Treatment of Severe Obesity. What tools are available?

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Duke Healthy Lifestyles Program

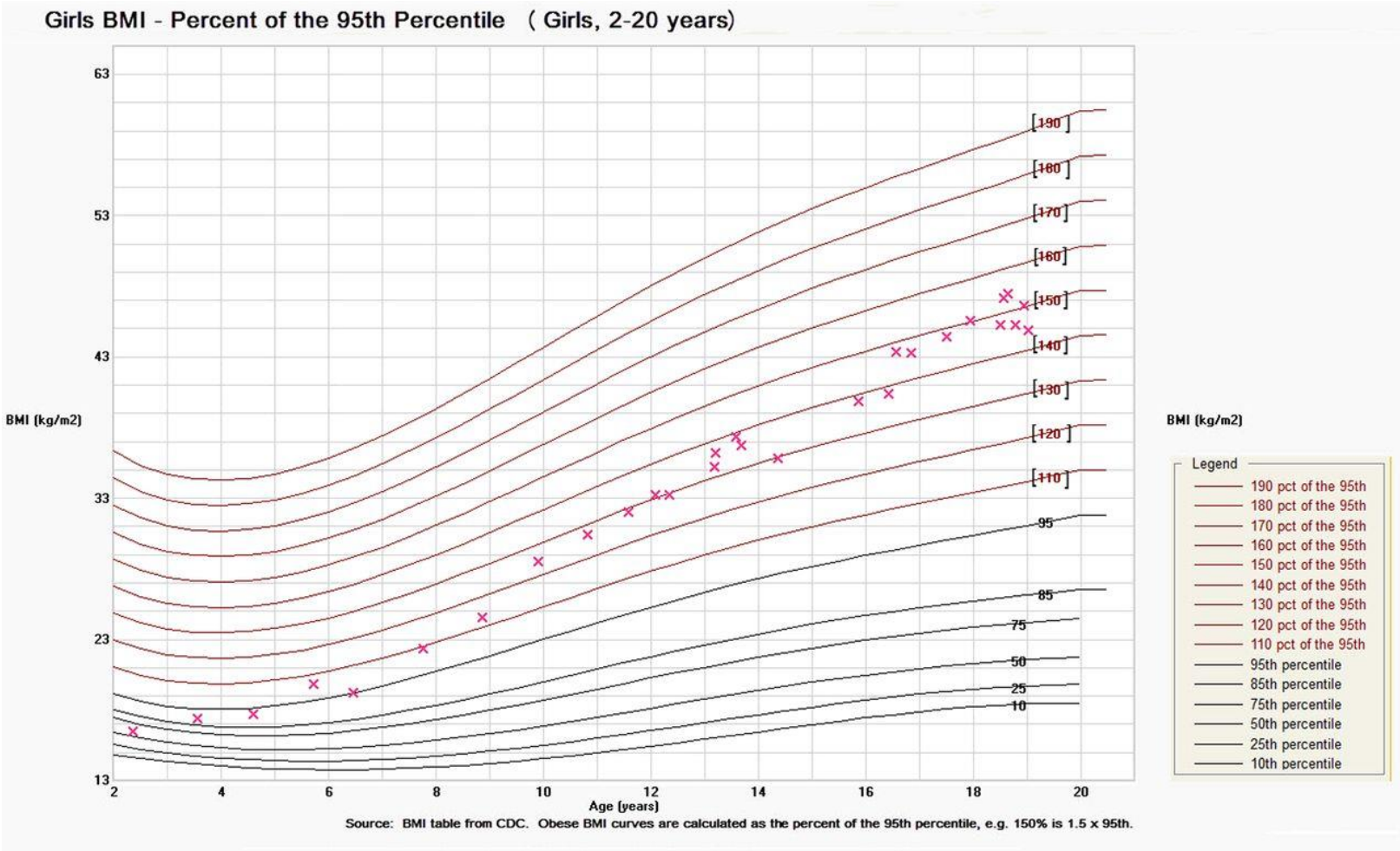
Objectives and Overview

- To describe the current epidemiologic prevalence of child and adolescent obesity and severe obesity in the US
- Behavioral/clinical approaches – tertiary care
- Innovations in Behavioral Treatment: Community partnerships, use of technology
- Diets
- Medications
- Surgery
- Devices
- Other considerations/Conclusions

Definition of Severe Pediatric Obesity

- BMI $\geq$ 120% of 95%ile for age and sex, OR
- BMI $\geq$ 35
- This accounts for all children and adolescents in Class II or III category of obesity.

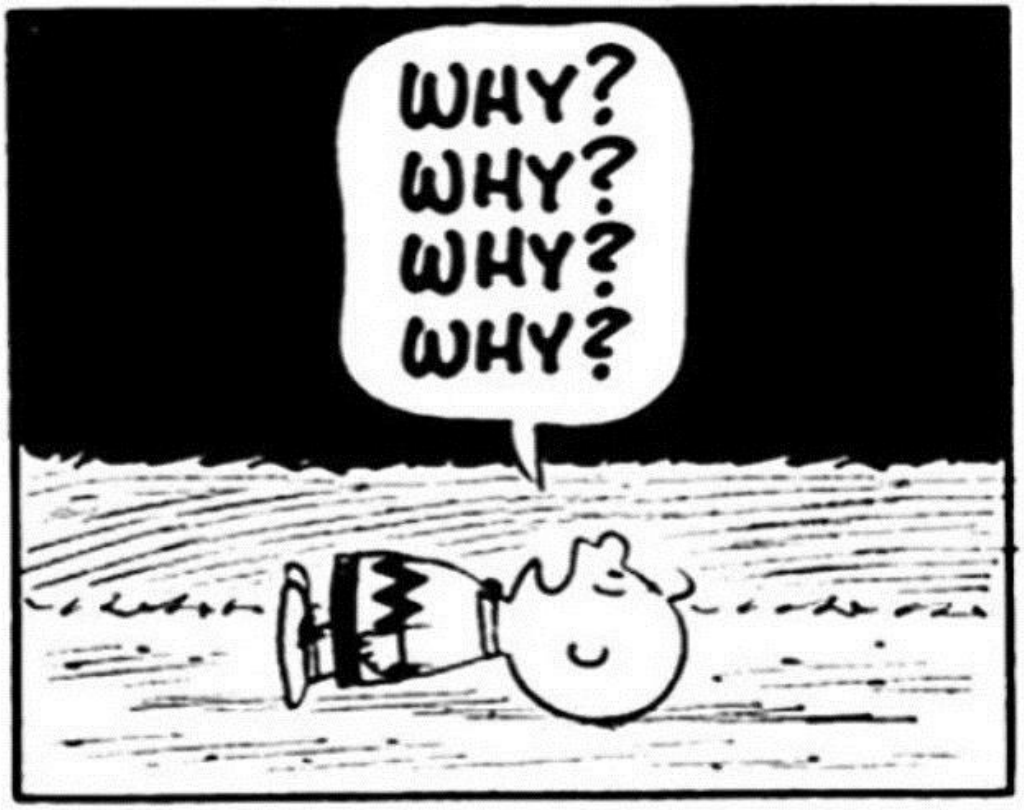
Defining Obesity/Severe Obesity in Children



Gulati A K et al. Pediatrics 2012;130:1136-1140

PEDIATRICS®

Why is severe obesity different?



Consequences

Now

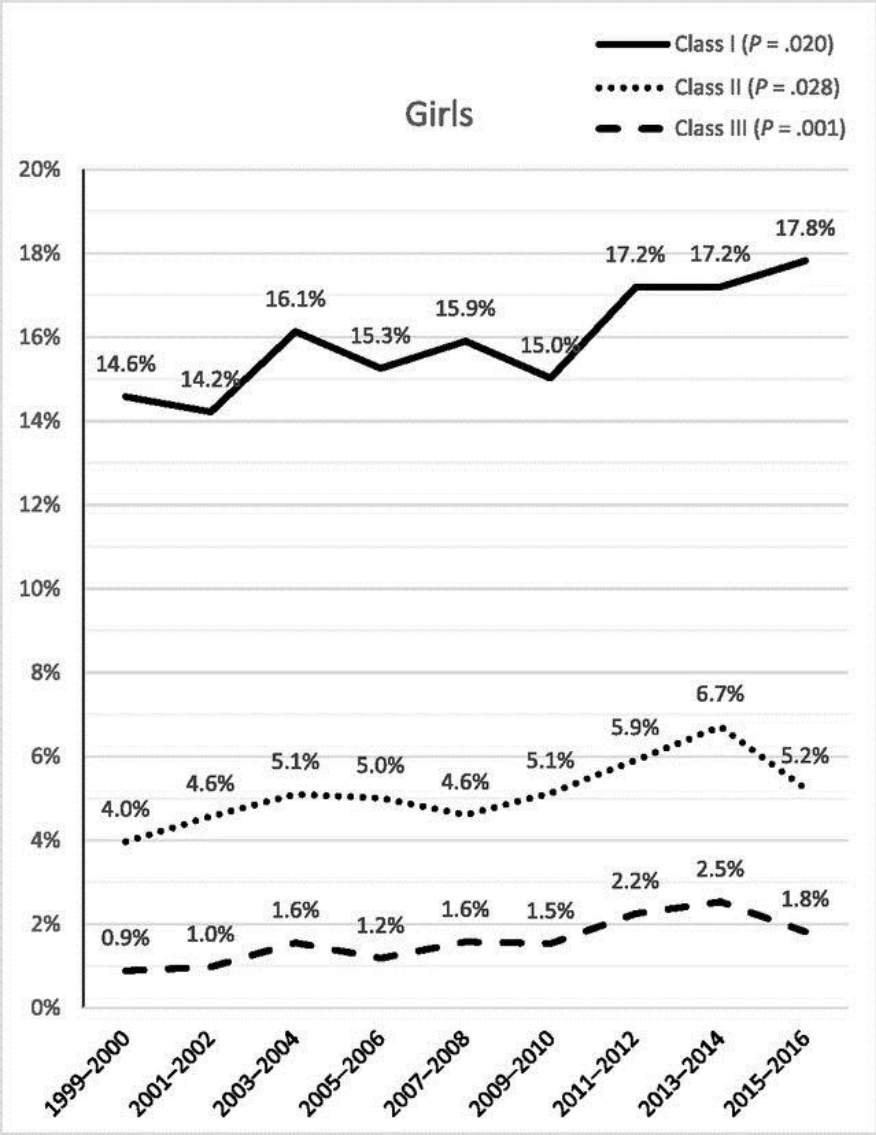
- Mental health
- Teasing/bullying
- Low Quality of Life
- Asthma
- Obstructive sleep apnea
- Orthopedic problems
- Adverse cardiovascular and metabolic conditions
  - High blood pressure
  - Abnormal lipids
  - Insulin resistance

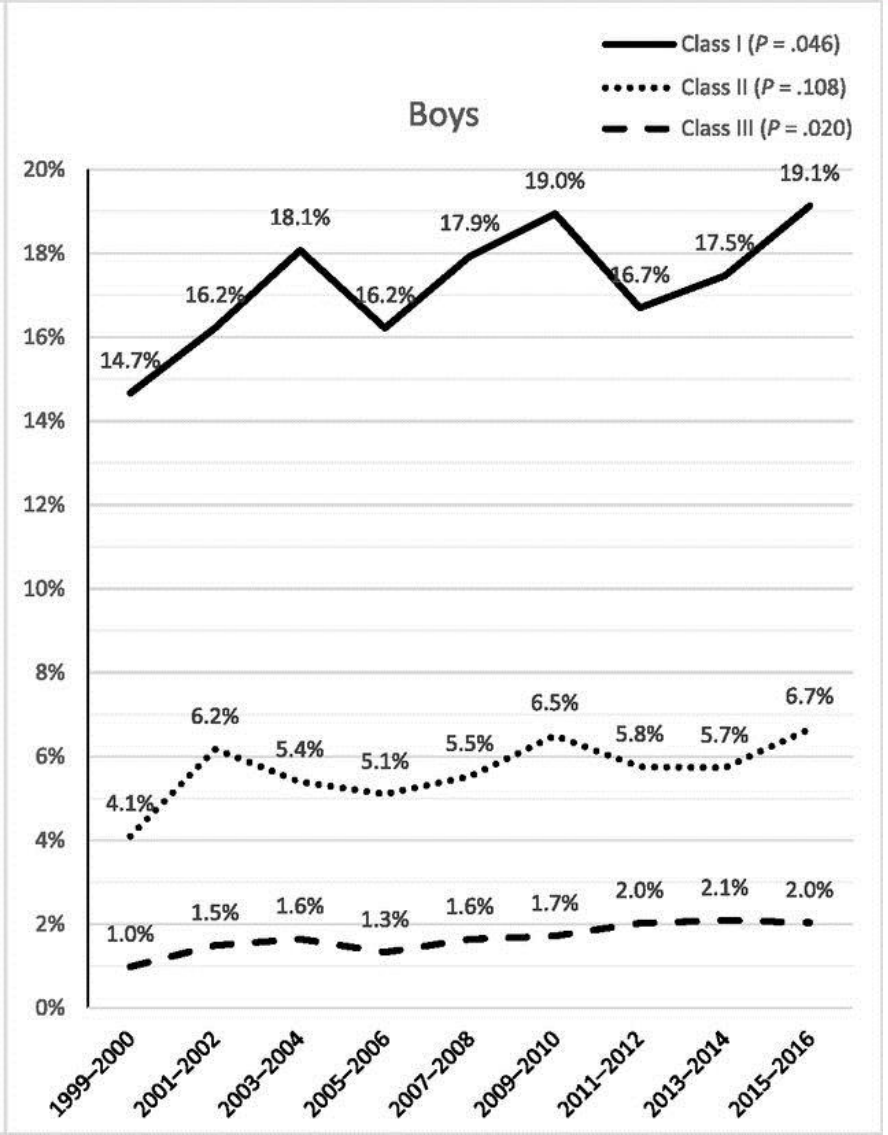
Later

- Continued obesity
- Type 2 Diabetes
- Adverse cardiovascular outcomes
  - Hypertension
  - Coronary artery disease
  - MI
  - Stroke
- Early mortality

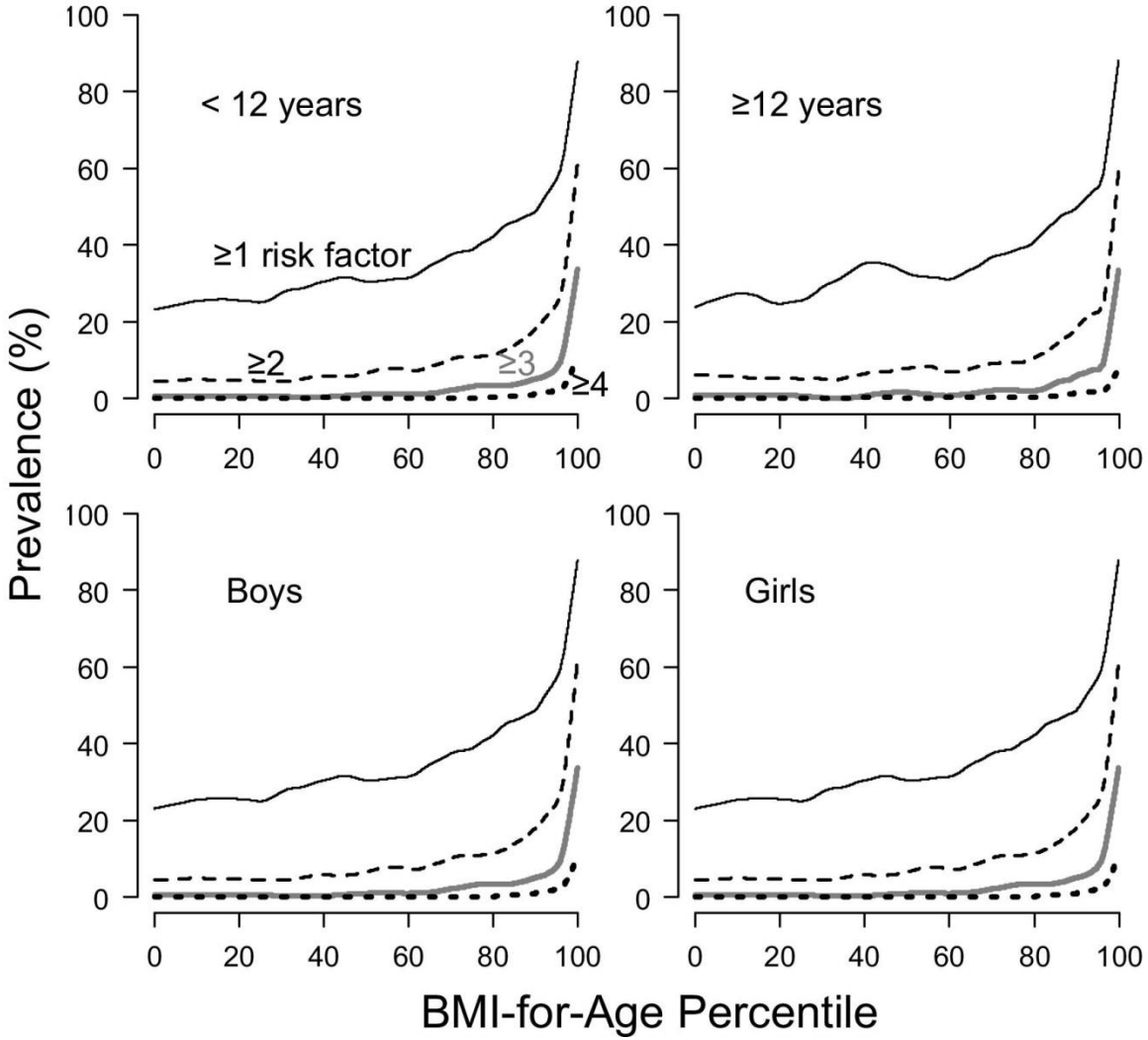
Skinner et al. New England Journal of Medicine, 2017

National Health and Nutrition Examination Survey, 1999-2016



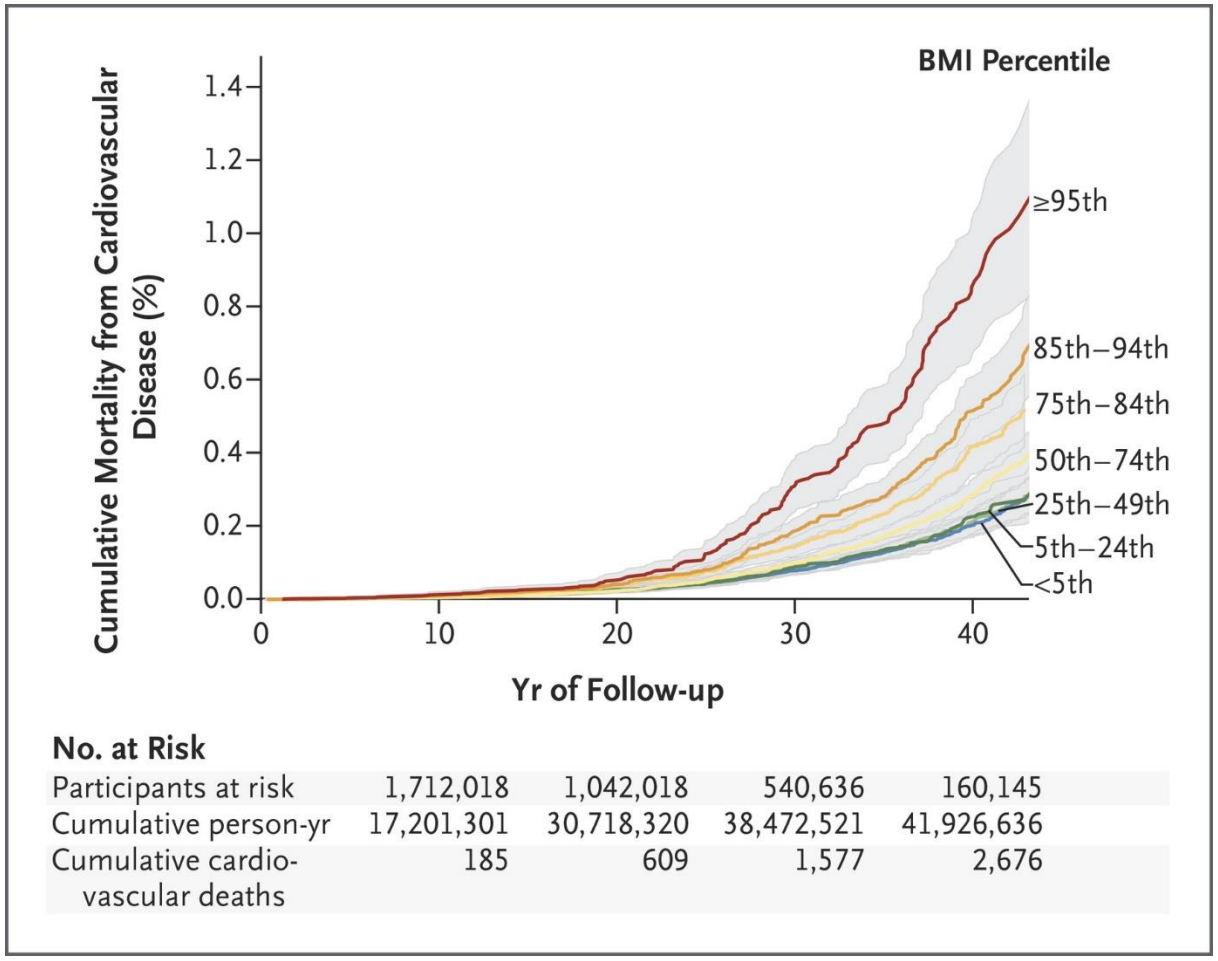


Skinner, Skelton, Perrin, Armstrong, "Prevalence of Obesity and Severe Obesity among US Children and Adolescents, 1999-2016. Pediatrics., 2018



Cardiovascular Risk Factors and Excess Adiposity Among Overweight Children and Adolescents: The Bogalusa Heart Study
Freedman, David S. et al.
The Journal of Pediatrics , Volume 150 , Issue 1 , 12 - 17.e2

Increase risk of mortality



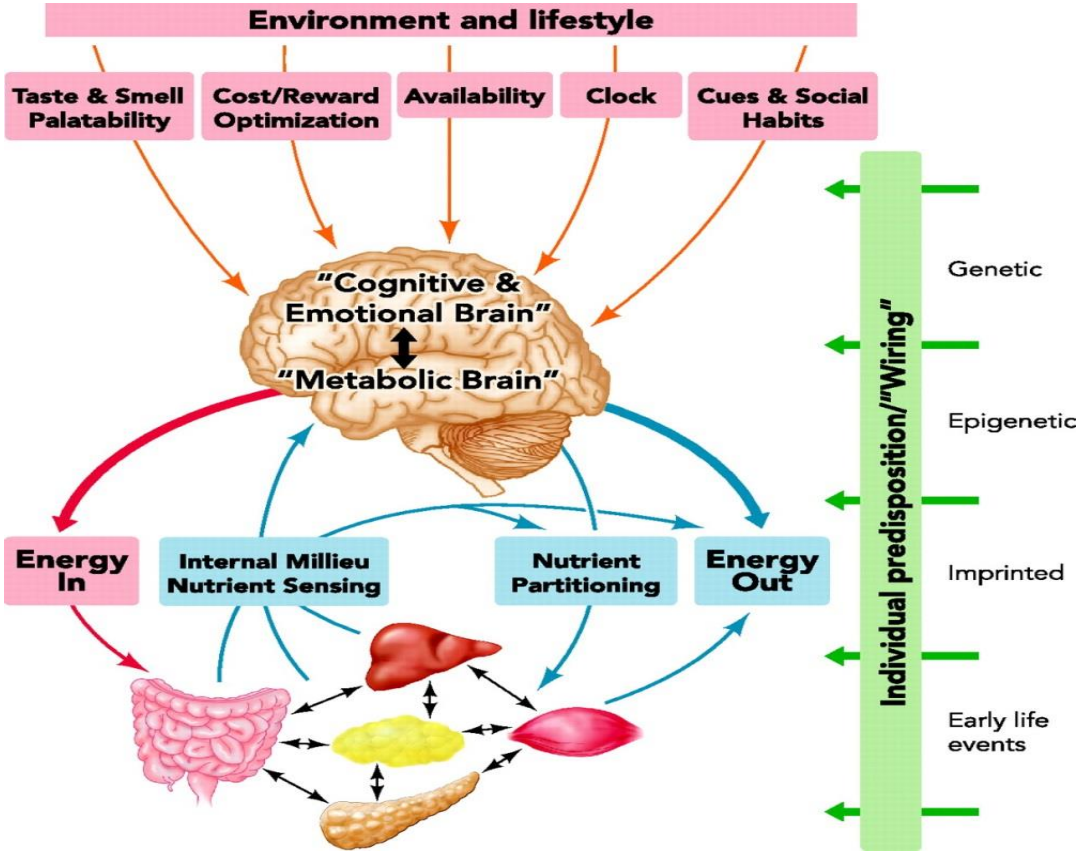
No. at Risk

Participants at risk	1,712,018	1,042,018	540,636	160,145
Cumulative person-yr	17,201,301	30,718,320	38,472,521	41,926,636
Cumulative cardio-vascular deaths	185	609	1,577	2,676

Why are we still struggling with this epidemic?

Obesity and Weight Bias

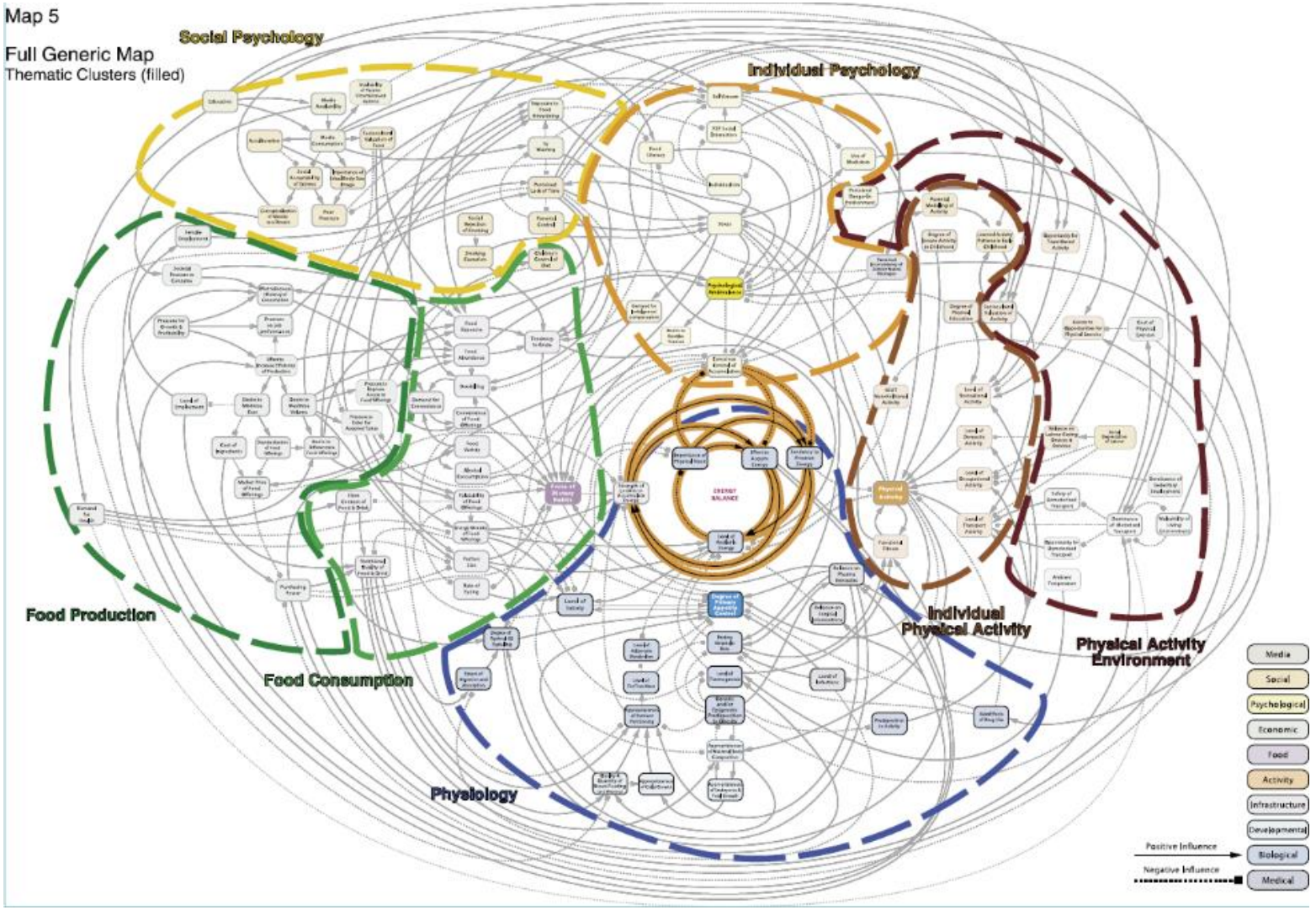
- Continued misconception:
  - Food intake – Energy expenditure = Net weight gain



Obesity and Weight Bias

- **Weight Bias**
  - June 2013 AMA recognized obesity as disease in adults.
- Whereas, The suggestion that obesity is not a disease but rather a consequence of a chosen lifestyle exemplified by overeating and/or inactivity is equivalent to suggesting that lung cancer is not a disease because it was brought about by individual choice to smoke cigarettes; (quote from the resolution).
- Negative imaging in news media.

Complexity of Obesity



Obesity as a Chronic Disease

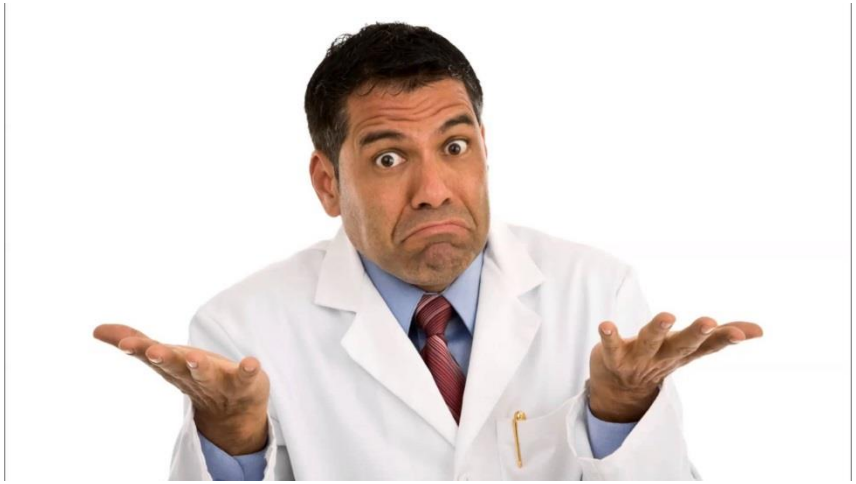
- Children and teens who struggle with severe obesity will likely always struggle with weight.
- Ups and downs over the course of a lifetime.
- All about "managing" the disease to reduce long term health risk.
- Multiple interventions over course of lifetime will likely be needed.

Clinical Case: "Anna"

- Anna is a 9-year old Hispanic female with severe obesity, 135 percent of the 95th percentile (Class 2).
  - ❑ TG = 170, LDL 120, HDL 30; ALT 50, HbA1c 5.7
  - ❑ Getting teased at school, mom does not speak English and cannot talk with teacher
- Lives at home with her mother and 2 brothers. Mom works 3 jobs, dad lives in Mexico, kids attend public school.

Behavioral Interventions

- Multiple recommendations based on >20 years of clinical trial data
  - American Academy of Pediatrics (2007)
  - National Heart, Lung, Blood Institute (2012)
  - United States Preventative Services Task Force (2017)



Population	**Children and adolescents 6 y and older**
Recommendation	**Screen for obesity; offer or refer children and adolescents with obesity to comprehensive, intensive behavioral interventions to promote improvements in weight status.** **Grade: B**

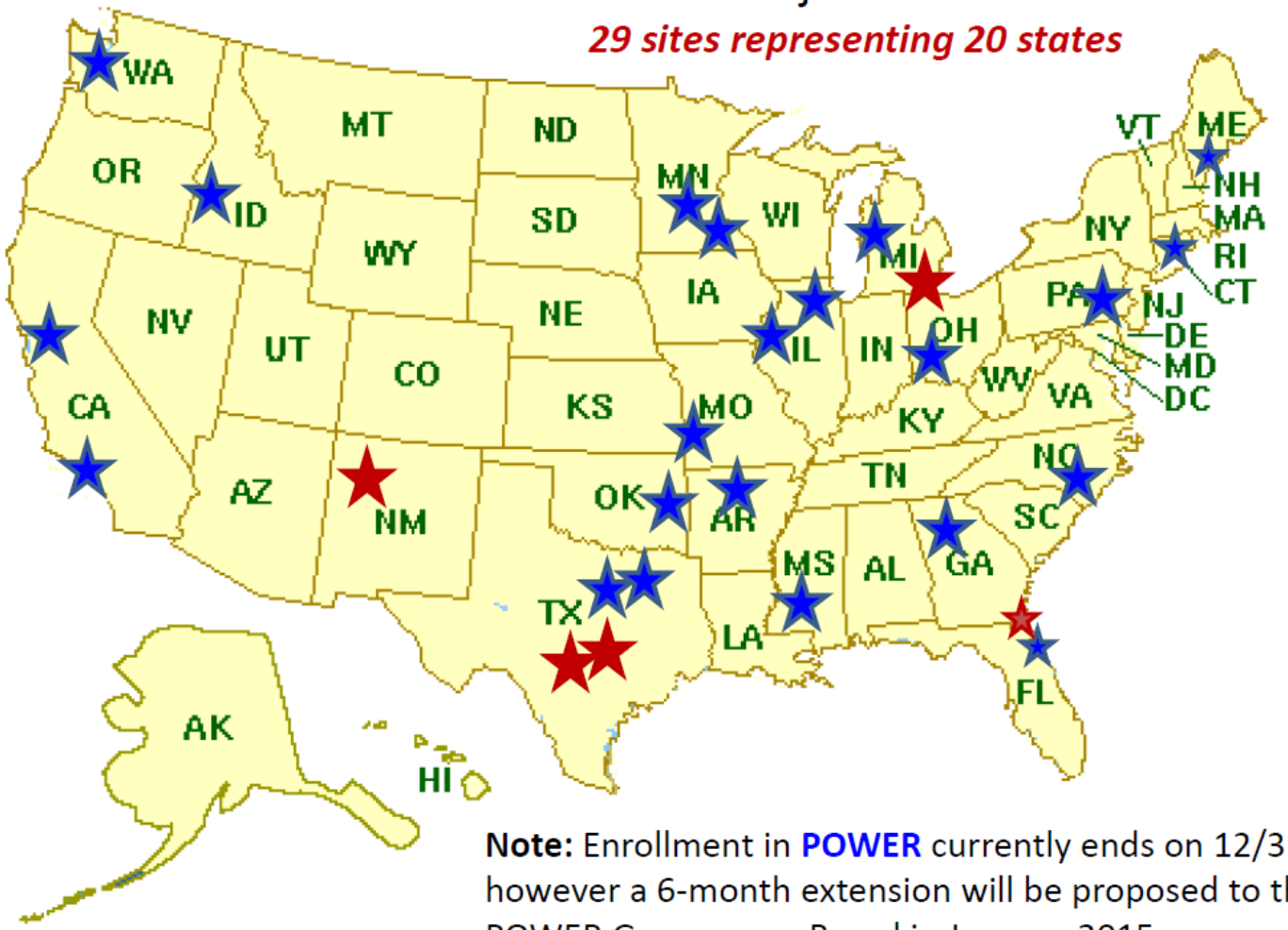
Risk Assessment	All children and adolescents are at risk for obesity and should be screened; specific risk factors include parental obesity, poor nutrition, low levels of physical activity, inadequate sleep, sedentary behaviors, and low family income.
Screening Tests	BMI measurement, using height and weight, is the recommended screening test for obesity. Obesity is defined as an age- and sex-specific BMI in the 95th percentile or greater.
Interventions	Comprehensive, intensive behavioral interventions of ≥26 contact hours resulted in weight loss. Effective interventions consisted of multiple components, including: sessions targeting both the parent and child (separately, together, or both); offering individual sessions (both family and group); providing information about healthy eating, safe exercising, and reading food labels; encouraging the use of stimulus control (eg, limiting access to tempting foods and screen time), goal setting, self-monitoring, contingent rewards, and problem solving; and supervised physical activity sessions. Providers included primary care clinicians, exercise physiologists, physical therapists, dietitians, diet assistants, psychologists, and social workers, but the more intensive interventions usually involved referral outside the primary care office. Evidence regarding pharmacotherapy interventions was inadequate.
Balance of Benefits and Harms	The USPSTF concludes with moderate certainty that the net benefit of screening for obesity in children and adolescents 6 y and older and offering or referring them to comprehensive, intensive behavioral interventions to promote improvements in weight status is moderate.
Other Relevant USPSTF Recommendations	The USPSTF has made recommendations on screening for primary hypertension and lipid disorders in children and adolescents. These recommendations are available on the USPSTF website (https://www.uspreventiveservicestaskforce.org).

For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, please go to https://www.uspreventiveservicestaskforce.org.

No POWER sites achieve ≥ 26 hours/6m

POWER: Projected enrollment

29 sites representing 20 states



Note: Enrollment in **POWER** currently ends on 12/31/14, however a 6-month extension will be proposed to the POWER Governance Board in January 2015.

★ = completed enrollment (n=23)

Brooke Sweeney, MD – Kansas City, MO
Associate Director of Recruitment

Duke Healthy Lifestyles Program

What other options exist for Anna?

Enhanced Behavioral Approaches/Community Collaborations

- To increase contact hours outside of clinic setting.
- To address a variety of the factors contributing to patients obesity
  - Cooking classes
  - Parenting classes
  - Access to organized physical activity
  - Grocery store tours…

Durham Parks and Recreation and Bull City Fit

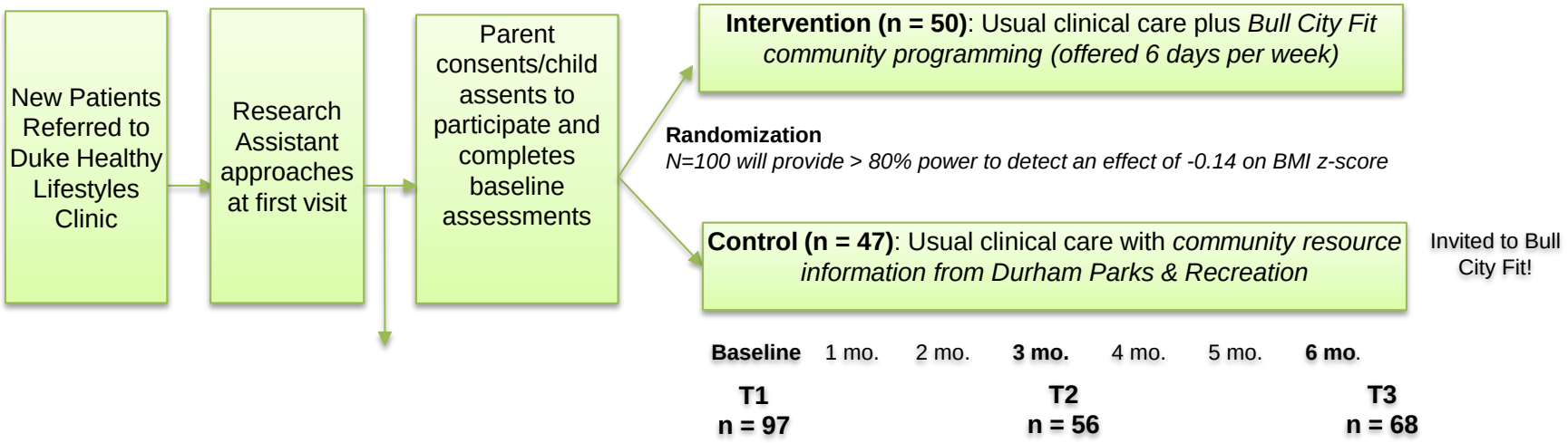
A place Anna feels like she belongs

Freedom to move

To develop friendships

To discover new foods

Bull City Healthy and Fit Study Design

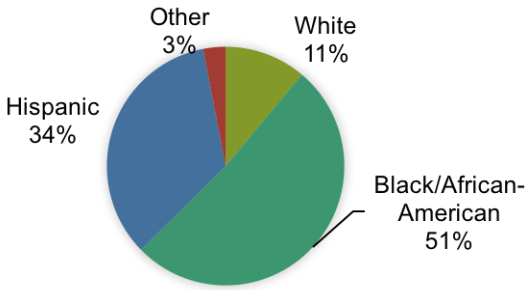


Hoffman et al, An Integrated Clinic-Community Partnership for Child Obesity treatment: A Randomized Pilot Trial. Pediatrics, 2018.

Bull City Healthy and Fit Baseline

Child

- Mean age: 9.1; 53% female
- Child race/ethnicity (primary)



- Mean BMI z-score: 2.28
  - ***55% in Class II or III with "severe obesity"***
- 12% with HbA1c ≥ 5.7%

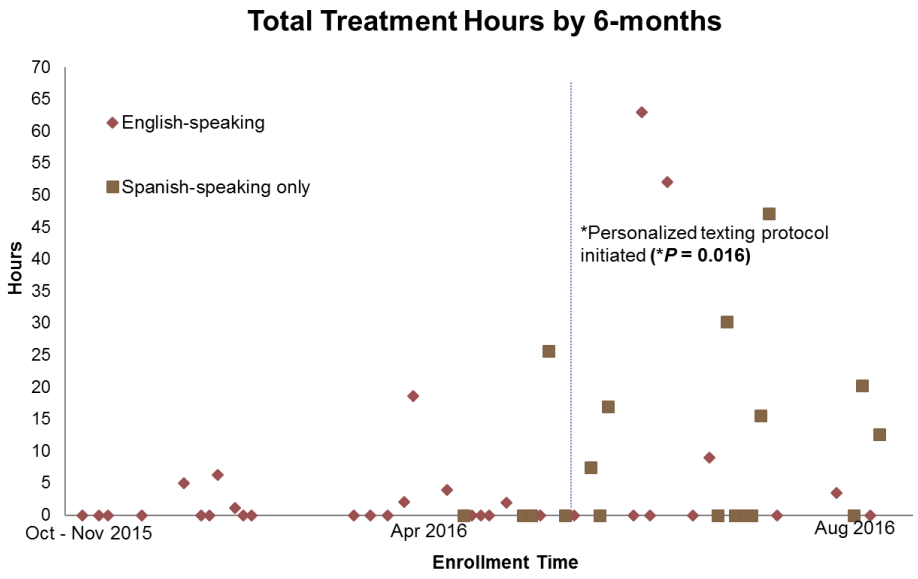
Parent

- Mean age: 35.4; 87% female
  - *48% single parent*
  - *43% born outside the USA*
  - *26% mono-lingual Spanish-speaking*
- Mean BMI: 34.6 kg/m^2
- Total household income *per year*

Hoffman et al, An Integrated Clinic-Community Partnership for Child Obesity treatment: A Randomized Pilot Trial. Pediatrics, 2018.

Bull City Healthy and Fit Primary Outcome: Treatment Hours

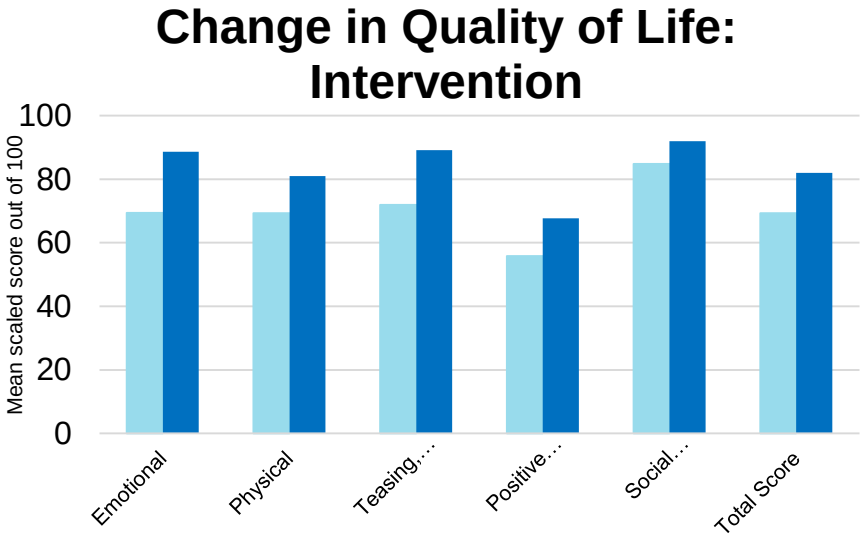
	Total n(%)	Control HL n(%)	Intervention HL + BCF n(%)
Hours	N = 97	N = 47	N = 50
Total	8.2 (SD 11.6)	**4.4 (SD 1.6, range 2-9)**	**11.7 (SD 15.3, range 2-67.8)**
0-2	14 (14.4)	8 (17.0)	6 (12.0)
3-5	53 (54.6)	28 (59.6)	25 (50.0)
6-<10	16 (16.5)	11 (23.4)	5 (10.0)
10<26	8 (8.3)	0 (0.0)	8 (16.0)
26+	6 (6.2)	0 (0.0)	6 (12.0)

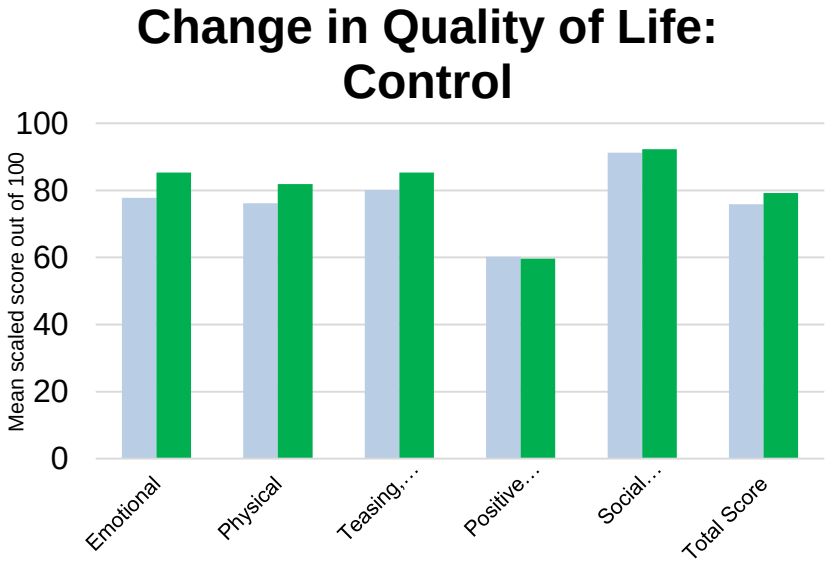


Hoffman et al, An Integrated Clinic-Community Partnership for Child Obesity treatment: A Randomized Pilot Trial. Pediatrics, 2018.

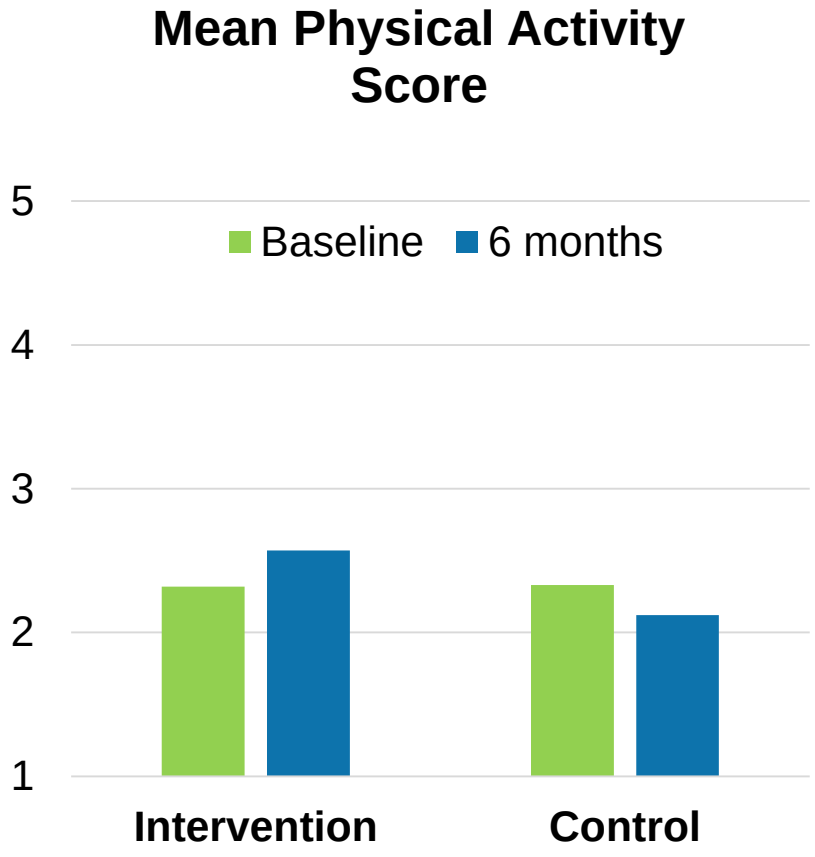
Bull City Healthy and Fit Secondary Outcomes: Quality of Life

- Significantly IMPROVED in the intervention vs. control at BOTH 3- and 6-months.
  - 3-months: total QOL, **+10.43 vs. +0.42** *(95% CI -15.40 to -4.62, P < 0.001)*
  - 6-months: total QOL, **+12.66 vs. +3.31** *(95% CI -16.15 to -2.56, P = 0.008)*





Bull City Healthy and Fit Secondary Outcomes



❖Significantly IMPROVED in intervention vs. control at 6-months (p=0.03)

No differences observed between intervention and control for:

- Child or parent BMI
- Blood pressure
- LDL

Using Technology TEXT-MI Study

	Total (n=100)	Control (n=53)	Intervention (n=47
Age (y)	9.5 (7-11)	9 (7-11)	10 (8-11)
Gender (%male)	39	42	36
Race (%Black)	48	43	53
Parental education (%HS or less)	46	49	43
REALM	65 (62-65)	65 (61-65)	65 (62-65)
Child BMI (kg/m^2)	29.1 (24.7 – 32.8)	28.9 (23.3 – 32.7)	30.5 (25.8 – 34.0)
Mobile device (%smart phone, unlimited texts)	97, 99	94, 98	100, 100

Armstrong et al, Texting Motivational Interviewing: A randomized controlled trial of motivational interviewing text messages to augment child obesity treatment. Child Obes, 2018.

TEXT-MI: Texting Motivational Interviewing to Improve Engagement

	Total (n=81)	No texting (n=42)	Texting (n=39)	P value
BMI Z-score change (mean change)	+0.01 (p=0.97)	+0.02 units	0.00 units	p=0.14
Parent weight change	+0.35 (p=0.45)	+ 0.61 kg	+ 0.04 kg	p=0.25
3-min step test, beats per minute (BPM) change	-2.4 BPM (p=0.09)	-2 BPM	-3 BMP	p=0.83
Parent Global Self-Efficacy Scale	-0.1 (p=.22)	-0.4	0.0	p==0.69
Number of HL clinic appts total (3 mo)	2.5	2.1	3.3	p<0.001

Armstrong et al, Texting Motivational Interviewing: A randomized controlled trial of motivational interviewing text messages to augment child obesity treatment. Child Obes, 2018.

Diets?

- Dieting is a robust predictor of weight gain.
  - 2013 meta-analysis 40 studies
  - Finland study 2000 twins – 2-3x increased risk
- Project EAT dieting associated with:
  - unhealthy eating behaviors at time of dieting
  - higher BMI at 5 years
  - higher rate of eating disorders at 5 years
- Most diets produce short term weight loss only
- Some short term studies on low carb in children. Hard to maintain over time
- No real information on Mediterranean diet and children.

Lowe et al, Front Psychol, 2013
Pietilaineet et al, 2011.
Neumark-Sztainer et al, J Am Diet Assoc, 2006.
Whitlock et al, Pediatrics, 2010.

Diets

- ***Lifestyle-based eating plans show no harm. Focus on macronutrients, how to eat, when to eat, how to pair foods.***
- Some newer studies on timing of eating in children (time limited eating)
- Some hospitals will admit patients for ketogenic, or protein-sparing diet. Often to prep for surgery for complicating co-morbidity.

Medications?

- **Review current med list**
- **Orlistat (FDA approved 12+)**
  - Intestinal Lipase inhibitor
  - Side effects of incontinence and steatorrhea make use unrealistic
  - Only fair efficacy
    - 12 months of treatment showed small change in BMI of – 0.85 kg/m2 compared to control.

Off-label Medication for Children

- Metformin
  - FDA indication for T2D in adolescents.
  - Safety data profile reassuring down to age 10.
  - Meta-analysis shows modest short-term benefit (as adjunct to lifestyle therapy):
    - Tx for 6 months = BMI change -1.38kg/m2 (CI -1.93, -0.82)
    - 3.6% above lifestyle alone.
    - Starting BMI 33kg/m2, amounted to 8lb wt loss/6 months.

(McDonagh MS, JAMA Peds, 2014)

- Topiramate
  - Anti-epileptic, FDA approved for adolescents with chronic migraine.
  - One retrospective chart review of 28 adolescents enrolled in pediatric weight management program showed 5% change in BMI at 6 months (Fox CK, Clin Pediatr, 2015).

Medications for Adult Obesity

Medication	Average weight loss	Mechanism of action	Potential side effects
Phentermine	5%	Adrenergic	Tachycardia, HTN
Phentermine/ Topiramate (Qsymia)	10%	Adrenergic, CNS	Tachycardia, HTN, cognitive dysfunction
Buproprian/ Naltrexone (Contrave)	4.5%	CNS, opiod antagonism	Worsening mood symptoms, worsening migraines, HTN
Lorcaserin (Belviq)	3.5%	Serotonergic ($5HT_{2c}$)	Headache
Liraglutide (Saxenda)	7%	GLP-1 agonist	Nausea
Orlistat	3%	Lipase Inhibitor	Steatorrhea, incontinence

POWER meds

Pharmacologic Agents

10 programs offer pharmacologic agents specific for weight control

Pharmacologic agent	# of Programs
Metformin	8
Orlistat	4
Topiramate	3
Phentermine	2
Bupropion	2
Naltrexone	1
Exenatide	1
Topiramate+Phentermine (Qsymia)	1
Liraglutide	1
Sandostatin	1

Weight Loss Surgery in Adolescents

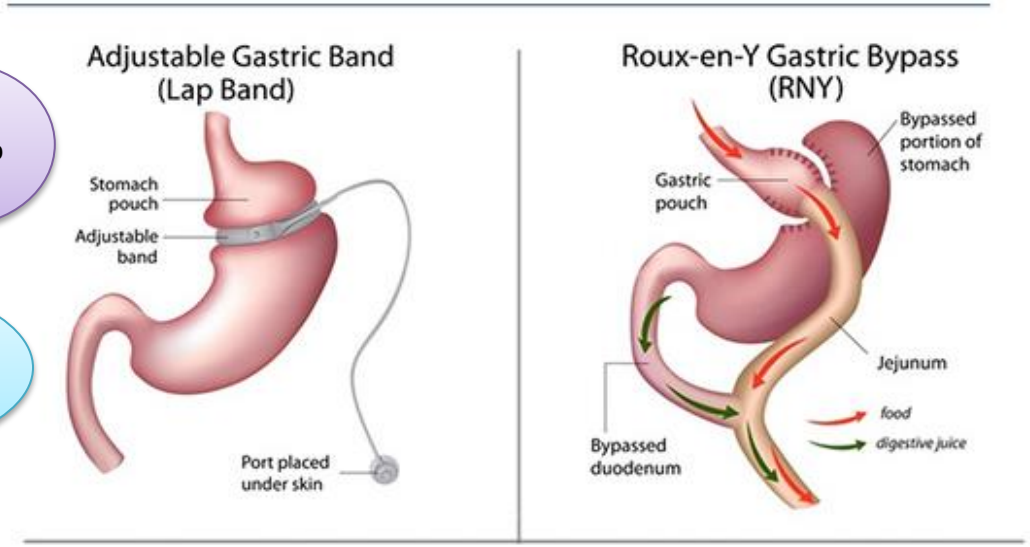
- Obesity is a serious chronic disease
  - Affects the majority of body systems
  - Affects the health and quality of life of millions of children and adolescents
  - Obesity related co-morbid conditions being seen at younger ages.
- This leads to an imperative and acceptance of much more aggressive treatment options for patients at a younger age.
- Performing surgery during adolescence will likely have a much more profound affect on psychosocial trajectory of patient as well as prevention of associated chronic diseases and mortality.

Weight Loss Surgery?

15K

7.1%

-11.6kg/m2



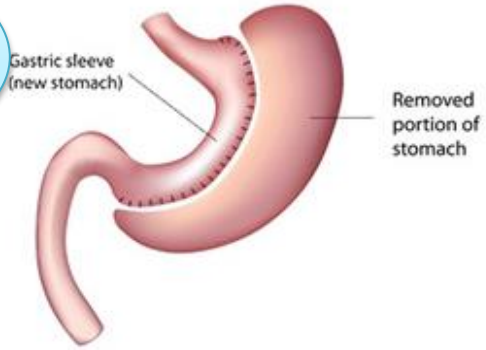
24K

9.3%

-16.6kg/m2

Vertical Sleeve Gastrectomy

-14.1kg/m2



19K

4.5%

BARIATRIC SURGERY SOURCE

www.bariatric-surgery-source.com

POWER Program Survey 2014

Bariatric Surgery

14 programs offer Bariatric Surgery for Severely Obese Youth

Types	# of Programs
Gastric Sleeve	10
Roux-en-Y Gastric Bypass	6
Lap-Band System	4

AWLS at Duke History

- March 2010 – team goes to CME at Cincinnati Childrens
- Early 2012 Health System approves surgery for adolescents at Duke
- June 2013 – first surgery done on adolescent
- One patient had surgery per year for first 3 years (2013-2015)
- 3 patients had surgery in 2016
- 5 patients had surgery in 2017.

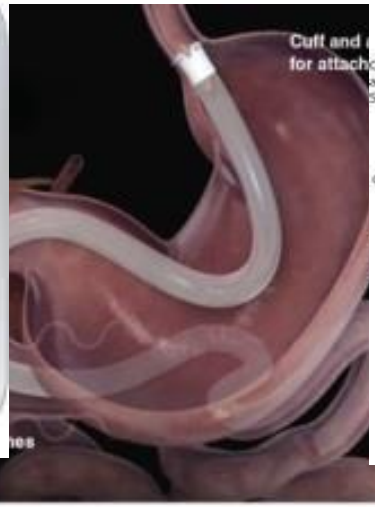
AWLS Surgical Experience at Duke

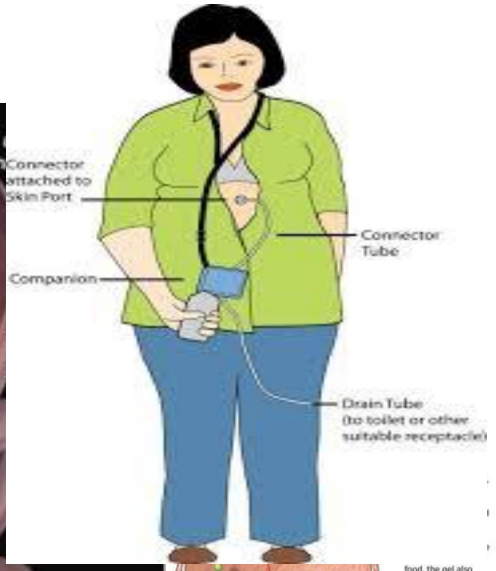
Patient	Sex	Age	Procedure	Starting BMI	Δ BMI (kg/m2)	% EBW lost
1	F	17	Bypass	62	-36 (30)	86 (3 yr) *
2	F	16	Bypass	42.6	-15.2	84 (1 yr)
3	F	19	Sleeve *	43.7	-7.3	39 (8 mo)
4	F	16	Sleeve	51.8	-12	51 (1 yr)
5	F	17	Sleeve	36	-10.3	95 (1 yr)
6	M	16	Sleeve	106	-9.5	16 (1 yr)
7	F	16	Sleeve	44.2	-4.3	20 (4 mo)
8	F	19	Sleeve	47.7	-13.3	53 (6 mo)
9	M	15	Sleeve	56.7	-8.9	28 (3 mo)
10	F	15	Sleeve	48.2	-6.7	30 (6 mo)
11	F	15	Sleeve	51.8	-7.9	32 (6 mo)
12	F	14	Sleeve	60.2	-4.8 (1mo)	

AWLS Experience at Duke

- 62 patients have entered surgical track
- 12 patients have gone on to surgery
- 17 patients currently active in track
- 33 patients did not go on to surgery (changed mind, lost to follow up, had surgery elsewhere, one pregnancy, not covered by insurance plan)

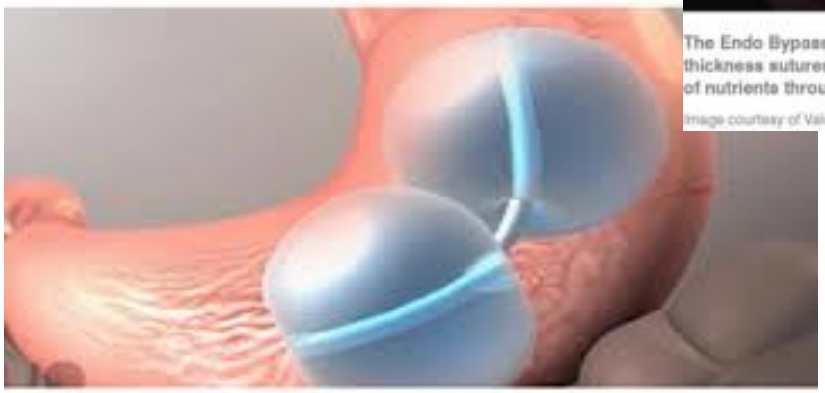
Other approaches?

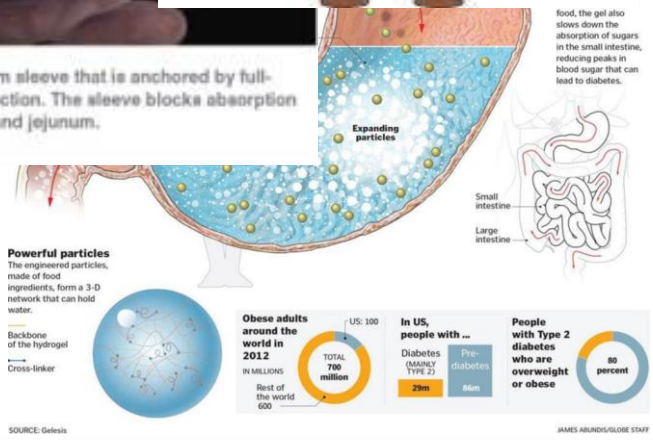




The Endo Bypass System (ValenTx) is a 120-cm sleeve that is anchored by full-thickness sutures at the gastroesophageal junction. The sleeve blocks absorption of nutrients through the stomach, duodenum and jejunum.

Image courtesy of ValenTx, Inc.





Parting Thoughts

- Redefine outcome measures and study design.
- Pharmaceuticals and medical device companies need to study effects and outcomes in children simultaneously or soon after adults.
- Move towards identifying characteristics of responders and non-responders and personalizing approach to treatment.

Address the Socioeconomics of Obesity

- Social determinants of health
- Health care disparities
- Trauma informed care

Advocacy Local and National

- Built environments
- Food Policy
- Payment for medical and dietary visits related to obesity care

Be a Role Model and Never Give Up!

In the families' words…

https://vimeo.com/123779196