

Severe obesity: surgical and non-surgical management

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Obesity increases 1999-2016

Adult

Youth
(2-19y)



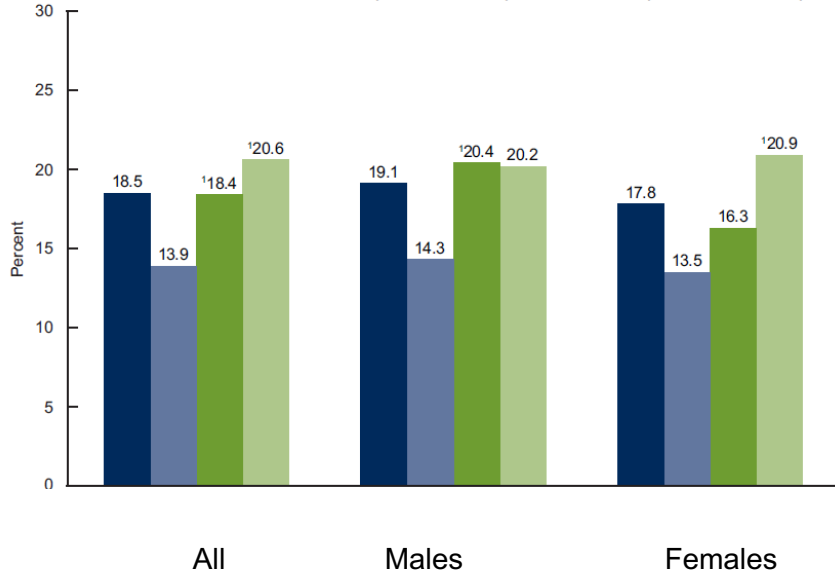
Ogden 2017. NCHS data brief no 288. Hyattsville, MD

Prevalence of obesity: NHANES 2015-2016

Children:

2-19 y (all) 2-5 y 6-11 y 12-19 y

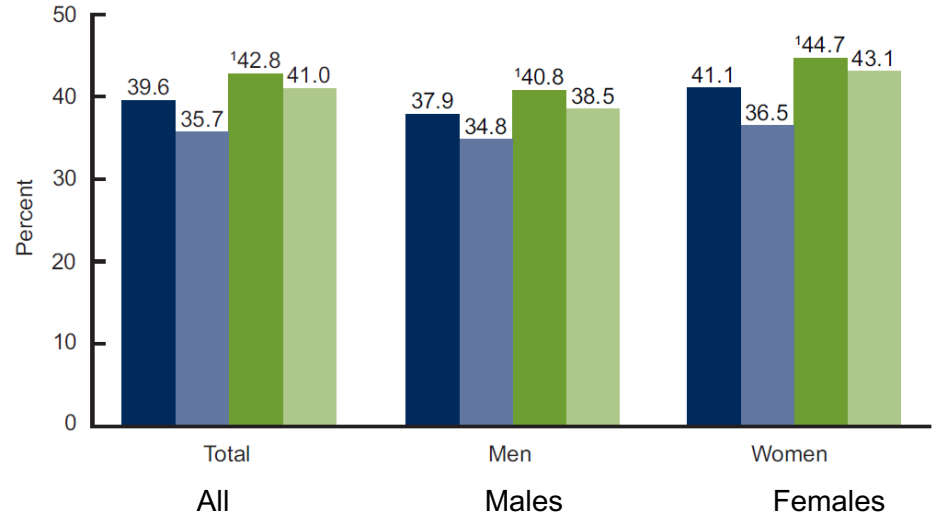
■ 2-19 years ■ 2-5 years ■ 6-11 years ■ 12-19 years



Adults:

≥ 20y (all) 20-39y 40-59y ≥ 60 y

■ 20 and over ■ 20-39 ■ 40-59 ■ 60 and over



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Measurement of obesity

Body mass index

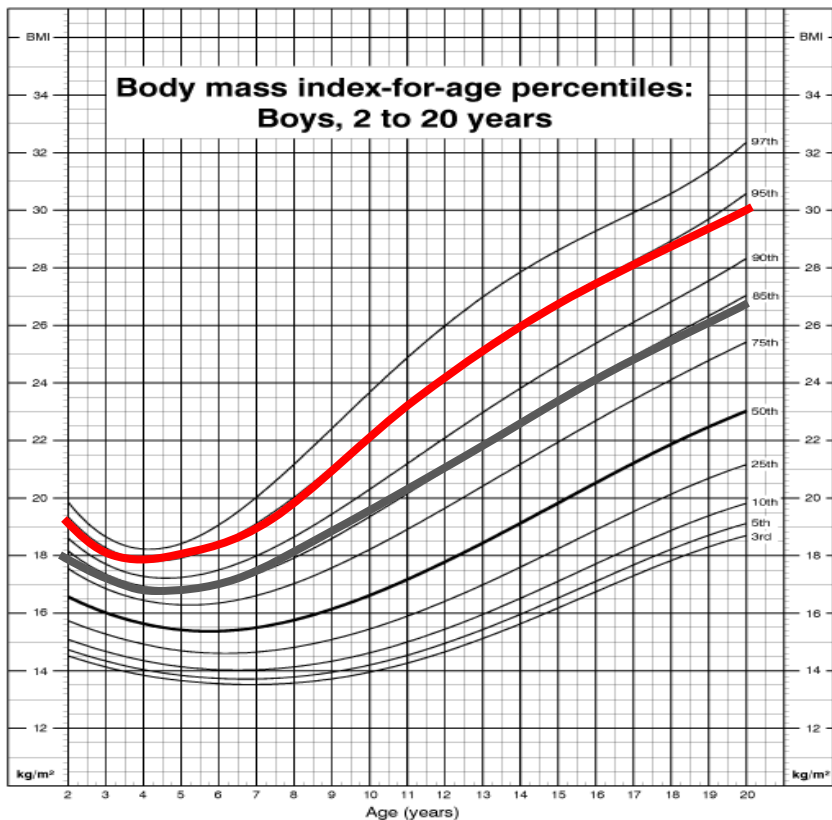
weight ÷ height ²

Validity in children

- Correlates with adiposity (correlation .82-.88) ¹
- Correlates with adult adiposity ²
- Correlates with cardiovascular risk factors ³, and long-term mortality ⁴

1. Field AE et al *Obes Res* 2003 11:1345
2. Freedman DS et al *Pediatrics* 2005; 115: 22
3. Freedman DS et al *J Pediatr* 2007;150:12
4. Must A et al *Int J Obes* 1999;

CDC Growth Charts: United States



SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).



Overweight:

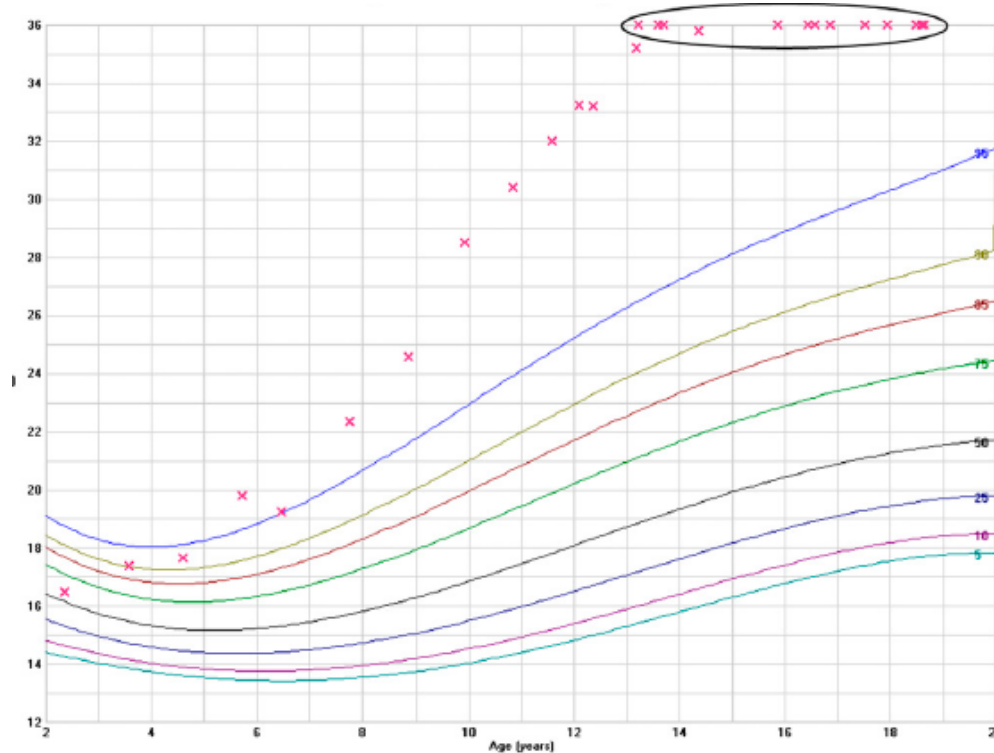
85th – 94th percentile

Obese:

≥ 95th percentile



The charts are not big enough...



Gulati AK et al.
Pediatrics 2012

Severe obesity is not new but it is more common

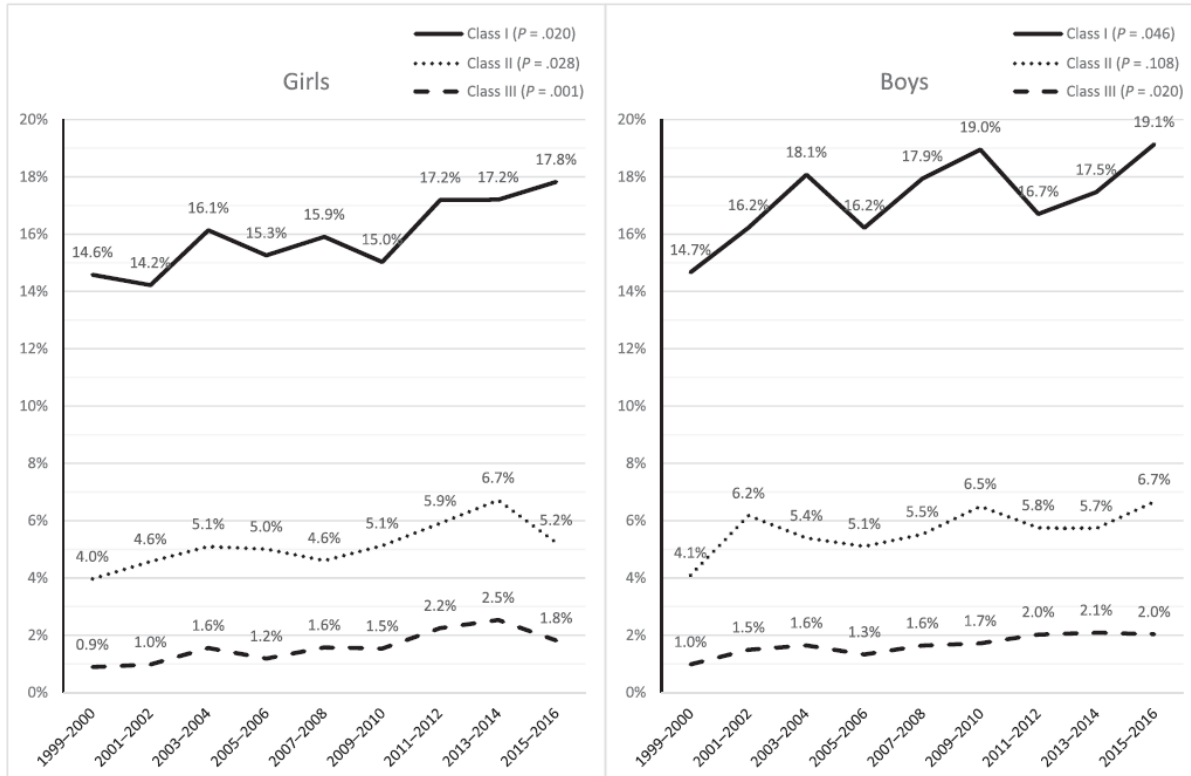


Artist

Juan Carreno de Miranda, 1680

Museo del Prado, Madrid

Significant increases for obesity, severe (class 2) obesity and very severe (class 3) obesity in children



Prevalence of severe obesity 2015-2016

Class 2 = 5.2% (F), 6.7% (M)

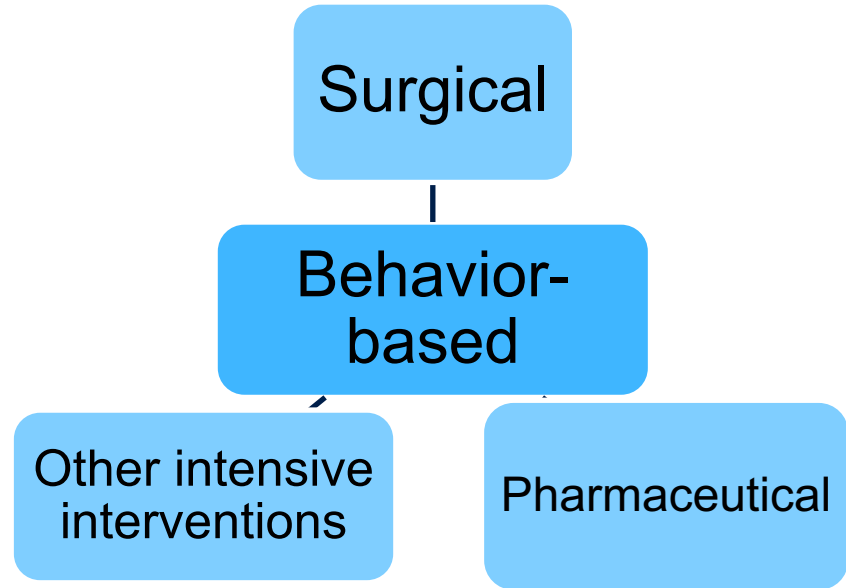
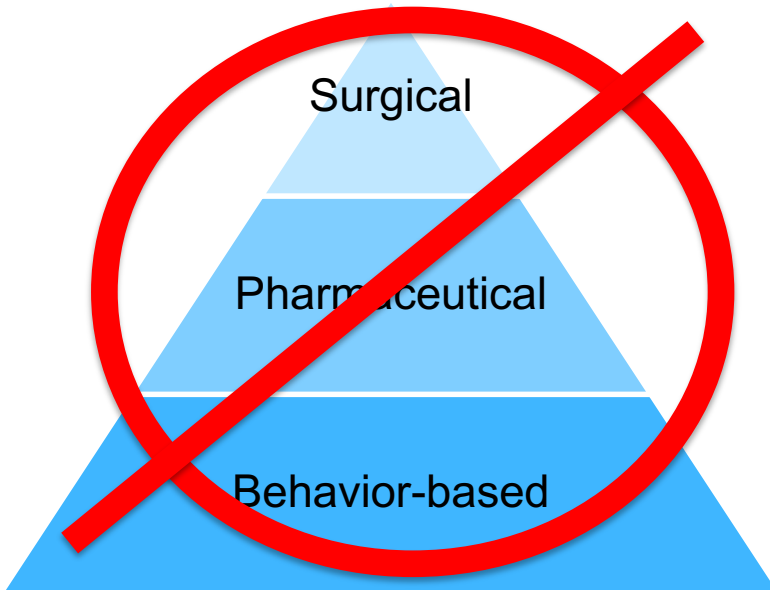
Class 3 = 1.8% (F), 2.0% (M)

Absolute numbers of severe obesity

	Total US Population 2010 Census	Severe Obesity Class ≥ 2 BMI ≥ 35 or equivalent	Severe Obesity Class 3 BMI ≥ 40 or equivalent
5-13 yo	36 million	1.9 million (5%)	720,000 (2%)
14-17 yo	17 million	850,000 (5%)	340,000 (2%)
≥ 18 yo	235 million		14 million (6%)

Non-surgical Intervention

Treatment strategies



Orlistat for adolescent obesity

54 week double-blind RCT

539 subjects: 12 to 16 years of age, BMI 36 ± 4 kg/m²

<u>BMI change</u>	<u>Treat</u>	<u>Control</u>	<u>Diff</u>
kg/m ² (mean)	- .55	+ 0.31	-0.86
Fecal urgency (%)	20.7	11.0	
Flatulence (%)	9.1	4.4	
Fecal incontinence (%)	8.8	0.6	

Chanoine et al. JAMA 2005;293:2873

Approved for adults: Lorcaserin (Belviq) and topiramate and phentermine (Qsymia)

Weight-Loss Efficacy of Lorcaserin (Belviq) and Phentermine plus Extended-Release Topiramate (Qsymia) at 1 Year.*		
Drug, Study, and Treatment	Mean Percentage Change in Body Weight (Mean Efficacy Criterion)	Proportion of Patients Losing $\geq 5\%$ of Body Weight (Categorical Efficacy Criterion)
Belviq[†]		
Studies 1 and 2 combined		
10 mg BID	-5.8	47
Placebo	-2.5	23
Study 3		
10 mg BID	-4.5	38
Placebo	-1.5	16
Qsymia[‡]		
Study 1		
15 mg/92 mg	-10.9	67
Placebo	-1.6	17
Study 2		
7.5 mg/46 mg	-7.8	62
15 mg/92 mg	-9.8	70
Placebo	-1.2	21

Lorcaserin: 5-HT_{2C} agonist
 •Concerns about breast and CNS tumors, abated

Phentermine: sympathomimetic
 Topiramate: anti-epileptic
 •Concerns about teratogenicity and elevate resting HR

Colman *NEJM* 2012;376:1577

Additional recently approved medications

Naltrexone/Bupropion: opioid receptor antagonist and dopamine & norepinephrine reuptake inhibitor with synergistic effect on weight

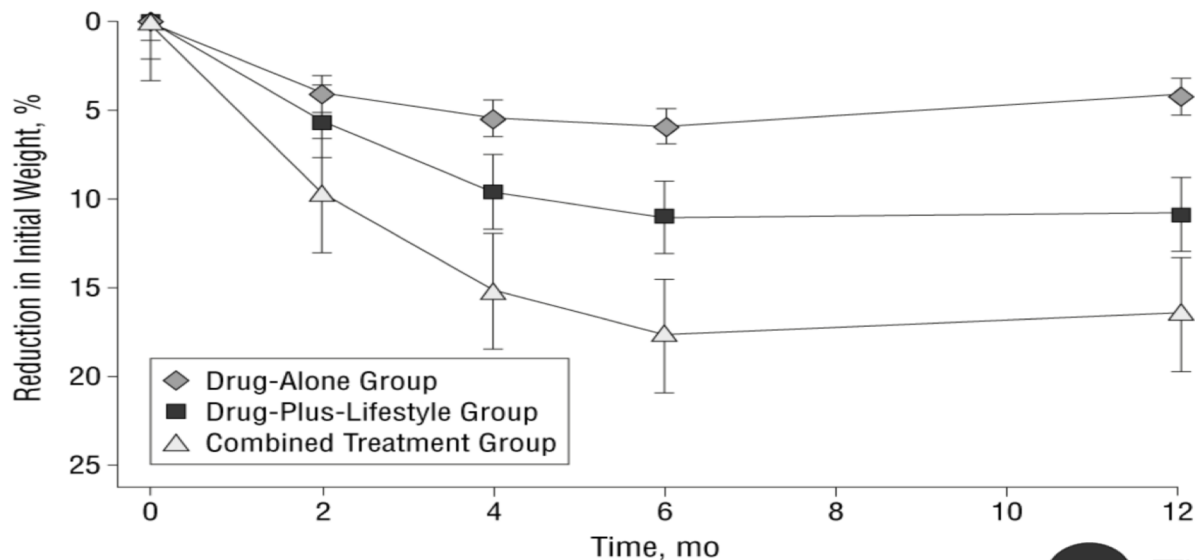
- Mean weight reduction = 6.7% (placebo = 2.4%)
- 5%-weight-↓ = 52%, 10%-weight-↓ = 28% (vs placebo 24% and 10%)
- Adverse events: nausea, constipation, headache. Suicidal ideation from bupropion in adolescents. Sleep disorders

Liraglutide: GLP-1 receptor agonist, which increases insulin secretion, decreases glucagon release, increases satiety, and slows gastric emptying.)

- Mean 6.5% reduction in weight after 1 year (vs placebo 1.6%)
- 5%-weight-↓ = 56%, 10%-weight-↓ = 28% (vs placebo 23% and 7%)
- Adverse events: gallbladder disorders

Combination of pharmacologic treatment and lifestyle modification is superior to drug alone

From: **Benefits of Lifestyle Modification in the Pharmacologic Treatment of Obesity: A Randomized Trial**



 The **JAMA** Network

Arch Intern Med. 2001;161(2):218-227. doi:10.1001/archinte.161.2.218

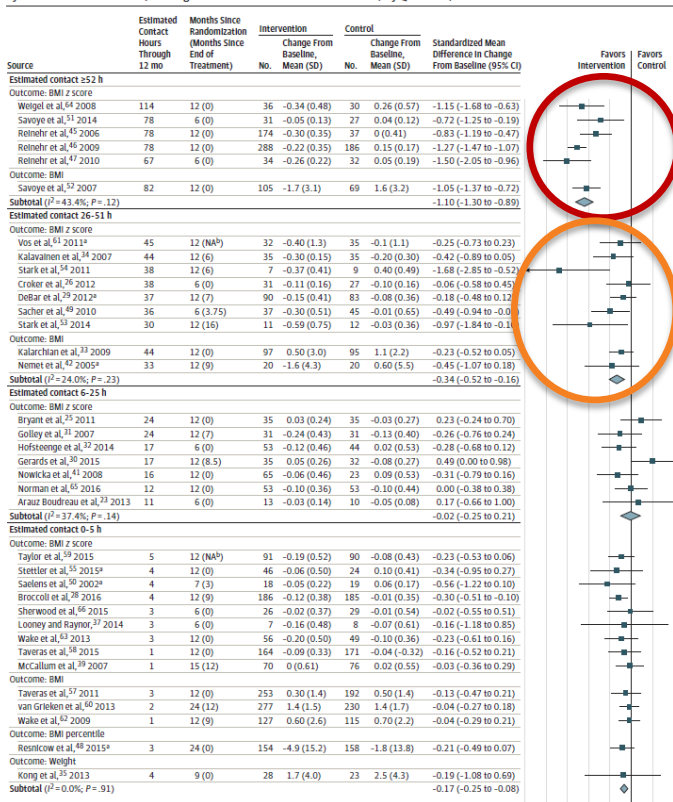
Characteristics of children presenting for weight management at 13 academic centers (n=6737)

Table 2. BMI Status at Baseline by Demographic Characteristic of Youth in POWER Study

Characteristic	Obesity ^b (n = 1674)	Severe obesity			
		Class 2 ^c (n = 2337)		Class 3 ^d (n = 2726)	
	%	%	vs. obesity OR ^e (95% CI)	%	vs. obesity OR ^e (95% CI)
Sex					
Male	20.8	33.0	1.3 (1.2, 1.5)	46.2	1.8 (1.5, 2.0)
Female	27.9	34.2	Ref	37.8	Ref
Age					
2–5	16.1	36.4	1.5 (1.1, 2.0)	47.4	2.0 (1.5, 2.6)
6–11	26.5	35.1	Ref	38.4	Ref
12–14	26.1	34.1	0.93 (0.8, 1.1)	39.8	1.0 (0.9, 1.2)
15–17	22.0	28.9	0.95 (0.8, 1.1)	49.0	1.5 (1.3, 1.8)

Evidence for comprehensive behavior-based programs for childhood obesity

Figure 4. Change in Weight (BMI z Score, BMI, Weight in Kilograms, or BMI Percentile) in Behavior-Based Weight Loss Intervention Trials, by Estimated Hours of Contact, Showing DerSimonian and Laird Pooled Estimates (Key Question 4)



36 randomized controlled studies, arranged by hours of contact.

“Comprehensive, intensive behavioral interventions (≥ 26 contact hours) in children and adolescent 6 years and older who have obesity can result in improvements in weight status for up to 12 months.”

USPSTF: Screening for obesity in children and adolescents. *JAMA* 2017. 317:2417

Bright Bodies: 12 month program for 8 to 16 year olds

Who: 209 ethnically diverse and low income
Mean BMI 35 kg/m²

What: Randomized, controlled trial
Nutrition education, behavior modification, physical activity
Twice weekly for 6 months, then twice monthly for 6 months

Outcome:

12 month	Intervention - 1.6 kg/m ²	Δ 3.3 kg/m ² , ~8 kg, ~18 lb
	Control + 1.7 kg/m ²	

24 months (43%)	Intervention - 0.9 kg/m ²
	Control + 1.9 kg/m ²

Savoye *JAMA* 2007;297:2697; Savoye : *Pediatr* 2011; 3: 402

Barriers to obesity intervention

REVIEW ARTICLE

Parental Underestimates of Child Weight:
A Meta-analysis

Lundahl 2014 *Pediatrics*

50.7% of parents under-estimate weight status of child with overweight or obesity

Low enrollment in available programs (pediatric)

- Reasons include lack of perceived health problem, time constraints, stigma

Aiff F 2012 PLoS ONE. Perez A. 2015. *Paediatr Child Health*

High attrition (pediatric)

- Often over 50%. Reasons include schedule, location, “not meeting needs”

Skelton *Obes Rev* 2011; Sallinen Gaffka *Child Obes* 2013 Dhaliwal *Child Obes* 2014

Healthcare payment systems as barrier

Medicaid: obesity consistently covered in 10 states (2008)

Figure 3. State Medicaid EPSDT program coverage of recommended childhood obesity treatment*

Coverage of nutritional and/or behavioral therapy for obesity	States
Likely to be covered	Alaska, Arizona, Indiana, Iowa, Kansas, Kentucky, Montana, New Mexico, Oklahoma, Washington
Not likely to be covered	Alabama, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Georgia, Idaho, Illinois, Indiana, Maine, Maryland, Massachusetts, Minnesota, Nebraska, Nevada, North Carolina, Pennsylvania, Virginia, West Virginia, Wyoming

Texas: "not likely to be covered"

*Based on an online document review of Medicaid benefit manuals and fee schedules as of July 1, 2008
 EPSDT = Early and Periodic Screening, Diagnosis, and Testing

Commercial: 35 states allowed exclusion of obesity treatment from benefit plan

Figure 4. State laws regarding private insurance coverage of obesity treatment and underwriting based on obesity^{ab}

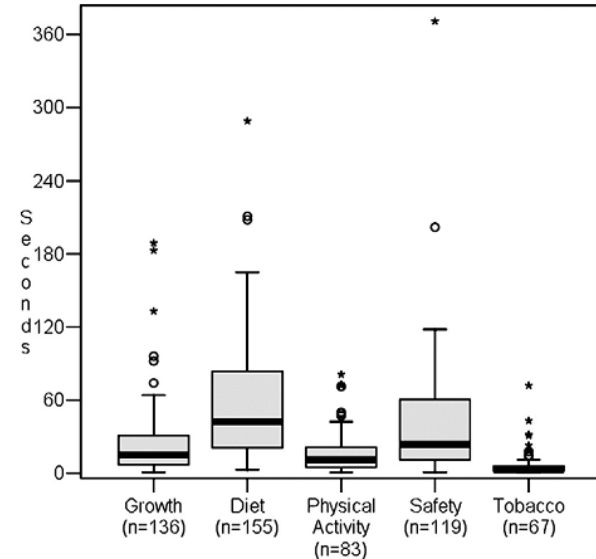
Medical underwriting or exclusions based on obesity or health status as an independent risk factor		
Type of state health insurance market restrictions	Statute expressly allows for rate adjustments or exclusions	Statute expressly prohibits adjustments in rates or exclusions
	Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Idaho, Illinois, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, North Carolina, North Dakota, Ohio, Oklahoma, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia,	Connecticut, Maine, Maryland, Massachusetts, New Jersey, New York, Oregon, Vermont, Washington
		Maine, Massachusetts, New Jersey, New York, Vermont
		Maine, Massachusetts, New Jersey, New York, Oregon, Vermont, Washington

Texas: "state expressly allows for rate adjustments and exclusions"

Time constraints among primary care providers

Time spent on health supervision topics in 163 visits of children 2 – 10 y

- **Diet counseling** 42 seconds (interquartile [IQ] 21-85)
- **Growth** 15 seconds (IQ 7-31)
- **Physical activity** 12 seconds (IQ 5-22)



Martin. *J Pediatr* 2008;153:706

Medicare Obesity Benefit, starting 2011

“Intensive” behavior therapy when BMI ≥ 30 kg/m²:

- Month 1: visits weekly
- Months 2-6: visits every 2 weeks
- Months 7-12: monthly visit *if 3 kg weight loss at 6 months*

Visits are 15 minutes, provided by primary care provider

Low use:

50,000 seniors participated in 2013, which represents 0.38% (1 in 260) seniors with obesity.

Kaiser Health News, 2015

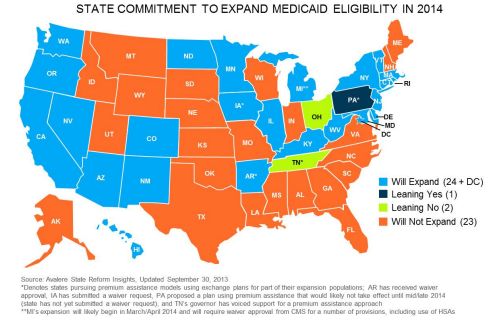
Affordable Care Act policies, Medicaid, and Obesity

ACA starting Jan 2014

1. Healthcare exchanges and states with Medicaid expansion must provide USPSTF grade A and B
2. State Innovations Models are established

Report to Congress on Preventive Services and Obesity-Related Services Available to Medicaid Enrollees

Kathleen Sebelius 2014





State Innovations Models: Round 2

2015: Round 2 models must include a statewide plan for population health of the state, focusing at minimum on diabetes, tobacco and obesity.

To achieve this goal, models need to integrate clinical services, public health programs, and community-based infrastructure

JA Auerbach et al. Institute of Medicine. [Nam.edu/wp-content/uploads/2015/06/SIMs Round2](http://nam.edu/wp-content/uploads/2015/06/SIMs_Round2)

Future of CMMI?

APR 09 | MORE ON POLICY AND LEGISLATION

HHS Secretary Alex Azar appoints Adam Boehler as director of CMMI

Former Landmark Health CEO will likely follow through on Seema Verma's initiative to take the innovation center in a new direction.

Summary

1. Behavior-based programs alone are inadequate for those with severe obesity
 - However, structured lifestyle modification is always part of rigorous surgical and pharmaceutical programs
 - Yet significant system barriers prevent broad implementation
2. Pharmaceutical options have improved
 - Evaluating use in children should be a priority
3. Much work needed:
 - Earlier/younger intervention
 - Novel, safe interventions to fill efficacy gap between non-surgical and surgical