Status report from the front lines:

Comprehensive treatment of severely obese children and adolescents: what is working, what is not, what we need to be successful.

Sarah Armstrong, MD
Director, Duke Healthy Lifestyles
Medical Director, Bull City Fit
Assistant Professor, Pediatrics
Duke University

March 26, 2014
The right tools for the job?
Objectives

- Understand definition and epidemiologic trend of severe obesity among children.
- Identify current treatment options and efficacy.
- Describe the Duke model of care, including Healthy Lifestyles and Bull City Fit.
- Introduce innovative treatment strategies.
Definition of ow/ob in youth

- Cutpoints are age- and gender-specific
- Reported as a percentile
  - <5th%ile: underweight
  - 5-85th%ile: normal
  - >85th%ile: overweight
  - >95th%ile: obese
  - >99th%ile: severely obese
- Language to use when discussing child weight with parents

Severe obesity among children and adolescents in the US

- Between 1970-2010, prevalence of child obesity increased from 5% to 17%.
- Recent data suggest slowing or “plateau” in prevalence of child obesity, and a recent decline in obesity among children aged 2-5 (NEJM, 2014).
- Childhood “severe” obesity (BMI ≥ 99th %ile) continues to increase, and is currently the fastest-growing subcategory of obesity.
- Severe obesity affects between 4% to 6% of all youth 2-17 in the US. Boys > girls, minority > non-minority
- Severe obesity in youth:
  - Immediate and long-term health consequences
  - Demonstrate early signs of vascular dysfunction and atherosclerotic changes
  - Tracking into adulthood is very strong
  - Public health strategies ineffective

Epidemiologic shift since 1960


Flegal & Troiano, International J of Obesity, 2000
Durham Community Health Assessment, 2011


- Age 2-4: 15.00%
- Age 5-11: 25.00%
- Age 12-18: 30.00%

- 2002
- 2008
Increased risk for adverse health outcomes at extremes of BMI distribution

Freedman, J Peds, 2007
Prevalence of multiple risk factors according to BMI percentile

<table>
<thead>
<tr>
<th>BMI%</th>
<th>≥1</th>
<th>≥2</th>
<th>≥3</th>
<th>≥4</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 25</td>
<td>25</td>
<td>5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>85-94a</td>
<td>51</td>
<td>19</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>≥ 95b</td>
<td>70</td>
<td>39</td>
<td>18</td>
<td>5</td>
</tr>
<tr>
<td>99c</td>
<td>84</td>
<td>59</td>
<td>33</td>
<td>11</td>
</tr>
</tbody>
</table>

Freedman et al, J Peds, 2007
Treatment options and efficacy: a single approach?

8 yo, BMI > 99%

2 yo, BMI > 99%

16 yo, BMI > 40
Behavioral treatment?

Patients and Providers often have Multiple Goals

The best way to achieve good health is to take care of yourself.

Your lifestyle is destroying you.

You should change your eating habits, and stop smoking and drinking.

Start an exercise program. Get plenty of rest. Learn how to handle stress.

You're right, doc. Thanks!

Man! I've got to find another doctor.

blueprints.for.better.care

2012
Early guidance for clinicians

- 1998: recommendations from AAP for which evidence-based behaviors clinicians should focus on
- 2005: USPSTF report concludes insufficient evidence to recommend for or against screening for obesity in clinical practice.
2007 AAP Guidelines

I. Prevention Plus: Primary care, q1-2mo visits, use of Motivational Interviewing, 3-6 months.

II. Structured Weight Management: Primary care, schools, community, q1mo visits, more structure/support +/- RD visits, 3-6 mo.

III. Comprehensive, Multidisciplinary Intervention: Primary care with support, school, community, weekly visits for 8-12 weeks, group setting, multidisciplinary care team, more prescriptive diet plan.

IV. Tertiary Care Intervention: BMI >99th, academic setting, offer multidisciplinary team/subspecialists +/- options for medication, diets, surgery.

2010 USPSTF updated report

- Based on 13 behavioral intervention trials including 1258 ow/ob youth aged 4-18.
- Recommended screening for obesity (using BMI) in primary care and referring obese children for treatment. Grade “B”
- Hours of contact
  - Very low: <10
  - Low: 10-25
  - Moderate: 26-75
  - High: >75
- Treatment duration
  - short-term (6-12 months)
  - maintenance (at least 12 mo after intervention)
- “Comprehensive-ness”
  - Dietary
  - Physical activity
  - Behavioral counseling
Okay, that’s progress. But....
Real-world Controversy #1: Implementation

- Primary care physicians unlikely to screen
  - 11% of pediatricians use BMI to screen at every well child check, and only 20% of parents of severely obese children recall that their child’s physician discussed this as a health concern.

- Poor reimbursement for lifestyle counseling
  - Very few existing reimbursement policies for clinical care of obese children
  - BCBSNC experience
  - ACA provisions for preventative services
  - 2011 NACHRI report on comprehensive obesity treatment clinics

- Treatment capacity
  - 25 Million ow/ob children and teens in the US today

- USPSTF statement concedes: “the intervention will rarely be practical in the primary care setting.”

Whitlow (USPSTF), Pediatrics, 2010
Perrin, Archives of Pediatrics, 2011
Simpson, Pediatrics, 2009
Real-world Controversy #2: Efficacy

- Lifestyle modification studies largely done in research settings.
- Patient populations typically middle class, minorities under-represented.
- Few studies in clinical settings are academic, and not clearly staged.
- In best-designed behavioral intervention, average BMI change is 1.9 to 3.3kg/m2 reduction in BMI over 6-12 months. Equivalent to (at most):
  - 8 yo boy losing 13lbs/1 year
  - 16 yo girl losing 19lbs/1 year

Dolinsky, Clinical Pediatrics, 2011
### Real-world Controversy #3: Targeted weight goals

<table>
<thead>
<tr>
<th>Age (yr)</th>
<th>BMI 95-98th percentile</th>
<th>BMI ≥99th percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-5</td>
<td>weight maintenance</td>
<td>Gradual weight loss of up to 1 lb/mo</td>
</tr>
<tr>
<td>6-11</td>
<td>weight maintenance or gradual loss</td>
<td>Weight loss up to 2lb/wk</td>
</tr>
<tr>
<td>12-18</td>
<td>Weight loss up to 2lb/wk</td>
<td>Weight loss up to 2lb/wk</td>
</tr>
</tbody>
</table>

### BMI change over 1 year to reduce risk of CVD

Armstrong et al, PAS 2012.

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>BMI Percentile</th>
<th>Initial</th>
<th>After 12 months</th>
<th>12-Month Change in BMI</th>
<th>12-month Change in Weight in kilograms, by Height Percentile</th>
<th>12-month Change in BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Males</td>
<td>Females</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50th</td>
<td>75th</td>
<td>95th</td>
</tr>
<tr>
<td>2</td>
<td>95</td>
<td>87</td>
<td>-1.8</td>
<td>1.3</td>
<td>1.4</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>97</td>
<td>93</td>
<td>-2</td>
<td>1.3</td>
<td>1.3</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>99</td>
<td>97</td>
<td>-2.3</td>
<td>1.1</td>
<td>1.1</td>
<td>1.3</td>
</tr>
<tr>
<td>5</td>
<td>95</td>
<td>87</td>
<td>-0.7</td>
<td>1.7</td>
<td>1.8</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>97</td>
<td>93</td>
<td>-0.7</td>
<td>1.8</td>
<td>1.9</td>
<td>2.1</td>
</tr>
<tr>
<td></td>
<td>99</td>
<td>97</td>
<td>-0.6</td>
<td>2</td>
<td>2.2</td>
<td>2.4</td>
</tr>
<tr>
<td>8</td>
<td>95</td>
<td>87</td>
<td>-1.1</td>
<td>1</td>
<td>1.1</td>
<td>1.3</td>
</tr>
<tr>
<td></td>
<td>97</td>
<td>93</td>
<td>-1.4</td>
<td>0.7</td>
<td>0.8</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>99</td>
<td>97</td>
<td>-2.5</td>
<td>-0.8</td>
<td>-0.8</td>
<td>-0.7</td>
</tr>
<tr>
<td>11</td>
<td>95</td>
<td>87</td>
<td>-1.7</td>
<td>-0.05</td>
<td>0.02</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>97</td>
<td>93</td>
<td>-2.3</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td></td>
<td>99</td>
<td>97</td>
<td>-4.4</td>
<td>-5</td>
<td>-5.3</td>
<td>-5.6</td>
</tr>
<tr>
<td>14</td>
<td>95</td>
<td>87</td>
<td>-2.1</td>
<td>-0.8</td>
<td>-1.2</td>
<td>-1.9</td>
</tr>
<tr>
<td></td>
<td>97</td>
<td>93</td>
<td>-2.7</td>
<td>-2.2</td>
<td>-2.7</td>
<td>-3.5</td>
</tr>
<tr>
<td></td>
<td>99</td>
<td>97</td>
<td>-4.7</td>
<td>-7.1</td>
<td>-8</td>
<td>-9.4</td>
</tr>
<tr>
<td>17</td>
<td>95</td>
<td>87</td>
<td>-2.1</td>
<td>-5.7</td>
<td>-6</td>
<td>-6.5</td>
</tr>
<tr>
<td></td>
<td>97</td>
<td>93</td>
<td>-2.6</td>
<td>-7.1</td>
<td>-7.5</td>
<td>-8.1</td>
</tr>
<tr>
<td></td>
<td>99</td>
<td>97</td>
<td>-3.9</td>
<td>-11.2</td>
<td>-11.9</td>
<td>-12.8</td>
</tr>
</tbody>
</table>
“Remember, only gravy in his drip. He’s on Atkins.”
Weight-loss diets for children

- 2006 systematic review: low calorie, low fat, low carbohydrate and low glycemic index diets roughly equivalent, but only 7 studies and none high-quality. (Gibson et al, Int J Epi 2006)

- Low sugar diets: 125 studies in children, only 15 relate to obesity.
  - Low CHO: Lower adherence, similar wt reduction as standard “portion control” diet at 12 months (Kirk et al, J Peds, 2012), and no differences among AA girls aged 9-14 at 3 months (Casazza, J. Peds GI, 2010).

- Current AAP guidelines emphasize restrictions only on fat grams per day and avoidance of sugary beverages and snacks.

- What do families want?
  - Focus-goup data demonstrate that families want a structured dietary plan (92%), and 50% of these prefer a low-carbohydrate approach, 43% low-fat, and 7% standard care. (Truby et al, J Peds, 2010)

Weight loss medications?
Weight-loss medications for children

- 38 unique medications that have been tested for weight loss in adults, 10 of these tested in children.
- Currently approved:
  - Orlistat – intestinal lipase inhibitor, currently approved for teens aged 12 and older. Prescription strength 120mg tid. OTC “Alli” strength 60mg bid/tid. One month at OTC dose costs $90.00. Insurance coverage for prescription dose varies widely.
- Used off-label:
  - Metformin
  - Topamax
  - Wellbutrin
  - ADHD medications
  - Adult weight loss drugs: Lorcaserin, Belviq
  - Drugs in development: cannabinoid receptor inhibitors, hormones (ghrelin, incretin, amylin, octreotide).

USPSTF recommendations

- Seven trials of combined pharmacotherapy (sibutramine or orlistat) with behavioral treatment in 1294 teens 12-18 years.
- Added benefit of orlistat 0.85kg/m² loss in 6-12 months as compared with behavior alone.
- No long-term maintenance studies.
Surgery?
Weight-loss surgery for adolescents

- Becoming more common (328 v. 987 procedures from 2000 to 2003); 1/3 banding and 2/3 RYGP.
- Short-term (up to 5 years) data on RYGP wt loss (-15 to -20kg/m2), CV and psychological benefit, and safety profile.
- Benefit and risk/safety profile both appear to be superior to the adult data.
- Duke has had an adolescent weight loss surgery program since 2011 (discussed later).

The CHASM of pediatric obesity treatment

Diets, drugs, surgery

Lifestyle modification
Duke Children’s Childhood Obesity Program

Clinical care “Healthy Lifestyles”

Community partnerships “Bull City Fit”

Education

Research
Healthy Lifestyles Clinic
Healthy Lifestyles Clinical Protocol

- Patients with BMI ≥95th percentile aged 22 or younger
- Comprehensive assessment includes:
  - Anthropometrics
  - Laboratory testing
  - Standardized nutrition recall
  - Standardized fitness evaluation
  - Spirometry
  - Validated surveys (Lifestyle, QOL, BED, ADHD, depression)
  - Parent height, wt, BMI
- Recommend monthly visits for one year with MD/RD, PT and LCSW as indicated
- Participation in community–based activities offered to all who qualify (Bull City Fit)
- Annual re-assessment includes repeating all measures above, meeting with provider to determine ongoing eligibility, goals for subsequent treatment cycle.

Referral from PCP or self-refer

Baseline Assessment and Consults (MD and RD)

Periodic Intervention visits (MD, RD, PT, LCSW)

Annual Assessment and re-consult (MD and RD)

Exit program or re-enroll
Baseline Characteristics of HLP Group

- Age: median 11 (IQR 8-14)
- Sex: 58% female
- Race/ethnicity: 61% non-White/non-Hispanic, 8% Hispanic
- Insurance: 40% public, 30%BCBS, 20%DS, 10% other
- Average starting BMI: 98.9\textsuperscript{th} %ile
- Average number of co-morbid health conditions: 4
- Average new patient assessments per year: 800

Dolinsky, Clinical Pediatrics, 2011
HL outcomes and attrition

- Outcomes
  - Sample 282 patients
  - After 6-8 months of treatment in HL, patients achieved a mean reduction in zBMI of 0.10 (std dev = 0.2).
  - Statistically significant reductions in blood pressure, triglycerides, total cholesterol, and insulin resistance.

- Attrition
  - Sample 983 patients
  - In adjusted analysis, NW/NH patients more likely to be early dropouts (OR 1.46, CI 1.03 – 2.07) and non-completers (OR 2.56, CI 1.34 – 4.90) than W/NH and H patients.
  - Young, Hispanic children aged 6-10 were most adherent to treatment visits.

DUHS-approved adolescent weight loss surgery program (AWLS)

Referral
- All patients aged 14-18 seeking surgery referred first to HL program for evaluation and medical weight management

Screening
- Patient/caregiver meets monthly for 6+ visits with HL multidisciplinary team (MD, LCSW, RD, PT)
- Screening protocol based on best practice guidelines (ASMBS) and data shared by Cincinnati Children’s (established AWLS program with published outcomes)

Surgery
- If patient meets inclusion criteria and completes 6 monthly visits, and felt to be a good candidate, is then referred to Center for Metabolic and Weight Loss Surgery for standard intake.
- Offer gastric bypass only; anticipate 3 patients in year 1.

Postop
- Follow up in both MWLS and HL clinics according to pre-established visit protocol (3wks, 2mo, 3mo, 4mo, 6mo, 9mo, 1yr and yearly after)
- Long term f/u in HL and MWLS will allow reporting of longitudinal outcomes and safety information
Julia Wacker, MSW MPH
Director, Bull City Fit
Soccer field and Walking Trail
How much do you agree with each of these statements?

- Active Teens has helped me get healthier. 100%
- Active Teens has helped me stay committed to coming to my Healthy Lifestyles appointments. 80%
- Because of Active Teens, I feel more confident exercising in public. 60%
- Active Teens has helped me make friends. 40%
BCF – Teen Member & Parent Survey

What is your favorite thing about BCF?
Pediatric Obesity Treatment: Opportunities for Innovation
Pilot study: Staged transitional eating plans (STEPS)

- **Rationale**
  - “Low carb” diet: 2 studies comparing LC/LF show greater wt loss (-9.9kg vs. -4.1kg; BMI change -1.5 vs. -0.05) and TG reduction in LC group after 12 weeks, however difficult to sustain.

- **STEP 1**
  - Low carbohydrate (CHO<30g/day)
  - Weekly visits to monitor adherence/SE
  - 12 weeks

- **STEP 2**
  - High fiber, maintain low glycemic load
  - Aim for CHO 40-75g/day
  - 6 months

- **STEP 3**
  - Personalize CHO intake capacity
  - Maintain low glycemic load
  - CHO up to 120g/day
  - Lifestyle

Sondike, Pediatrics 2003
Krebs, Am J of Clin Nut, 2010
Technology-based approach: HLP4U

- Utilizes secure provider-to-parent text messaging to enhance between-visit motivation and support
- Focused on providing support to parents or caregivers of children aged 5-12
- Motivational interviewing as conceptual framework.

(IRB Pro00050555)
Technology-based approach: MeTree, Jr.

Welcome to MeTree. This program will ask questions about your health and your family’s health. Your answers will be used to give you personalized suggestions for your health care. Please answer as best you can.

CLICK HERE TO START
MeTree,Jr.

- Funded by Center for Personalized Medicine
- Collects baseline data from families enrolling in HL
  - Family history
  - Lifestyle
  - Self-efficacy
  - Readiness to Change
  - Clinical data
- Dual output: provider and parent
- Supports referrals to community programs
- Supports provider capacity to counsel and remain adherent to Motivational Interviewing.
Metabolomics

- Using metabolomics to predict insulin resistance and early detection (UMPIRE)
  - To evaluate the association between a range of metabolites and the presence of insulin resistance among children entering the Healthy Lifestyles Program.
  - To integrate measures of individual characteristics, including clinical and demographic factors, the metabolomic profile, and environmental factors, to develop risk prediction models for insulin resistance among obese children and adolescents.
  - 90 baseline samples analyzed.

- Biobanking
  - 85 blood samples currently stored for future use
Data collection

- RedCap
  - Pertinent elements of clinical data collected from each encounter
  - Retrospective ACCESS database 8600 stored records through Jan. 2012

- POWER (Pediatric Obesity Weight Registry)
  - First prospective child obesity registry nationally
  - Data coordination at Cincinnati Children’s
  - Need 20 sites to launch
  - Data collection begins May 2014
Malinda

http://www.onlyakid.org/malinda/
THANK YOU