos Design



Case-Management

- Four one-on-one counseling sessions:
  - Barriers to weight loss
  - Getting started with diet and activity
- 15 group health education sessions:
  - Shopping, cooking, portion control, physical activity, behavior change strategies
  - “Virtual Walking Tour” of N. and S. America

Environmental Support

- 7 home visits to participants
  - Cooking issues – demo and quick inventory
  - Physical activity – walking in neighborhood
  - Negotiations with family members
- “Photo voice” exercise with one-time use cameras – document and set goals

Randomized Controlled Trials

- Experimental design as opposed to observational (cohort case-control)
- Researcher randomly assigns treatment
- Balances treatment arms with respect to measured and UN-MEASURED confounders

Inclusion/Exclusion Criteria

Inclusion:

- 18 years +
- BMI > 30 & <40
- 1 + obesity-related CHD risk factors

Exclusion:

- Unwillingness to attempt weight loss
- Significant other co-morbidities
- Pregnant/lactating
- Family member enrolled in study
- Does not speak Spanish
- Others to limit loss to follow-up

Design issues

- Randomization strategy
- Avoiding contamination of the control group
- Limiting loss to follow-up
- Strategies for intervention fidelity and adherence
- Internal vs. external validity
- Primary and secondary outcome measures
- Blinding

Statistical analysis and hypothesis testing

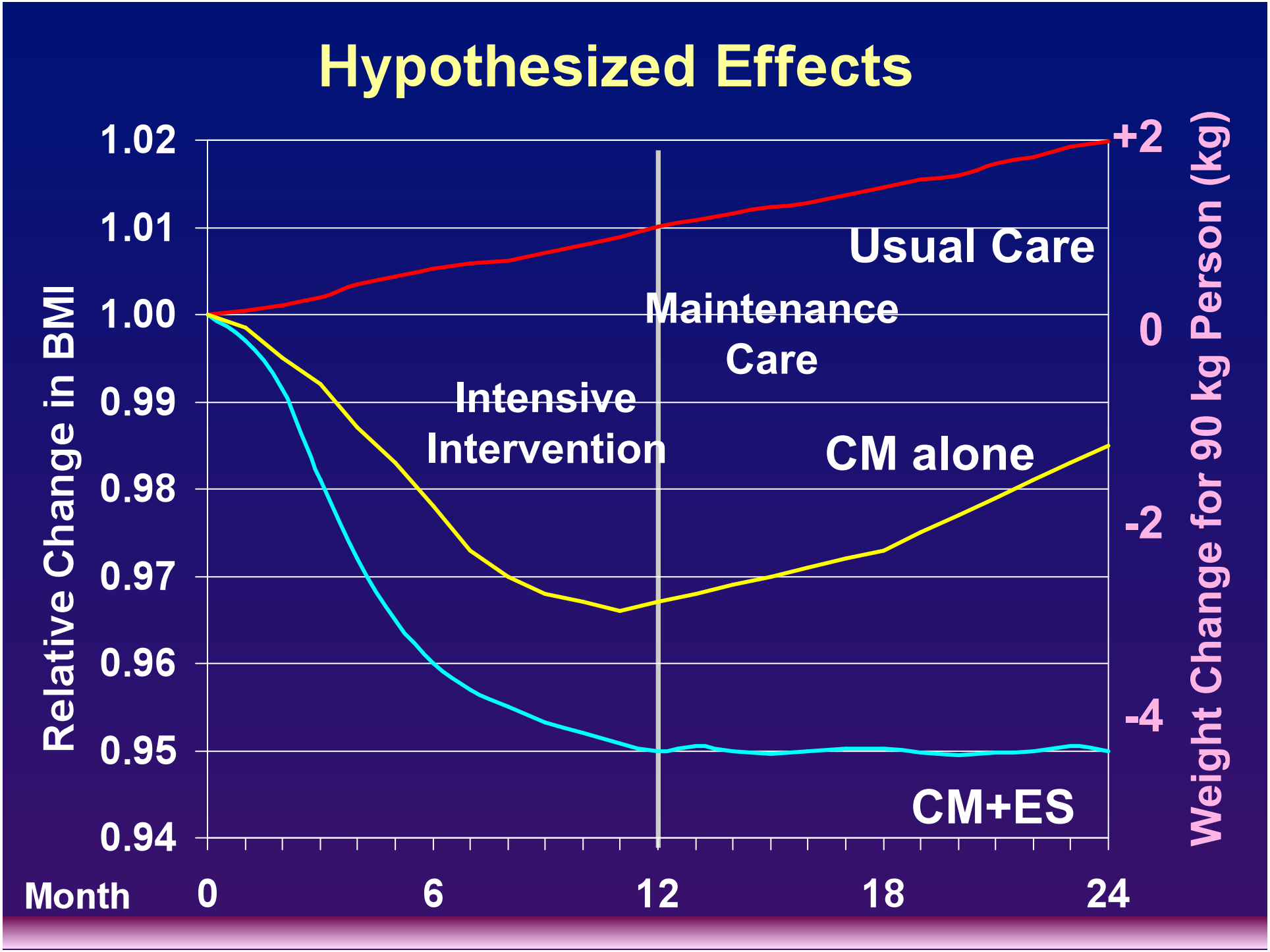
Primary Hypothesis

- Patients managed through the CM + ES intervention will show greater reductions in BMI over 24 months than those in CM.
  - Depends on subsidiary hypotheses that CM and CM + ES will have higher BMI reductions compared to usual care
- Random effects regression on an intention-to-treat basis using SAS PROC GLIMMIX

$$BMI_{iklm} = \mu + \beta_1 Int_i + \beta_2 B\text{-}BMI_{ikl} + \beta_3 T_m + \beta_4 (Int^*T)_{im} +$$
$$\beta_5 Sex_{ikl} + \beta_6 Eth_{ikl} + \beta_7 (Sex^*Eth)_{ikl} + \alpha_{(j)} + e_{iklm}$$

Secondary hypotheses

1. Patients in CM or CM +ES will experience reduced CHD risk through favorable changes in obesity-related risk factors relative to those in usual care
2. Patients in the CM + ES intervention will experience smaller increases in BMI from 12 months to 24 months than those in the CM
3. The change in BMI and other CHD risk factors attributable to the intervention arms will be cost-effective relative to usual primary care


Hypothesized Effects
1.02
1.01
1.00
0.99
0.98
0.97
0.96
0.95
0.94
Relative Change in BMI
+2
0
-2
-4
Weight Change for 90 kg Person (kg)
Usual Care
Maintenance Care
Intensive Intervention
CM alone
CM+ES
Month
0
6
12
18
24

Socio-demographic and Psychosocial Characteristics

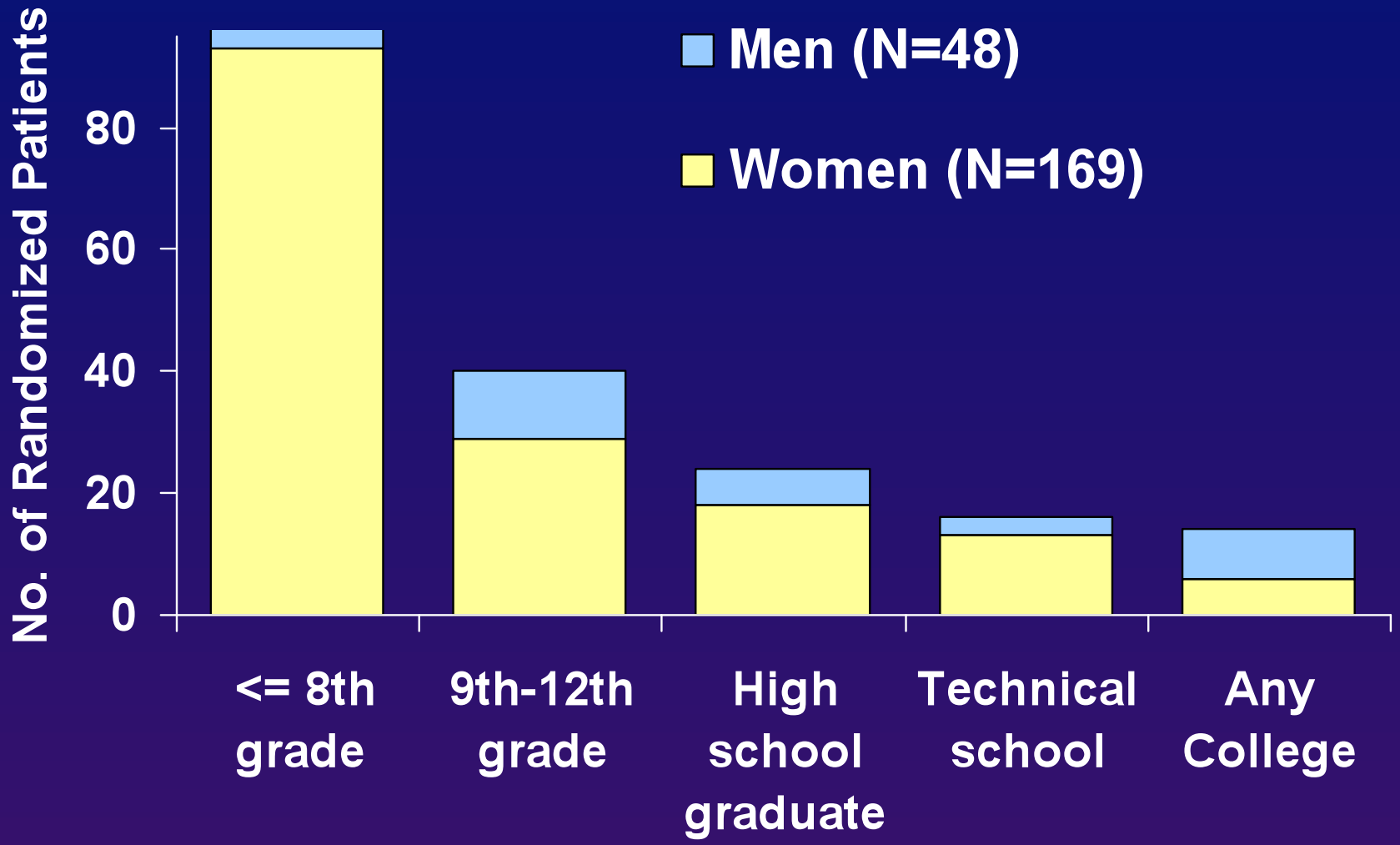
Variable	Male	Female	All
		Number (%)	
Sex	48 (100)	159 (100)	207 (100)
< high school education	31 (64.6)	122 (76.7)	153 (73.9)
Low food security	13 (27.1)	67 (42.1)	80 (38.7)
Very low food security	6 (12.5)	20 (12.6)	26 (12.6)
		Mean (SD)	
Age	46.0 (11.5)	47.5 (11.1)	47.1 (11.1)
Age when came to USA	28.6 (12.4)	31.8 (11.9)	31.1 (12.1)
CESD	7.5 (3.4)	9.4 (3.8)	9.0 (3.8)
Annual income ($)*	19.4 (13.3)	15.3 (9.2)	16.2 (10.4)
Food sec.**	1.4 (1.9)	1.9 (1.9)	1.7 (1.9)
Steps per day*	7.4 (3.6)	6.0 (2.9)	6.3 (3.1)
Calories per day*	2.0 (5.9)	1.9 (6.8)	1.9 (6.6)
Daily fruit and vegetable servings	6.0 (3.6)	6.4 (3.2)	6.3 (3.3)
% calories from carbohydrates	49.2 (6.9)	49.4 (8.4)	49.4 (8.1)
% calories from fat	35.6 (7.1)	36.9 (7.6)	36.6 (7.5)

*Expressed in thousands **Food security score interpretation: 0 high, 1 marginal, 2-4 low, 5-6 very low

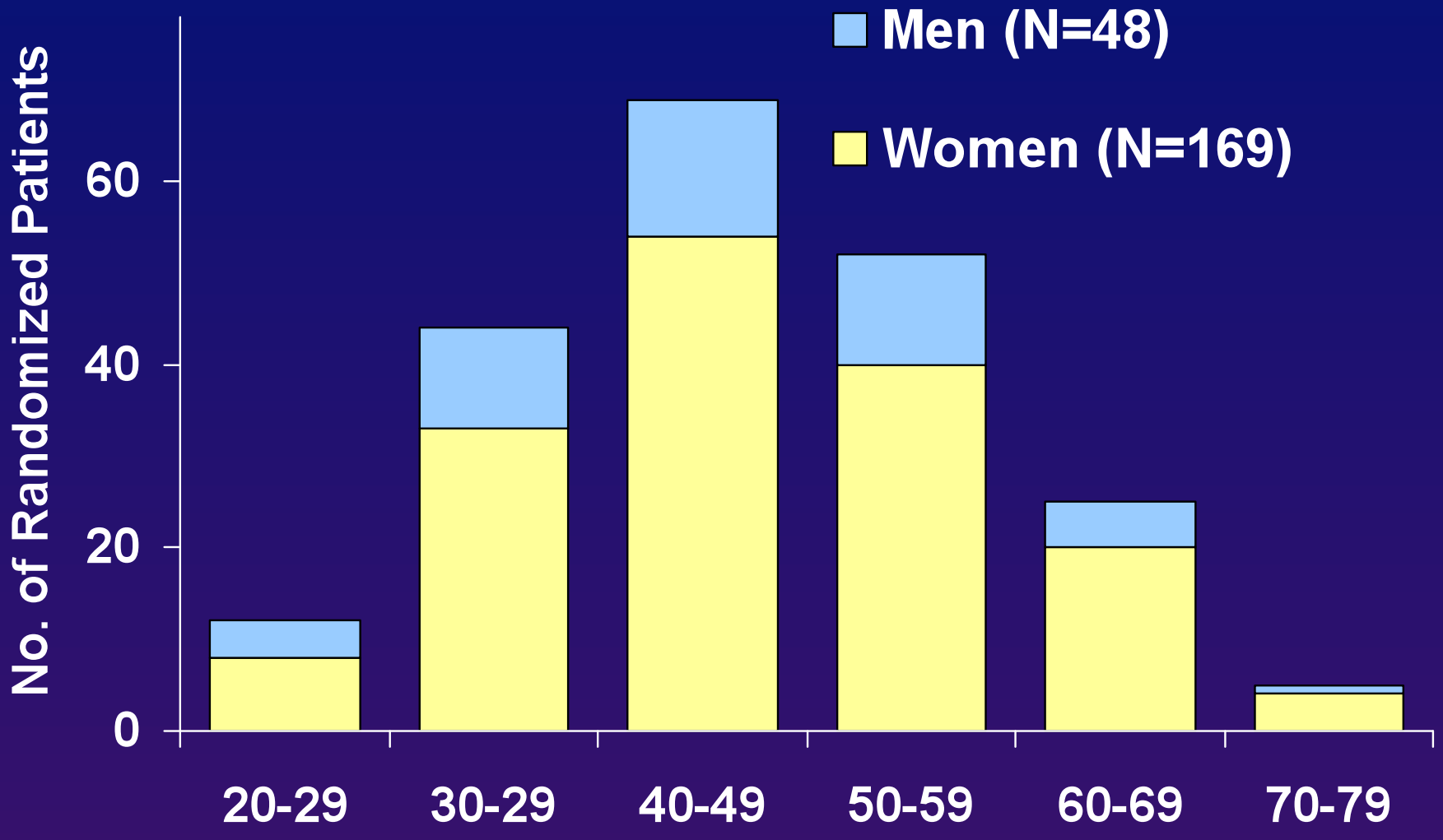
Baseline Characteristics

- 49% were depressed
- 41% low or very low food security
- 38% < 5,000 steps per day
- 41% < 5 fruits and vegetables per day

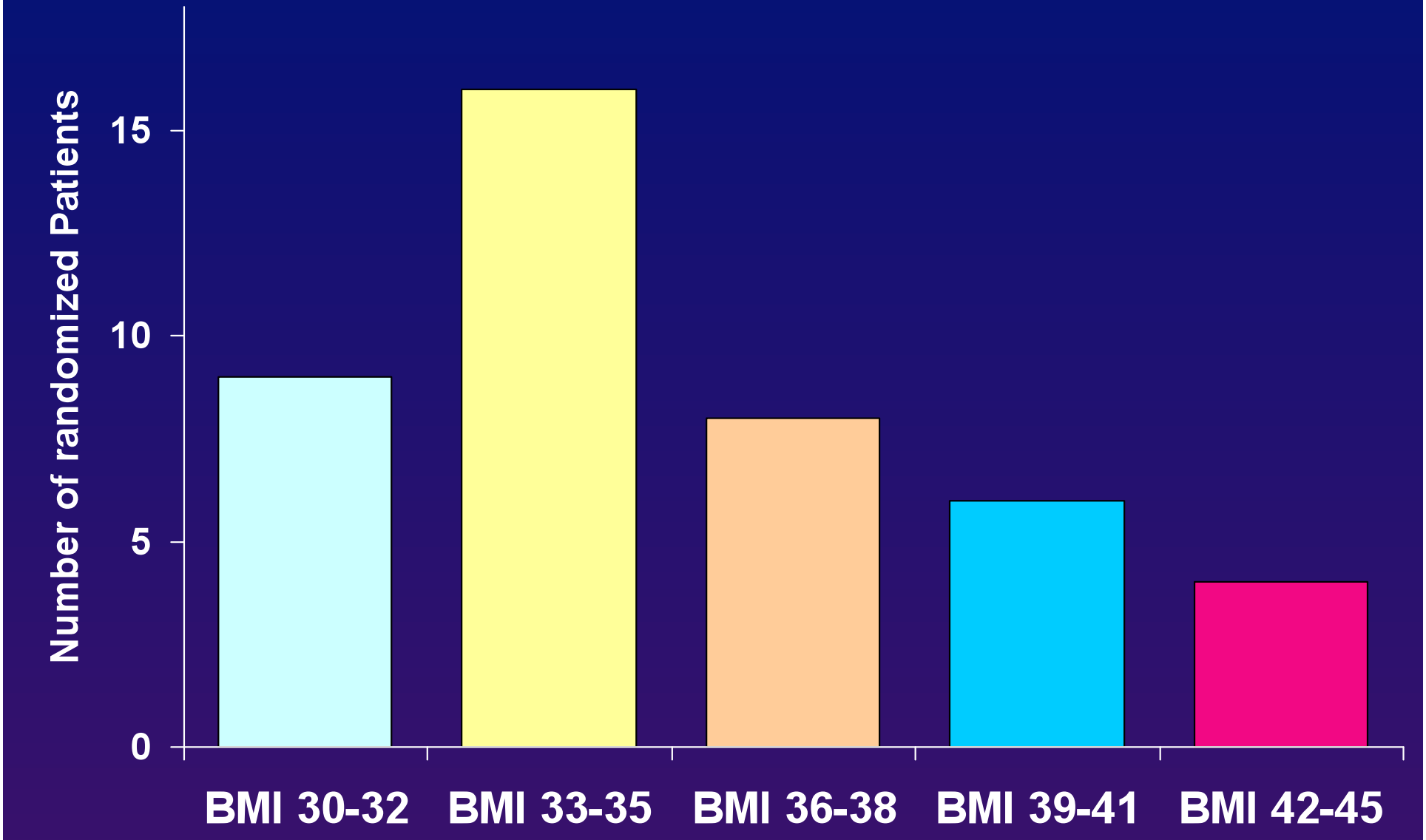
VA Baseline Results: Education



VA Baseline Results: Age



VA Baseline Results: BMI



Baseline Lab Values

Measure	CM+ ES (N=82)	CM Alone (N=84)	Usual Care (N=41)
BMI	35.5	36.0	34.9
Systolic BP	114.8	114.5	117.2
Dystolic BP	74.1	73.0	73.8
LDL-Chol	107.8	100.6	107.8
HDL-Chol	47.2	44.3	44.9
TRG	147.1	175.4	176.2
Total-Chol	181.6	178.5	188.0
Fasting Gluc	111.9	116.6	110.0
HbA1c	6.4	6.5	6.4
CRP	0.8	0.6	0.6

Associations between Physical Activity and Predictive Factors

Estimated difference in steps per day from 25th to 75th percentile: linear regression results*

Variable	Male			Female			All		
	Change	95% CI	P-value	Change	95% CI	P-value	Change	95% CI	P-value
CESD	-6.6	-21.9, 11.7	0.45	-8.1	-16.8, 1.6	0.10	**-11.6**	**-20.3, -1.9**	**0.02**
Education	**-27.9**	**-39.4, -14.2**	**<0.01**	2.6	-2.4, 7.8	0.31	-4.1	-13, 5.7	0.40
Income	1.9	-16.2, 23.8	0.68	4.3	-7.0, 16.9	0.46	6.8	-5.3, 20.4	0.24

*Estimated difference in steps per day from 25th percentile to 75th percentile presented as percent difference using log transformation of steps per day.

- CESD score of 6 vs. 12 associated with 692 (11.6%) fewer steps
- College education vs. less than 8th grade education associated with 2,222 (27.9%) few steps among males

Associations between Dietary Habits and Predictive Factors

Estimated difference in dietary characteristics from 25th to 75th percentile: linear regression results

Variable	Male			Female			All		
	Change	95% CI	P-value	Change	95% CI	P-value	Change	95% CI	P-value
Daily fruit and vegetable servings									
CESD	**-1.1**	**-2.1, -0.1**	**0.04**	-0.1	-0.8, 0.6	0.76	-0.3	-1.0, 0.4	0.39
Education	0.0	-1.1, 1.1	0.99	0.0	-0.3, 0.3	0.99	0.0	-0.6, 0.5	0.93
Food sec.	-0.3	-1.5, 0.8	0.56	-0.3	-0.9, 0.2	0.22	-0.3	-0.8, 0.2	0.21
Income	0.9	-0.5, 2.3	0.19	-0.2	-0.9, 0.4	0.51	0.1	-0.6, 0.9	0.75
Percent of daily calories from carbohydrates									
CESD	0.6	-1.8, 3.1	0.62	1.3	-0.2, 2.9	0.09	1.4	-0.1, 3.0	0.07
Education	**-2.3**	**-4.5, -0.2**	**0.04**	0.0	-1.0, 1.1	0.95	-0.6	-2.3, 1.0	0.47
Food sec.	0.0	-1.1, 1.1	1.00	-0.3	-1.3, 0.7	0.54	-0.2	-1.0, 0.6	0.58
Income	0.3	-1.8, 2.3	0.80	-1.1	-2.8, 0.6	0.19	-0.9	-2.5, 0.8	0.30
Percent calories from fat									
CESD	-1.9	-4.8, 0.9	0.18	-0.7	-2.2, 0.8	0.40	-0.9	-2.4, 0.7	0.30
Education	1.2	-1.4, 3.8	0.36	0.2	-0.7, 1.1	0.65	0.5	-0.9, 2.0	0.47
Food sec.	-0.2	-2.9, 2.5	0.87	-0.3	-1.9, 1.4	0.77	-0.2	-1.6, 1.2	0.81
Income	0.3	-2.1, 2.7	0.83	0.2	-1.4, 2.8	0.50	0.4	-1.1, 1.9	0.64

- Among males:
  - CESD score associated with fewer fruits and vegetables
  - More education associated with less energy from carbohydrates

Strategies in Community RCTs

- Recognize and confront valid community suspicion about experimentation
- Consultation and inclusion of community-based and governmental orgs as partners
- Integrate study within primary care setting
- All participants have primary care physician
- Incentives to participants for research aspects of program (not for intervention)
- “Delayed intervention” as model for control group, everybody receives benefits

Challenges of Community-Based Research

- Multiple logistical obstacles to success
- Less infrastructural resources available
- Including community organizations adds complexity & work to research development
- Difficult to overcome skepticism about the value of research & fear of experimentation
- Partner organizations will not have the same commitment to scientific rigor
- Turf wars over funding and people common

Charms of Community-Based Research

- Re-envision health from a community's perspective (barriers vs. societal divisions)
- Work with populations in great need
- Work with grateful organizations that value the resources and expertise you contribute
- Committed organizations that serve their populations and want info to be successful
- If it works here, it can work anywhere
- Contribute to reducing health disparities

Final Thought

If our work is not directly addressing health care disparities, it contributes to their perpetuation. Not only do we inadvertently reinforce existing social inequities, we often make them worse.